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Recommendations for Better Adoption of Medical Photography as a Clinical Tool

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Abstract

The use of photography in routine clinical practice has the potential to increase the efficiency of overall patient care as well as improve clinical documentation and provider-to-provider communication. This is particularly important in the setting of provider burnout in the electronic health record era and during the COVID-19 pandemic. Despite the potential of photographs to enhance workflows and patient care, challenges remain that hinder the successful incorporation of medical photography into clinical practice, often because of inconsistent structure and implementation. Our proposed consolidated framework for clinical photography consists of five key aspects: appropriate informed consent; proper preparation and positioning; image acquisition with consideration of the field of view, orientation, focus, resolution, scale, and color calibration; streamlined and secure image storage and documentation; and interoperable file exchange. Overall, this viewpoint is a forward-looking paper on leveraging medical photography as an electronic health record tool for clinical care, research, and education.

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KEYWORDS

medical photography; photo documentation; EMR; electronic medical record; electronic health record; EHR; interoperability; interoperable; photography; photograph; imaging; image capture; image; image storage; clinical instrument; clinical tool

Introduction

Medical photography remains underused as a clinical instrument. Despite the well-acknowledged potential of photographs to improve workflows and patient care, challenges hinder their integration into clinical care [1]. Nevertheless, provider burnout during the electronic health record (EHR) era and COVID-19 pandemic is a growing concern [2] that requires health information technology that supports rather than burdens providers. As the common saying goes, a picture is worth a thousand words; thus, medical photography has the potential to increase efficiency of patient care and improve quality of documentation and provider-to-provider communication. In this viewpoint, we present an overview of the current state of photo documentation, the existing challenges of its adoption and integration into clinical care, and our recommended framework for better use of medical photography as a clinical tool.

Background: Value of Photo Documentation

Capturing visual representations of patients' conditions has been essential throughout the history of medicine, from initial documentation through artists' depictions to the current era of clinical photography using smartphone cameras [3]. In fact, photo documentation has been perceived as less biased than the text record. Providers from diverse fields use photography to record clinical findings. Physicians have reported that photo documentation improves their patient assessment and enhances confidence in clinical decision-making [4]. Patients also perceive the value of photographs and generally approve of the use of

clinical images in medical records and coordination of care [4,5], a practice that can help avoid repeated or uncomfortable examinations. Integration of clinical images when communicating with specialists has also been shown to improve the accuracy of the diagnosis [3,6]. Despite all-around interest in photo documentation, there remains a lack of industry consensus for the efficient capture, storage, retrieval, and exchange of digital images in medicine [7-9].

Current Challenges

Although EHR systems have the capability to store clinical photographs, image capture, documentation, and interoperability are not standardized. Provider workflows range from copying and pasting images into clinical notes to storing images in a dedicated media hub of the EHR. The variability in practices and capability of EHR systems pose challenges in longitudinal patient care, communication between providers, and information sharing with patients. In the longitudinal care of patients, EHR systems usually support trending of vital signs and laboratory values to discern whether a condition remained stable, improved, or worsened. The same functionality is not commonplace with clinical photography, minimizing its utility in tracking conditions over time. Although information exchange has been a long-standing meaningful use objective of the Centers for Medicare & Medicaid Services [10], image file attachments do not reliably display in a consistent manner in the EHR. Some systems strip out file attachments all together. This hinders communication between providers, especially in a medical neighborhood where the patient sees multiple providers using disparate EHRs. Similarly, variable EHR adoption of clinical photography services, transport standards, support of attachments, and inconsistent provider documentation practices complicates the release of images to patients.

Development of Recommendations

To formulate the following outlined recommendations, we first reviewed prior publications on medical photography. In our review of the literature, we extracted key themes surrounding the challenges in medical photography. Afterward, we enumerated the key aspects for an integrated approach to medical photography based upon both review of the literature and our experiences as medical practitioners working with the EHR for patient care.

Five Key Steps for an Integrated Approach to Medical Photography

To mitigate ongoing challenges and use medical photography more efficiently, we propose that providers follow these essential steps.

Obtain Informed Consent

Prior to capturing any images, it is essential to obtain the patient's informed consent for photography if not already included in the patient's consent for overall medical care. The process should cover the purpose of clinical photos, access control, identity protection, and image storage. Images intended for publication usually require a separate consent [3,11].

Prepare and Position

After informed consent, proper preparation and positioning are necessary to obtain high quality photos and minimize any legal risk. Use broad spectrum lighting to avoid shadowing and hot spots. A solid background can improve contrast and prevent artifacts. For image deidentification, move any recognizable information out of the camera's view to lessen risks for breach of protected health information [11,12].

Capture Images

Once the area of interest is properly prepared and positioned, verify the patient's identity and proceed with image capture with the following considerations: field of view (ie, center area of interest), orientation (ie, cephalic orientation), focus (ie, focus on area of interest with camera oriented perpendicular to surface), resolution (ie, when relevant, use the level of resolution that sharply depicts hair follicles or skin markings), scale (ie, place physical scale in area of image capture without obscuring area of interest), and color calibration (ie, ensure that imaging parameters allow for color comparison across images) [12].

Ensure Streamlined and Secure Image Storage and Documentation

After the images are taken, it is necessary to use a streamlined image archival system linked with the EHR to display the photographs. Ideally, the images should be securely saved directly to the patient's electronic record from the device capturing the image [11]. This is important because providers can err when taking additional steps during image upload that requires selecting the correct patient and encounter information.

Establish Image File Exchange Standards to Promote Interoperability

Standards around image file exchange are essential for both provider-to-provider communication and image sharing with patients. Provider-to-provider communication includes two main settings: within the same health system and between separate practices. Typically, image sharing in the same health system is technically and operationally simple. However, for provider communication in unrelated systems, one should consider technical aspects for image transmission. Infrastructure around national image exchanges between systems can draw from examples within radiology and imaging data exchange standards that have been developed for radiographic images [13]. Additionally, implementing transmission standards is essential to ensure data transmission between a trusted and verified sender and receiver for both providers and patients [14].

Conclusion and Outlook

Numerous areas in medicine can be enhanced through advances in standardization, facilitation, and interoperability of EHR photo documentation, from better tracking of clinical findings over time to improvements in clinical care by improving communication between providers, specialists, and patients. A comprehensive and vast database of deidentified images could allow for development and integration of machine learning

algorithms into the EHR. Furthermore, deidentified images can support education of students, trainees, allied practice providers, nurses, and physicians alike. Ultimately, with increasing technological advances in imaging, the possibilities of medical photography to enhance both the patient and provider experience are endless.

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Conflicts of Interest

None declared.

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Abbreviations

EHR: electronic health record

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Viewpoint

Addressing Medicine's Dark Matter

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Abstract

In the 20th century, the models used to predict the motion of heavenly bodies did not match observation. Investigating this incongruity led to the discovery of dark matter—the most abundant substance in the universe. In medicine, despite years of using a data-hungry approach, our models have been limited in their ability to predict population health outcomes—that is, our observations also do not meet our expectations. We believe this phenomenon represents medicine's "dark matter"— the features which have a tremendous effect on clinical outcomes that we cannot directly observe yet. Advancing the information science of health care systems will thus require unique solutions and a humble approach that acknowledges its limitations. Dark matter changed the way the scientific community understood the universe; what might medicine learn from what it cannot yet see?

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big data; AI; artificial intelligence; equity; data collection; health care; prediction; model; predict; representative; unrepresented

Background

In this viewpoint paper, CR and his colleagues explore the limitations of current health care data and call for an acknowledgment of and action toward a more inclusive data environment.

In the early 20th century, the scientific community faced a mystifying conundrum: despite the continued growth of observational data from the most advanced measurement equipment of the time, it appeared that the mass of every visible star in the universe was not enough to keep galaxies from drifting apart. Real-world observations were not congruous with the predicted outcomes of Einstein's Theory of General Relativity. Given that galaxies were indeed not spraying their contents across the universe but rather maintaining their place in space, something that could not be seen must have been exerting a tremendous force on the system. Now in the 21st century, the medical community faces a similar problem—a disconnect between data and outcomes. How will we uncover and address medicine's "dark matter"? We must quantify what we are currently missing, broaden our perspective, and acknowledge our limitations.

It took a complete paradigm shift to bridge the gap between theory and observation for astrophysicists. In the 1970s, Vera Rubin and W. Kent Ford confirmed that there must be a mass at the center of galaxies that we simply cannot directly observe yet. Its existence could be inferred only by how it affected the entirety of the system. It was called "dark matter" because it did not lend itself to measurement, although it paradoxically makes up the vast majority of our universe and determines the very nature and future of our world [1].

The Limits of Health Care Data

In the early 2000s, the Institute of Medicine noted that a similar chasm existed between the theoretical health care quality

expected for our communities and the quality they actually observed. It was believed that to solve this problem, more and better health care data were needed to make more accurate predictions and provide higher quality care. Thus, since the Health Information Technology for Economic and Clinical Health Act's enactment in 2009, the digital health landscape has grown rapidly under this assumption [2,3]. More health care data are being produced daily than ever before. Genetic test results, physiologic monitors, cell phone data, social media posts, and web searches are being incorporated into predictive algorithms.

However, if improved quality of care is the measure by which we guarantee the success of our predictions, we have little to show for our efforts [4]. Health care costs in the United States continue to increase relative to other high-income nations with minimal return on improved health care outcomes [5]. Life expectancy has remained essentially unchanged for a decade (it was actually decreasing in the United States, even before the COVID-19 pandemic) [6]. Models still fail to accurately predict health care patterns for the American population. A chasm remains between our observations and the benefits we expect from advances in health care data.

Astronomy and medicine both suffer from detection bias [7]. Researchers disproportionately value features that we can perceive and undervalue the effects we do not directly detect or understand. We have a natural preference to believe that the world we observe is the whole truth, and we exhibit little ability to think in terms of missing information. Just as the telescopes and radio receivers of astronomy were designed and used to more accurately observe the small fraction of already known entities in the universe, so too do the electronic health record, genomic sequencing machinery, and extant digital health tools make accessible data from the patient populations on which we have already focused the most resources [8,9]. The rest is medicine's dark matter.

That Which We Cannot See

Currently, even our largest clinical data sets contain information on only a portion of the population [8]. However, we expect data collected from this small subset to determine the course and future of our health care establishment. Gender imbalances and the underrepresentation of systematically oppressed and marginalized populations belie some of the most impactful limitations of medical data [10]. These populations rarely make it into our observations and calculations, not because they lack the need, but rather because the medical community has rarely effectively engaged them. Therefore, as we have rarely looked, we cannot see the whole truth.

The data we are missing is a reflection of our priorities. Resources for and attention to identifying and investigating even important conditions such as maternal mortality have been insufficient. Data collection varies by state, and reported statistics are incomplete [11]. Similarly, we have not prioritized diversity in clinical trials, which have historically excluded members of marginalized racial and ethnic groups [12]. The federal government acknowledged this lacuna and mandated improved representation in trials through the National Institutes of Health Revitalization Act of 1993. Nevertheless, racial and ethnic diversity among clinical trial participants remains low to this day [13]. This lack of representation limits not only the generalizability of results from clinical trials but also the potential impact of new treatments on health care quality, especially for vulnerable populations [14].

The COVID-19 pandemic has blatantly demonstrated this point. The health outcomes of the people we account for the least—the people who cannot, do not, or rarely interface with the health care enterprise—are often those at the greatest risk for poor outcomes.

Addressing "Dark Matter"

Quantifying What Is Missing

One solution seems to lie in making the invisible visible. If we can simply acquire the data we are missing, catalog it, and add it to our models, then we might begin to reap the benefits we expect. However, this logic is flawed [15]. If we believe that more representational data sets are a solution to this missing information, we must first address how we gain insights from communities who may already have concerns of over-surveillance or otherwise problematic visibility. As we have seen from policies such as "stop-and-frisk," increased observations may not improve outcomes but rather worsen disparities and limit the equitable distribution of resources across communities [16]. Despite the rapid growth of artificial intelligence and its requisite data-hungry approach in health care, little attention is being given to the way data sets are collected and how this might affect the performance of the systems built upon them [17].

Even when medicine has attempted to account for these unseen populations, the proxies we use to represent complicated phenomena can be misunderstood and inappropriately related to the phenomena they approximate. This is evident in the conflation of race with racism as risk factors in medical research. Furthermore, in "Towards a Critical Race Methodology in Algorithmic Fairness," the authors warn that "the creation of metrics and indicators which are race-like will still be interpreted as race" [18], which is to say that even as we move toward broadening our attention to those consistently left out, we must carefully consider how they are represented in data and, just as importantly, what our modeling techniques may not be able to represent about them.

Similarly, our approaches to data analysis can become barriers to better understanding. To be usable in predictive modeling, data must be quantified. Quantifying information can both allow large magnitudes of data to be efficiently processed as well as obscure the challenges underlying attempts toward the robust numerical representation of complex social processes. Classification schema may valorize certain points of view over others [19]—that is, the application of classification schema, such as census categories, can lead to trusting their validity in contexts where they may not actually be valid. This limits our attention to popular or dominant ways of categorizing data. For example, analyzing historical health outcomes of people who identify as both Black and Latino is greatly hindered or even

made impossible by data collection standards that treat those categories as mutually exclusive [20].

A good place to start might be by acknowledging what we have and what is missing. Big data sets, many of which are open source, are often used to extract knowledge or train predictive models. The aim is usually to use them to improve patient outcomes, but the data they are made from are rarely assessed for generalizability or relation to the particular community of interest. Instead of blindly using them, we might explore the nature of their data and compare it to our communities. This exercise may in itself improve the knowledge of how well systems relate to each other—an internal/external audit for validity. To aid this effort, the data sets we use (and reuse) should be accompanied by robust documentation such as datasheets, which serve as a kind of nutrition label for data sets while also documenting their motivation and intended uses [21]. By cataloging the provenance of data, we can more easily assess what—and who—is missing.

Broadening Our Perspective

With this acknowledgment of what is missing, we must then design mechanisms to solve the problem. Although more data alone will not likely solve the problem, perhaps a broader spectrum of measures can offer some short-term hope. We must begin to move beyond traditional clinical measures such as mortality, vital signs, age, or family history and include more sociocultural and even environmental data [22-24]. We now know that the risk of developing some diseases is as, if not more, reliant on an individual's social environment rather than their genetic heritability, and yet these social determinants of health are extremely poorly captured in large data sets [25]. Perhaps there are other unknowns that we have yet to consider?

Engaging with members of the communities we seek to serve might also allow us to begin to see what we otherwise may not. An inadequately diverse representation in the medical profession is itself a barrier to patients perceiving that their own interests lie at the heart of medical research [26]. However, community members, regardless of their ties to the medical field, maintain important perspective and expertise on the questions and solutions that should be prioritized. A community-based participatory research model might help us to co-construct knowledge and build trust with communities.

Not only are these factors important independently, but they have also been proven to make the data we *do* have more accurate by their inclusion and relation to the outcomes of interest that both patients and providers alike care about, such as identifying genetic polymorphisms or predicting painful lesions from diagnostic imaging [27,28]. Similar to how binocular telescopes added depth and dimensionality to celestial images, additional perspectives to health care data might actually improve our ability to understand the realities of our patients' experience.

Acknowledging Our Limitations

It is possible that the solution will not lie in the data itself. Astrophysicists still cannot directly measure dark matter but that does not prevent almost every physicist from valuing it and assessing its impact on our world. Rather, it was the recognition and awareness of the biases and limitations of perception that allowed scientists to begin to account for dark matter's immense volume and strength. When they humbled themselves to the limitations of their data, they gained insight and perspective into an even grander, more complex universe.

Here again, we might learn from our astrophysics colleagues by investigating the incongruities between model and observation. Although most studies simply impute for the missing data, perhaps we might pay more attention to why those data are missing in the first place. When the scientific community asked, "why can we not see dark matter?" the answer led to a better understanding of measurement devices and new knowledge of the effects of subatomic particles. In medicine, when we asked questions such as "why are communities of color less likely to be represented in genetic studies?" we found answers such as limited access to enrollment and mistrust in the medical community, which have solutions that are not simply related to data acquisition [29].

It was Albert Einstein himself who set the example for the scientific community, saying "We cannot solve our problems with the same thinking we used when we created them." Medicine suffers from the expectation that it can find answers if only there were more data, more time, or more support. Perhaps a far more impactful approach would be to acknowledge the limitations of what we know and how we have come to know it and shift our focus from oversampling immense data from the patients within view and humble ourselves to reach the patients who do not come through our doors. The first step is for the medical community to look at our environment of care—our universe—through a critical lens, understanding that there is far more out there than what we have already seen.

Key Messages

Despite decades of dedication to data collection, health care models continue to poorly predict real-world behaviors accurately. This may result from the fact that even the largest data sets only collect information from a fraction of the population, leaving large swaths of the population unrepresented and further limiting progress on health care quality. Solving this problem will require the acknowledgment of what is missing from health care data sets so that we can improve health care outcomes for all.

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Authors' Contributions

CR is an assistant professor at Stanford University School of Medicine and a dual-boarded emergency physician and clinical informaticist specializing at the intersection of clinical medicine, informatics, and human-centered innovation. MD is a research scientist in ethical artificial intelligence with a focus on social bias and the use of algorithmic technologies to analyze human behavior, particularly the behaviors of underrepresented social groups. TD is an assistant professor of emergency medicine specializing in advocacy, policy, medical education, and diversity in medicine. All authors contributed equally to the conceptualization and writing of this work. CR is the guarantor of this paper.

Conflicts of Interest

None declared.

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Viewpoint

How Digital Therapeutics Are Urging the Need for a Paradigm Shift: From Evidence-Based Health Care to Evidence-Based Well-being

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Abstract

A scientific paradigm consists of a set of shared rules, beliefs, values, methods, and instruments for addressing scientific problems. Currently, health care embraces the paradigm of evidence-based health care (EBH). This paradigm prompts health care institutions to base decisions on the best available evidence, which is commonly generated in large-scale randomized controlled trials. We illustrate the application of EBH via the evaluation of drugs. We show how EBH is challenged when it is applied to the evaluation of digital therapeutics, which refers to technology and data to prevent, manage, or treat a medical disorder or disease. We conclude that amid the growing application of digital therapeutics, the paradigm of EBH is challenged in four domains: population, intervention, comparison, outcome. In the second part of this viewpoint, we argue for a paradigm shift in health care so we can optimally evaluate and implement digital therapeutics, and we sketch out the contours of this novel paradigm. We address the need for considering design in health care and evaluation processes, studying user values so that health care can move from a focus on health to well-being, focusing on individual experiences rather than the average, addressing the need for evaluation in authentic use contexts, and stressing the need for continuous evaluation of the dynamic relations between users, context, and digital therapeutics. We conclude that the transition from EBH toward evidence-based well-being would improve the successful implementation of digital technologies in health care.

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digital therapeutics; digital health; paradigm shift; paradigm; health policy; health care; evidence; evidence-based; decision-making; challenges; implementation; well-being; digital; technology

Introduction

Digital health refers to all “technology and data that inform medical practice and improve health” [1]. In recent years, investments in digital health have soared. In 2019, the global digital health market was already worth about US $175 billion, and it is expected to reach US $660 billion in 2025 [2]. Such investments are justified by the promises of digital health to improve the quality and efficiency of health care, increase health care accessibility via remote care delivery, and democratize health care for large populations [3]. Also, the World Health Organization (WHO) believes that digital health will help achieve the 17 Sustainable Development Goals [4]. However, given the promising benefits of digital health, it is remarkable that, currently, only a minority of digital health technologies are implemented successfully in health care. Indeed, some authors claim that as many as 98% of all digital health start-ups fail [5]. Not meeting the needs and values of users is identified

as one of the major reasons for the unsuccessful implementation of digital health [6].

Digital health can be classified into various categories. Following a recent categorization by the US Food and Drug Administration and the nonprofit association Digital Therapeutics Alliance, in this paper we particularly address the category "digital therapeutics" [7,8]. Digital therapeutics refers to all digital health interventions that are employed to *prevent, manage, or treat a medical disorder or disease* [7,8]. Many digital therapeutics are employed today. Examples are mobile apps for health tracking, medication adherence, or monitoring of blood glucose values [9-11]. In addition, virtual reality (VR) and other forms of serious gaming can be considered digital therapeutics when applied as a means for, among other things, pain distraction, pain therapy, or rehabilitation [4,12,13]. Another important area of digital therapeutics relates to artificial intelligence models to assess, for example, abnormal patient behavior, malignant melanoma, or wounds [14-16]. In all cases, patients or health care providers are interacting with *evidence-based* digital technologies to improve patients' health [8].

We explain in this viewpoint why the current health care landscape, which we will call the "evidence-based health care paradigm," does not allow for digital therapeutics to meet user needs and values and, consequently, does not reach successful implementation. Building on our experiences as researchers in digital health, we call for a paradigm shift in health care and sketch out a future paradigm that would enable more successful evaluation and, consequently, implementation of digital therapeutics.

The Current Paradigm in Health Care: Evidence-Based Health Care

Paradigm

The theory of *paradigms* by Thomas Kuhn provides a framework for understanding the context in which digital therapeutics are implemented today [17]. In the 1960s, Kuhn published his book, The Structure of Scientific Revolutions, in which he argued that science is not continuously progressing but consists of a set of alternating periods of "normal" science when scientists adhere to a shared set of rules and values. They share what problems are worthy of investigation and what instruments and methods are appropriate for solving problems. Kuhn termed this a paradigm [18]. At a certain point in time, periods of normal science become challenged by anomalies: new phenomena, ideas, or novel methodologies that are incompatible with the current paradigm. This can result in a crisis, which is only solved when a novel paradigm is found that can accommodate such anomalies. A scientific revolution occurs when this novel paradigm is adopted—a process called a paradigm shift [17,18]. We will build on Kuhn's theory to illustrate why health care is in a digital health crisis and emphasize the need for a paradigm shift to solve the crisis.

Implementation of digital therapeutics generally takes place in the broadly adopted paradigm of evidence-based health care (EBH) or, as it is also termed, evidence-based medicine and evidence-based practice. EBH was developed around 1980 in response to the poor quality of care and high health care costs in the United States [19]. Before its establishment, decision-making was broadly based on expert experience and judgment. EBH aimed to increase the safety, cost-effectiveness, and efficacy of health care while creating an accurate and reliable system for decision-making based on evidence. A typical EBH design and evaluation process was established that particularly guided the development and evaluation of drugs. The process consists of five phases. During phase 1—discovery and development—a new drug is developed in the laboratory. The safety of the drug is tested in phase 2 during preclinical research in laboratory settings. In phase 3, the drug is tested for efficacy via clinical research in people. The drug is reviewed for market approval in phase 4. Phase 5 relates to postmarket safety monitoring of the drug [20]. The collection of evidence is key to these phases of design and evaluation. Evidence is collected, analyzed, and used to inform implementation decisions [21]. Evidence is collected via scientific studies. All studies follow a hierarchy of evidence levels, with the highest-quality evidence created via the systematic review of randomized controlled trials (RCTs). One level lower includes evidence created by RCTs. In an RCT, two or more substantial patient groups are subjected to similar conditions. Only one condition, the intervention, varies. Patients are randomly assigned to one of the groups—ideally blind—to prevent placebo effects. The RCT results in insight into the efficacy of the intervention within the defined patient population. Following the RCT in the evidence tree is evidence from cohort studies, followed by case studies and, finally, expert opinions [22]. The latter three forms of scientific research are rarely considered in health care. Ideally, all evidence in EBH would result from RCTs and their systematic reviews. To guarantee that an RCT generates trustworthy results, studies are standardized by the PICO (population, intervention, comparison, outcome) model [23]. This model prescribes defining the patient or population, intervention, control group, and outcome at the onset of the study.

Today, the need for evaluation results in the tendency to apply the whole EBH pathway—from development and early testing to national implementation—to digital therapeutics [24]. Yet, where this pathway might work for the development and evaluation of drugs, it is not optimal for digital therapeutics. This has been acknowledged before by several authors who provided suggestions on how to evaluate digital therapeutics as part of EBH. Guidelines, for example, exist on the type of research questions to address [25] and the methods of reporting RCTs of digital therapeutics [26]. Also, the WHO has suggested studying acceptability, feasibility, resource use, and gender, equity, and human rights in addition to clinical effectiveness [27]. Nonetheless, even with these guidelines, the gold standard of EBH cannot provide the desired outcomes for achieving a successful evaluation of digital therapeutics resulting in technology meeting the needs and values of all its users. Based on the traditional PICO model of RCTs, we explain below the differences between traditional drug research and digital therapeutics research, and we continue to show why clinical research into the added value of digital therapeutics requires a novel paradigm. Thereby, we do not argue that digital

therapeutics do not require evaluation—a view that is termed as "digital exceptionalism" [28]—but we argue that other methods of evaluation are required to understand the added value of technology. For simplicity, we present our arguments as if traditional drug research and research into digital therapeutics are poles. In reality, traditional health is also challenging the strict application of EBH, but this is beyond the scope of this viewpoint [22,29,30].

Population

The first element of the PICO model traditionally refers to "population" or "patient." A specific group of patients is identified and studied to evaluate the effectiveness of an intervention. In the evaluation of drugs, the patient population is delimited by a specific medical condition and a specific age group. In digital therapeutics, however, it is generally more difficult to identify one group of patients. Digital therapeutics, for example, might be developed for one medical condition in many age groups (eg, serious gaming for rehabilitation) or for many medical conditions in only one age group (eg, a VR playground for children). It could apply to the entire population (eg, a personal online health tracking app), and it extends beyond disease only (eg, wellness apps focused on the prevention of disease).

Even more challenging than identifying the right patient population is engaging patients in the study. Evaluating digital therapeutics typically involves a time- and effort-intense interaction with a technology that drug research does not require. The health condition of patients could prohibit them from spending time and effort on this interaction, which complicates research [31,32]. As a consequence, today, the involvement of patients in digital therapeutic evaluation often seems to be tokenistic. Typically, only a few users are involved, generating the appearance of diversity and inclusiveness, while many users are left out of the study's scope or are out of reach [33]. The result? A misalignment between design and the needs and values of all users [6]. To conclude, digital therapeutics challenge the "P" in the PICO model.

Intervention

We again consider the "intervention" in traditional health care to refer to drug development and its preclinical and clinical evaluation. Phase 1 of drug development starts in the laboratory and follows the rules of EBH. Once a drug is developed, a phase of preclinical evaluation starts, in which the safety effects of the drug are tested in vitro (ie, research in cells) and in vivo (ie, research in animals). The process continues with a clinical evaluation, in which the effects of the drug on the human body are evaluated [20]. A different process is required for digital therapeutics. A digital therapeutic is developed by a team of designers and engineers that conform to different rules, methods, and procedures than those that are known in the EBH paradigm. Design processes, for example, are less structured, rely on qualitative input, and generally do not require evidence for decision-making [24,34]. In addition, designers cannot conduct in vitro evaluation tests but rather they must involve humans directly. Phase 2 of the development pathway is thereby in its current form impossible to conduct. Multiple phases of design and evaluation with users are necessary to design a product that meets user needs. This challenges the current way of evaluating interventions. Consider the example of a VR treatment for chronic pain [35]. First, the current EBH paradigm does not allow for an iterative development and evaluation cycle, while the VR treatment would benefit from cocreation with users. Evaluation with users leads to novel design insights to improve the design, after which a new evaluation cycle should follow [28]. The three typical linear phases of EBH—development, preclinical research, and clinical research—do not support an efficient digital therapeutics design and evaluation process. Second, a typical evaluation study might take months or even years to conduct, with an occasional exception, such as the fast development of vaccines during the COVID-19 pandemic. Digital therapeutics (ie, VR technology) evolves at such a fast pace that an EBH evaluation process only delays progress. With the fast advancements in VR technology, evaluation outcomes might already be outdated once the study ends [24]. Various alternatives have been proposed to RCTs that better meet the needs of digital therapeutic development. For example, a multiphase optimization strategy applied to the RCT allows for adapting of the design during the evaluation process [36]. Also, methods exist to evaluate the principle of a solution rather than the specific technology itself, solving issues of rapid technology advancement [37]. Unfortunately, these novel methods have not been adopted widely [38,39]. To conclude, traditional design and evaluation procedures of EBH do not align with a digital therapeutic as an intervention.

Comparison

A control group is typically identified in phase 3 of drug research. A comparison of the average results of a large control group with the average results of a large intervention group should show an intervention's relative effectiveness. Ideally, group allocation is blind to prevent placebo effects. A digital therapeutic questions such an approach on three of its core features: identification of a control group, the placebo effect, and the mean.

First, the creation of a reliable control group in digital therapeutics is challenging [40]. Consider, for example, children with cerebral palsy using a therapeutic digital game for training fine motor skills. These children can be compared with children not using the digital therapeutic solution. These nonusers could include children not receiving any training, although that is generally considered unethical. Nonusers could also refer to children receiving standard training or children receiving the digital intervention in a nondigital way. Related to the example, this would mean that children receive similar exercises that are then visualized in real life, which would make for a poor comparison. Further, a possible control group could include children receiving the training via television, a lower-tech solution. Finally, an interesting control group includes children using a sham placebo to which children using the digital game are compared; the control group children would be using the same digital game without the therapeutic effect and educational lessons in it [41]. Unfortunately, the development of such a sham placebo is expensive. The study outcomes depend on what type of control group is considered, which could challenge the validity of the study.

Second, dealing with placebo effects differs in digital therapeutics. A placebo effect refers to the positive effect of an intervention on a person's health, not because the intervention has an objective biological effect but because of the subjective psychological effect of a patient believing in the intervention [42]. In the third phase of drug research, the placebo effect is commonly eliminated through blind group allocation to distinguish the objective from the subjective outcomes [43]. Consequently, during implementation in phase 5, clinicians add the placebo effect to the objective biological effect for an optimal therapeutic outcome. In digital therapeutics research, blind group allocation is difficult when not making use of sham interventions. In addition, the distinction between objective outcomes and subjective placebo experiences is difficult to make. Digital therapeutics typically aim at subjective outcomes, such as self-management [44], which challenges the ability to make a distinction between the real effect of a digital therapeutic and its placebo effect [45]. This ultimately challenges the prescription of digital therapeutics, and no consensus exists on the ethical acceptability of prescribing interventions solely based on their placebo effect [46]. Digital therapeutics could, therefore, provide a novel perspective to this ethical debate by challenging the traditional role of placebo in health care.

Finally, the comparison of the mean of two groups is critical in digital therapeutics. Whereas such comparison provides insight into the efficacy of a certain drug, it will not generate the detailed insights that a digital therapeutic requires. In digital therapeutics, the outliers and experiences matter. Consider two patients: patient 1 benefits from using VR for chronic pain whereas patient 2 does not, as this patient needs more technical support for optimal use. The average is a mediocre outcome. The conclusion? The VR treatment is not proven efficacious. It worked for patient 1, and it might have worked for patient 2 once this patient had received additional support. Many individual preferences affect the use of digital therapeutics (eg, the reasons for use, the "dosing of use" [ie, one person might benefit from intense use whereas another desires sporadic use], and the necessary support in use). This requires a move from general outcomes to individual experiences. Promising alternatives to the RCT already exist but are not commonly used. One example is the single-case experimental design, which prescribes studying individual experiences over a longer period while manipulating the treatment [47]. To conclude, the traditional way of using a control group to evaluate an intervention's effectiveness does not align with the practical reality of evaluating digital therapeutics.

Outcome

EBH mostly considers the so-called "hard impacts" of a studied intervention as major evidence. Hard impacts are quantitative outcome measures [48]. Examples of outcomes in drug research include the ability to cure disease and cost-effectiveness. These outcomes are identified at the design phase of the study. Improvement of these outcomes justifies implementation. Although a focus on hard impacts was needed to improve the quality of health care two decades ago [49], solely considering hard impacts in digital therapeutics results in missing important insights required to implement them successfully. EBH has been criticized for its overemphasis on cost-effective decision-making [50,51]. So-called "soft impacts" [48], such as social, ethical, and psychological outcomes, are rarely considered. These are particularly important in the context of digital therapeutics as they provide valuable information on the alignment of a design with users' needs and values [24]. Authors have already stressed the importance of considering these soft impacts in the evaluation of digital therapeutics. Michie et al [52], for example, addressed the need for considering the ethics of digital therapeutics. Maramba et al [53] called for the application of qualitative methods in the evaluation of digital therapeutics. The WHO has recently addressed the need to study user behavior, knowledge, attitude, acceptability, and feasibility [27,54]. Also, concepts such as patient-reported outcome measures and patient-reported experience measures have been introduced to health care [55]. Nonetheless, research practice and reimbursement of digital therapeutics continue to value hard outcomes over soft ones [38,39]. The current paradigm does not motivate studying soft impacts, as these are considered to be low-quality sources of evidence [22]. In addition, these soft impacts cannot always be identified before the study, which challenges the traditional way of evaluating in EBH. Solely focusing on hard outcomes results in the unsuccessful implementation and reimbursement of many valuable digital therapeutics.

In addition to missing important insights required for the successful implementation of digital therapeutics, the narrow focus on hard outcomes in health care prevents the definition of "health" from moving beyond the "absence of disease or infirmity" [56,57]. This definition is also referred to as "negative health." Several initiatives have aimed to redefine health within the domain of health care toward "positive health" that considers it as "well-being" and aspires to individual flourishing [58-61]. Adoption of positive health remains low [62], but it would do more justice to the opportunities of digital therapeutics to encourage self-management and a healthy lifestyle. A larger focus on soft outcomes in digital therapeutics would, therefore, not only improve the implementation of digital technologies but would also enable health care to move its focus from health to well-being [63].

Context

A digital therapeutic is not a drug that can be administered with a prescription. It needs support structures and logistics and it requires education and behavior change in patients, care professionals, and other actors involved. For example, the real effect of VR on chronic pain can only be measured reliably when VR is implemented as part of a pain treatment offered by a medical doctor, supported by logistical and technical structures, and properly used by patients. Namely, it is not only the VR technology but the whole health care service supporting it that should lead to effective pain treatment. This way, a digital therapeutic can be seen as a social intervention. All actors, existing health care procedures, and the time of use should be closely addressed for successful implementation. We, therefore, introduce "context" as a novel element of the PICO model (PICCO). Numerous authors have underlined the importance of considering the context of digital therapeutics. Shaw et al [64], for example, addressed the importance of studying the health care team and its current routines. Lehoux and Blume

[65] illustrated the importance of considering the sociopolitical context of digital health by identifying all people involved with the digital health solution, the power dynamics between people, the resources necessary to implement digital health, and the knowledge necessary to use it. Likewise, Reuzel et al [66] called for a study of the social context of technology from a "social shaping" perspective for understanding how technology affects the norms and values of the various users. With the importance of context, there is also a need for another order of development phases. Instead of evaluation preceding implementation, digital therapeutics require implementation to precede final evaluation [67]. Hence, the added value of a digital therapeutic can only be reliably measured when the technology is implemented and has become part of standard care. This is problematic as implementation decisions in EBH are currently made based on evaluation outcomes. Despite all frequent requests, spatial and temporal complexities of digital therapeutics are rarely addressed, as the PICO model currently does not allow for consideration of this context [6,34,68].

A Novel Paradigm for Digital Therapeutics: Evidence-Based Well-being

From Health to Well-being

Digital therapeutics are creating anomalies in the paradigm of EBH. The PICCO formulation above clearly indicates what anomalies occur when applying EBH to digital therapeutics. A novel transdisciplinary paradigm is required that enables studying the added value of digital therapeutics in health care. Below, we attempt to outline five elements to which a novel digital therapeutics paradigm should adhere. We explain that the full potential of digital therapeutics is only reached when a transition is made from *health* (ie, the absence of disease or infirmity) to *well-being* (ie, a state of persons that designates that they are happy or flourishing and that their life is going well for them) [56,57,69]. We, therefore, name the paradigm "evidence-based well-being." Rather than disregarding clinical research entirely in health care, this novel paradigm focuses on user experiences of well-being as reliable sources of best available evidence for designing, evaluating, and implementing digital therapeutics in addition to the more objective evaluations of better health, security, safety, and cost-effectiveness.

Consider Design in Evaluation

Digital therapeutics introduce a novel discipline into the domain of health care: design. The framework of evidence-based design was established to bridge gaps between health care and design by embedding scientific evaluation in design processes [70]. This framework considers an interdisciplinary approach to health care design by adopting principles of EBH in design [71]. Instead, we aim for a transdisciplinary approach in which design and health care form a novel paradigm without forcing one culture onto the other. This requires moving away from the linear processes of design preceding evaluation [72]. Instead, an iterative process should be established in which health care practitioners and designers constantly collaborate and set up multiple design and evaluation phases. Today, health care generally questions the "yes" or "no" regarding the implementation of digital therapeutics, but a more effective collaboration would explore *how* digital therapeutics can optimally benefit health care [36,37,73].

Consider Values

Digital therapeutics provide many opportunities to positively affect the well-being of patients. Technology can, for example, enable patients to control their health, improve their social relations, and facilitate participation in daily life [35]. Soft outcomes should receive more appreciation to encourage health care to look beyond health and toward well-being. To encourage the adoption of soft outcomes as a source of reliable evidence, evaluation could focus on measuring "values." These relate to everything that people consider important in life and can include both moral and nonmoral values [74]. But this focus on values should not be confused with the increasingly popular health care delivery model of value-based health care (VBH), which aims to measure health outcomes against the costs of health care delivery [75]. Whereas VBH thereby mainly considers economic value, we call for an improvement in individual values, such as autonomy, safety, and privacy. A values-based focus supports the inclusion of a wide variety of soft, delimited outcomes without needing to identify these before the onset of the study. Multiple tools already exist to design and evaluate for values in digital health, which facilitates the adoption of this viewpoint [76,77]. By adopting a values-based focus, health care could shift from health to well-being, and digital therapeutics can reach their full potential.

Consider Individual Experiences

Digital therapeutics require a different evaluation methodology than solely considering the RCTs valued by EBH. There is a need for a move beyond the average result of a large group toward an evaluation of a wide variety of individual experiences, while preventing cherry-picking [47]. Obtaining insight into individual experiences enables the personalization of digital therapeutics (eg, its user interface or user experience design and service implementation), which is a key factor in improving adherence and engagement [78]. Not only should health care researchers value such individual experiences and personalized technology, but health care insurance and investors should also share the value of experience to optimally support and implement digital therapeutics.

Consider the Authentic Context of Use

Digital therapeutics only work when they are part of a supporting health care service. As a result, a design process should not be restricted to the technology. Instead, it should consider designing the complete service that the technology is part of. This includes designing, among other things, interactions between patients and health care professionals, communication lines for expectation management of patients, digital therapeutics distribution lines, and technical support lines. During evaluation, the full service needs to be assessed and optimized. Design and evaluation, therefore, should take place in the authentic context of use. The added benefit of studying technology in the authentic use context is that it facilitates user involvement. User involvement requires adjusting the research tool toward the abilities and time of the various users [79]. Observation of users' lived experiences (ie, empirical understanding of action and

perception in daily context) is an accessible way to involve users in the process [80,81]. Facilitating users to make use of digital therapeutics in their daily lives enables them to spend time on the interaction, without being burdened too much by the research objectives. Such observations provide insight into users' preferences for digital therapeutics (eg, the ideal time and location of use, frequency of use, and support in use) and enable users to provide recommendations for the design of the solution along the way.

Consider Dynamism

Once a technology is implemented, it might restructure current practices and relations. Digital therapeutics could, for example, affect how patients experience their health, the workload of care providers, and the relationship between care providers and patients [82,83]. Furthermore, what users considered to be important might change once digital technologies are introduced (ie, value mediation) [84]. A digital therapeutic forms a dynamic web of temporal and spatial relations and interactions. The configuration of the web dictates what function the technology fulfills. The same technology, for example, can be used for prevention, monitoring, and recovery, depending on what support services are established [85]. This requires a different mindset for evaluation. It requires a study into the optimal configuration of the web and a structural re-evaluation and reordering once conditions change, long after initial implementation [86].

Stimulating a Paradigm Shift

We have argued that the shift from EBH to evidence-based well-being would benefit the design, evaluation, and implementation of digital therapeutics. Yet, what can be done to stimulate a paradigm shift to this novel paradigm? An interesting view on stimulating change is the approach of transition management [87]. The authors of this approach illustrate how changes in complex systems, such as the current EBH paradigm, can be accelerated. They stress the importance of niche creation, frontrunners, and diversity. Based on their recommendations, we propose the following for stimulating a transition in health care:

1. Allocate resources and attention to the creation of niches of digital therapeutics research and implementation.
2. Give audience to, and be inspired by, visionaries within digital therapeutics.
3. Stimulate novel ideas and approaches to digital therapeutics in health care.
4. Establish physical spaces where designers and health care providers work together on digital therapeutics to enable a transdisciplinary culture in health care innovation.

Conclusion

Amid the growing application of digital health technologies, it is time for a change. In this viewpoint, we have shown that the application of EBH to the clinical evaluation of digital therapeutics is problematic. The current paradigm of EBH is challenged by the introduction of digital therapeutics. Instead of proposing a digital exceptionalism in which digital therapeutics do not need to meet safety standards and clinical efficacy, we have argued for the need for other sources of evidence to inform the design and evaluation of digital therapeutics prior to implementation. Instead of EBH, we proposed the paradigm of evidence-based well-being. In this paradigm, design and evaluation become transdisciplinary fields, values are important outcome parameters, individual experiences are a major source of evidence, research is conducted in users' authentic context of use, and the dynamics between users, context, and technology are constantly evaluated. In addition to being valuable for digital health, these recommendations might even inspire a novel approach to traditional health (ie, drug research). The anomalies in our traditional scientific paradigm are clear; it is time for a paradigm shift to evidence-based well-being to optimally align digital therapeutics with the needs and values of each user.

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Authors' Contributions

MS was responsible for conceptualization of the viewpoint, the literature search, writing the original draft, and writing, reviewing, and editing the paper. GDSL and PPV were responsible for conceptualization of the viewpoint, supervision, and writing, reviewing, and editing the paper. HvG was responsible for conceptualization of the viewpoint, funding acquisition, supervision, and writing, reviewing, and editing the paper. All authors accept responsibility for submission of this viewpoint for publication.

Conflicts of Interest

None declared.

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Abbreviations

EBH: evidence-based health care
PICCO: population, intervention, comparison, context, outcome
PICO: population, intervention, comparison, outcome
RCT: randomized controlled trial
VBH: value-based health care
VR: virtual reality
WHO: World Health Organization

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Viewpoint

A New Approach to Enhancing Engagement in eHealth Apps

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Abstract

This viewpoint presents a 3-phase conceptual model of the process of user engagement with eHealth apps. We also describe how knowledge gleaned from psychosocial, behavioral, and cognitive science can be incorporated into this model to enhance user engagement with an eHealth app in each phase of the engagement process.

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KEYWORDS

user engagement; eHealth; attrition; adherence; apps; app design; user experience

Introduction

Effective user engagement is essential for the success of eHealth apps [1]. Yet, effective engagement with these apps remains a persistent problem [2]. Engagement tends to be highly variable and inconsistent [2-6], leading to problems in retention, data quality, and clinical impact [7,8]. Two factors may contribute to suboptimal user engagement with an eHealth app. The first is that a health care app differs from an app such as TikTok or Instagram. With TikTok and Instagram, the engagement systems consist primarily of providing people with more of what they already want [9]. In health care, people are asked to do things that they do not necessarily want to do. Someone may be very committed to losing weight but still want to eat cake. A person may be committed to participating in a clinical trial for many good reasons, but they may still not want to fill out a survey when tired or distracted by competing interests. To date, solutions to improve engagement have been offered but have had limited success [10-12].

A second factor is that sustained user engagement is a complex process [10]. Historically, engagement was defined by a variety of operational metrics; for example, the number of logins, number of pages visited, and number of tasks or modules completed [11]. However, these metrics do not capture or reflect the actual experience of the user [10,12-14]. More recently, the concept of engagement has been further differentiated from interface design and user experience. These two fields of knowledge contribute to the usability, ease, and pleasure of interacting with a digital technology and are important contributors to user engagement [15].

User engagement is characterized by attention, commitment, and involvement [12,14]. O'Brien and Toms [16] define engagement as "a quality of user experiences with technology that is characterized by challenge, aesthetic and sensory appeal, feedback, novelty, interactivity, perceived control and time, awareness, motivation, interest, and affect." The resulting conceptual model of engagement distinguishes different phases of the engagement process: "Upon a point of engagement, the user initiates and sustains engagement in a task, he disengages, and potentially reengages several times with the system" [16]. These phases offer targets for interventions and content to enhance engagement and provide a useful structure for organizing and sequencing engagement-enhancing design.

A Conceptual Model of Engagement

A conceptual model guiding the design and selection of interventions integrated into an eHealth app is needed to

optimize patient engagement. A report by the Standing Committee for Psychology and Health and the E-Health Taskforce of the European Federation of Psychologists' Associations stated, "Utilization of a theoretical design framework in digital intervention planning cultivates and maintains user engagement and motivation to adhere to the intervention throughout its intended duration. Examining the literature on digital interventions suggests that most digital programs evaluated are not rooted in specific theoretical frameworks" [12]. A coherent, theory-based model draws upon established bodies of psychosocial, behavioral, and cognitive science to enhance the process, depth, and consistency of patient engagement with eHealth apps. This viewpoint describes and illustrates a model structured around 3 phases of the engagement process: initiation, strengthening, and maintenance incorporating knowledge from psychosocial, behavioral, and cognitive science.

Initiation of Engagement

Three components of initiation can be informed by the aforementioned science: (1) design of the app's user experience; (2) decision and intent to participate; and (3) technical competence, digital anxiety, and health literacy.

Design

An effective user interface design is essential for both inducing participation and reducing barriers and friction points that can impede participation. Through better design, the user experience is enhanced and engagement is increased. The 5 Principles of Intentional Design [17], Rogers' 5 attributes of product perception, and Rogers' 5-category model of adopter types and innovation diffusion [18] are established bodies of psychosocial knowledge that provide practical guidance for effective app design.

Decision and Intent to Participate

This is informed by 3 relevant bodies of work—Prochaska and DiClemente's [19] transtheoretical model of Stages of Change, Motivational Interviewing [20], and Hibbard et al's [21] Patient Activation Measure.

Technical Competence, Digital Anxiety, and Health Literacy

Barbeite and Weiss' [22] model of digital anxiety and technical self-efficacy directly informs the initiation of engagement. This model posits that the ability to competently use a digital app has 2 aspects: (1) an actual technical competence to operate the digital app and its associated device and (2) a subjective sense of anxiety, usually driven by the fear of making an app-disabling mistake. From an information-processing perspective, the negative feelings associated with high anxiety detract cognitive resources from task performance. Similarly, health literacy—the ability to understand the information that the app provides and respond accurately and completely where required—should be assessed and improved as needed. A large body of research supports the importance of adequate health literacy for effective user engagement [23].

Strengthening of Engagement

After engagement has been initiated, 2 well-studied processes can strengthen engagement: (1) the therapeutic alliance [24] and (2) behavioral conditioning to convert controlled processes that require conscious thought to automatic processes [25].

A Digital Analog of the Therapeutic Alliance

The therapeutic alliance in psychotherapy is characterized by a relationship that is collaborative in nature and characterized by a positive affective bond between the patient and the therapist [26]. It is further characterized by a relationship in which the therapist and patient agree on the treatment's goals and tasks [27]. Establishing a positive therapeutic alliance is essential for successful psychotherapy, even apart from the type of psychotherapy or specific technical competence of the therapist [28]. Fortunately, much is known about how to establish and deepen such a therapeutic alliance [29-32]. Attention to these alliance-forming and deepening factors in the design and content of the eHealth experience transforms the affective nature of the patient's experience, engages the patient as a collaborator, and establishes clear agreement on the mutual and respective roles and tasks of the patient and the eHealth system. Such a relationship is a powerful motivator for the patient to remain engaged.

Behavioral Conditioning and Automaticity

The basic principles of behavioral conditioning, including both primary and secondary reinforcement to promote positive engagement behaviors and to transform consciously directed study-specific tasks into automatic habits, can be useful to deepen engagement. This transformation relieves the patient of cognitive burden and eases completion of study tasks. A converging body of work offers complementary methods to achieve this transformation, including habit theory [33-35], dual-process theory, and an understanding of the neurobiology of this transformation [25].

Maintenance of Engagement

Some factors can interfere with a patient's continued engagement with the eHealth app and result in missing tasks, sporadic participation, or complete attrition. These include boredom, fatigue, other demands of life, and other intercurrent events [36]. Psychological and social science provides possible remedies to help maintain engagement.

Stress Management

It has been demonstrated that intercurrent stress can interfere with a previously successful level of patient engagement [37]. Basic activities for stress self-management are well established and can be accessed as needed through the study app [38].

Adherence Management

The literature on health care adherence offers common reasons for nonadherence and describes interventions built to support continued adherence [39]. This work is relevant to ways to prevent attrition and retain engagement. For example, one successful intervention is a continuous adherence-monitoring system that identifies lapses in task completion and notifies the patient and treatment team of such lapses and of the opportunity for situation-specific intervention [40,41]. Such a system engages the patient at a point of possible disjuncture and can be readily implemented in an eHealth app.

Nudge Theory

Nudge theory [42] provides an understanding of human choice derived from behavioral economics and a demonstration of the effect of the choice environment on the decisions an individual makes. In the technology sphere, this is referred to as the choice architecture of the app design and its associated functions to help guide a user to a beneficial choice. Embodiments of nudge theory include recommender systems, reminder systems, and motivational messaging [43].

Assessing the Model

This viewpoint proposes that each implementation of these knowledge-based strategies be systematically tested to assess its individual contribution to improving user engagement before being introduced into the final eHealth app design using a standardized assessment such as O'Brien et al's [44] User Engagement Scale Short Form questionnaire. For example, in our own desk research work, we have developed a preliminary module to assess health literacy, and we have developed a library of educational materials that can be provided as needed to help the user achieve adequate literacy to successfully use a particular eHealth app. We propose to test this module and each subsequent module following the strategy described above before incorporating it into the final app design. We then propose to test an app with these enhancements against an app without them.

Conclusion

This conceptual model draws upon an extensive body of literature on behavioral, cognitive, and psychosocial science with the aim of improving the extent, quality, and clinical impact of user engagement with eHealth apps at each of the 3 major phases of the engagement process.

Conflicts of Interest

Both authors are affiliated with Medable Inc. IO-G is the Senior Vice President of Research and Strategy, and JD is a consultant to Medable and an Adjunct Professor of Psychiatry at Weill Cornell Medical College.

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Viewpoint

Recommendations for Successful Implementation of the Use of Vocal Biomarkers for Remote Monitoring of COVID-19 and Long COVID in Clinical Practice and Research

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Abstract

The COVID-19 pandemic accelerated the use of remote patient monitoring in clinical practice or research for safety and emergency reasons, justifying the need for innovative digital health solutions to monitor key parameters or symptoms related to COVID-19 or Long COVID. The use of voice-based technologies, and in particular vocal biomarkers, is a promising approach, voice being a rich, easy-to-collect medium with numerous potential applications for health care, from diagnosis to monitoring. In this viewpoint, we provide an overview of the potential benefits and limitations of using voice to monitor COVID-19, Long COVID, and related symptoms. We then describe an optimal pipeline to bring a vocal biomarker candidate from research to clinical practice and discuss recommendations to achieve such a clinical implementation successfully.

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KEYWORDS

vocal biomarker; COVID-19 symptoms; digital health; remote monitoring; artificial intelligence; voice; COVID-19; Long COVID; digital health solution; voice-based technology; health technology; health monitoring; digital health monitoring; health care application; remote patient monitoring

Introduction

Management of COVID-19 and Long COVID

Since February 2020, the COVID-19 pandemic has mobilized the entire research, medical, and pharmaceutical community for treatment and vaccine development as well as care and disease management of patients with COVID-19. Many countries adopted strategic measures to fight the pandemic, such as lockdowns, social distancing, or contact tracing, to reduce transmission [1]. In parallel, we observed rapid a development of digital tools to support the health care system and an increased use of telemedicine and teleconsultations. COVID-19 infection is caused by the SARS-CoV-2 virus and can take several forms, from asymptomatic to moderate or severe illness. At the onset of the illness, common symptoms are fever, cough, dyspnea, myalgia fatigue, loss of taste or smell, and sometimes gastrointestinal symptoms. Complications include acute respiratory distress syndrome, anemia, or acute cardiac injury [2].

After the acute phase, it has been estimated that up to 68% of patients with COVID-19 will have persisting symptoms after 6 months, and 49% after a year [3]. Long COVID syndrome is defined as a set of symptoms persisting and fluctuating beyond 4 weeks after infection, leading to long-term support and care needs [4]. Long COVID is multiorgan and can affect lungs, heart, brain, kidney, and blood vessels. Long COVID also affects cognitive functions and mental health with diverse symptoms such as brain fog [5], confusion, memory deficiencies, and even posttraumatic stress disorder [6]. The most frequently reported symptoms are fatigue, abnormalities of smell and taste, anxiety, sleeplessness, and dyspnea [4]. The severity of the acute illness seems not to be directly related to the development of Long COVID, and many people with Long COVID did not return to the same level of work and quality of life as before COVID-19

infection [7]. The absence of treatment and the specificities of Long COVID in terms of symptom types and fluctuation over time justifies the need to develop solutions for objective and qualitative symptom monitoring rapidly. As such, a panel of experts from the National Institute for Health and Care Excellence recently recommended developing telemonitoring and encouraging self-management of acute and Long COVID symptoms in a tailored and accessible way for each patient [8]. In particular, at-home self-monitoring is encouraged [9].

From Traditional to Enhanced Approaches of Patient Monitoring

The medical care of patients in real-life situations has been rapidly evolving since the pandemic started. Video or phone consultations have largely replaced traditional visits to the family doctor or specialist and have shown the utility [10] of these formats to follow up patients who are not able to travel or are located in geographic regions lacking medical doctors. In parallel, the use of medical devices for self-monitoring of physiological parameters such as blood pressure or blood glucose level has also increased. The next development step would be to unify and standardize telemedicine solutions with enhanced teleconsultations, including a real-time assessment of key physiological parameters. This would optimize the consultation time and enable a personalized follow-up with increased communication between the health care professionals and the patients.

Regarding clinical research, there was already, before the pandemic, a global trend toward completely remote, decentralized clinical trials [11,12]. The pandemic has now accelerated such digitization. Participant monitoring in clinical trials is progressively moving away from a paper-based approach (ie, paper informed consent, questionnaires, and medical records) to fully remote or hybrid setups, where patients' visits on-site and remote, 'in-between visits,' and follow-up in real-life are combined. Digitization and decentralization of clinical trials encompass three axes: digital participant recruitment and retention, digital data collection, and digital analytics [13], based on electronic documents (eg, e-consent and electronic case report forms), virtual study visits, and physical self-measurements. Digital data collection facilitates and standardizes data quality, whereas digital analytics using artificial intelligence techniques like machine and deep learning methods allow for deep phenotyping of participants.

Digital Technologies for the Clinical Management of Patients With COVID-19

Technologies already exist to facilitate remote patient monitoring in clinical practice or research, such as electronic patient-reported outcomes, sensors or devices to measure physiological parameters at home (eg, Holter for electrocardiograms, blood pressure, and heart rate), video-based methods, or mobile phone–based remote symptom monitoring systems [14]. In the context of COVID-19, hundreds of contact tracing mobile apps and artificial intelligence–based radiological technologies to facilitate early detection of COVID-19 emerged early during the pandemic [15]. In parallel, several digital technologies have been developed to respond to different patient needs, including diagnosis, prevention, treatment, adherence, lifestyle, or patient engagement [16]. For example, a smartwatch application has been developed in Germany to help COVID-19 diagnosis based on a few vital signs [17], and 2 remote monitoring systems—Telecare-COVID (based on phone calls) and CareSimple-COVID (a telemonitoring app)—are used in Canada and are well accepted by the users [18].

Voice assistants have also been identified as an innovative tool for health care services in the context of a pandemic, as a tool for health information exchange, for remote monitoring or to maintain continuous care with teleconsultations [19].

Voice is an easy-to-collect source of information, requiring less time than completing a questionnaire, being noninvasive, and inducing less burden for patients or study participants. The first use of voice dates back to 2003 in clinical studies and health care services with interactive voice response system [20], a phone-based system mainly used for patient randomization. Interactive voice response system was also used for symptom monitoring by calling participants and encouraging them to answer questions on their health status and in return, patients could receive specific recommendations to manage their treatment. However, voice is in itself a rich medium providing information on health status and emotions, allowing for a richer characterization of patients through the use of so-called vocal biomarkers. This opens many perspectives of using voice besides the practical aspect of using it as a collection tool.

As we are now at a turning point in telemedicine, we believe that the use of vocal biomarkers is among the most promising approaches to improve patient monitoring of COVID-19–related symptoms.

In the following sections, we provide an extensive description of the potential benefit and limitations as well as recommendations for the development of a digital health solution based on vocal biomarkers. Since the pandemic revealed specific needs, these recommendations are elaborated in the COVID-19 context but can be easily generalized to other diseases or symptoms.

Using Vocal Biomarkers for Remote Symptom Monitoring in the Future

What is a Vocal Biomarker?

As mentioned before, voice is a rich medium, characterized by thousands of different features, potentially affected by our health status. Thus, a vocal biomarker is an extension of a classical biomarker, a factor objectively measured and evaluated representing a biological or pathogenic process or a pharmacological response to a therapeutic intervention [21]. It can also be used as a surrogate marker of a clinical end point. A vocal biomarker can therefore be defined as a signature, a feature, or a combination of features from the audio signal of the voice associated with a clinical outcome. It must have all the properties of a traditional biomarker, needing to be analytically validated and qualified using an evidentiary assessment. A vocal biomarker can be used to monitor patients, diagnose a condition, or grade the severity of a disease [21].

Vocal biomarkers have already been described in pathologies such as Parkinson disease, depression, and cardiovascular diseases with the potential of early diagnosis or disease progression markers [21], but none of them is used in clinical practice yet. Since voice features can be specifically associated with these different pathologies, one can extrapolate that similar voice features could be associated with a COVID-19 infection or with a consequence of COVID-19. COVID-19 infection or complications can affect voice through different mechanisms. For example, respiratory insufficiency can lead to reduced airflow, and therefore, changes in voice parameters [22]. Other studies showed that voice quality was reduced in patients with COVID-19 due to repeated cough, laryngeal or pharyngeal erythema, or sore throat [22-24].

Potential Benefits and Limitations of Using Vocal Biomarkers in the Context of COVID-19

The first developments based on the use of vocal biomarkers in the context of COVID-19 were meant to enable the detection of COVID-19 infection. Vocal biomarkers for COVID-19 detection in cough and voice have been developed and could one day serve as a screening tool on a very large scale and in a short period of time, for example, at airports or border controls, leading to a direct benefit for the pandemic management [25,26].

Another benefit of vocal biomarkers to monitor COVID-19–related symptoms remotely is a reduced burden for the user by limiting the clinical visits on-site, replacing tedious questionnaires and physical examinations, and facilitating the reporting of symptoms or adverse events [27]. It could also allow for simultaneous monitoring of several COVID-19–related symptoms, with early detection of a worsening in the health or mental condition, or on the other hand, serve as a proxy to assess treatment or rehabilitation effectiveness. All of these benefits combined could in turn lead to reduced risk of hospitalization and increased quality of life.

From a clinician or a researcher's perspective, the use of vocal biomarkers can facilitate and objectivize patient evaluation, in particular when the results are transmitted by a visualization tool that might be easier to interpret than questionnaires. Vocal biomarkers could also serve as a proxy to assess the benefits of a rehabilitation program for people with Long COVID. As the collection of voice recordings is fast, fun, and limits the burden for patients, it could also reduce attrition in clinical trials. Lastly, voice collection reduces costs and allows for fast and high-volume recruitment in trials by helping the inclusion of patients unable to travel or with mobility issues, improving participant representativeness, and reducing selection bias. Participants' engagement should also be increased and limit attrition in the studies by involving them in the management of their pathology.

Integrating vocal biomarkers in care would also facilitate communication between patients and medical teams thanks to better follow-up and medical care; particularly in a pandemic, it would limit contacts and infection risks. Coupling vocal biomarkers with alert systems could improve patient care and safety. The inclusion of voice analysis in health calls or emergency centers would enable augmented consultations, more accurate caller authentication, and real-time analysis of important health-related features [21].

We believe that increased use of voice in the future will maximize the benefits for both the investigators and the study participants, thanks to the combination of the best of both traditional and digital approaches; it will ultimately increase the quality of the studies and saves time and costs. Besides, both for clinical practice and clinical research, there is a need to avoid the 'in-between clinical visits black hole' and to describe better what is happening to a patient between two follow-up visits. Telemonitoring solutions based on vocal biomarker monitoring could allow for a more accurate follow-up and complement on-site evaluations [28].

However, some researchers have challenged the relevance of a vocal biomarker for COVID-19 detection [29] and raised the issue of whether it is an actual marker of the disease or a proxy of the general health status, or worse, a proxy of the context of recording of the individuals.

Other limitations to the use of vocal biomarkers for remote monitoring of COVID-19–related symptoms include patients' acceptability and readiness of the health care system [19] for this new technology. The health status could also be a limitation, in the way that persons experiencing severe symptoms could be too affected to be willing to do the voice recording regularly, and therefore, affect adherence to the digital solution.

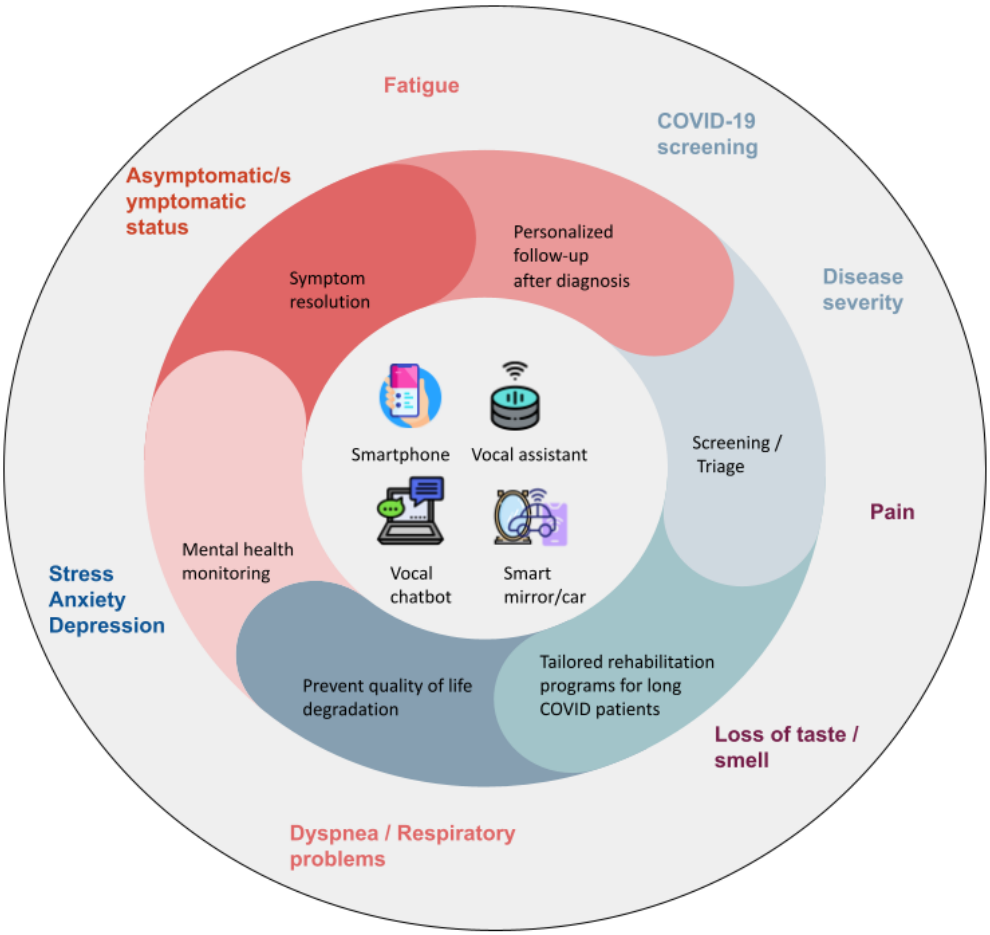
Development of a Digital Health Solution Based on Vocal Biomarkers to Monitor COVID-19–Related Symptoms

Identification of the Outcome to Be Monitored

Many previously cited COVID-19–related symptoms could theoretically be monitored using voice, including fatigue, dyspnea, loss of taste or smell, disease severity, presence or absence of symptoms, as well as impact on mental health (eg, stress, anxiety, and depression). However, the choice of monitoring one of these symptoms should be discussed with health care professionals to ensure its clinical relevance.

Potential clinical applications of vocal biomarkers for these symptoms are presented in Figure 1. Vocal biomarkers could be implemented in devices, such as smartphone apps, chatbots, smart mirrors or cars, and vocal assistants, to monitor symptom resolution (with a vocal biomarkers of symptomatic or asymptomatic status), mental health, and quality of life degradation (with vocal biomarkers of stress, anxiety, depression, chronic fatigue, or dyspnea); to propose personalized follow-up after diagnosis (with vocal biomarkers of disease severity); to perform a screening and a triage of patients at hospital (with vocal biomarkers of disease severity, pain, or loss of taste and smell); and to propose tailored rehabilitation programs for patients with long COVID (using vocal biomarkers of loss of taste and smell, pain, dyspnea, and fatigue).

Figure 1. Different use case of vocal biomarkers related to COVID-19. The outside layer represents different vocal biomarkers , the second layer represents the use cases, and the center shows different devices that could embark vocal biomarkers.



Data Collection

This step consists of voice data collection coupled with well-documented clinical data in screening platforms such as Colive Voice [30] or large prospective cohort studies [2,31]. The collected data have to be diverse enough and should represent the target population in terms of languages, accents, and socioeconomic backgrounds to decrease the risk of systemic biases and the risk of increasing a potential preexisting digital and socioeconomic divide in the population.

Different types of voice records, such as vowel phonation, reading a predefined text, counting, or semispontaneous voice tasks, as well as nonverbal vocalization (eg, coughing and breathing) can be collected depending on the future foreseen clinical application. The environment and conditions of voice recordings are critical, in particular in COVID-19 settings. Indeed, background noises and audio features may differ between COVID-19–positive and control participants due to the isolation of COVID-19–positive persons. For this reason, clear instructions to perform the voice recordings have to be provided before data collection.

Depending on the final use case, at home or at the hospital, recordings can be performed under either controlled conditions with high-quality microphones and standard processes or in real-life conditions with the patients' smartphones. As mentioned before, the recording situation may impact audio quality but can also allow for the training of more relevant algorithms based on more diverse data sets. Wearing a surgical mask has been shown to have no impact on vocal parameters, such as vocal intensity, jitter, shimmer, and harmonics-to-noise ratio [32]; voice collection can thus be performed safely at the hospital or during clinical visits. The validity of the data set can also be a concern, as the COVID-19 status may be self-reported [33] and may induce some mislabeling of the audio.

From Voice Recording Toward Vocal Biomarkers

After several preprocessing steps on the raw audio signals, the identification of vocal biomarkers candidates is based on machine and deep learning methods, such as support machine vectors, random forest, and visual geometry group, among many others, which can be supervised or unsupervised. When a limited data set is available, an alternative is to use transfer-learning methods. The interest of this method is to take advantage of a pretraining of the algorithm on a large data set from another domain and to fine-tune it for the defined target. Internal and external validations are then required in other settings and using other data sets.

At this stage, the vocal biomarker candidate has also to be clinically validated in one or several clinical studies in comparison to the gold standard measurement of the outcome of interest (eg, validated scales to assess fatigue or stress or, if

available, established physiological parameters such as blood pressure or glycemia). The design of the studies has to be chosen carefully, going from a very standardized double-blind study to a real-life prospective study.

Recommendations for the 3 steps for the evaluation of vocal biomarkers (ie, verification of audio quality, analytical validation, and clinical validation) have been provided by Robin et al [34].

Embedding the Vocal Biomarker in a Digital Health Solution

The next step after identification and validation of a promising vocal biomarker candidate is to design a digital health solution to embed it. Several digital devices can be imagined, such as smartphone apps, chatbots, smart mirrors, or voice assistants. The future end users of the device, namely the patients and the health care professionals, should be involved in the co-design of the final solution [35,36] to ensure it meets their needs and expectations. This is particularly important for voice-based technologies to ensure their future acceptability. Finally, feedback loops should be implemented to improve both the solution and the algorithm through lessons learned in population studies.

Particular caution should be taken when collecting voice; indeed, voice is considered as identifying and sensitive data, and its collection falls under different regulations or laws, such as General Data Protection Regulations [37] in Europe and Personal Information Protection and Electronic Documents Act in Canada. In the United States, there is no single data protection law but rather multiple laws enacted at a federal or state level. These different laws do not protect individuals at the same level, and to minimize future risks for the use of the digital health solution, it is highly recommended to obtain explicit consent prior to collection. Measures have to be implemented by design and by default to securely process voice without privacy leakage (eg, encryption of voice data, splitting data into random components, or using data representations from which sensitive identifiable information is removed).

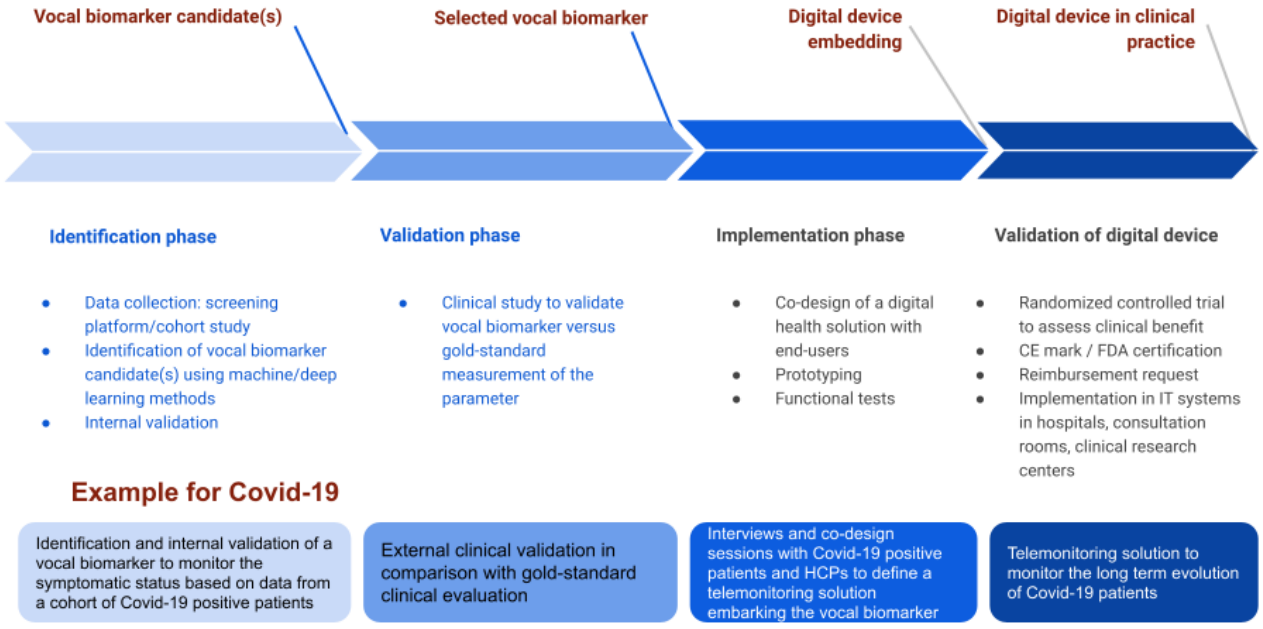
Once the digital health solution is developed, an additional validation step is mandatory to prove clinical benefit, effectiveness, and security in clinical trials. Indeed, most digital health solutions fall under the new Medical Device Regulation [38]. CE marking or Food and Drug Administration (FDA) certification will be mandatory to bring the solution to the market, and requirements for clinical evaluation are diverse, depending on the final device. The definition of the 'intend-to-use' (article 2 of Medical Device Regulation) of the device should be done early in the development process to define clinical evaluation requirements. It is highly recommended to consult guidance documents for digital health interventions (eg, MEDDEV 2.1 [39], FDA's benefit-risk framework for medical devices [40], and the World Health Organization's monitoring and evaluating digital health interventions [41]) and to take advice from regulatory authorities or a notified body.

Requests for reimbursement of the device or solution can be made to national health insurance funds after the clinical and economic interest of the new digital system is proved.

An overview of the pipeline to develop a digital remote monitoring solution based on vocal biomarkers is presented in Figure 2.

Finally, as mentioned above, some vocal biomarkers have been identified in several pathologies, but none of them are currently used in clinical or real-life practice; indeed, the field of vocal biomarkers is recent, and the way is still long until a health solution based on them can be commercialized. Companies are currently in the process of requesting FDA authorization or CE mark but are facing challenges related to data security, ethical issues, as well as reliability and reproducibility of the algorithms.

Figure 2. Pipeline from identification to implementation in clinical practice of a vocal biomarker. CE: conformite europeenne; FDA: Food and Drug Administration; HCP: health care provider; IT: information technology.



Conclusions

This viewpoint presents the need for new digital remote monitoring technologies in the context of COVID-19 and the potential benefit of using vocal biomarkers for this purpose. We also propose a pathway and recommendations for a successful implementation in clinical practice of a digital health solution based on vocal biomarkers.

Implementation of vocal biomarkers in a digital solution for remote patient monitoring of frequently reported symptoms of COVID-19 is of high interest. Its full potential can be achieved in the short term but still includes challenging steps and hurdles to overcome before launching reliable solutions in practice. Vocal biomarker acceptability remains to be properly evaluated, as the use of voice is a rather new technique and needs to be integrated into existing health information technology systems. The future of digital solutions embedding such vocal biomarkers will be diverse and will probably evolve toward multitechnologies solutions combining voice, video, and sensors to offer the most comprehensive view of a patient's health status.

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Authors' Contributions

AF wrote the first draft of the manuscript. All other authors critically revised the manuscript and approved the final version of the manuscript.

Conflicts of Interest

None declared.

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Abbreviations

FDA: Food and Drug Administration

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Viewpoint

Levels of Autonomous Radiology

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Abstract

Radiology, being one of the younger disciplines of medicine with a history of just over a century, has witnessed tremendous technological advancements and has revolutionized the way we practice medicine today. In the last few decades, medical imaging modalities have generated seismic amounts of medical data. The development and adoption of artificial intelligence applications using this data will lead to the next phase of evolution in radiology. It will include automating laborious manual tasks such as annotations, report generation, etc, along with the initial radiological assessment of patients and imaging features to aid radiologists in their diagnostic and treatment planning workflow. We propose a level-wise classification for the progression of automation in radiology, explaining artificial intelligence assistance at each level with the corresponding challenges and solutions. We hope that such discussions can help us address challenges in a structured way and take the necessary steps to ensure the smooth adoption of new technologies in radiology.

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KEYWORDS

artificial intelligence; automation; machine learning; radiology; explainability; model decay; generalizability; fairness and bias; distributed learning; autonomous radiology; AI assistance

Introduction

Advancements in artificial intelligence (AI) and machine learning have enabled the automation of time-consuming and manual tasks across different industries [1]. With substantial developments in the digital acquisition of data and improvements in machine learning and computing infrastructures, AI applications are also expanding into disciplines that were previously considered the exclusive province of human expertise [2]. From automobiles to the health care sector, the world is actively adopting AI to transform these respective industries.

The confluence of information and communication technologies with automotive technologies has resulted in vehicle autonomy. This growth is expected to continue in the future due to increasing consumer demand, reduction in the cost of vehicle components, and improved reliability [3]. The Society of Automotive Engineers has classified the progression of driving automation into 6 levels [4], ranging from *No Automation* (Level 0) to *Full Automation* (Level 5). The levels of driving automation are characterized by the specific roles played by each of the 3 principal players, that is, the human user (driver), the driving automation system, and other vehicle components. As vehicle autonomy increases with each level of automation, driver intervention is reduced [4].

Similar to the automobile industry, AI is progressively transforming the landscape of health care and biomedical research. A simulated deployment of natural language processing–based classification algorithm has been shown to enable automated assignment of computed topographic and magnetic resonance radiology protocols with minimal errors, resulting in a high-quality and efficient radiology workflow [5]. More recently, applications of diagnostic imaging systems have expanded the capabilities of AI in the previously unexplored and more complex health care sector [2]. In radiology, AI applications are being widely adopted for assisted image acquisition, postprocessing, automated diagnosis, and report generation. Automation in this field is still in its infancy, and

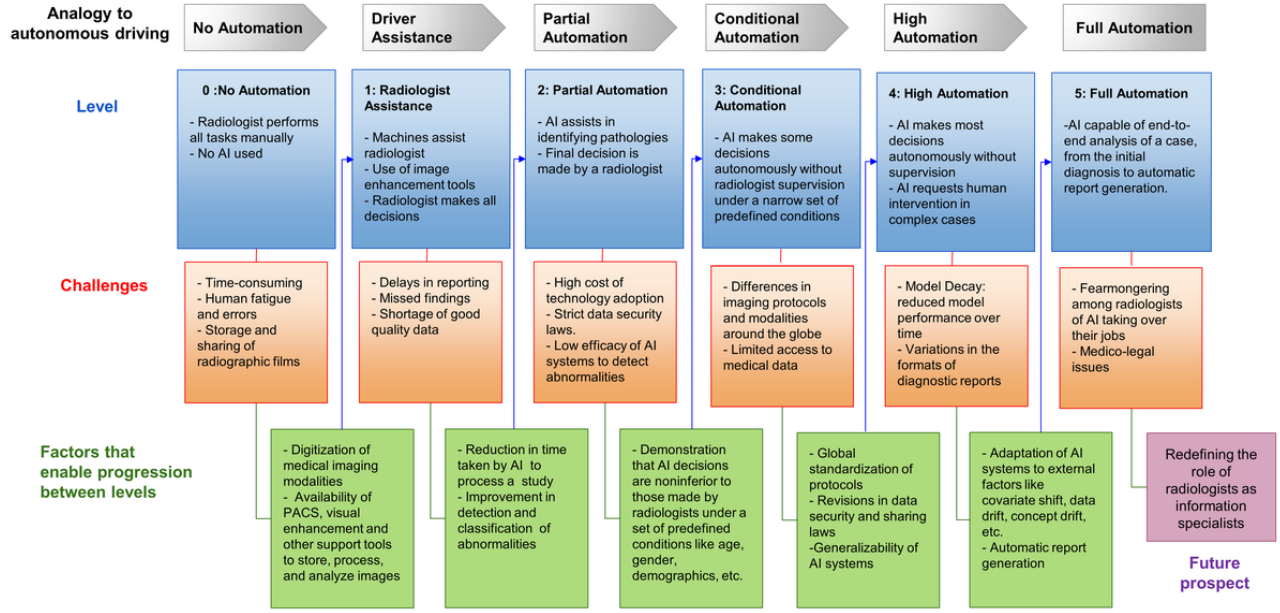
several clinical and ethical challenges must be addressed before further progress can be made [6].

In this perspective, we attempt to categorize and map the advancements and challenges of automation in radiology into 6 levels, similar to driving automation, with radiologists, AI systems, and advanced technologies playing important roles at each level. The subsequent parts of the paper briefly discuss each level, its technical challenges, plausible solutions, and enabling factors required for transitioning into the next level.

Levels of Automation in Radiology

The advancement of AI in the health sector has substantially bridged the gap between computation and radiology, paving the way for automation in radiology practice. We describe the 6 levels of automation in radiology using a taxonomy similar to that used in driving automation. We further attempt to provide a futuristic vision of the challenges that the radiology field may encounter as we progress toward the complete automation of this field. Figure 1 illustrates different levels of automation in radiology, including the challenges at each stage and the factors that enable the progression between levels.

Figure 1. Flowchart depicting the various levels of automation in radiology practice. At each level, the role of the radiologist and artificial intelligence (AI) is outlined, along with the enabling factors required to mitigate the potential challenges for progression to the next level. PACS: picture archiving and communication systems.



Level 0: No Automation

Level 0, also known as *No Automation*, is the stage where a radiologist manually performs every task from image acquisition and radiographic film processing to diagnostic analysis without the assistance of AI. We are well past this stage as the recent advances in medical imaging modalities have enabled digital storage and processing of the scans along with some automated assistance to aid in the imaging workflow.

Level 1: Radiologist Assistance

At Level 1 automation, a radiologist performs most tasks manually with assistance from machines. Recent technological advancements have digitized medical scans, making it easier for radiologists to store, maintain, and distribute data. Furthermore, newer solutions include features such as contrast-brightness adjustment, assisted stitching of scans, assisted focus adjustment, etc, which simplify the imaging workflow and enable detailed radiological analysis. With everything digitized, these modalities generate enormous amounts of data, and the biggest challenge at this stage is the proper maintenance and storage of data [7]. This is where technologies such as picture archiving and communication systems have provided an economical solution to compress and store data for easy retrieval and sharing [8]. With the advancement in automation, the radiology field is currently experiencing a major paradigm shift in the principles and practices of many computer-based tools used in clinical practice [9].

Level 2: Partial Automation

Partial automation in radiology refers to the use of computer-assisted diagnostic modalities to automate prioritization. However, the automation at level 2 requires radiologist supervision, and the diagnostic decision is not final without the radiologist's approval. With the advancement of picture archiving and communication systems technology, radiology practices frequently consider upgrades and renovations to further improve efficiency. For example, radiomics is an emerging subfield of machine learning that converts radiographic images into mineable high-dimensional data by providing additional features to analyze and characterize the disease. Machine learning algorithms can be used to extract features from radiographic images that can help make prognostic

decisions [10]. Feature extraction includes the texture, intensity, shape, and geometry of the region of interest [11]. Besides feature extraction from images, clinical and molecular profile data could sometimes be essential to comprehend complex diseases and ensure the right diagnosis to deliver the best possible treatment [12]. The amalgamation of machine learning, radiomics, and clinical information has the potential to improve its application in precision medicine and clinical practices. Since these technologies are still in their nascent stages of development, radiologists will most likely use them as ancillary tools in making final decisions.

The progress at this level of automation is slow and can be attributed to three major factors:

1. Lack of high-quality data: There is a limited amount of good quality medical data because the annotation and documented diagnosis by an expert are time-consuming and expensive processes [13]. This becomes a challenge when developing an AI system that can generalize well across unseen data, because the performance of machine learning models is significantly influenced by the size, characteristics, and quality of the data used to train them. The problem of insufficient training data, particularly in cases of rare diseases, can be addressed through data augmentation, in which synthetic data are generated to increase the prevalence of the target category, making the models more robust for analyzing independent information on the test sets [14]. Generative adversarial networks are the most commonly used neural network models for generating and augmenting synthetic images for rare diseases, such as rheumatoid arthritis and sickle cell diseases. Although these techniques allow models to be trained on sparse data sets and produce promising results, the adoption of generative adversarial networks in medical imaging is still in its early stages [15].
2. Stringent data laws: Medical data are often governed by several data security laws, regulations, and compliances, making it extremely difficult to share and use this data outside a clinical setting [6]. Collaborations between hospitals and tech companies are critical to bypass the barriers of data-sharing laws and make the best use of rich medical data to develop advanced solutions for automated and accurate diagnoses.
3. Cost of technology adoption: Current algorithms for analyzing radiological scans are computationally resource intensive, which significantly increases the cost of adopting these technologies in clinical practices. Therefore, it is important to develop low-power and cost-effective solutions that can be easily adopted by medical organizations. Edge devices can be used as low-cost prescreening tools as they can be deployed remotely and deliver instant results without consuming much bandwidth [16].

Level 3: Conditional Automation

Unlike partial automation, where the final decision is entirely dependent on the radiologist, the systems at *Level 3: Conditional Automation* are robust enough to diagnose and make decisions under a predefined set of conditions (ie, those used to train the model) without radiologist supervision. If these conditions are not met, a radiologist must be available to override the AI analysis. The efficiency of human-AI collaboration in clinical radiology is dependent on clinicians properly comprehending and trusting the AI system [17]. One of the major requirements to enable such human-AI interfaces in radiological workflows is an effective and consistent mapping of explainability with causability [18]. Specialized explainer systems of explainable AI (widely acknowledged as an important feature of practical deployment of AI models) aim at explaining AI inferences to human users [19]. Explainability in radiology can be improved by using localization models, which can highlight the region of suspected abnormality (region of interest) in the scan, instead of using classification models, which only indicate the presence or absence of an abnormality [20]. Although an explainable system does not refer to an explicit human model and only indicates or highlights the decision-relevant parts of the AI model (ie, parts that contributed to a specific prediction), causability refers primarily to a human-understandable model. Causability is the degree to which an explanation of a statement to a human expert achieves a defined level of causal understanding while also being effective, efficient, and satisfactory within the context of use [18].

Radiology scans often suffer from high interreader variability that arises when 2 or more readers disagree on the results of a scan. This may lead to uncertainty in the ground truth labels. The problem of ambiguous ground truth can be mitigated by using expert adjudication [21] or multiphasic review [22] to create high-quality labels, which may help yield better models than other approaches in improving model performance on original labels [20]. Additionally, imaging protocols, manufacturers of imaging modalities, and the process of storing and processing medical data differ between organizations, which impedes the use of data from different sources for AI applications [23]. These factors result in the development of AI systems on a limited distribution of data, making them highly susceptible to failure if certain conditions, such as demographics, race, gender, time, etc, are not met. For example, Dou et al [24] developed a COVID-19 detection model using data sets from internal hospitals in Hong Kong. The model performed extremely well in identifying abnormalities in Chinese data sets but underperformed in German data sets with different population demographics [24]. Cross-center training of the AI model for different demographics and distinct cohort features would help the model learn from multiple sources and mitigate the problem of generalizability.

Level 4: High Automation

Advancing from level 3, the AI systems at *Level 4: High Automation* would make decisions without the assistance of a radiologist. Human intervention would only be required in complex cases where the AI requests it. Such systems would require extensive clinical validations before they could be reliably used. As summarized by Kulkarni et al [20], these systems would need to undergo internal as well as external validations to evaluate the system's performance on unseen data. The Transparent Reporting of a Multivariable Prediction Model for Individual Prognosis or Diagnosis (TRIPOD)

statement [25] specifies guidelines for reporting the development and validation of such diagnostic or prognostic models. Since these AI systems must work independently of conditions, they must generalize across a wide variety of data from different sources without inducing any bias from the training data. For example, Obermeyer et al [26] exposed a shortcoming in a widely used algorithm in the health care system that identified Black patients as being healthier than equally sick White patients. The racial bias exhibited by this system led to an unequal distribution of health care benefits to Black patients.

Elgendi et al [27] observed that adopting simple data augmentation and image processing techniques such as normalization, histogram matching, and image reorientation can aid in standardizing images from different sources. The standardization of annotation, data processing, and storage protocols are also vital for this data to be efficiently used for the development of AI systems. To learn and understand the differences and nuances of abnormalities in images from different regions, these AI systems would need to be developed on radiographic image data from various sources around the world.

The sharing of medical data has its own logistic and legal challenges as several government policies and compliances such as the Health Insurance Portability and Accountability Act [28] restrict the cross-border sharing of medical data. This is where privacy-preserving distributed learning techniques such as federated learning [29] and split learning [30] could play an important role in training the AI models at the source without moving the data to a centralized location. In the current state of development, the adoption of these distributed learning techniques is challenging because of the high costs involved in software development and infrastructure maintenance at multiple locations [31]. Despite these challenges, distributed learning appears to be a viable and promising approach to develop AI systems on multiple centralized data sets without the egress of sensitive medical data [32].

Level 5: Full Automation

Level 5, referred to as *Full Automation*, is the ultimate stage of automation in radiology, where an AI application would be capable of end-to-end analysis of a case, from the initial diagnosis to automatic report generation. With the standardization of diagnostic reporting protocols and the recent advances in natural language generation models such as Generative Pre-trained Transformer 3 [33], results can be automatically reported in a structured format.

With such a high level of automation, it is crucial to maintain these AI systems at their optimal performance levels; however, their efficiency often deteriorates over time [34]. This phenomenon is referred to as model decay. One of the reasons for model decay is covariate shift [35], where the distribution of the input data is different from the training data. Another reason for such a decay could be prior probability shift [36], where the distribution of the target or the prevalence of an abnormality in a population changes. The change in the definition of the relation between the input and target data, referred to as concept drift [37], could also contribute to model decay. These changes may occur gradually over time or suddenly when the AI system is deployed in a different location with a different population. Therefore, it is crucial to continuously monitor these AI systems and fine-tune them as required to maintain optimal performance [20].

The complete automation of radiology in clinical practice will be challenged by medico-legal concerns about assigning liability in cases of AI misdiagnosis. A challenging legal question is whether doctors, radiologists, and health care providers would still be held accountable to bear ultimate legal responsibilities when they are no longer liable for the interpretation of radiological studies or would the data scientists and the manufacturers involved in the development and implementation of AI systems be held responsible [38]. It is important to focus on ethical questions concerning the implications of full automation for patient-centered medical care. In any event, responsibility must be assigned to humans for their involvement in this extremely complex field of AI in medicine [39]. Another challenge at this stage would be to address the fear among radiologists of AI systems taking over their jobs [40]. However, jobs will not be lost, but rather, roles will be redefined. With the influx of new data, radiologists would be the information specialists capable of piloting AI and guiding medical data to improve patient care [41]. AI will undoubtedly be an integral part of medicine, particularly radiology, but the final decision will be made by human radiologists because only a human expert's knowledge and subject expertise can enable a reliable diagnosis [42]. We believe that AI systems will become smart assistants for radiologists, capable of automatically performing mundane tasks, such as preliminary diagnosis, annotations, report generation, etc, under radiologist supervision. This will not only reduce the workload of radiologists but also allow them to collaborate with clinicians and actively participate in other aspects of patient care.

Conclusion

The advancement in AI is bringing the field of radiology to a higher level of automation. We propose a level-wise classification system for automation in radiology to elucidate the step-by-step adoption of AI in clinical practice. We also highlight the concerns and challenges that must be addressed as radiology advances toward complete automation. This includes the development of AI models that are transparent, interpretable, trustworthy, and resilient to adversarial attacks in medical settings. Developers of AI algorithms must be cautious of potential risks such as unintended discriminatory bias, inadvertent fitting of confounders, model decay, the constraints of generalization to unseen populations, and the imminent repercussions of new algorithms on clinical outcomes.

There are numerous ethical issues and unanticipated repercussions associated with the introduction of high-level automation in health care. To address these issues, regulatory standards for the development, management, and acquisition of technology and AI; public-private institutional collaborations; and ethical and responsible application of AI in the health care sector are required [43]. Most people envision AI fully replacing the driver or completely bypassing the doctor when they think

about complete automation in the automobile or health care industry, respectively. Although there could be many good reasons to entirely replace drivers with autonomous vehicles, this approach could be detrimental in the health care sector. We must acknowledge the distinct advantages of augmentations over complete automation in health care practices [44]. In this regard, "expert-in-the-loop" ideology facilitates the collaboration between AI scientists, software developers, and expert radiologists. This substantially improves the quality and quantity of expert clinical feedback and guidance at every stage of development. As we move closer to the complete automation of radiological analysis, such collaborations are crucial for expediting the automation process.

Authors' Contributions

SG contributed to the presented idea, reviewed literature, and wrote the original draft of the manuscript. VK conceived the manuscript framework and assisted in editing the manuscript. RP contributed to the presented idea, reviewed literature, wrote and edited the manuscript, and helped shape the contents of the manuscript. AK validated the manuscript from the perspective of clinical and radiology workflows.

Conflicts of Interest

None declared.

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Abbreviations

AI: artificial intelligence
TRIPOD: Transparent Reporting of a Multivariable Prediction Model for Individual Prognosis or Diagnosis

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Viewpoint

Health System Resilience in the Eastern Mediterranean Region: Perspective on the Recent Lessons Learned

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Abstract

Background: Public health has a pivotal role in strengthening resilience at individual, community, and system levels as well as building healthy communities. During crises, resilient health systems can effectively adapt in response to evolving situations and reduce vulnerability across and beyond the systems. To engage national, regional, and international public health entities and experts in a discussion of challenges hindering achievement of health system resilience (HSR) in the Eastern Mediterranean Region, the Eastern Mediterranean Public Health Network (EMPHNET) held its seventh regional conference in Amman, Jordan, between November 15 and 18, 2021, under the theme "Towards Resilient Health Systems in the Eastern Mediterranean: Breaking Barriers." This viewpoint paper portrays the roundtable discussion of experts on the core themes of that conference.

Objective: Our aim was to provide insights on lessons learned from the past and explore new opportunities to attain more resilient health systems to break current barriers.

Methods: The roundtable brought together a panel of public health experts representing Field Epidemiology Training Programs (FETPs), Centers for Disease Control and Prevention in Atlanta, World Health Organization, EMPHNET, universities or academia, and research institutions at regional and global levels. To set the ground, the session began with four 10-12–minute presentations introducing the concept of HSR and its link to workforce development with an overall reflection on the matter and lessons learned through collective experiences. The presentations were followed by an open question and answer session to allow for an interactive debate among panel members and the roundtable audience.

Results: The panel discussed challenges faced by health systems and lessons learned in times of the new public health threats to move toward more resilient health systems, overcome current barriers, and explore new opportunities to enhance the HSR. They presented field experiences in building resilient health systems and the role of FETPs with an example from Yemen FETP. Furthermore, they debated the lessons learned from COVID-19 response and how it can reshape our thinking and strategies for approaching HSR. Finally, the panel discussed how health systems can effectively adapt and prosper in the face of challenges and barriers to recover from extreme disruptions while maintaining the core functions of the health systems.

Conclusions: Considering the current situation in the region, there is a need to strengthen both pandemic preparedness and health systems, through investing in essential public health functions including those required for all-hazards emergency risk management. Institutionalized mechanisms for whole-of-society engagement, strengthening primary health care approaches for health security and universal health coverage, as well as promoting enabling environments for research, innovation, and learning should be ensured. Investing in building epidemiological capacity through continuous support to FETPs to work toward strengthening surveillance systems and participating in regional and global efforts in early response to outbreaks is crucial.

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KEYWORDS

health systems resilience; resilience; vulnerability; public health; Eastern Mediterranean Region countries; COVID-19

Introduction

Public health has a pivotal role in strengthening resilience at individual, community, and system levels as well as building resilient and healthy communities. During crises, resilient health systems can effectively adapt in response to evolving situations and reduce vulnerability across and beyond the systems. Health system resilience (HSR) is defined as follows [1,2]:

> *[T]he ability to prepare for, manage (absorb, adapt, and transform) and learn from shocks.*

Hence, it is a key factor to coping with a crisis such as the economic crisis and the COVID-19 pandemic [2]. Although catastrophe risk reduction is based on the concept of resilience, it is only recently been applied to health systems. It has been widely characterized as institutions and health actors' capacities to prepare for, recover from, and absorb shocks while sustaining basic activities and fulfilling the community's continuing and acute care needs [3,4].

Even though the 680 million people of Eastern Mediterranean Region (EMR) make up only 9% of the global population [5], it is home to 43% of those in need of humanitarian assistance [6] and is the source of 64% of the world's refugees [7]. The current resilience of health systems in the EMR varies from country to country, mostly based on the governmental and financial situation of the countries [8].

However, for the achievement of HSR, individuals, communities, and systems must be enabled to address challenges, such as poverty, inequality, unemployment, and other factors that endanger health and well-being. Relative success for HSR will depend on how the existing health systems can benefit from the newly learned lessons [9].

Global Health Development (GHD) is a regional initiative created to support countries in the EMR and strengthen their health systems to respond to public health challenges and threats. GHD was initiated to advance the work of the Eastern Mediterranean Public Health Network (EMPHNET) by building coordinating mechanisms with Ministries of Health, international organizations, and other institutions to improve population health outcomes. Serving as a collaborative platform, GHD|EMPHNET is dedicated to serving the region by supporting efforts to promote public health policies, strategic planning, sustainable financing, resource mobilization, public health programs, and other related services.

GHD|EMPHNET and the EMR's Field Epidemiology Training Programs (FETPs) have made significant contributions to preparing for and responding to the present COVID-19 crisis. GHD|EMPHNET has the scientific competence to help raise country alert and preparation in the EMR and provide technical support through health promotion, training and training materials, guidelines, coordination, and communication. The FETPs are now involved in surveillance and screening at ports of entry, the development of communication materials and guidelines, as well as the dissemination of information to health professionals and the general public. However, several countries are still underequipped, have inadequate diagnostic capabilities, and require more capacity development to respond to public health issues. It is critical that GHD|EMPHNET and FETPs continue to create capacity to respond to COVID-19 and increase support for public health emergency preparedness and response [10]. If broadly and efficiently shared, there are crucial lessons that can help countries improve their preparedness, response, and strategy to tackle future health issues. Our local, national, regional, and global capacities face a variety of concerns and problems in this new era. Our region (ie, the EMR), like the rest of the world, must prepare for and respond to such threats by taking necessary measures. HSR, entailing the ability to adapt and thrive in the face of obstacles and hurdles, is more important than ever to recover from today's extreme disruptions while preserving basic health system operations.

To engage national, regional, and international public health entities and experts in a discussion of public health challenges hindering the achievement of HSR in the EMR countries, EMPHNET held its seventh regional conference in Amman, Jordan, between November 15 and 18, 2021, under the theme "Towards Resilient Health Systems in Eastern Mediterranean: Breaking Barriers." A panel of public health experts discussing the core theme of the conference represented FETPs, Centers for Disease Control and Prevention in Atlanta, World Health Organization, EMPHNET, universities or academia, and research institutions at regional and global levels. This viewpoint aims to portray the "Health System Resilience (HSR)" roundtable that took place during the conference.

Objectives

The aim of our viewpoint is to provide insights on lessons learned from the past and explore new opportunities to attain more resilient health systems to break current barriers.

Roundtable Panel Discussion

The roundtable brought together a panel of public health experts and to set the ground for the discussion, the session began with 10-12–minute presentations introducing the concept of HSR and its link to workforce development. The presentations were followed by an open question and answer session to allow for an interactive debate among panel members and the roundtable audience.

The panel of experts discussed challenges faced by health systems and lessons learned during the new public health threats to move toward more resilient health systems, overcome current barriers, and explore new opportunities to enhance the health systems' resilience. Moreover, they presented the role of National Public Health Institutes in HSR and reviewed the role

of the FETPs in strengthening the health systems' resilience in the EMR.

The roundtable panel presented a structured approach to the resilience-building processes of health systems and formulated implementation of building back better approach; they also discussed the role of FETPs during the COVID-19 pandemic and other priority emergencies in the EMR. The panel discussion included oral presentations and an interactive discussion of questions and comments from participants, which covered the following topics: introduction to HSR—transforming challenges into opportunities, national public health institutes, and health systems' resilience; the contribution of the health workforce to health system's resilience—empirical and personal experiential examples; building resilient health systems—the role of the FETPs and Yemen FETP experience; and overall reflections about the presented topics and the lessons learned.

The panelist stressed that HSR is about transforming challenges into opportunities. An organized approach to resilience-building will ensure smooth recovery from emergencies and crises such as those observed during the COVID-19 pandemic or any other emergencies in the region and beyond. The panel members saw resilient health systems as a priority for all countries in the region. Adequate investments in health for socioeconomic development, investments for emergency preparedness, as well as an integrated approach to health security and universal health coverage are warranted. This should be supplemented by a robust primary health care foundation, investments in the essential public health functions, application of the whole-of-society approach, and attention to vulnerable and marginalized groups.

The ability to learn from country responses to emergencies like the last COVID-19 outbreak depends on the resilience of health systems. In this context, the panel confirmed earlier findings of an assessment of COVID-19 responses in 28 countries [11], which emphasized the activation of comprehensive response mechanisms, adapting health system capacity with cost-effective measures such as public-private partnerships, preserving health system functions and resources, and adopting effective measures to reduce vulnerability.

On the other hand, strong national public health institutes (NPHIs) [12] help countries avoid, detect, and respond to public health hazards more effectively. NPHIs are science-based organizations that lead and coordinate critical public health responsibilities. They are often housed in the government's ministries of health or are closely associated with them. By generating, integrating, and interpreting public health data to make timely recommendations, NPHIs play a key role in health policy and decision-making during crises and challenging settings. NPHIs aid in the integration of public health decision-making activities by bringing together the required evidence and by coordinating efforts across sectors.

The contribution of the health workforce to health systems' resilience was another area that was extensively discussed. The health workforce is considered the most important element for a health system to be able to absorb the increased health needs generated by shocks, adapt to deliver services with often less resources than usual, and transform themselves according to changes in the environment generated by the shock. However frontline health workers are often the most vulnerable individuals, such as in the case of epidemics, and often in armed conflicts when they become primary targets [1,13,14]. During the discussion, empirical examples were also given on the contribution of the health workforce to health systems' resilience, for example, the flexible approach adopted by the government in Zimbabwe to adapt policies for deployment of health workers. This allowed for better retention, which in turn increased the capacity of the health system to continue delivering services in remote hard-to-reach areas even during the peak of the socioeconomic crisis [15]. Postconflict Timor-Leste, with a vast majority of population living in rural areas, is nowadays more able to address their public health needs after the contribution of Cuban government in producing more than 1000 medical professionals with a public health orientation. It is to be noted that this intervention greatly contributed to transform the health system's focus from a "curative or hospital-centered" to a more "primary health care–based" system [16]. Within the EMR, the Lebanese health system adopted some workforce measures to be more able to cope with the increased health needs caused by the massive influx of Syrian refugees between 2012 and 2014. On the one hand, the Lebanese authorities increased nurses' salaries to increase their attraction and retention, and on the other, they increased the number of scholarships available for applicants to nursing studies to increase production and availability of this key cadre [16]. According to Physicians for Human Rights reports of 2016, the Syrian health system decision makers decided to relax and adapt their regulations to allow physicians engaged in surgery training to undertake operations to address the increased workload generated by the conflict in Aleppo. Other examples of health workforce interventions that increased the resilience of health systems based on field experience include task-shifting (ie, allowing lower cadres to assume responsibilities previously attributed to higher level cadres). This was adopted in Angola during the armed conflict in 1975-2002 and in Pakistan after the earthquake of 2005. Other interventions reported include training of community health workers to assume basic public health functions. The example of the network of community health workers deployed in refugee camps during the massive influx into Tanzania following the genocide of 1994 in Rwanda was given. Finally, another example reported was the spontaneous initiative adopted by private providers in Syria to cover gaps in home care of patients with COVID-19 left by the public system in Syria in 2020-2021.

The panel also discussed how the FETPs are designed to build resilient public health systems and strengthen those systems through increasing the number and quality of field epidemiologists in the public health workforce. Such workforce is crucial for timely detection, investigation, and response to public health emergencies. By improving capacity to collect public health data through improved disease surveillance systems and using the collected data effectively, the application of evidence-based approaches in public health decision-making and policies can be promoted [17].

It has been shown that today more than 19,000 FETP alumni are trained worldwide, as the "boots on the ground" to detect

and respond to public health threats, including infectious disease outbreaks, chronic and noncommunicable diseases, natural disasters, and humanitarian crises [18]. Having such workforce on the ground, responsive as quickly as possible to any emergency situation worldwide, would not have been possible without the investment in establishing FETPs [19].

The US Centers for Disease Control and Prevention and the World Health Organization have reinforced the central role of the FETPs for strengthening capacities of the health workforce in emergency management for greater resilience and health care response capacity [20].

The emergence and reemergence of infectious and noninfectious diseases is a major issue of public health concern. Previous outbreaks (eg, Ebola, Lassa fever, and cholera) have highlighted the need for a multisectoral public health workforce with the requisite competencies to effectively address these situations [21-23].

Today, the ongoing COVID-19 pandemic has highlighted the need for a well-trained public health workforce to save lives through timely outbreak detection and response [24,25].

Studies from different parts of the world have shown that since the early phase of COVID-19 epidemic, FETP trainees and graduates have been mobilized to support preparedness and response activities in their countries, and they have played a crucial role in HSR.

A survey of 65 FETPs around the world indicated that FETP residents and graduates have engaged in the COVID-19 response across all 6 regions of the World Health Organization. Response efforts focused on country-level coordination (98%), surveillance, rapid response teams, case investigations (97%), activities at points of entry (92%), as well as risk communication and community engagement (82%). Descriptions of FETP contributions to COVID-19 preparedness and response are categorized into the following 7 main themes: conducting epidemiological activities, managing logistics and coordination, leading risk communication efforts, providing guidance, supporting surveillance activities, training and developing the workforce, and holding leadership positions [26].

In the EMR, where the current COVID-19 situation continues to be of concern, the FETPs have also actively participated in surveillance and screening at the ports of entry, development of communication materials and guidelines, as well as sharing information with health professionals and the public [10]. Furthermore, The FETP graduates are found to be fully aware of the epidemiology of COVID-19 and the safety measures required, and they were well positioned to investigate and respond to the COVID-19 pandemic [27].

During the panel, the situation in Yemen, a country witnessing a protracted conflict limiting the capacity for public health and outbreak response, was discussed. Despite difficulties, the Yemen FETP has been instrumental in supporting COVID 19 response through participating in country-level coordination, planning, and monitoring, in addition to developing guidelines, standard operating procedures, and strengthening surveillance capacities. Other contributions of the program included outbreak investigations, contact tracing, case management, infection prevention and control, risk communication, and evidence-based research [28].

The panel members underlined that the COVID-19 pandemic and the varied national-level responses have reinforced the need for countries to invest in a trained public health workforce. The countries have learned that epidemiological skills are valuable assets and that other skills and disciplines such as data science need to be part of the modern field epidemiology training. Finally, the available evidence on the key role of the FETPs to support country response and ensure better HSR should reinforce the need for countries to invest in a trained public health workforce. The FETPs not only have the power to improve health systems during normal times but also can make health systems resilient to crises that may emerge over the longer run. This part of the panel discussion highlighted that a resilient health system can only be capable of managing the emerging and reemerging crises when it has an adequate, well-trained, and willing epidemiologists' workforce.

Roundtable Major Themes

The roundtable discussion provided an opportunity to explore the HSR concept; the importance of adapting to changing situations, including emergencies and crises; the tenets of a resilient health system; and the ways vulnerability can be reduced across and beyond health systems. It focused on how to create resilient and healthy communities and how to strengthen such resilience at the individual, community, and system levels. Finally, the region's collective experience, the most important lessons learned, and how existing health systems can benefit from these lessons were discussed in particular.

The panel members highlighted the importance of enhancing HSR and provided their recommendations in the following 3 major areas: (1) global involvement, health systems, and governance; (2) research, innovation, and workforce capacity development; and (3) addressing inequities and engaging communities. The activities classified under these major areas are as follows:

- Global involvement, health systems, and governance:
  - Leverage the current response to strengthen both pandemic preparedness and health systems.
  - Invest in EPHFs, including those needed for all-hazards emergency risk management.
  - Strengthen primary health care approaches for health security and universal health coverage.
  - Improve organization and functioning of health systems for pandemic preparedness.
  - Invest in addressing foundational health system gaps and essential public health functions for emergency management.
  - Provide equal priority for maintaining essential health services and ensuring emergency preparedness and response.
  - Increase domestic and global investment in health system foundations and all-hazards emergency risk management.

- Ensure good governance and leadership for effective emergency risk management with multisectoral coordination.

- Research, innovation, and workforce capacity development:
  - Promote enabling environments for research, innovation, and learning.
  - Use technology and new ways of organizing health services to provide alternative platforms for health service delivery and epidemic response.
  - Adopt health workforce interventions to increase health systems resilience, such as increasing the number and quality of field epidemiologists in the public health workforce to ensure an adequate, well-trained, and willing epidemiologists' workforce; task-shifting; and training of community health workers to assume basic public health functions.

- Addressing inequities and engaging communities:
  - Address preexisting inequities and the disproportionate impact of COVID-19 on marginalized and vulnerable populations.
  - Build and maintain public trust through community engagement and participation.
  - Invest in institutionalized mechanisms for whole-of-society engagement.

Conclusions

In conclusion, the lessons learned from COVID-19 response can reshape our thinking and strategies for approaching HSR. Considering the current situation in the EMR, there is a need to strengthen both pandemic preparedness and health systems, through investing in the essential public health functions, including those required for all-hazards emergency risk management. Institutionalized mechanisms for whole-of-society engagement strengthening the primary health care approaches for health security and universal health coverage, and promoting enabling environments for research, innovation, and learning should be ensured. Finally, investing in building epidemiological capacity through workforce development and continuous support to FETPs to work toward strengthening surveillance systems and participating in regional and global efforts in early response to outbreaks is needed.

The experience in the EMR and beyond has clearly shown the critical role of the health workforce in ensuring resilience. Capacity building for the public health workforce, in particular the FETP, proved to be instrumental in this respect. The implications for countries and the global community should include the development of a vision and strategy for enhancing resilience, streamlining and harmonizing global and country-level efforts, as well as mobilizing funding and resources for the effective implementation of the required interventions.

Conflicts of Interest

None declared.

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Abbreviations

EMPHNET: Eastern Mediterranean Public Health Network
EMR: Eastern Mediterranean Region
FETP: Field Epidemiology Training Program
GHD: Global Health Development

HSR: health system resilience
NPHI: national public health institute

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Review

Implementation Strategies for Knowledge Products in Primary Health Care: Systematic Review of Systematic Reviews

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Abstract

Background: The underuse or overuse of knowledge products leads to waste in health care, and primary care is no exception.

Objective: This study aimed to characterize which knowledge products are frequently implemented, the implementation strategies used in primary care, and the implementation outcomes that are measured.

Methods: We performed a systematic review (SR) of SRs using the Cochrane systematic approach to include eligible SRs. The inclusion criteria were any primary care contexts, health care professionals and patients, any Effective Practice and Organization of Care implementation strategies of specified knowledge products, any comparators, and any implementation outcomes based on the Proctor framework. We searched the MEDLINE, EMBASE, CINAHL, Ovid PsycINFO, Web of Science, and Cochrane Library databases from their inception to October 2019 without any restrictions. We searched the references of the included SRs. Pairs of reviewers independently performed selection, data extraction, and methodological quality assessment by using *A Measurement Tool to Assess Systematic Reviews 2*. Data extraction was informed by the Effective Practice and Organization of Care taxonomy for implementation strategies and the Proctor framework for implementation outcomes. We performed a descriptive analysis and summarized the results by using a narrative synthesis.

Results: Of the 11,101 records identified, 81 (0.73%) SRs were included. Of these 81, a total of 47 (58%) SRs involved health care professionals alone. Moreover, 15 SRs had a high or moderate methodological quality. Most of them addressed 1 type of knowledge product (56/81, 69%), common clinical practice guidelines (26/56, 46%) or management, and behavioral or pharmacological health interventions (24/56, 43%). Mixed strategies were used for implementation (67/81, 83%), predominantly education-based (meetings in 60/81, 74%; materials distribution in 59/81, 73%; and academic detailing in 45/81, 56%), reminder (53/81, 36%), and audit and feedback (40/81, 49%) strategies. Education meetings (P=.13) and academic detailing (P=.11) seemed to be used more when the population was composed of health care professionals alone. Improvements in the adoption of knowledge products were the most commonly measured outcome (72/81, 89%). The evidence level was reported in 12% (10/81) of SRs on 62 outcomes (including 48 improvements in adoption), of which 16 (26%) outcomes were of moderate or high level.

Conclusions: Clinical practice guidelines and management and behavioral or pharmacological health interventions are the most commonly implemented knowledge products and are implemented through the mixed use of educational, reminder, and audit and feedback strategies. There is a need for a strong methodology for the SR of randomized controlled trials to explore their effectiveness and the entire cascade of implementation outcomes.

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KEYWORDS

knowledge translation; knowledge product; implementation strategies; review; health care professionals; primary care

Introduction

Background

The effective implementation of knowledge products is essential for improving and sustaining the well-being of populations and reducing waste in health care. In 2019, health care spending represented 17.7% of the US gross domestic products [1] and 11.5% of that for Canada [2]. However, the underuse of effective knowledge products that would be beneficial to the population, combined with the misuse or overuse of knowledge products that offer no added value or even provide more harm than benefits to populations, contribute to this lack of impact and waste [3,4]. Knowledge products include a wide range of health interventions or policies, programs, practices, or processes of technological, pharmacological, behavioral, or managerial nature and guidelines [5,6].

Given this gap between the production of knowledge products and their application in clinical practices and health policies, a growing emphasis has been placed on knowledge translation (KT) [7,8] and implementation strategies [8-10]. Implementation strategies can be understood as an actively planned and deliberately initiated set of processes, methods, techniques, activities, and resources, with the intention of translating a given knowledge product into practice within a particular setting and context [5,11-13].

In recent years, given the many constraints on resources (human and financial) faced by most, if not all, health care systems, which have recently been made even worse by the COVID-19 pandemic [14], there has been a growing urgency in regard to synthetizing what is known about effective implementation strategies [9,15-24]. Despite these efforts, gaps in KT remain in relation to overviews of variable methodological and reporting qualities [25], which sometimes lead to conflicting conclusions and make it challenging for health care stakeholders to decide which strategies are effective for the implementation of a given knowledge product. This concern has not been explicitly addressed in the existing literature.

Therefore, we planned a 3-phase project, with the ultimate goal to identify, for each category of knowledge product, the most effective implementation strategies for their uptake into health care professionals' clinical practice. The first phase was to critically analyze the existing literature overviews to determine their strengths and weaknesses. This allowed us to highlight many methodological challenges such as the definition of eligibility criteria and literature search, the way in which data were synthesized, the methodological quality assessment of the literature reviews included, and the assessment of the evidence level. These points informed the realization of the present systematic review (SR) of SRs, which is the second phase of our project.

Objective

We sought to characterize which knowledge products are frequently implemented, the implementation strategies used in primary care, and the implementation outcomes measured.

Methods

Project Design and Registration

To optimize the identification of effective implementation strategies in the area of primary care, we conducted a 3-phase project using SR methodologies. In phase 1 (completed review), we conducted a critical analysis of the methodological strengths and weaknesses of the existing overviews. In phase 2 (current overview), we conducted an SR of SRs to characterize the most frequently implemented knowledge products, implementation strategies used, implementation outcomes measured, and reported levels of evidence in individuals or stakeholders participating in the provision of health care (referred to as health care professionals) or in health care professionals and end users (patients and clients) in the context of primary health care. In the included SRs, primary studies may either be of more robust experimental designs (randomized controlled trials [RCTs]) or less robust designs. Therefore, the effectiveness of key knowledge products and key implementation strategies was measured in a separate phase 3 (future review) using an SR of RCTs.

The protocol of the project was registered on the Open Science Framework platform on February 7, 2020 [26] and then published [27]. The review was conducted following the Cochrane methodology [28] and is reported in accordance with the PRISMA (Preferred Reporting Items for Systematic Reviews and Meta-Analyses) guidelines [29].

Eligibility Criteria

We used the population, intervention, comparison and outcomes format [30] to delineate our inclusion criteria.

Population and Clinical Context

We included any person involved in health care provision, that is, health care professionals or caregivers and end users (patients). By caregivers, we mean the parents, guardians, friends of patients, community health workers, or any other nonclinician who provides health care. The empirical studies in the included reviews could concern either health care professionals or caregivers alone, or health care professionals or caregivers and patients. They were excluded from cases in which only the patients were concerned. We did not place restrictions on age, gender, or health conditions. Reviews had to cover the primary care setting [31], as it is a major level of health service use. Rather than targeting the physical location of activities, we were interested in primary health care services, such as health promotion and prevention, diagnosis, and treatment of illness and injury. By primary health care services, we refer to family physicians, nurse practitioners, and pharmacists who ensure the direct provision of health care services to clients and coordinate to ensure the continuity of care to upper levels [31].

Intervention

We focused on implementation strategies that were predetermined in our protocol [27] and based on the Effective Practice and Organization of Care (EPOC) [8] to include the following implementation strategies: audit, feedback, audit and feedback, clinical incident reporting, monitoring the performance of the delivery of health care, communities of practice, continuous quality improvement, educational games, educational materials, educational meetings, educational outreach visits or academic detailing, clinical practice guidelines, interprofessional education, local consensus processes, local opinion leaders, managerial supervision, patient-mediated interventions, public release of performance data, reminders, routine patient-reported outcome measures, and tailored interventions. A review may have included primary studies that use exclusively 1 type of implementation strategy (mono-faceted) or exclusively more than 1 type (multifaceted). Within the same review, some primary studies may have used exclusively one implementation strategy, whereas others may have used exclusively more than one implementation strategy (mixed). We excluded interventions that were used to develop the knowledge product and the scaling up and sustainability of interventions (studies that were housed under a separate project). Knowledge products are tools used to share knowledge with users [32,33]. They include tools such as clinical practice guidelines, decision support tools, policy briefs or decision-making tools, one pagers, and health interventions (technological, pharmacological, behavioral, or management). In the clinical practice guidelines category, we included clinical practice guidelines, disease management protocols, clinical recommendations, and clinical procedures. For health interventions, we included knowledge products for which the implementation aimed to change professional behavior or attitude (behavioral), professional competencies or processes or quality of care (management), prescribing or testing (pharmacological), and the use of technologies (technological). In the shared decision-making and support tools category, we included clinical decision support systems and tools aimed at improving clinical decision-making. In a given SR, 1 type of knowledge product (single) or more than 1 type (multiple) may have been implemented. A review was included if the knowledge product and implementation strategies were specified.

Comparators

We considered either usual practice (no predetermined implementation strategies as defined previously) or any of the predetermined implementation strategies defined earlier.

Outcomes

Our interest was focused on implementation outcomes, including acceptability, adoption, appropriateness, feasibility, adherence or fidelity, implementation costs, and penetration or reach of a knowledge product, as defined in the taxonomies by Proctor et al [34] and Lewis et al [35]. Detailed definitions are provided in Multimedia Appendix 1. Several of these outcomes may have been studied in the same SR.

Design of Included Reviews

We included both Cochrane and non-Cochrane SRs (with or without meta-analyses) and mixed method reviews that used a comprehensive and reproducible approach and met our inclusion criteria. The reviews may have included one or more types of experimental or observational primary study designs. We excluded reviews of reviews, non-SRs, original research, protocols, comments, editorials, conference abstracts, working groups and colloquium reports, experts' opinions, and pilot studies.

Information Sources and Search Strategy

We searched MEDLINE (Ovid), EMBASE, CINAHL (EBSCO), Ovid PsycINFO (Ovid), Web of Science (Web of Science), and Cochrane Library (Cochrane Library) databases from their inception to October 18, 2019, without restrictions on language or geographic settings. We searched the bibliographies of the included reviews to identify additional relevant ones.

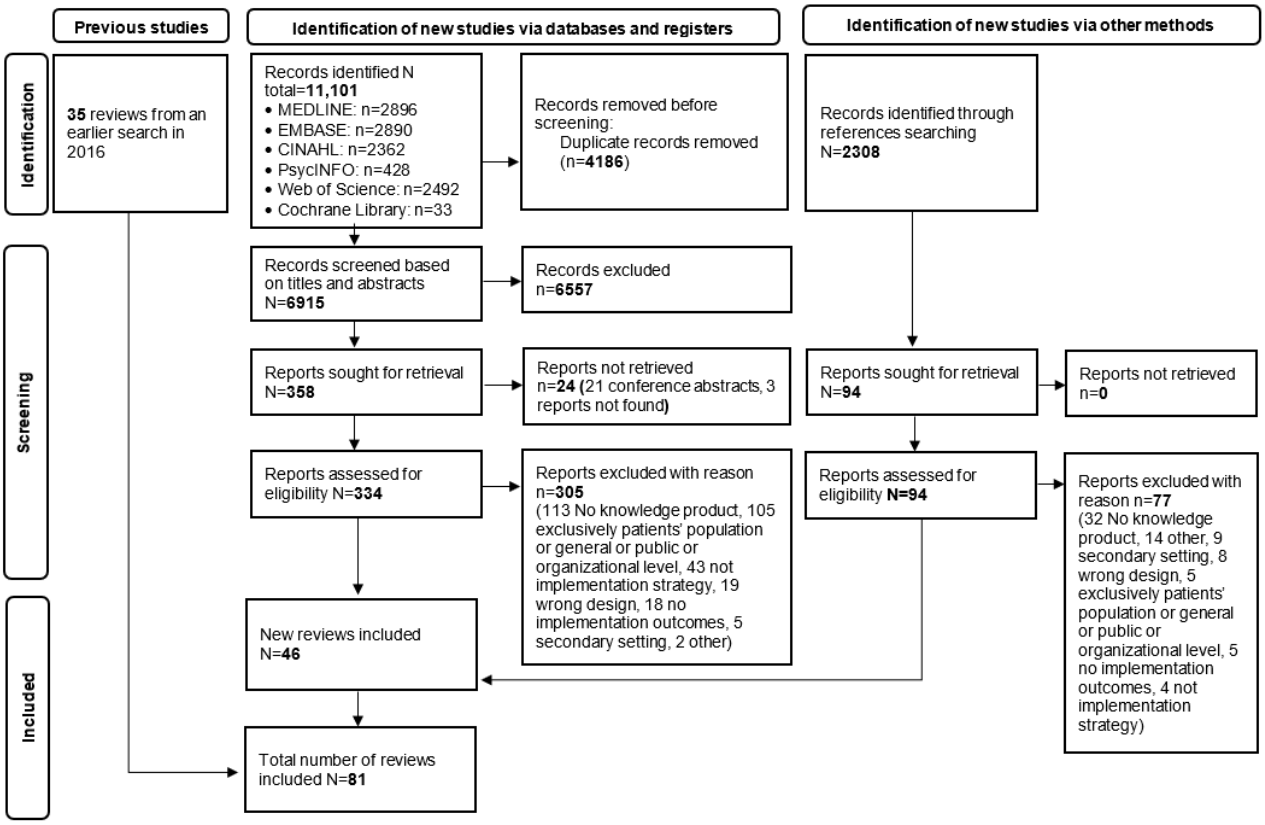
We followed an extensive literature search process to identify SRs of interventions that implement health knowledge products. In March 2017, an information specialist (NR) designed the search strategy for each database. The initial search strategy developed in MEDLINE was reviewed and approved by some of the team members before its translation into other bibliographic databases by the information specialist. During the selection process, gaps were identified in the search strategy. The search strategy was modified and rerun in October 2019. We used the following main concepts: KT, strategies, reviews,

health professionals, and primary care. Multimedia Appendix 2 details the search strategy for each of the aforementioned databases. The records found were exported to the EndNote software (Clarivate), and duplicates were removed.

Study Selection

We used Microsoft Excel developed for our review to perform the study selection in 3 steps. First, our reviewers performed pilot selection and held discussions regarding any discordance to ensure a common understanding of the eligibility criteria before subsequent steps were taken. Second, pairs of reviewers independently screened the titles and abstracts. Records coded as *included* or *unclear* were eligible for a full report review against the inclusion criteria by pairs of reviewers. Third, full reports were coded on one side as *included* or *unclear* and as *excluded* on the other side. At each step, consensus discussions were held to resolve disagreements. A senior reviewer validated the final list of included SRs. We did not need to contact any of the review authors. A flow diagram, according to the PRISMA guidelines [29], was produced to summarize the process of study selection (Figure 1).

Figure 1. PRISMA (Preferred Reporting Items for Systematic Reviews and Meta-Analyses) flowchart of study screening and selection.



Data Extraction

We used the piloted Microsoft Excel format developed for our review to extract the data. To develop the format, we used the taxonomies of the EPOC [8] for the categories of implementation strategies and complemented the information by specifying whether the implementation strategies were mono-faceted, multifaceted, or mixed. For the outcome definitions, we used the Proctor et al [34] and Lewis et al [35] evaluation frameworks. These frameworks integrate more dimensions not found in other frameworks, such as acceptability, appropriateness, feasibility, and implementation costs. They also provide outcome synonyms found in the literature, thus facilitating recategorization when needed. For each outcome, we specified whether the measurement was objective and the measurement tools used, if reported. Evidence-based interventions are practices in which health professionals use available evidence-based information to make decisions for individual patients or community health [6,36]. It operates by appraising evidence and formulating recommendations or guidelines [6,37,38] and by integrating evidence and community preferences for policy and practice changes at the public health level (health interventions) [6,38]. We were unable to find a formal taxonomy of knowledge products; therefore, we used the literature [5,6,32,33] to categorize whether they were clinical practice guidelines, health interventions, or shared decision-making and support tools. In cases where they were health interventions, we specified their technological, pharmacological, behavioral, or management nature. Furthermore, we extracted information regarding whether the type of implemented knowledge product was single (eg, clinical practice guidelines alone) or multiple (eg, clinical practice guidelines and health interventions). The population was defined as health care professionals only or health care professionals and patients and their number and characteristics of age and gender were extracted where available.

To give context to our review, the following additional information was also extracted: general characteristics of the included review (such as year of publication, number and names

of databases searched, search date ranges considered, any language restriction, method of synthesizing data, medical area of concern, settings, designs, and number of primary studies), whether the authors of the included reviews completed methodological quality assessment (tools used and overall result), whether they completed publication bias assessment (tool used and whether any treatment was done), and whether they completed the assessment of quality of evidence (tool used and level of evidence by each reported outcome).

Pairs of reviewers piloted the tool on at least 2 reviews and independently carried out extractions and validations by comparing the extracted information. Discussions for consensus were held in case of discrepancies.

Assessment of Methodological Quality

The methodological quality of the included reviews was assessed using *A Measurement Tool to Assess Systematic Reviews* (AMSTAR; AMSTAR 2) [39]. In contrast to the first version, this updated version allows the assessment of SRs that include RCTs, nonrandomized studies of health interventions, or both [39]. We conducted a pilot phase and held discussions on discordance. Where necessary, the pilot phase was extended until a common understanding of the assessment criteria was achieved. Pairs of assessors independently scored each of these 16 items. An overall rating was also provided, which indicated high (no or one noncritical flaw), moderate (more than one noncritical flaw), low (one critical flaw with or without noncritical flaws), or critically low (more than one critical flaw with or without noncritical flaws) ratings [39]. Critical flaws included protocol not registered before the beginning of the review (standard 2), lack of adequacy and comprehensiveness of the search strategy (standard 4), no provision of the justification for excluding individual reviews (standard 7), the use of an unsatisfactory technique to assess the risk of bias from individual included reviews (standard 9), the inappropriateness of meta-analytical methods (standard 11), no consideration of the risk of bias when interpreting the results of the review (standard 13), and lack of suitability for the assessment of the presence and the likely impact of publication bias (standard 15) [39]. Reviewers compared their results and reached a consensus in cases of disagreement by discussion or by the arbitration of a third reviewer.

Data Synthesis

For the second phase, reanalysis by meta-analysis was not performed [27]. Using SAS software (SAS Institute Inc) and taking the included review as the unit of analysis, we performed a descriptive analysis that aimed to summarize the characteristics of the implemented knowledge products, implementation strategies used, outcomes measured, and levels of evidence reported. We summarized the data as numbers and percentages for categorical variables and as means and SDs or medians and IQRs for continuous variables. Counts were performed overall and then stratified according to methodological quality scores (high, moderate, low, and very low). We grouped *Technological Health Interventions and Decision Support Tools* as implemented clinical decision support tools were electronic or computerized decision support systems.

For reviews in which the level of evidence of outcomes was measured and reported, we summarized what was reported as the level of evidence for the reported implementation outcome by the implementation strategy used and by the specific implemented single knowledge product. We used the number of outcomes as the unit of analysis.

Results

Search and Selection Process

Our database search identified 11,101 records, of which 6915 (62.29%) titles and abstracts were screened after removing duplicates. Among these 6915, a total of 428 (6.19%) full reports were screened for eligibility, after which 81 (18.9%) admissible SRs remained [40-120] (Figure 1). The reasons for the exclusion of each examined full report are provided in Multimedia Appendix 3.

General Characteristics of the Included Reviews and Participants

Table 1 shows the key general characteristics of the 81 included SRs. They were published between 1989 and 2019, with a mean of 8 (SD 5.8) years since the last bibliographic search in 2019. The authors of SRs searched an average of 6 databases, whereas more than half of the reviews (41/81, 51% of the SRs) restricted their search to SRs in the English language [40-43,45,47,49,50,52,55-57,64,66,69-73,79,83-85,88-91,93,96-100,104,105,107,109,114,118-120]. Individual SRs included a mean number of 29 primary studies. Of 81 SRs, with the exception of 8 (10%) SRs [43,46,54,68,70,78,89,107], all remaining SRs (n=73, 90%) included primary studies designed as RCTs. Non-RCTs were included in 42% (34/81) of SRs [40,42,45,48,50,51,53,55,64,67,69-74,76,79-81,83,84,88,90-93,96,97,101,108,109,114,115]. The settings covered were either primary or secondary health care (56/81, 69%) or primary health care alone in 31% (25/81) of SRs [43,45,46,48,50,52,57,71,78,81,83,86,88,90,91,95-98,102,104-106,111,114]. A total of 58% (47/81) of SRs involved health care professionals alone [40,42,44,45,49,50,53-55,60,62,63,65-68,70,71,73-76,79,81-84,86-88,93-95,99,101,102,107-110,112-115,117,119,120], whereas the remaining 42% (34/81) involved health care professionals and patients at the same time. In 83% (67/81) of SRs, primary studies were critically appraised for methodological quality [40-42,44,45,47-53,55-68,70-87,89,91-96,99,100,102,104,106-115,117,119], and the narrative approach was used to synthesize information in 80% (65/81) of SRs [40-43,45,46,48-56,60,62-64,66-70,72-76,78-80,83,85-101,103, 105-109,112-120]. A detailed table of the key general characteristics for each included review is available in Multimedia Appendix 4 [40-120].

Table 1. General characteristics of included reviews overall and by methodological quality scores (reviews: N=81).

Characteristics	Overall	Methodological quality			
		High	Moderate	Low	Critically low
Analyzed systematic reviews, n (%)	81 (100)	9 (11)	6 (7)	17 (21)	49 (61)
Age of reviews (years), n (%)	81 (100)	9 (11)	6 (7)	17 (21)	49 (61)
Value, mean (SD)	8.0 (5.8)	4.8 (3.1)	9.1 (5.9)	6.0 (3.3)	9.1 (6.6)
Value, median (IQR)	6.8 (3.8-10.8)	3.8 (2.8-6.8)	7.3 (5.8-8.8)	5.8 (3.8-7.8)	7.8 (3.8-12.8)
Databases searched in included reviews, n (%)	81 (100)	9 (11)	6 (7)	17 (21)	49 (61)
Value, mean (SD)	6.3 (3.8)	10.3 (5.6)	9.7 (4.1)	6.6 (3.3)	5.0 (2.8)
Value, median (IQR)	5.0 (3.0)	7.0 (10.0)	9.5 (3.0)	6.0 (4.0)	5.0 (4.0)
Search language restriction in included reviews, n (%)	81 (100)	9 (11)	6 (7)	17 (21)	49 (61)
Yes	48 (59)	1 (11)	2 (33)	12 (70)	33 (67)
No	19 (24)	5 (56)	4 (67)	4 (24)	6 (12)
Not reported	14 (17)	3 (33)	0 (0)	1 (6)	10 (21)
Language restrictions, n (%)	48 (100)	1 (2)	2 (4)	12 (25)	33 (69)
English only	41 (85)	1 (100)	2 (100)	11 (92)	27 (82)
English and other languages	7 (15)	0 (0)	0 (0)	1 (8)	6 (18)
Primary studies included in included reviews, n (%)	80[a] (100)	9 (11)	6 (8)	17 (21)	48 (60)
Value, mean (SD)	29.2 (34.7)	20.3 (12.2)	16.8 (13.1)	27.2 (20.3)	33.1 (42.3)
Value, median (IQR)	19.5 (10.5-34.5)	19.0 (12.0-26.0)	14.0 (8.0-19.0)	22.0 (11.0-38.0)	19.0 (11.0-38.0)
How many reviews included the following designs of primary studies[b], n (%)	81 (100)	9 (11)	6 (7)	17 (21)	49 (61)
Randomized controlled trials	73 (90)	9 (100)	6 (100)	15 (88)	43 (88)
Nonrandomized controlled trials	34 (42)	2 (22)	4 (67)	9 (53)	19 (39)
Interrupted time series	20 (25)	4 (44)	3 (50)	5 (29)	8 (16)
Cohorts	11 (17)	1 (11)	0 (0)	2 (12)	8 (16)
Before-after	26 (32)	0 (0)	2 (33)	5 (29)	19 (39)
Other	22 (27)	1 (11)	0 (0)	5 (29)	16 (33)
Settings (health domains), n (%)	81 (100)	9 (11)	6 (7)	17 (21)	49 (61)
Primary and secondary health care	56 (69)	9 (100)	6 (100)	13 (76)	28 (57)
Primary health care only	25 (31)	0 (0)	0 (0)	4 (24)	21 (43)
Method of analysis for included reviews, n (%)	81 (100)	9 (11)	6 (7)	17 (21)	49 (61)
Narrative	65 (80)	5 (56)	5 (83)	15 (88)	40 (82)
Mixed synthesis	10 (12)	3 (33)	1 (17)	1 (6)	5 (10)
Meta-analysis	6 (8)	1 (11)	0 (0)	1 (6)	4 (8)
Were primary studies critically appraised for methodological quality, n (%)	81 (100)	9 (11)	6 (7)	17 (21)	49 (61)
Yes	67 (83)	9 (100)	6 (100)	17 (100)	35 (71)
No	10 (12)	0 (0)	0 (0)	0 (0)	10 (21)
Not reported	4 (5)	0 (0)	0 (0)	0 (0)	4 (8)
Population of reviews, n (%)	81 (100)	9 (11)	6 (7)	17 (21)	49 (61)
Health care professionals only	47 (58)	6 (67)	5 (83)	8 (47)	28 (57)
Health care professionals and patients	34 (42)	3 (33)	1 (17)	9 (53)	21 (43)

[a]One study without a number of included studies.

[b]Categories are not mutually exclusive.

Implementation Strategies, Knowledge Products, and Outcomes

Implementation Strategies

In 6% (5/81) of SRs [57,98,102,110,117], all primary studies in SR used only 1 type of implementation strategy (mono-faceted). In 11% (9/81) of SRs [40,58,60,66,86,89,97,111,112], all primary studies in SR exclusively used more than 1 type of implementation strategy (multifaceted). In the remaining 83% (67/81) of SRs, some primary studies used 1 type of implementation strategy, whereas others used more than 1 type of implementation strategy (mixed; Table 2). Educational strategies were the most frequently used, mainly educational meetings in 74% (60/81) of SRs [40-42,44-46,49,50,52,53,55,58-66,68-71,73-79,81-89,91,92,94-100,103,104,107,109,111-114,118-120], educational materials distribution in 73% (59/81) of SRs [40-42,44-46,48-55,58,60-66,69-71,73-77,79-81,83-89,91,92,94-97,100,103,105,108,110,112-116,118-120] and educational outreach in 56% (45/81) of SRs [40-42,44,46,48,50-52,54,55,60,63-65,69,71,73-77,79,81-83,85-88,92,94,95,97,99,100,103-105,108,112-115,119] (Table 2). Other frequent strategies used were reminders in 65% (53/81) of SRs [41,42,44,47,48,50,51,53-58,60-64,66,67,69-71,73,76,77,79,81,83,85,86,88,89,91,92,94-97,99-102,105,106,111-116,118,119], audit and feedback for 49% (40/81) of SRs [40,42,44,50,51,53-55,60,61,63-65,70,73,74,76,77,79,81-83,85,87,91-94,97,99,100,104,106,111,113-116,118,119] and the use of local opinion leaders for 43% (35/81) of SRs [40,41,44-46,49,51,52,54,60,63,66,69,73-77,79,81,85,86,89,91,92,94,96,97,99,105,108,109,112,118,119] (Table 2).

Table 2. Characteristics of included reviews related to knowledge products, implementation strategies, and outcomes by methodological quality (reviews: N=81).

Characteristics	Overall, n (%)	Methodological quality, n (%)			
		High	Moderate	Low	Critically low
Analyzed systematic reviews	81 (100)	9 (11)	6 (7)	17 (21)	49 (61)
Type of knowledge products implemented	81 (100)	9 (11)	6 (7)	17 (21)	49 (61)
Single	56 (69)	4 (44)	4 (67)	13 (76)	35 (71)
Multiple	25 (31)	5 (56)	2 (33)	4 (24)	14 (29)
Categories of single knowledge products	56 (100)	4 (7)	4 (7)	13 (23)	35 (63)
Clinical practice guidelines	26 (46)	0 (0)	1 (25)	9 (70)	16 (46)
Management, behavioral, and pharmacological health interventions	24 (43)	3 (75)	3 (75)	2 (15)	16 (46)
Health technology interventions and decision support tools	6 (11)	1 (25)	0 (0)	2 (15)	3 (8)
Types of implementation strategies	81 (100)	9 (11)	6 (7)	17 (21)	49 (61)
Mixed	67 (83)	7 (78)	5 (83)	15 (88)	40 (82)
Multifaceted only	9 (11)	2 (22)	1 (17)	2 (12)	4 (8)
Mono-faceted only	5 (6)	0 (0)	0 (0)	0 (0)	5 (10)
Implementation strategies categories[a]	81 (100)	9 (11)	6 (7)	17 (21)	49 (61)
Educational meetings	60 (74)	8 (89)	5 (83)	12 (71)	35 (71)
Educational materials	59 (73)	8 (88.9)	6 (100)	10 (59)	35 (71)
Reminders	53 (64)	8 (89)	2 (33)	12 (71)	31 (63)
Educational outreach visits or academic detailing	45 (56)	5 (56)	5 (83)	9 (53)	26 (53)
Audit and feedback	40 (49)	6 (67)	4 (67)	10 (59)	20 (41)
Local opinion leaders	35 (43)	3 (33)	4 (67)	7 (41)	21 (43)
Feedback	32 (40)	5 (56)	1 (17)	5 (29)	21 (43)
Clinical practice guidelines	23 (28)	3 (33)	1 (17)	4 (24)	15 (31)
Local consensus processes	18 (21)	2 (22)	2 (33)	2 (12)	12 (25)
Tailored interventions	15 (17)	3 (33)	0 (0)	2 (12)	10 (20)
Audit	13 (16)	1 (11)	0 (0)	4 (24)	8 (16)
Patient-mediated interventions	11 (14)	1 (11)	0 (0)	1 (6)	9 (18)
Interprofessional education	9 (11)	1 (11)	0 (0)	3 (18)	5 (10)
Continuous quality improvement	9 (10)	2 (22)	0 (0)	2 (12)	5 (10)
Monitoring the performance of the delivery of health care	6 (7)	1 (11)	0 (0)	1 (6)	4 (8)
Managerial supervision	6 (7)	0 (0)	0 (0)	0 (0)	6 (12)
Educational games	5 (6)	0 (0)	0 (0)	1 (6)	4 (8)
Communities of practice	2 (3)	0 (0)	0 (0)	0 (0)	2 (4)
Clinical incident reporting	1 (1)	0 (0)	0 (0)	0 (0)	1 (2)
Routine patient-reported outcome measures	1 (1)	1 (11)	0 (0)	0 (0)	0 (0)
Public release of performance data	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
How outcomes were measured[a]	81 (100)	9 (11)	6 (7)	17 (21)	49 (61)
Not reported	47 (58)	4 (44)	4 (67)	7 (41)	32 (65)
Objective	29 (36)	6 (67)	4 (67)	8 (47)	11 (23)
Both	18 (22)	1 (11)	1 (17)	4 (24)	12 (25)
Self-administered	11 (14)	0 (0)	2 (33)	1 (6)	8 (16)
Implementation outcomes[a]	81 (100)	9 (11)	6 (7)	17 (21)	49 (61)

Characteristics	Overall, n (%)	Methodological quality, n (%)			
		High	Moderate	Low	Critically low
Adoption	72 (89)	8 (89)	6 (100)	14 (82)	44 (90)
Other	28 (35)	4 (44)	4 (67)	4 (24)	16 (33)
Implementation costs	16 (20)	1 (11)	2 (33)	3 (18)	10 (20)
Acceptability	15 (19)	2 (22)	2 (33)	3 (18)	8 (16)
Fidelity	9 (11)	1 (11)	0 (0)	1 (6)	7 (14)
Penetration	6 (7)	0 (0)	0 (0)	0 (0)	6 (12)
Appropriateness	5 (6)	0 (0)	0 (0)	1 (5.9)	4 (8)
Sustainability	4 (5)	0 (0)	0 (0)	0 (0)	4 (8)
Feasibility	3 (4)	0 (0)	0 (0)	0 (0)	3 (6)
Other outcomes[a]	28	4 (14)	4 (14)	4 (14)	16 (58)
Knowledge	19 (68)	1 (25)	4 (100)	3 (75)	11 (69)
Attitudes	10 (36)	2 (50)	2 (50)	1 (25)	5 (31)
Performance in a test situation	9 (32)	1 (25)	1 (25)	1 (25)	6 (38)
Satisfaction	8 (29)	2 (50)	2 (50)	1 (25)	3 (19)

[a]Categories are not mutually exclusive.

Knowledge Products

Of the 81 SRs, 56 (69%) focused on the implementation of single-type knowledge products, including 26 (46%) for clinical practice guidelines [41,48,51,54-56,69,70,72-78,81,83,91,100,101,108,110-112,114,115], 24 (43%) for health interventions of management and behavioral or pharmacological nature [46,52,57-60,67,71,82,84,86,88,92,94-96,98,102-104,106,107,113,116], and 6 (11%) for health technology interventions and decision support tools [47,53,65,68,80,93]. In the remaining 31% (25/81) of SRs, multiple knowledge products were the subjects of implementation (Table 2).

Knowledge Products by Implementation Strategy

The strategies used varied based on the knowledge product being implemented; clinical practice guidelines were commonly implemented using educational material distribution (21/26, 81%) [41,48,51,54,55,69,70,73-77,81,83,91,100,108,110,112,114,115], reminders (20/26, 77%) [41,48,51,54-56,69,70,73,76,77,81,83,91,100,101,111,112,114,115], and academic detailing (18/26, 69%) [41,48,51,54,55,69,73-77,81,83,100,108,112,114,115]. The simultaneous use of these 3 strategies to implement clinical practice guidelines was reported in 60% (15/26) of SRs [41,48,51,54,55,69,73,76,77,81,83,100,112,114,115].

For health interventions of management and behavioral or pharmacological nature, the implementation strategies included education meetings (19/24, 79%) [46,52,58-60,71,82,84,86,88,92,94-96,98,103,104,107,113], educational material distribution (15/24, 63%) [46,52,58,60,71,84,86,88,92,94-96,103,113,116], and reminders (15/24, 63%) [57,58,60,67,71,86,88,92,94-96,102,106,113,116]. Their simultaneous use was reported in 42% (10/24) of SRs [58,60,71,86,88,92,94-96,113].

The same pattern was observed for health technology interventions and decision support tools implemented using education meetings (3/6, 50%) [53,65,68], educational material distribution (3/6, 50%) [53,65,80], and audit and feedback (3/6, 50%) [53,65,93]. The simultaneous use of these strategies has been reported in 17% (1/6) of SRs [53].

We compared the proportions of implementation strategies used when the population was health care professionals alone and when the population was health care professionals and patients. Education meetings and academic detailing seem to be used when the population is composed of health care professionals alone, without any statistical significance (Table 3).

Table 3. Implementation strategies used by type of population (reviews: N=81).

Implementation strategies[a]	Health care professionals alone (n=47), n (%)	Health care professionals and patients (n=34), n (%)	*P* value
Education meetings	38 (81)	22 (65)	.13
Educational materials	37 (78)	22 (65)	.21
Academic detailing	30 (64)	15 (44)	.11
Reminders	30 (64)	23 (68)	.81
Audit and feedback	26 (55)	14 (41)	.26
Local opinion leaders	21 (45)	14 (41)	.82

[a]Categories are not mutually exclusive.

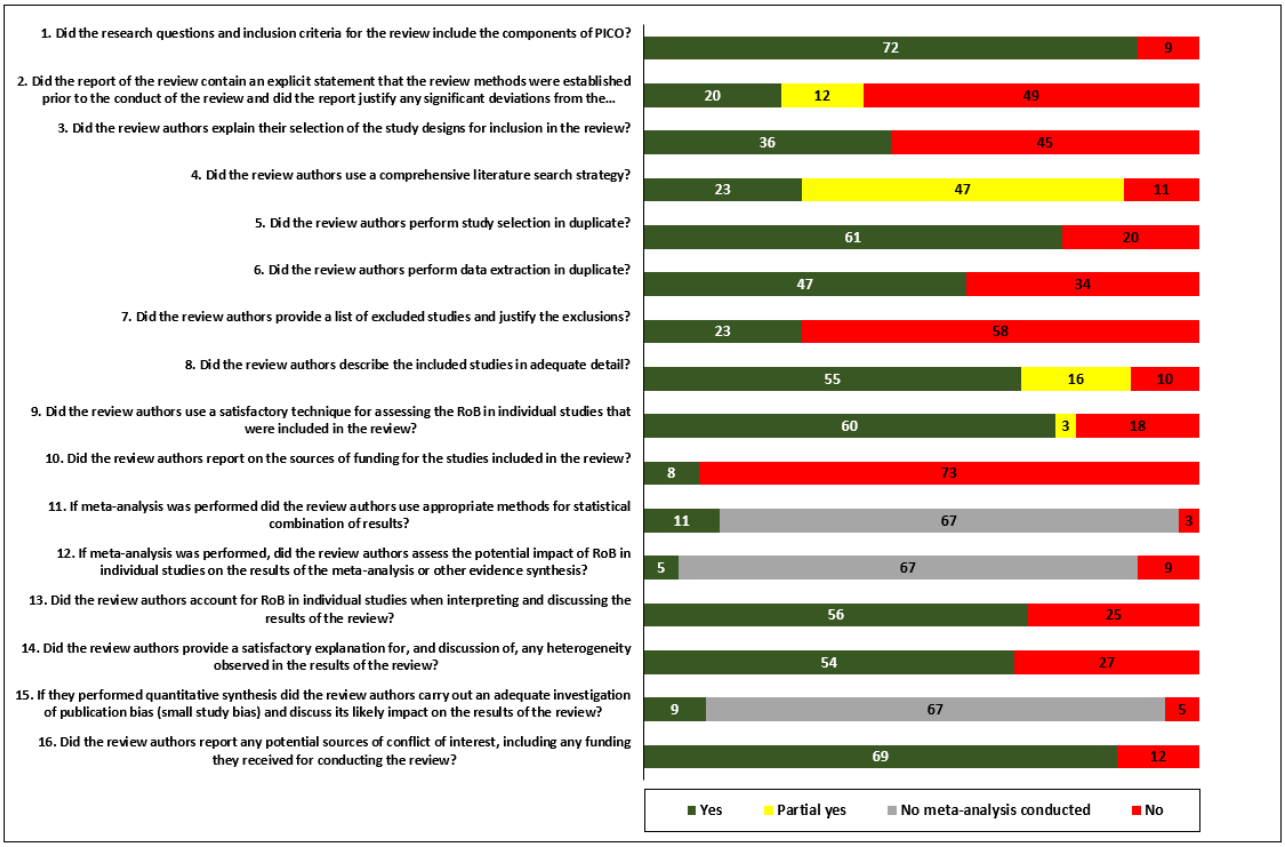
Outcomes

The adoption of knowledge products was the commonly measured implementation outcome in 89% (72/81) of SRs [40-50,53,54,56-60,62-77,79-84,86-88,90-95,97-113,115-120], followed by implementation cost in 20% (16/81) of SRs [42,43,47,50,61,73,78,85,87,90,97,99,106,108,112,114], and acceptability in 19% (15/81) of SRs [40,43,47,50,58,61,70,89,96,97,107,108,114,115,118]. Knowledge (19/81, 24%) and attitudes (10/81, 12%) were the other outcomes reported (Table 2). Further details are provided in Multimedia Appendix 5 [40-120].

Quality Assessment for the Included Reviews

Of the 81 included SRs, 15 (19%) received scores that indicated high or moderate methodological quality [40,44,58,60-65,67,84,87,92,94,108]. The remaining 81% (66/81) received scores that indicated low or very low methodological quality (Table 1). The quality was lowered by 3 criteria: lack of reporting on the funding sources of the studies included in the reviews (73/81, 90%), nonprovision of the list of excluded studies (with reasons for their exclusion; 58/81,72%), and no statement on the existence of the protocol or methodology before the conduct of the review (49/81, 61%; Figure 2). Details for each included SR are provided in Multimedia Appendix 6 [40-120].

Figure 2. Number of included systematic reviews by A Measurement Tool to Assess Systematic Reviews 2 (AMSTAR 2) methodological quality items and rating scores. PICO: patient or population, intervention, comparison, and outcomes; RoB: risk of bias.



Reported Effectiveness of Implementation Strategies and Level of Evidence of Outcomes in the Included Reviews

We synthesized the evidence by combining information on the reported level of evidence for the outcomes measured, among single knowledge products implemented, and by the implementation strategy used (Table 4). For SRs in which single knowledge products were implemented (56/81, 69%), the level of evidence was reported in 10 SRs with 62 specified outcomes (Table 4). Of these, 50 outcomes were related to the implementation of clinical practice guidelines in 6 SRs [74,77,83,91,110,114], 5 outcomes on management and behavioral or pharmacological health interventions in 3 SRs [60,67,103], and 7 outcomes for health technology interventions or decision support tools in one SR [47] (Table 4).

Regarding clinical practice guidelines (50 outcomes with the level of evidence reported), the following implementation strategies were used: educational material distribution for 42% (21/50) of outcomes [74,77,83,91,110], 71% (15/21) were about adoption [74,77,83,91,110], and 27% (4/15) provided a high or moderate level of evidence [77,91,110]; educational meetings for 30% (15/50) of outcomes [74,77,83,91], all were about adoption, 13% (2/15) provided a high or moderate level of evidence [74,77]; audit and feedback for 26% (13/50) of outcomes [74,77,83,91], all were about adoption, 23% (3/13) of them provided a high or moderate level of evidence [74,77,91]; and reminders for 24% (12/50) of outcomes [77,83,91]; all were about adoption, 33% (4/12) provided a high or moderate level of evidence [77,91] (Table 4).

For management and behavioral or pharmacological health interventions, educational meetings were evaluated for all 100% (5/5) of outcomes [60,67,103], all were about adoption, and 20% (1/5) of them provided a high or moderate level of evidence [103]. Feedback was evaluated for 80% (4/5) of outcomes [60,67,103]; all were about adoption, and 25% (1/4) provided a high or moderate level of evidence [103] (Table 4).

Health technology interventions or decision support tools used reminders for 100% (7/7) of outcomes [47], 43% (3/7) for acceptability [47], with 33% (1/3) providing a high or moderate level of evidence [47]; furthermore, there were 29% (2/7) for implementation costs [47], with 50% (1/2) providing a high or moderate level of evidence [47]. In addition, feedback was used for 86% (6/7) of outcomes [47], 33% (2/6) for acceptability [47], with 50% (1/2) providing a high or moderate level of evidence [47]; furthermore, there were 33% (2/6) for implementation costs [47], with 50% (1/2) providing a high or moderate level of evidence [47] (Table 4).

Table 4. Reported level of evidence for measured outcomes for single knowledge products and by implementation strategies used (outcomes: N=62).

Knowledge products, implementation strategies[a], and categories of outcomes[b,c]	Level of evidence
Clinical practice guidelines (n=50 outcomes)	
Educational meetings (n=15)	
Adoption (n=15)	• High (n=1) • Moderate (n=1) • Low (n=12) • Very low (n=1)
Educational materials (n=21)	
Adoption (n=15)	• High (n=1) • Moderate (n=3) • Low (n=10) • Very low (n=1)
Knowledge (n=3)	• Moderate (n=2) • Low (n=1)
Performance in a test situation (n=2)	• Low (n=2)
Satisfaction (n=1)	• Low (n=1)
Reminders (n=12)	
Adoption (n=12)	• High (n=1) • Moderate (n=3) • Low (n=7) • Very low (n=1)
Educational outreach visits or academic detailing (n=6)	
Adoption (n=6)	• High (n=1) • Moderate (n=1) • Low (n=3) • Very low (n=1)
Audit and feedback (n=13)	
Adoption (n=13)	• High (n=1) • Moderate (n=2) • Low (n=9) • Very low (n=1)
Local opinion leaders (n=4)	
Adoption (n=4)	• High (n=1) • Moderate (n=1) • Low (n=2)
Feedback (n=12)	
Adoption (n=12)	• High (n=1) • Moderate (n=1) • Low (n=9) • Very low (n=1)
Clinical practice guidelines (n=3)	
Adoption (n=3)	• High (n=1) • Low (n=1) • Very low (n=1)
Local consensus processes (n=3)	
Adoption (n=3)	• Moderate (n=1) • Low (n=2)

Knowledge products, implementation strategies[a], and categories of outcomes[b,c]	Level of evidence
Tailored interventions (n=5)	
Adoption (n=5)	• High (n=1) • Moderate (n=2) • Low (n=1) • Very low (n=1)
Audit (n=11)	
Adoption (n=11)	• High (n=1) • Moderate (n=1) • Low (n=8) • Very low (n=1)
Interprofessional education (n=3)	
Adoption (n=3)	• High (n=1) • Low (n=1) • Very low (n=1)
Continuous quality improvement (n=10)	
Adoption (n=10)	• High (n=1) • Low (n=8) • Very low (n=1)
Monitoring the performance of the delivery of health care (n=3)	
Adoption (n=3)	• High (n=1) • Low (n=1) • Very low (n=1)
Management and behavioral or pharmacological health interventions (5 outcomes)	
Educational meetings (n=5)	
Adoption (n=5)	• Moderate (n=1) • Low (n=3) • Very low (n=1)
Educational materials (n=2)	
Adoption (n=2)	• Moderate (n=1) • Very low (n=1)
Reminders (n=2)	
Adoption (n=2)	• Low (n=1) • Very low (n=1)
Educational outreach visits, or academic detailing (n=2)	
Adoption (n=2)	• Moderate (n=1) • Very low (n=1)
Audit and feedback (n=1)	
Adoption (n=1)	• Very low (n=1)
Local opinion leaders (n=1)	
Adoption (n=1)	• Very low (n=1)
Feedback (n=4)	
Adoption (n=4)	• Moderate (n=1) • Low (n=2) • Very low (n=1)
Local consensus processes (n=2)	

Knowledge products, implementation strategies[a], and categories of outcomes[b,c]	Level of evidence
Adoption (n=2)	• Moderate (n=1) • Very low (n=1)
Patient-mediated interventions (n=1)	
Adoption (n=1)	• Moderate (n=1)
Health technology interventions and decision support tools (7 outcomes)	
Reminders (n=7)	
Acceptability (n=3)	• Moderate (n=1) • Low (n=2)
Adoption (n=1)	• Low (n=1)
Fidelity (n=1)	• Low (n=1)
Implementation costs (n=2)	• Moderate (n=1) • Low (n=1)
Feedback (n=6)	
Acceptability (n=2)	• Moderate (n=1) • Low (n=1)
Adoption (n=1)	• Low (n=1)
Fidelity (n=1)	• Low (n=1)
Implementation costs (n=2)	• Moderate (n=1) • Low (n=1)
Clinical practice guidelines (n=1)	
Implementation costs (n=1)	• Moderate (n=1)

[a]Categories are not mutually exclusive.

[b]Positive outcome (eg, increase in adoption and increase in knowledge).

[c]Within the same review, it may have implemented 1 type of single knowledge product (eg, clinical practice guidelines) but used different specific practices (eg, general obstetric care guidelines and emergency obstetric care guidelines). Although these practices may report the same category of implementation outcome (eg, adoption), if those practices presented and reported different levels of evidence specific for each one (eg, *low* for general obstetric care guidelines and *moderate* for emergency obstetric care guidelines), then their outcomes were extracted separately and analyzed separately.

Discussion

Principal Findings

In this paper, we report the results of an SR of SRs, thus providing a detailed portrait of (1) the knowledge products or innovations implemented in primary health care, (2) the implementation strategies used by health care professionals in primary care, and (3) implementation outcomes evaluated as well as their reported level of evidence in primary care.

The findings of this review will be used to inform future SRs of RCTs on the effectiveness of implementation strategies for specific knowledge products.

In this review, which summarized a total of 81 studies, for most (56/81, 69%) of the included SRs, only 1 type of knowledge product (single) was implemented, the majority of which were clinical practice guidelines or health interventions (of management and behavioral or pharmacological nature). Implementation strategies commonly combine education-based strategies (material distributions, meetings, and outreach), reminders, and audits and feedback. Improvement in the adoption of knowledge products was the most measured outcome.

Education-based strategies, audits, feedback, and reminders were mainly used to improve the adoption of clinical practice guidelines and health interventions related to management, behavior, or pharmacology. In contrast, reminders and audit and feedback were used to improve the acceptability and implementation costs of health technology interventions. The reported effectiveness of these strategies was of a high or moderate level of evidence in a few cases and of a low or very low level of evidence in most cases.

Comparison With Prior Work

Clinical practice guidelines and management, behavioral or pharmacological health interventions, and health technology interventions and decision support tools have been developed to improve clinical practice and patient health outcomes. Despite

their comparable effectiveness, the level or degree of implementation varies widely. For instance, as seen in this review, health technology interventions and decision support tools appear to be less implemented or less frequently reported. This does not mean that they are less developed than other knowledge products, but they are probably less commonly addressed in formal research or possibly less known by end users. These interventions, which are generally in the format of mobile-based or computerized-based interventions, are created to accelerate the accessibility and use of KT interventions. A decade ago, such interventions were considered new in the health domain, and it was reasonable that they were minimally implemented [65]. Currently, it is unclear why this situation persists, when health technology interventions and decision support tools are generally recognized as important aspects of care and the way of the future. The reasons may be attributed to the policy-making and funding level (health technologies are often short-term projects, ie, no long-term vision, nonexistence, and unpredictable changes in policies and regulations, financial constraints, eg, affordability, lack of infrastructure [such as office space, supplies, equipment, etc], human resource availability, and digital literacy) [121,122], or the implementation level (unawareness of the technology, perceived usefulness, ie, acceptability, etc) [121,122]. Finally, barriers may differ across settings and cultures [121,122].

The predominance of education-based, reminder, and audit and feedback implementation strategies suggests that they were prioritized based on existing barriers and facilitators of the implementation of the mentioned knowledge products. In fact, some of the most recent systematic and scoping reviews on the topic highlighted a lack of both provider awareness and knowledge of the existence of guidelines, and unfavorable attitudes about them [123-125], in response to which educational and audit and feedback strategies were judged to be suitable [123,125]. In contrast, a lack of access to guidelines and limited time available to providers was also mentioned [124,125], thereby calling for the use of decision support systems or reminders [125]. However, it is important to know whether these strategies are effective in implementing knowledge products. The included SRs demonstrated an *all-directions effect*, which was sometimes consistently positive or negative, or inconsistent, depending on factors such as single versus combined strategies [41,50,71,100] or type of comparator [110]. For example, in a study by Al Zoubi et al [41], single educational strategies appeared to have a small effect, whereas multifaceted strategies that combine educational strategies and other types of strategies, such as reminders, appeared to be more effective, although inconsistent. Kovacs et al [81] found the opposite result, showing that a single intervention is more effective. Others found that effectiveness may depend on the format in which education strategies are delivered; for example, by multimedia and computers [96].

Adoption, which is also referred to as “uptake or utilization,” is “the intention, initial decision, or action to try or employ an innovation or evidence-based practice” [34]. This outcome occurs early or in the middle of the implementation process, is preceded by acceptability and appropriateness, and occurs at the same time as feasibility, followed by fidelity, implementation costs, penetration, and sustainability [34]. All proximal and distal implementation outcomes are important for measurement. The ongoing focus of the literature on the proximal outcome of adoption is more easily understood for recently introduced health technology interventions and strategies but is more difficult to explain when traditional strategies, such as education, are predominantly used.

Regarding the level of evidence of effectiveness, very few SRs have evaluated the level of evidence, as most reviews are narrative. The authors were unable to perform meta-analyses owing to high heterogeneity. In contrast, among the few reviews that assessed the level of evidence, most scored a low or very low grade. This makes it difficult to recognize potentially effective strategies and calls for more methodologically strong SRs to obtain reliable conclusions on the topic.

Strengths and Limitations

One strength of this SR is its broad objective, which included all EPOC strategies used to implement a variety of health knowledge products, with consideration given to the different implementation outcomes. No type of health care provider was excluded, and even if our target was primary health care, most included SRs covered both primary and secondary health care settings. We did not target any health area. We performed an extensive search and included both Cochrane and non-Cochrane reviews. It has been estimated that including only Cochrane reviews may lead to a loss or change in a median of 31% of the outcome data [126]. The objective of this phase was to characterize rather than measure effectiveness. Both types of SRs offered a large database of 81 reviews for future projects dealing with individual, unique RCTs. Therefore, we believe that our conclusions can be applied to many different contexts.

Few of the included reviews were of high or moderate methodological quality. The criteria lowering the scores may be linked to the unavailability of reporting guidelines at the time of publication or nonadherence to those guidelines when they were available. As per many other overviews, we used the AMSTAR tool and, as suggested, did so in a dual independent team format with a consensus process [25]. It is also possible to exclude reviews based on methodological quality issues when the aim is to produce a detailed picture of a topic [127], as in our case.

With regard to the quality and completeness of the extracted information, in many of the included SRs, the categories of knowledge products, implementation strategies, and outcomes were not reported as per the standard taxonomies used, thereby requiring us to recategorize. This may have introduced some misclassification of information. We addressed this issue and its potential impact on our conclusion by piloting our data extraction process and reaching a consensus for all disagreements (by reviewing the discordant information together).

In the field of overviews, overlapping occurs when one primary study is included in more than one review or when more than one review addresses the same topic [128]. We cannot guarantee that our review will be free of overlapping issues. In addition, we did not evaluate the quality of evidence of outcomes for the

included reviews, as we did not intend to demonstrate the effectiveness of the interventions. These 2 issues will be addressed in future projects on the effectiveness of strategies using the design of SRs of individual RCTs. For the comprehensiveness of our strategy, we searched 5 key databases in the field of intervention studies. In addition, we searched the reference lists of all included SRs. However, gray literature was not searched. For efficiency considerations, it was planned to update the search strategy in phase 3 of the project to avoid missing any recently published RCTs on the effectiveness of implementation strategies. We could look for gray literature in this phase.

Conclusions and Future Directions

Through this SR of SRs, we demonstrated that in the field of implementation, clinical practice guidelines and management, behavioral, or pharmacological health interventions are the most commonly implemented knowledge products, mainly through educational, reminder, and audit and feedback implementation strategies. However, the literature still focuses on the proximal outcomes of improving the adoption of knowledge products, generally with a limited level of evidence.

This SR aimed to provide insight into which knowledge products are frequently implemented, how they are implemented (implementation strategies), and the implementation outcomes measured, rather than providing information on the effectiveness of the implementation strategies. Therefore, in this step, we do not suggest changes in practice; rather, this review provides a good foundation for planning future research on effectiveness. Only detailed and contextualized information on knowledge products and implementation strategies will lead to changes in practice.

We constructed a database of SRs that may be used to strengthen the methodology for the SR of RCTs to overcome the issue of the variable effectiveness of commonly used implementation strategies, such as educational, reminder, and audit and feedback strategies. Future well-designed SRs of RCTs should fully describe the implementation strategy attributes of dose and intensity, format and duration of delivery, geographic location of interventions, and so on. In addition, qualitative studies and reviews involving a variety of collaborators from different domains and levels should be conducted to better understand the barriers and facilitators that contribute to why health technology interventions remain poorly implemented. Future implementation research should explore the entire cascade of implementation outcomes, including proximal and distal outcomes.

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Authors' Contributions

HTVZ, JM, AB, AT, DK, CBU, NR, ABC, ED, LL, ST, SAG, and FL designed the protocol. NR designed the search strategy. FL, JM, LL, MD, ABC, and HTVZ reviewed the search strategy. NR implemented the search strategy. SAG, CBU, and ST screened the citations. SAG, CBU, JM, LP, and ST checked reviews for eligibility. HTVZ validated the list of included reviews. SAG, CBU, ED, ABC, MD, LP, and HTVZ assessed methodological quality of reviews. SAG, CBU, JM, ST, MD, LL, ED, and LK extracted data. LK and CBU analyzed data. CBU drafted the first version of manuscript. All authors critically reviewed and approved the manuscript.

Conflicts of Interest

None declared.

Multimedia Appendix 1
Definitions of implementation outcomes.
[DOCX File , 16 KB - ijmr_v11i2e38419_app1.docx]

Multimedia Appendix 2
Search strategy.
[DOCX File , 151 KB - ijmr_v11i2e38419_app2.docx]

Multimedia Appendix 3
Excluded studies and reasons.
[DOCX File , 67 KB - ijmr_v11i2e38419_app3.docx]

Multimedia Appendix 4
General characteristics of included reviews.
[DOC File , 42 KB - ijmr_v11i2e38419_app4.doc]

Multimedia Appendix 5
Knowledge products, implementation strategies, and outcomes measured in included reviews.
[DOC File , 46 KB - ijmr_v11i2e38419_app5.doc]

Multimedia Appendix 6
A Measurement Tool to Assess Systematic Reviews 2 quality appraisal of included reviews.
[DOC File , 83 KB - ijmr_v11i2e38419_app6.doc]

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Abbreviations

AMSTAR: A Measurement Tool to Assess Systematic Reviews
EPOC: Effective Practice and Organization of Care
KT: knowledge translation
PRISMA: Preferred Reporting Items for Systematic Reviews and Meta-Analyses
RCT: randomized controlled trial
SR: systematic review

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Original Paper

Published Research on COVID-19 in the Eastern Mediterranean Region: Bibliometric Analysis

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Abstract

Background: The challenges presented by the COVID-19 pandemic have led to unprecedented global research activity. The Eastern Mediterranean Region (EMR) continues to contribute to COVID-19 research driven by the unique challenges of the region, including the protracted conflicts, already stressed health systems, and serious health and social inequalities.

Objective: This study aims to provide an overview of the publication activities and trends in COVID-19 research in the EMR from the onset of the disease to early 2022 using bibliometric methods.

Methods: A literature search using Scopus was conducted from December 1, 2019, to January 31, 2022, using keywords relevant to COVID-19 and the World Health Organization (WHO) EMR country list. Data were exported and analyzed using Microsoft Excel and the Citation Overview function on Scopus. The quality of journals was determined using SCImago Journal Rank and CiteScore. VOSviewer software was used to visualize the relationships between authors, countries, and key terms used in the retrieved documents.

Results: A total of 6880 documents were retrieved, of which 1805 (26.24%) were from the Kingdom of Saudi Arabia (KSA) and 1782 (25.90%) from Iran, followed by Pakistan, Egypt, and Jordan. Most published documents were affiliated with EMR universities, primarily the Tehran University of Medical Sciences in Iran and King Saud University in KSA (396/6880, 5.76%, and 370/6880, 5.4%, respectively), while only 407 (5.92%) of 6880 documents were associated with universities outside the EMR. For most of the identified publications (5020/6880, 72.97%), no funding source was reported, while King Saud University contributed the largest share (282/1860, 15.16%) of funded publications. Retrieved documents were cited 53,516 times, with an average of 7.78 (SD 34.30). Iran was the EMR country with the most links to other countries (77 links and total link strength of 1279). The 5 authors with the most publications were from KSA, Qatar, and Jordan. There were 290 high-frequency keywords that occurred ≥10 times and were linked in 7 different clusters. The cluster with the most linked keywords was related to epidemiology and mortality. Recent topics included vaccines, vaccination, machine learning, and online learning.

Conclusions: This is the first study to show trends in and project future developments of COVID-19 research activity in the EMR. Authors and institutions who led research on COVID-19 in the region were from Iran and KSA. There were multiple regional collaborative efforts; however, international collaboration was limited. Recently, interest has been shifting toward topics related to vaccination, machine learning, and online learning. Understanding the current state of research is instrumental to future research production, and our study will inform regional research initiatives on emerging concepts, as well as opportunities for collaboration and funding.

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KEYWORDS

COVID-19; Eastern Mediterranean Region; bibliometric analysis; literature; research; health care system; social inequality; epidemiology; depression; research trend; bibliometry

Introduction

The COVID-19 pandemic continues to be a major global challenge, placing a heavy burden on the economy, social life, public health systems, and the delivery of health services in all countries worldwide [1]. Despite the rapid development of various vaccines to prevent severe illness and treatment modalities, the world still faces numerous challenges in controlling COVID-19 and its impacts [1]. Disparities in global access to vaccines, increasing vaccine hesitancy, impractical long-term implementation of preventive public health measures, and the continuous emergence of new variants are some of these challenges [1-3]. The Eastern Mediterranean Region (EMR) remains at high risk of COVID-19 case surges with the associated short- and long-term consequences primarily due to the combination of the aforementioned causes, added to which are the specific regional environment with protracted conflicts; high denial attitude toward the pandemic; chronically stressed health systems; and the presence of health, economic, and social inequities [4-7].

As of April 1, 2022, there have been 21,576,432 confirmed cases and 340,628 deaths attributable to COVID-19 in the EMR [8]. The EMR has a population of nearly 700 million people in 22 countries with high susceptibility to infectious diseases due to numerous political, economic, social, cultural, and human-animal interactions [5,9]. Almost 40% of the world's population in need of humanitarian assistance lives in the EMR and is at high risk of coronavirus transmission and associated severe consequences due to overpopulation, suboptimal sanitation, a high caseload of noncommunicable diseases (NCDs), and limited resources and health system capacity [5]. Furthermore, a number of EMR countries have limited testing facilities, weak health system infrastructure and response, and inadequate vital registration and documentation, all of which have been associated with the possibility of underreporting or undertesting or both of COVID-19 cases [4,5,10]. The introduction of vaccination programs in the EMR continues to be hampered by logistical, economic, security, and population hesitancy issues, as well as reaching people living in hard-to-reach areas [11].

COVID-19 had a strong impact on scientific publications worldwide, as evidenced by the rapid increase in the volume and pace of COVID-19 publications, with many journals dedicating special sections or issues to COVID-19, even at the expense of other topics [12,13]. The COVID-19 crisis has also stimulated an unprecedented level of multidisciplinary research involving not only those with a direct interest in COVID-19 research and health, such as virologists, epidemiologists, and clinicians, but also researchers from diverse fields, such as artificial intelligence and business [14,15]. The projected long-term impact of COVID-19 and the fact that it affects multiple areas of life have led to a burst of studies examining the impact of COVID-19 on many nonmedical and nonclinical research areas, such as education, business and management, tourism, and agricultural food supply [16-19]. The global research funding mechanisms and magnitude have also changed. Between the beginning of January 2020 and July 2021, more than US $21.7 trillion was reportedly committed globally to different COVID-19 activities according to data analysis on Devex's funding platform [20]. Some governments with limited fiscal space or limited prearranged funding sources had to reallocate their existing budgets and allocate funds to COVID-19 studies, even at the expense of other disease control programs, such as for malaria and HIV/AIDS in Africa [21,22]. In the EMR, COVID-19 research has flourished, with countries and organizations dedicating special effort, in addition to technical and financial support for such research [23,24]. Our aim is to provide an overview of the published research activities and trends in COVID-19 research in the EMR by applying bibliometric methods to identify research collaborations, trends, and emerging research themes.

Methods

Search Strategy

We conducted a literature search on January 31, 2022, using the Scopus database, covering the period from December 1, 2019, to January 31, 2022. Scopus was chosen for its data mining and bibliometric functions, as well as its compatibility with Visualization of Similarities Viewer (VOSviewer) software. Additionally, Scopus is the largest indexing database, combining the characteristics of both PubMed and Web of Science, and thus allows for enhanced utility, both for literature research and academic needs, including citation analysis [25]. As Scopus does not use subject headings but instead assigns index terms to papers, our search query included the field code KEY, which combines both author keywords and indexed terms [26]. Our search query included keywords relevant to COVID-19 and the World Health Organization (WHO) list of countries in the EMR (Multimedia Appendix 1) [27]. Keywords for COVID-19 included "severe acute respiratory syndrome coronavirus-2," "SARS-CoV-2," "sars-2," and "2019-nCoV," as well as the words "novel," "new," "2019," "Wuhan," "Hubei," and "China" adjacent to the words "coronavirus" and "COVID." We additionally used wildcards and truncations, as needed, to refine the search. We limited the search to papers, reviews, chapters, and books published in English, associated with any of the EMR countries. We included both published papers and papers in press (accepted for publication by a journal but not assigned to a specific journal issue).

Scientific Literature Bibliometric Indicators

We exported the data from Scopus to Microsoft Excel and calculated the following bibliometric indicators: number of documents published by publication stage (in press or

published), number of open-access documents, number of documents by type of publication (original paper, review, book chapter, book), number of documents by year, number of documents published per country, number of documents published per author, number of documents published per organizational affiliation (publications combined into 5 categories of affiliations: universities in the EMR, universities outside the EMR, ministries of health in the EMR, health centers in the EMR, global health agencies), number of documents per funding source, number of documents per journal, and number of documents published by subject category as indexed by Scopus.

Citations and Quality Assessment

The Citation Overview function in Scopus enabled us to determine the mean, median, and range of citations of all retrieved documents, as well as identify the topmost cited documents. Additionally, author details were reviewed on Scopus to determine the topmost productive authors' H-index and citation score.

We assessed the quality of the most productive journals on the topic of COVID-19 in the EMR using the 2021 SCImago Journal Rank (SJR), CiteScore (CS), and the Source-Normalized Impact Per Paper (SNIP). The SJR is based on centrality concepts and data from Scopus, and it limits self-citations and falsely inflated quality ranks, while the CS gives a comprehensive, transparent, and current view of a journal's impact [28]. SNIP is also based on data from Scopus, and it measures impact by weighing citations based on the total number of citations in a subject field, enabling direct comparison of sources in different subject fields [29]. Using the SCImago ranking website, we identified the subject area of each journal and its corresponding SJR rank divided into 4 equal quartiles, with Q1 comprising the quarter of the journals with the highest values, Q2 the second-highest values, Q3 the third-highest values, and Q4 the lowest values [30].

Visualization of Similarities

To analyze and visualize relationships among authors, countries, and the key terms used in the retrieved publications, we exported the citation information, bibliographical information, abstracts and keywords, and funding details and included references from Scopus into VOSviewer v.1.6.16 (Centre for Science and Technology Studies, Leiden University) [31].

In constructing the networks and maps, we used a clustering resolution of 1 and a minimum cluster size of 12 to eliminate small clusters, and we illustrated each cluster (eg, group of linked authors, countries, or keywords) using a different color. We scaled the maps based on document weights, unless otherwise specified, so the diameter of each label denotes the number of occurrences of the author, country, or keyword specified by the label, in the documents, and the distance between 2 labels represents the degree to which they are associated [32].

Coauthorship network analysis was performed based on the full counting method. When we used authors as the unit of analysis, we excluded papers authored by >25 authors, and we set both the minimum number of papers published by an author and the minimum number of citations of an author at 5 to identify prominent authors who have published on the topic. When we used countries as the unit of analysis, we excluded papers authored by >25 countries and only included countries with ≥5 published papers. We did not place a restriction on the number of citations during the countries' coauthorship analysis. We identified the number of coauthorship links countries have with one another and the total strength of the links using the "links" and the "total links strength" attributes provided by VOSviewer.

To identify trending topics relating to COVID-19 in the EMR, we used co-occurrence analysis of author keywords occurring at least 10 times in publications. We excluded the names of countries and regions from the list of keywords to focus on scientific themes, and we also excluded all synonyms of COVID-19, which might obscure the results. We applied normalization based on the association strength to eliminate redundancy in similar keywords that define the same concept. Additionally, we mapped the keyword co-occurrence using overlay visualization to determine the evolution of themes with time.

Results

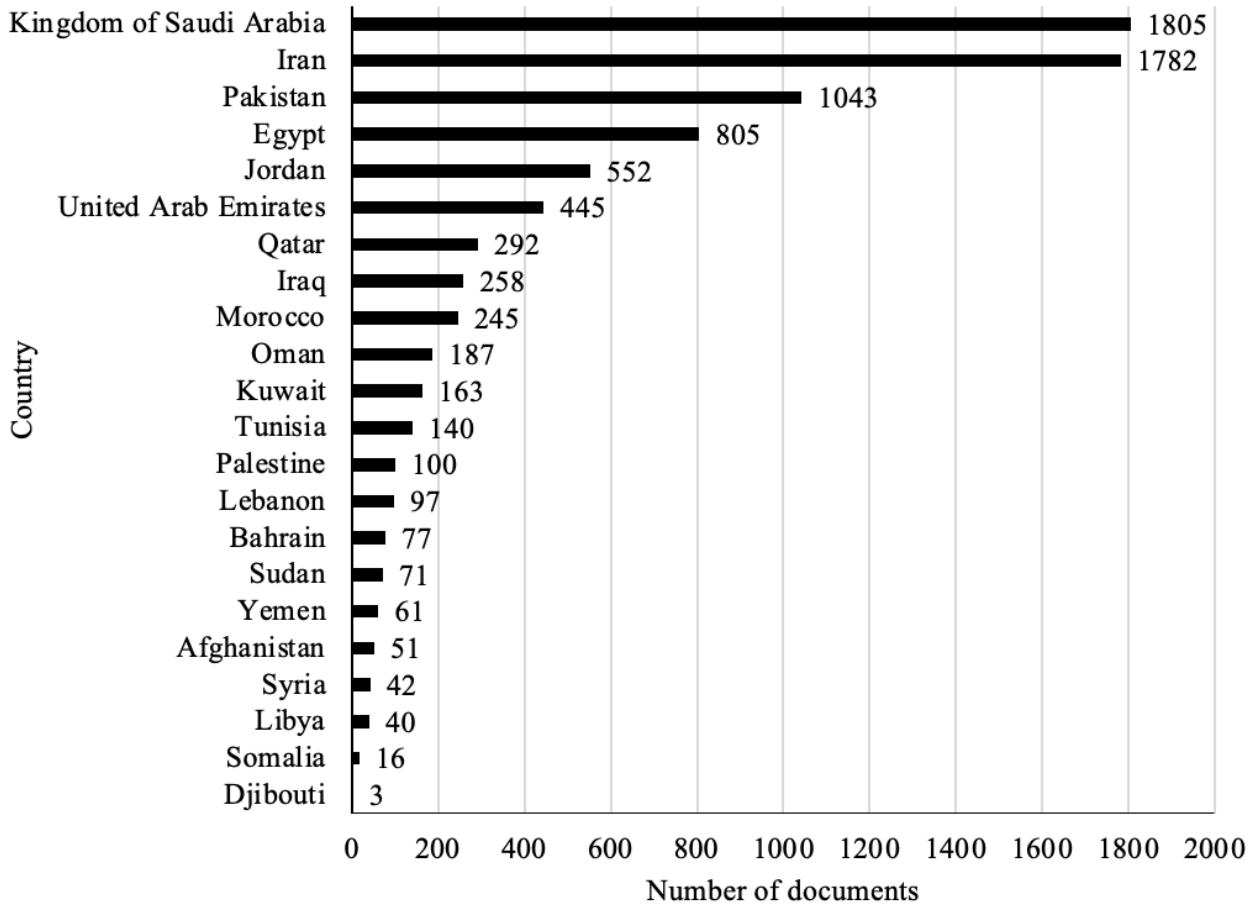
Volume and Type of Publications

Our search retrieved 6880 documents. Most were published documents, and only 586 (8.52%) were still in press. Almost 5439 (79.05%) of 6880 documents were open-access documents, and about 6182 (89.85%) were original papers. Reviews and book chapters constituted only 9.29% (639/6880) and 0.86% (59/6880), respectively. The majority of documents (4630/6880, 67.30%) were published in 2021, whereas 1851 (26.90%) and 39 (0.57%) were published in 2020 and 2019, respectively. Since the beginning of 2022 and until January 31, 2022, 360 (5.23%) documents have been published.

Publication Distribution by Country

Most publications on COVID-19 in the EMR were from the Kingdom of Saudi Arabia (KSA) and Iran (1805/6880, 26.24%, and 1782/6880, 25.90%, respectively). This was followed by Pakistan (1043/6880, 15.6%), Egypt (805/6880, 11.70%), and Jordan (552/6880, 8.02%). Eight other EMR countries produced ≥100 publications each: the United Arab Emirates (UAE), Qatar, Iraq, Morocco, Oman, Kuwait, Tunisia, and Palestine. However, 5 EMR countries produced <55 publications (ie, Afghanistan, Djibouti, Somalia, Libya, and Syria), where each contributed to <1% (n=3-51) of the overall publication output (Figure 1).

Figure 1. Number of published documents on COVID-19 by country in the EMR. EMR: Eastern Mediterranean Region.



Publication Distribution by Affiliation

Each publication had 1 or more institutional affiliations. Most of the published documents were associated with 117 universities in the EMR, with 396 (5.76%) and 370 (5.4%) of 6880 documents being associated with the Tehran University of Medical Sciences in Iran and King Saud University in KSA, respectively (Table 1). Of the 6880 identified publications, only 407 (5.92%) were associated with other universities outside the EMR (n=12), most notably the Universiti Sains Malaysia and Johns Hopkins School of Medicine, each associated with 38 (0.55%) of the 6680 documents.

With regard to affiliations with health centers, 10 health centers from the region were associated with publications on COVID-19 in the EMR, half of which were located in KSA (5/10, 50%), namely King Faisal Specialist Hospital and Research Centre, King Abdulaziz Medical City Riyadh, King Fahad Medical City, Johns Hopkins Aramco Healthcare, and King Saud Hospital Riyadh. These 5 health centers, in addition to the Imam Khomeini Hospital in Iran, were each involved with more than 50 publications on the topic.

Ministries of health, including those of KSA, Oman, Kuwait, and Iran, were associated with around 392 (5.69%) of the published 6880 documents, with the Saudi Ministry of Health being the major contributor of 276 (70.41%) of 392 documents. The only international health agency that was associated with COVID-19–related research in the EMR was WHO, being a contributor to 62 (0.90%) of 6880 documents.

Table 1. EMR[a] universities associated with more than 150 published documents on COVID-19 in the EMR.

University	Country	Documents (N=6880), n (%)	Total citations, N	Total citations, excluding self-citations, n (%)	H- index
Tehran University of Medical Sciences	Iran	396 (5.76)	3875	3322 (85.7)	35
King Saud University	KSA[b]	370 (5.38)	2953	2552 (86.4)	26
Shahid Beheshti University of Medical Sciences	Iran	316 (4.59)	2959	2645 (89.4)	27
King Abdulaziz University	KSA	272 (3.95)	2012	1734 (86.2)	23
Iran University of Medical Sciences	Iran	229 (3.33)	2644	2288 (86.5)	25
Cairo University	Egypt	190 (2.76)	2219	2115 (95.3)	14
Jordan University of Science and Technology	Jordan	183 (2.66)	1331	1180 (88.7)	19
Shiraz University of Medical Sciences	Iran	181 (2.63)	2069	1907 (92.2)	23
University of Jordan	Jordan	163 (2.37)	2567	2300 (89.6)	21
Imam Abdulrahman Bin Faisal university	KSA	161 (2.34)	660	582 (88.2)	13
King Saud bin Abdulaziz University for Health Sciences	KSA	157 (2.28)	1169	1046 (89.5)	18

[a]EMR: Eastern Mediterranean Region.

[b]KSA: Kingdom of Saudi Arabia.

Source of Funding

Most of the identified publications did not report a source of funding (5020/6880, 72.97%). However, of those that did, most were funded by King Saud University (282/1860, 15.16%). The majority of those funded by King Saud University were published in 2022 (183/282, 64.89%). Additionally, Shahid Beheshti University of Medical Sciences in Iran, King Abdulaziz City for Science and Technology in KSA, and King Abdulaziz University in KSA each funded more than 50 publications on the topic (55/1860, 3.00%; 51/1860, 2.74%; and 51/1860, 2.74%, respectively), and most of these funded papers were published in 2022 (98/157, 62.42%).

The US National Institutes of Health (NIH) and the National Natural Science Foundation of China each funded 37 (2%) of 1860 publications. WHO funded 31 (1.67%) of 1860 publications, of which 12 (38.71%) were published in 2020 and 13 (41.94%) in 2021.

Most Productive Citing Journals

Of the 6821 papers published in journals, 3279 (48.07%) were published in 169 distinct scientific journals, whereas the source of the rest was not defined. The top 15 most productive journals on the topic of COVID-19 in the EMR published 1023 (31.20%) of the 3279 papers (Table 2). Their median 2021 CS and 2021 SJR were 4.5 (range 1.0-18.8) and 0.986 (range 0.283- 2.656), respectively. Of these journals, the *International Journal of Environmental Research and Public Health* (CS=4.5, SJR=0.814) published the maximum papers on COVID-19 in the EMR (155/1023, 15.15%). Most of the top publishing journals were categorized as medical journals or health-related journals, except for 1 journal, *Sustainability Switzerland*, which focuses on energy, environmental science, and social sciences.

Table 2. The 2021 CS[a], SJR[b], SNIP[c], H-index, subject area and category, and Scimajo 2020 quarter of the 15 most productive journals on COVID-19 in the EMR[d].

Journal	Papers (N=3279), n (%)	CS 2021	SJR 2021	SNIP 2021	H-index	Subject area: category; 2021 quarter[e]
International Journal of Environmental Research and Public Health	155 (4.72)	4.5	0.814	1.44	138	• Environmental science: health, toxicology and mutagenesis, pollution; Q2 • Environmental science: health, toxicology, and mutagenesis; Q1 • Medicine: public health, environmental and occupational health; Q2
PLoS ONE	126 (3.84)	5.6	0.852	1.368	367	• Multidisciplinary; Q1
Frontiers in Public Health	100 (3.05)	4.0	1.298	1.949	64	• Medicine: public health, environmental and occupational health; Q1
Journal of Infection and Public Health	85 (2.59)	8.0	1.277	2.018	46	• Medicine: infectious diseases; Q1 • Medicine: miscellaneous, public health, environmental and occupational health; Q1
Annals of Medicine and Surgery	63 (1.92)	1.4	0.373	0.965	30	• Medicine: miscellaneous, surgery; Q3
Vaccines	58 (1.77)	4.5	1.004	1.167	50	• Immunology and microbiology: immunology; Q2 • Medicine: pharmacology; Q1 • Medicine: infectious diseases; Q2 • Pharmacology, toxicology, and pharmaceutics: drug discovery, pharmacology; Q1
International Journal of Infectious Diseases	56 (1.71)	10.8	1.433	2.494	104	• Medicine: infectious diseases, miscellaneous, microbiology; Q1
Disaster Medicine and Public Health Preparedness	54 (1.65)	3.8	0.723	1.011	47	• Medicine: public health, environmental and occupational health; Q2
Environmental Science and Pollution Research	49 (1.49)	6.6	0.831	1.154	132	• Environmental science: environmental chemistry and pollution; Q2 • Environmental science: health, toxicology, and mutagenesis; Q1 • Medicine: miscellaneous; Q2
Pan African Medical Journal	48 (1.45)	1.0	0.283	0.509	36	• Medicine: miscellaneous; Q3
BMC Public Health	47 (1.43)	4.9	1.156	1.703	159	• Medicine: public health, environmental and occupational health; Q1
Risk Management and Healthcare Policy	46 (1.40)	2.1	0.556	1.007	29	• Medicine: health policy, public health, environmental and occupational health; Q2
Sustainability Switzerland	46 (1.40)	5.0	0.664	1.31	109	• Energy: energy engineering and power technology, renewable energy, sustainability, and the environment; Q2 • Environmental science: miscellaneous, management, monitoring, policy and law; Q2 • Social sciences: geography, planning and development; Q1
Frontiers in Psychology	45 (1.37)	4.0	0.873	1.605	133	• Psychology: miscellaneous; Q1
Journal of Medical Virology	45 (1.37)	18.8	2.656	2.756	137	• Immunology and microbiology: virology; Q1 • Medicine: infectious diseases; Q1

[a]CS: CiteScore.

[b]SJR: SCImago Journal Rank.

[c]SNIP: Source-Normalized Impact per Paper.

[d]EMR: Eastern Mediterranean Region.

[e]The 2021 quarter corresponds to the SJR quartile rank per subject area, divided into 4 equal quartiles, with Q1 comprising the quarter of the journals with the highest values, Q2 the second-highest values, Q3 the third-highest values, and Q4 the lowest values.

Publications by Subject Category

Each published document was categorized under 1 or more subject category in Scopus. Most of the retrieved documents (4211/6880, 61.21%) were categorized under medicine. Approximately 915 (13.30%) were categorized under social sciences and 627 (9.11%) under immunology and microbiology.

Of the 4211 documents categorized under medicine, 131 (3.11%) to 232 (5.51%) were labeled with index terms related to disease prevention, 120 (2.85%) to 262 (6.22%) with terms related to vaccination, 119 (2.83%) to 263 (6.25%) with terms related to treatment, 117 (2.78%) to 329 (7.81%) with mental health–related issues, 149 (3.34%) to 443 (10.52%) with disease severity terms, and 255 (6.56%) to 443 (10.52%) with mortality index terms (Table 3).

Table 3. Number of documents categorized under medicine and indexed with the index terms related to disease prevention, vaccination, treatment, mental health, disease severity, and mortality.

Index terms	Documents (N=4211), n (%)
Disease prevention	
Quarantine	232 (5.51)
Prevention and control	229 (5.44)
Infection prevention	172 (4.08)
Lockdown	167 (3.97)
Social distancing	149 (3.54)
Handwashing	131 (3.11)
Vaccination	
Vaccination	262 (6.22)
SARS-CoV-2 vaccine	156 (3.70)
Vaccine	120 (2.85)
Treatment	
Hydroxychloroquine	263 (6.25)
Lopinavir	160 (3.80)
Azithromycin	146 (3.47)
Treatment outcome	122 (2.90)
Antivirus agent	119 (2.83)
Mental health	
Anxiety	329 (7.81)
Psychology	272 (6.46)
Depression	266 (6.32)
Mental health	259 (6.15)
Mental stress	121 (2.87)
Stress	117 (2.78)
Disease severity	
Disease severity	443 (10.52)
Hospitalization	383 (9.10)
Intensive care unit	327 (7.77)
Hospital admission	249 (5.91)
Length of stay	149 (3.54)
Mortality	
Mortality	443 (10.52)
Mortality rate	255 (6.56)

Citation Metrics

The retrieved documents received a total of 53,516 citations, with an average of 7.78 (SD 34.30) citations per document (median 1, range 0-1462). The number of documents receiving ≥10, ≥50, ≥100, or ≥500 citations was 1112, 186, 78, and 5, respectively. Around 2758 (40.09%) of the 6880 publications had 0 citations.

The 3 most cited documents were all open-access multicountry collaborations, with the citation frequency equivalent to the 99th citation benchmarking percentile. The most cited document was “Physical Distancing, Face Masks, and Eye Protection to Prevent Person-to-Person Transmission of SARS-CoV-2 and COVID-19: A Systematic Review and Meta-Analysis,” which was a collaborative work between the American University of Beirut in Lebanon and researchers from Ontario, Canada, funded by WHO and published in the *Lancet* in 2020. It received a total of 1462 citations (n=1459, 99.8%, excluding author self-citations).

The second-most cited article was "The Fear of COVID-19 Scale: Development and Initial Validation," which was published in 2020 in the *International Journal of Mental Health and Addiction* and was a collaboration between 3 universities in Iran (Tabriz University of Medical Sciences, Qazvin University of Medical Sciences, and Baqiyatallah University of Medical Sciences) and Nottingham Trent University in the United Kingdom, Jönköping University in Sweden, and the Hong Kong Polytechnic University. It received a total of 1174 citations (n=1092, 93.01%, excluding self-citation by authors).

The third-most cited publication was "The SARS, MERS and Novel Coronavirus (COVID-19) Epidemics, the Newest and Biggest Global Health Threats: What Lessons Have We Learned?," which was published in the *International Journal of Epidemiology*. From the EMR, the National University of Medical Sciences in Pakistan and the Ofogh Kourosh Chain Stores in Iran collaborated with several other countries. This publication was funded by the National Key Research and Development Program of China. This study received a total of 664 citations (n=661, 99.54%, excluding self-citation by authors) and was published in 2021.

The top 5 most published authors, each publishing more than 25 documents on the topic (range 25-37), were from KSA (2 authors), Qatar (2 authors), and Jordan (1 author). Two of the authors, one from KSA and another from Qatar, were associated with their respective Ministry of Health, while the rest were associated with universities or medical centers in the region. Their average H-index on Scopus was 60 (SD 34; median 49, range 12-96), and their median citation frequency reported on Scopus was 10,094 (range 421-93,585).

Visualization of Similarities and Associations

Coauthorship

A total of 26,798 authors were identified to have worked on publications with ≤25 authors. Of those, 796 (2.97%) met the threshold of having published ≥5 papers on the topic and being cited ≥5 times. Of the 796, 719 (90.33%) authors were connected in a total of 16 different clusters (Figure 2). Similarly, 285 countries were identified to have coauthored publications (with ≤25 countries per publication). Of those, 82 (28.77%) countries had ≥5 papers published on the topic and were connected in 4 clusters (Figure 3). In both figures, the size of the circles represents the number of documents published by the author or country, and the thickness of the lines depicts the size of the collaboration between the authors or countries (Figures 2 and 3, respectively).

With regard to connections and collaborations, the EMR country with the most connections to other countries was Iran, with 77 links and a total link strength of 1279. KSA and Egypt came second, with 76 links each and a total link strength of 1759 and 1251, respectively. Pakistan had 75 links and a total link strength of 1247, the UAE had 68 links with a total link strength of 833, and Jordan had 66 links with a total link strength of 815. The United States and the United Kingdom had the most collaboration links (81 and 78, respectively), with a link strength of 1776 and 1361, respectively (Figure 4).

Figure 2. VOSviewer network of author coauthorship map representing 16 clusters of collaborations on COVID-19 research in the EMR. Included authors (N=719) were those with at least 5 publications, with up to 25 authors per publication, and who had been cited at least 5 times. EMR: Eastern Mediterranean Region; VOSviewer: Visualization of Similarities Viewer.

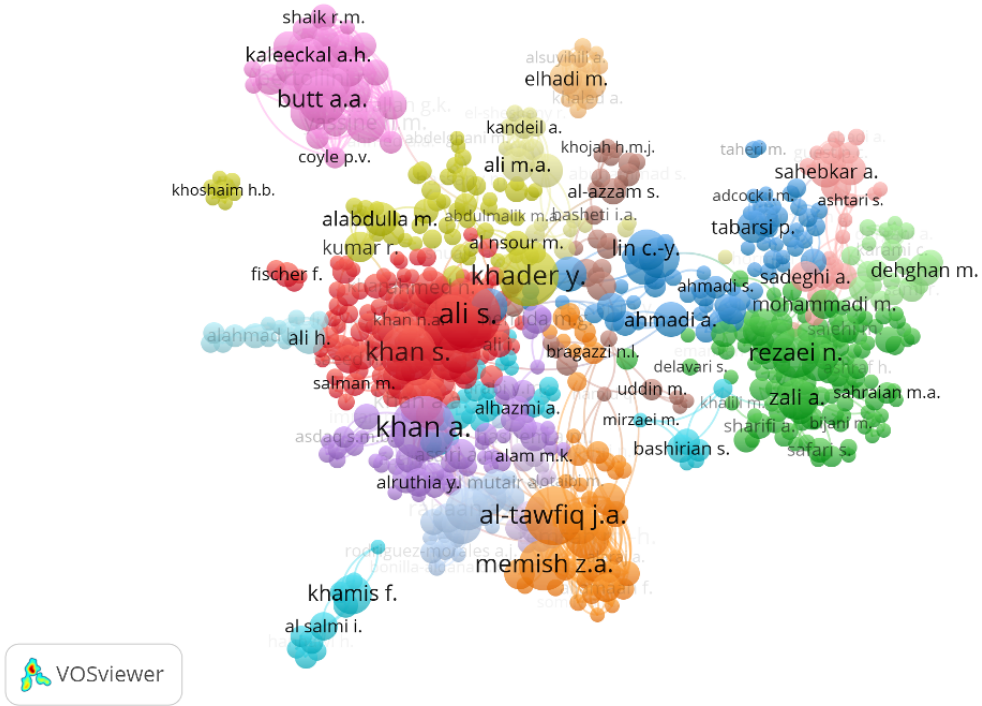


Figure 3. VOSviewer network of country coauthorship map weighed by the number of documents and representing 4 clusters of collaborations on COVID-19 research in the EMR. Included authors (N=82) were those with at least 5 publications, with up to 25 countries collaborating per publication. EMR: Eastern Mediterranean Region; VOSviewer: Visualization of Similarities Viewer.

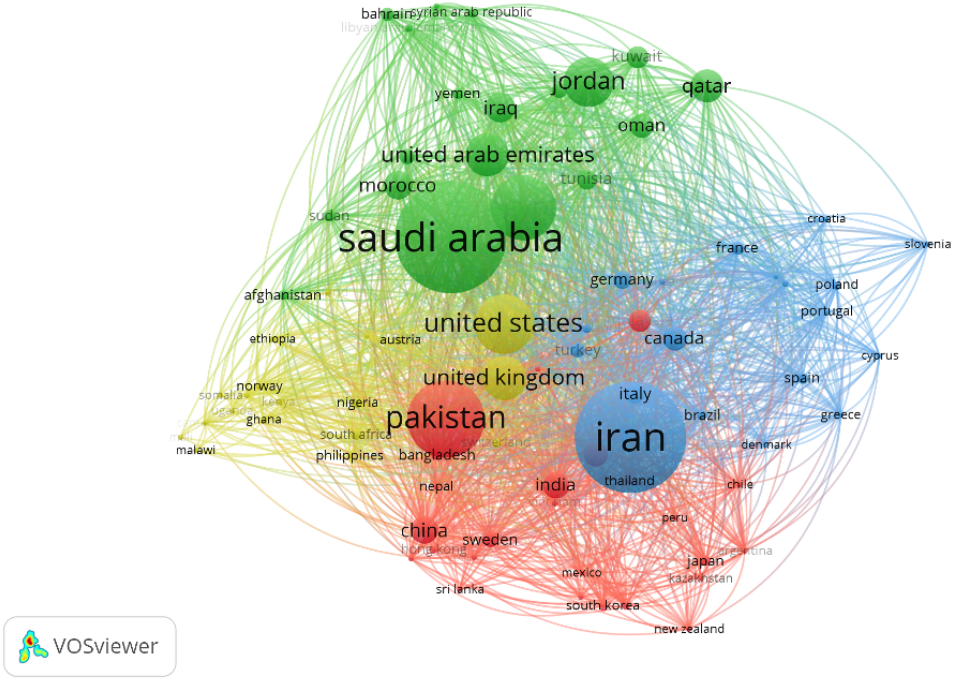
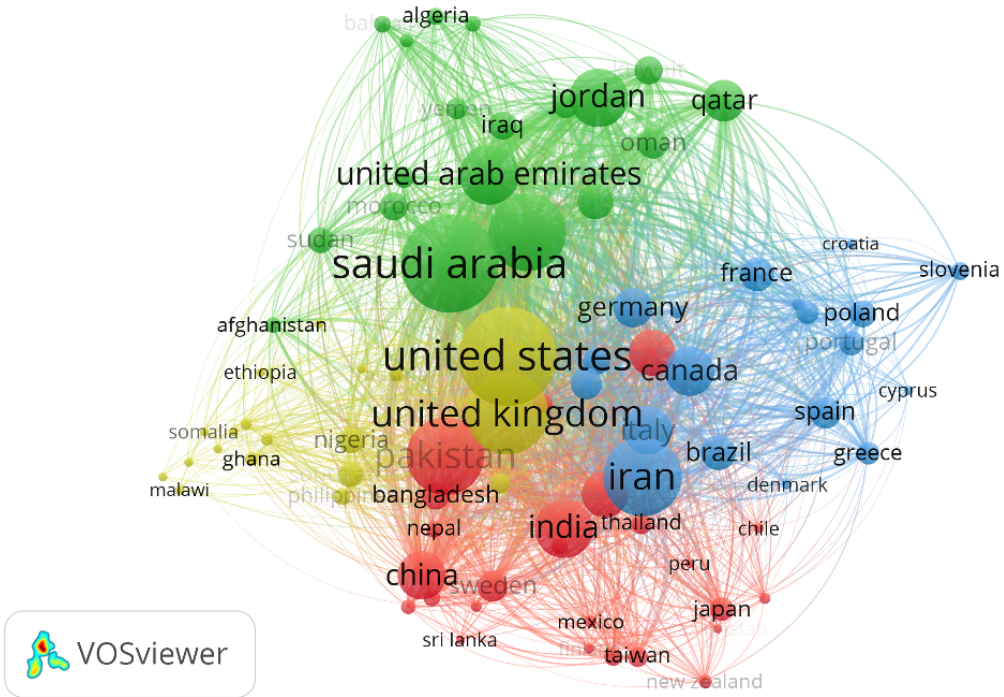


Figure 4. VOSviewer network of country coauthorship map, weighted by the total link strength, representing 4 clusters of collaborations on COVID-19 research in the EMR. Included countries (N=82) were those with at least 5 publications, with up to 25 countries collaborating per publication. EMR: Eastern Mediterranean Region; VOSviewer: Visualization of Similarities Viewer.



Co-occurrence

There were 290 high-frequency keywords, occurring ≥10 times, linked in 7 distinct clusters (Figure 5). The cluster containing the most connected keywords was related to epidemiology and mortality. The second cluster included anxiety and depression, which were the two most occurring keywords, occurring 260 and 198 times, respectively (Table 4). The most recent themes included vaccines, vaccination, machine learning, and online learning (Figure 6).

Figure 5. VOSviewer network of author keyword co-occurrence map weighted by occurrence, representing 7 clusters of keywords relating to COVID-19 research in the EMR. Included keywords (N=290) were those occurring at least 10 times. EMR: Eastern Mediterranean Region; VOSviewer: Visualization of Similarities Viewer.

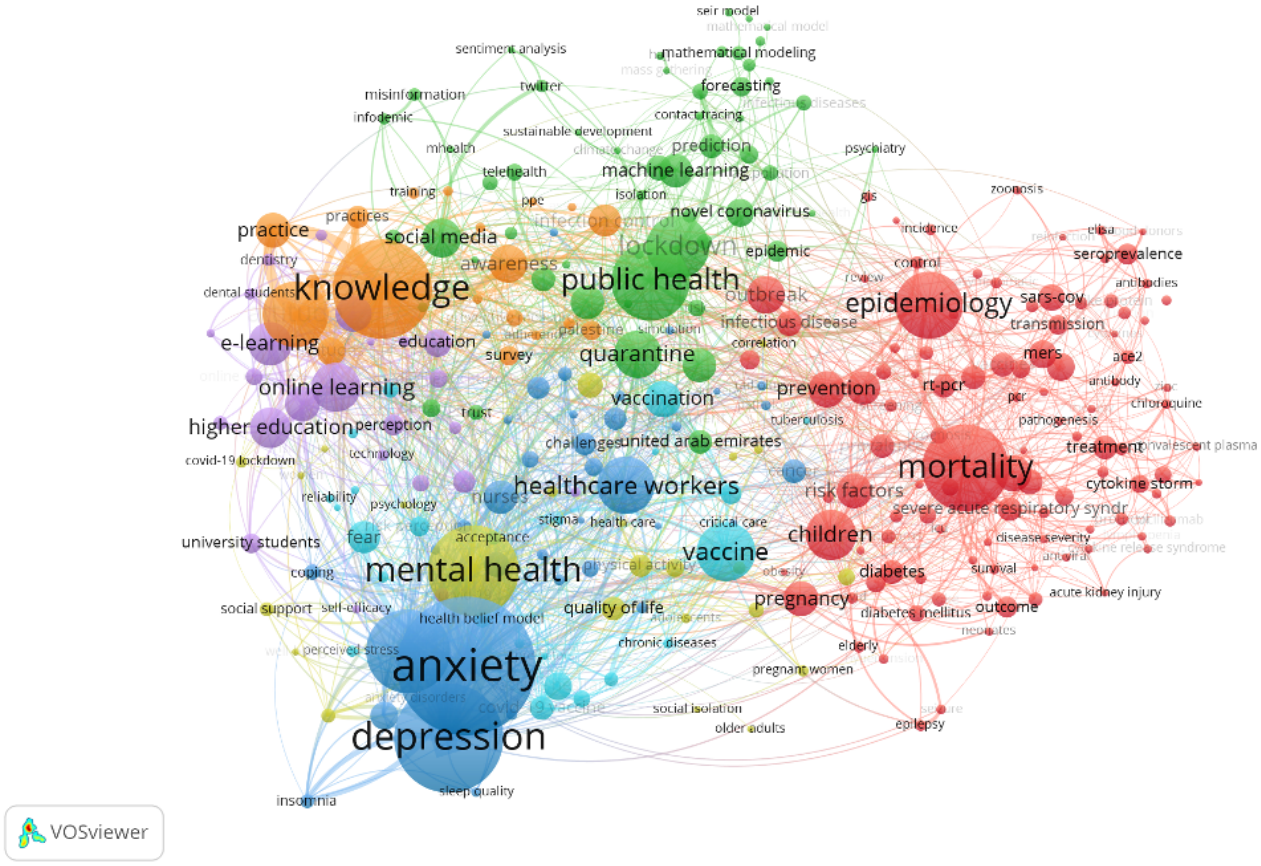
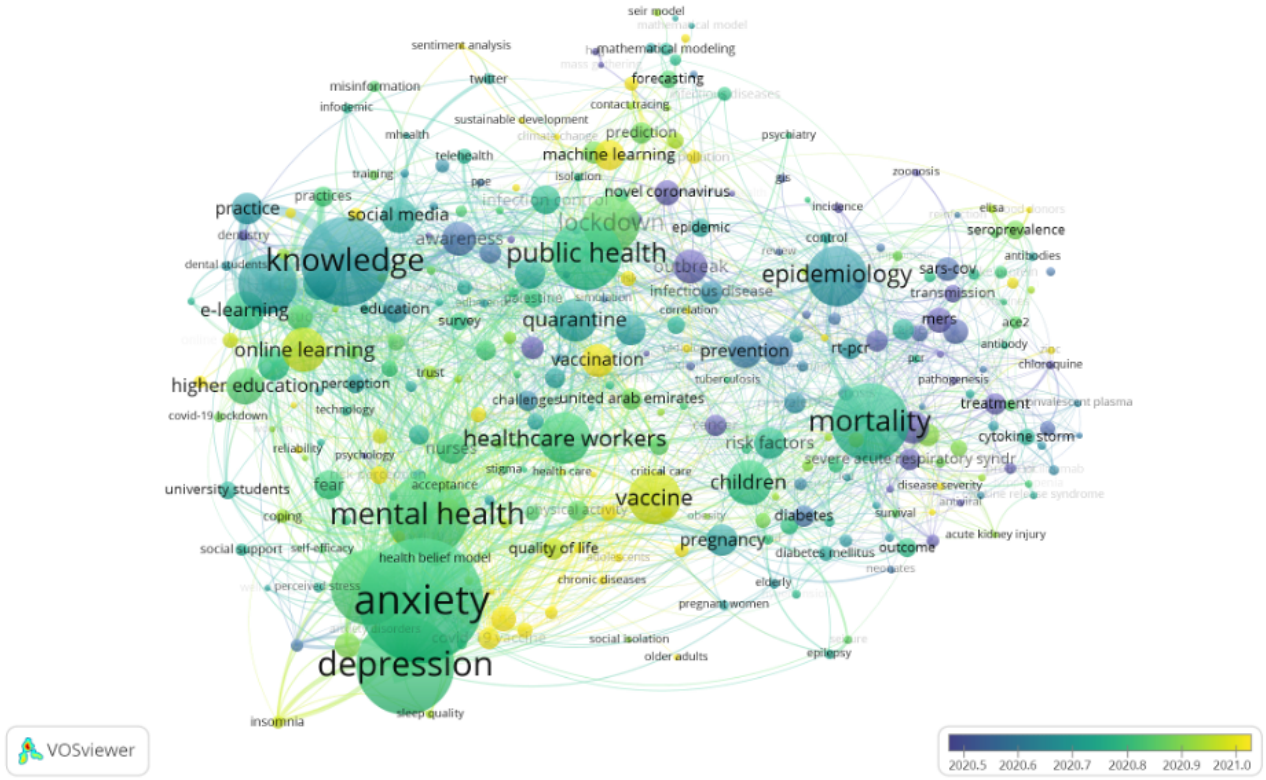


Table 4. The 15 most occurring author keywords, with their frequency of occurrence, total link strength, and cluster number to which they belong.

Author keyword	Frequency of occurrence	Total link strength	Cluster number
Anxiety	260	573	1
Depression	198	454	1
Knowledge	178	406	2
Mental health	160	288	5
Mortality	153	186	3
Stress	147	346	6
Public health	135	163	4
Epidemiology	115	140	3
Attitude	111	246	2
Lockdown	107	126	4
Vaccine	98	128	6
Health care workers	95	151	1
Children	84	76	3
Online learning	80	73	7
Quarantine	78	120	4

Figure 6. VOSviewer overlay visualization of author keyword relating to COVID-10 research in the EMR, weighted by occurrence and scored by the average publications per year. Included keywords (N=290) were those occurring at least 10 times. EMR: Eastern Mediterranean Region; VOSviewer: Visualization of Similarities Viewer.



Discussion

Principal Findings

The COVID-19 pandemic has led to unprecedented global research activity. To the best of our knowledge, our bibliometric analysis is the first to quantify the published literature on COVID-19 research that has been conducted by countries in the EMR up until early 2022. We provided a descriptive evidence-based analysis of the published research, identifying leading countries and organizational affiliations, with visualizations of collaborations and evolution of COVID-19 research output. Research on COVID-19 in the region has been led by authors and institutions from Iran and KSA. There were multiple regional collaborative efforts; however, international collaboration is limited. Output focuses on COVID-19 epidemiology, mortality, and anxiety and depression. Recently, interest has been shifting more toward topics related to vaccination, machine learning, and online learning.

Our results show that KSA and Iran are leading COVID-19 research in the EMR in terms of the number of publications. These results are not surprising, as KSA also leads the COVID-19 publications in the Arab world, with a 35.65% share of research production [33], and Iran has been the largest contributor to biomedical and health research in the EMR, with a 39% share during 2004-2013 [34].

The high number of COVID-19 research publications in both countries, especially by their leading universities (Tehran University of Medical Sciences in Iran and King Saud University in KSA), is due to many factors. First, both countries have relatively large populations, 35 million and 84 million in 2020, respectively [35], and both were among the countries most affected by the pandemic in the region, especially Iran [8]. Since the beginning of the pandemic and until April 1, 2022, more than 7 million confirmed COVID-19 cases were reported in Iran [8], which is the highest number in the region. The rapid spread of the disease in Iran in several waves was associated with many unique political, social, cultural, economic, and religious dimensions [36], providing a stimulating environment for research activities. For example, religious tourism in Qom, a pilgrimage site in Iran, which continued during the pandemic, was a major source of spread to other Iranian cities, Pakistan, and KSA in the early stages of the pandemic [37-39]. In KSA, mass gathering events, such as Umrah and Hajj, which were put on hold during the pandemic, may have also contributed to the high number of publications, not because of the high risk of transmission, but because of the successful measures that KSA took to prevent the progression of the COVID-19 pandemic locally and globally [39-41].

Second, both countries have invested extensively in the needed resources for medical and scientific research along the years. Iran has built a large human resource capacity with its unique Iranian Ministry of Health and Medical Education and its mandatory and credit-based continuing education programs for physicians for relicensing, along with the increasing number of Iranian journals indexed in international databases [42-44]. KSA has also rapidly become a major player in scientific research in the EMR, as research and development (R&D) is 1 of the main pillars of the Saudi Vision 2030, with the specific goal of having at least 5 Saudi universities among the top 200 in the world by

2030 [45,46]. These reasons may also explain why countries with fragile health systems, war torn, or with limited resources, such as Afghanistan, Djibouti, Somalia, Libya, and Syria, were less research-productive, although the number of cases in these countries may be higher than that officially reported and mandates further investigations.

Nevertheless, neither Iran nor KSA was reported to be at the top of the global COVID-19 literature in a recent global bibliometric analysis [47]. This adds to previous findings showing that the EMR share in global health research publications is low [34]. It is worth noting that Iran and KSA, like many other countries, faced various economic challenges during the pandemic that may have affected their research capacities. KSA was severely affected economically due to the radical decline in the global demand for oil, in parallel with the global economic recession, which was reflected in the sharp decline in oil prices during the first and second waves of the pandemic [48]. COVID-19 has also severely affected the Iranian economy, exacerbated by the concomitant international sanctions [49]. Generally, evidence shows that more support is needed for biomedical and health research in many of the EMR countries and institutions, especially those identified in our analysis as least productive.

International collaboration in COVID-19 research appears to be low in the EMR, as only 5.92% of the publications were associated with universities outside the EMR. The pandemic has shown that gaps in global cooperation, whether in research and information sharing, vaccine development and deployment, or travel policy, have affected the speed and equity of the global recovery [50]. In our study, the United States and the United Kingdom were at the center of collaboration and had the most extensive collaboration with EMR countries in COVID-19 research, similar to their role in COVID-19 research in the Arab world [33]. This could be due to the fact that both countries are among the top countries in scientific research [51] and specifically in global COVID-19 research [47]. The cross-border international flow of knowledge in the form cross-affiliation among researchers in the EMR with different international entities can be explained in several ways. First, the United States and the United Kingdom were by far the largest health donors to global health in 2019, with US $8.1 billion and US $2.9 billion, respectively [52], and when it comes to a donor-funded research project, most research funders require publication as a condition of a grant [53], triggering a cascade of cross-border research publications. Second, the United Kingdom and the United States have a network of research-intensive universities and scholarships, and both countries are hubs for international students, including those from the EMR, which could encourage cross-border collaboration. For example, the number of KSA students in the United Kingdom ranked eighth among international students from non–European Union countries, according to Higher Education Statistics Agency statistics for 2020/2021 [54]. In the United States, the number of KSA students ranked fourth among international students for the 2019-2020 academic year [55].

Most of the identified publications did not report a funding source, which could be due to limited funding opportunities or simply the likely dominance of cross-sectional studies and reviews, which are relatively less expensive, take less time to conduct, and require less infrastructure than, for example, clinical trials or prospective cohort studies [56]. The limited funding opportunities in the EMR may be related to the chronic underinvestment in research and development systems in the region, both financially and politically [57], exacerbated by the economic damage caused by the COVID-19 pandemic and the overreliance of some regional countries on external funding [58], although some major donors, such as the United Kingdom, have recently reduced their external funding [59]. Studies have also shown that research in the health care sector is not a top funding priority for governments, the private sector, or organizations in the EMR [57] and that R&D spending as a percentage of the gross domestic product (GDP) in the region is among the lowest in the world, despite significant differences in the GDP among member countries [58,60,61]. In EMR countries, R&D spending as a percentage of the GDP ranged from as low as 0.02% in Syria and Sudan in 2015 and 2019, respectively, to 1.3% in the UAE in 2018 compared to the global average of 2.27% in 2018 [58,61].

In our analysis of institutions funding COVID-19 research in the EMR, we found that 3 of the top 4 funders are from KSA, which is not surprising, given that KSA's spending on R&D as a percentage of the GDP was 0.82 in 2013 [61] and is likely to increase, given that KSA's GDP is still high [60], and the 2030 vision for R&D to increase universities' competitiveness and ranking will continue to create a more favorable environment for research [45].

Network analysis of coauthorship showed that the COVID-19 flow of information between EMR authors comes from a large and highly interconnected network with few isolated and small clusters. This indicates a high level of regional collaboration, either because of prepandemic collaboration and networking or because of governments and organizations' role in fostering collaboration since the onset of the pandemic. Regarding linkages, Iran had the most connections, consistent with another study showing that Iranian researchers have well-established international collaborations with leading countries in COVID-19 research [49].

Cultural differences could possibly have shaped COVID-19 research collaboration in EMR countries, which can be explained by Hofstede's theory of cultural dimensions [62]. A recent study analyzing research collaboration in the area of business and economics by 11 countries, including Iran from the EMR, before and after the onset of the pandemic, showed that Hofstede's uncertainty avoidance domain significantly influences the characteristics of research collaboration networks [63]. Uncertainty avoidance explains how cultures adjust to change and cope with uncertainty [62], and the pandemic has caused major changes and uncertainties at all levels of society worldwide [64]. However, using cross-national data from different EMR countries and interpreting them in the context of Hofstede's model of cultural dimensions will provide more accurate results and explore more details of the impact of culture on COVID-19 research collaboration in the EMR.

Evaluation of the co-occurrence network for keywords showed that the EMR COVID-19 research covers a wide range of

COVID-19–related areas. The most prevalent keywords were anxiety and depression, which may be related to the global increase in both conditions during the pandemic [65,66], especially in the EMR, given the limited mental health services and widespread stigma [67]. In addition, the EMR is fertile ground for high exposure to misleading and unknown information, which may exacerbate the status of mental disorders [68]. Recently developing topics in EMR COVID-19 research include vaccines, immunization, machine learning, and online learning. However, future research needs to address other underresearched topics, such as ethics, infodemiology, and the human-animal interface, in line with EMR-specific challenges and the recent recommendation of the WHO Research and Innovation Report for COVID-19 [69-71].

Limitations

Our study was limited by factors that are inherent to its bibliometric nature, including the lack of ability to assess the quality of published documents; the fact that the number of citations may be misleading; and authors, countries, or institutions publishing early in 2020 are more likely to be cited than authors, countries, or institutions publishing in 2022. Additionally, within the EMR, a number of documents are published in Arabic, or other local languages, and in local journals and thus might not be indexed by Scopus and so would have been missed by this analysis. As is the case with other bibliometric studies, the results are dependent on the indexing of the databases, and even though Scopus was used for this bibliometric study, it should not be considered a comprehensive source of all published literature.

Conclusion

The majority of available research on COVID-19 in the EMR is published by authors and institutions from Iran and KSA, with a paucity of publications from other EMR countries. Studies from these other countries are crucial to identify context-specific public health challenges and determine culturally and socially appropriate interventions and best buys. There were multiple regional collaborative efforts; however, international collaboration was limited, even though a pandemic is an opportune time for international communities to join forces. Recently, and in line with global interest, regional interest has been shifting more toward topics related to vaccination, machine learning, and online learning. This gradual shift to relatively new concepts can be considered a major step in the forward move of the state of knowledge of the EMR. Understanding the current state of research is instrumental to future research production, and our study will inform regional research initiatives on emerging concepts, as well as opportunities for collaboration and funding.

Conflicts of Interest

None declared.

Multimedia Appendix 1
Scopus search strategy.
[DOC File , 32 KB - ijmr_v11i2e38935_app1.doc]

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Abbreviations

CS: CiteScore
EMR: Eastern Mediterranean Region
GDP: gross domestic product
KSA: Kingdom of Saudi Arabia
R&D: research and development
SJR: SCImago Journal Rank
SNIP: Source-Normalized Impact per Paper
UAE: United Arab Emirates
VOSviewer: Visualization of Similarities Viewer
WHO: World Health Organization

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Review

Teledentistry Implementation During the COVID-19 Pandemic: Scoping Review

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Abstract

Background: COVID-19 spreads via aerosol droplets. The dental profession is at high risk of contracting the virus since their work includes treatment procedures that produce aerosols. Teledentistry offers an opportunity to mitigate the risk to dental personnel by allowing dentists to provide care without direct patient contact.

Objective: The purpose of this scoping review was to examine the implementation, challenges, strategies, and innovations related to teledentistry during the COVID-19 pandemic lockdown.

Methods: This scoping review evaluated teledentistry use during the pandemic by searching for articles in PubMed and Google Scholar using the search terms teledentistry, tele-dentistry, covid-19, coronavirus, telehealth, telemedicine, and dentistry. Inclusion criteria consisted of articles published in English from March 1, 2020, to April 1, 2022, that were relevant to dentistry and its specialties, and that included some discussion of teledentistry and COVID-19. Specifically, the review sought to explore teledentistry implementation, challenges, strategies to overcome challenges, and innovative ideas that emerged during the pandemic. It followed the 2020 Preferred Reporting Items for Systematic reviews and Meta-Analyses for Scoping Reviews (PRISMA-ScR). This approach is organized into 5 distinct steps: formulating a defined question, using the question to develop inclusion criteria to identify relevant studies, an approach to appraise the studies, summarizing the evidence using an explicit methodology, and interpreting the findings of the review.

Results: A total of 32 articles was included in this scoping review and summarized by article type, methodology and population, and key points about the aims; 9 articles were narrative review articles, 10 were opinion pieces, 4 were descriptive studies, 3 were surveys, 2 were integrative literature reviews, and there was 1 each of the following: observational study, systematic review, case report, and practice brief. Teledentistry was used both synchronously and asynchronously for virtual consultations, often employing commercial applications such as WhatsApp, Skype, and Zoom. Dental professionals most commonly used teledentistry for triage, to reduce in-person visits, and for scheduling and providing consultations remotely. Identified challenges included patient and

clinician acceptance of teledentistry, having adequate infrastructure, reimbursement, and security concerns. Strategies to address these concerns included clinician and patient training and utilizing Health Insurance Portability and Accountability Act-compliant applications. Benefits from teledentistry included providing care for patients during the pandemic and extending care to areas lacking access to dental care.

Conclusions: Pandemic lockdowns led to new teledentistry implementations, most commonly for triage but also for follow-up and nonprocedural care. Teledentistry reduced in-person visits and improved access to remote areas. Challenges such as technology infrastructure, provider skill level, billing issues, and privacy concerns remain.

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KEYWORDS

teledentistry; telehealth; COVID-19; pandemic; innovation; implementation; dental profession

Introduction

COVID-19 started in Wuhan, China in December 2019 and quickly spread worldwide [1]. Though genetically similar to SARS coronavirus 2, COVID-19 developed different characteristics, namely rapid upper respiratory tract replication and asymptomatic transmission [2]. Transmission occurs by droplets spread from infected individuals coughing and sneezing [3,4]. Individuals then contract the infection from droplet inhalation or by direct contact of the virus with mucous membranes (eg, oral cavity, nose, and eye) [1,3,4]. Many countries employed lockdowns to mitigate viral spread, including the United States in March 2020 [5].

Transmission through respiratory droplets is a concern for dental professionals and their staff since dental procedures can produce aerosols, which increase the risk of spreading COVID-19 [6]. During the pandemic lockdown, it was important for dental clinics to remain operational to meet community needs. Most dental clinics provided urgent care but deferred elective procedures to reduce disease spread. One option, teledentistry, or the provision of dental care through distance technology, became a significant tool for triaging patients and providing dental care in a safe environment [7].

Telemedicine is defined as the practice of using videoconferencing technologies to diagnose and provide advice about treatment over a distance [8]. In the late 1980s, teledentistry was first introduced as a subcategory of telemedicine [8]. Since its introduction, improved technology has made it possible for more dental patients to be managed without an in-person visit. Jampani et al [8] recognized teledentistry as a way to increase consultation capabilities through the sharing of photos, radiographs, and clinical information; improving communication between dental professionals; and extending care for patients living in rural areas where specialists may not be readily accessible. Prepandemic, teledentistry emerged as a method for triaging patients and providing long-distance care [7]. However, compared with other health care disciplines, dentistry has been slower to utilize telemedicine and adopt teledentistry as a mainstream tool [9].

The COVID-19 pandemic and lockdowns generated unparalleled economic and social disruption, creating an opportunity for expanding telemedicine [10]. In oral health, teledentistry became one strategy to mitigate the pandemic's impact by reducing face-to-face visits while supplementing patient care [11]. The wider use of teledentistry during the pandemic makes it important to understand issues related to its enhanced use.

The purpose of this scoping review was to evaluate teledentistry use during the pandemic. Specifically, the review sought to answer the following 4 questions:

1. How was teledentistry implemented during the COVID-19 pandemic?
2. What challenges occurred when implementing teledentistry during the COVID-19 pandemic?
3. What strategies were used to overcome these challenges?
4. Were there innovative ideas resulting from the implementation of teledentistry?

Methods

Scoping reviews map the available evidence of a content area. They are useful for identifying knowledge gaps, generating new research questions, guiding practice, and informing policy makers about an emerging area [12]. This scoping review explored the implementation and expansion of teledentistry during the COVID-19 pandemic.

The review followed the 2020 Preferred Reporting Items for Systematic reviews and Meta-Analyses for Scoping Review (PRISMA-ScR; Multimedia Appendix 1) [13]. This approach is organized into 5 distinct elements or steps: formulating a defined question, using the question to develop inclusion criteria to identify relevant studies, an approach to appraise the studies, summarizing the evidence using an explicit methodology, and interpreting the findings of the review.

To identify relevant articles, 2 authors (MN and TNP) systematically searched PubMed and Google Scholar to identify potentially relevant literature. Google Scholar was included since the growing literature supports the value of incorporating Google Scholar in relationship to other indexing databases such as PubMed [14,15]. For the initial step, we used the following article search terms: ((teledentistry) OR (tele-dentistry) OR (telehealth) OR (telemedicine)) AND ((covid-19[MeSH Terms]) OR (coronavirus)) AND (dentistry)) AND ((“2020/03/01”[Date - Publication]: “2022/04/01”[Date - Publication])). To broaden the search and capture other articles meeting the inclusion criteria, 2 authors (MN and TNP) reviewed the bibliographies of articles obtained from the initial search for additional papers that might be relevant to the review.

Inclusion criteria consisted of (1) articles published from March 2020 (the start of the pandemic lockdown in the United States) to April 2022 that evaluated the implementation or the discussion of teledentistry, (2) articles published in English, (3) articles relevant to dentistry or its specialties, (4) publications in a peer-reviewed journal, and (5) content related to the COVID-19 pandemic. Articles with little or no mention of teledentistry or articles that did not link to any of the research questions (ie, the implementation of teledentistry, challenges with implementation, strategies to address challenges, and innovative models of teledentistry) were excluded. Earlier teledentistry reviews noted a paucity of published research and that a substantial portion of publications was descriptive [9]. Therefore, to capture all the peer-reviewed teledentistry literature that addressed the study aims, this review included descriptive studies and review articles in addition to hypothesis-driven research. To explore the views of teledentistry thought leaders, the search also included opinion pieces such as essays, editorials, and letters to the editor.

After obtaining abstracts for the identified articles, 2 authors (MN and TNP) reviewed them for possible inclusion. Full-text articles of these abstracts were retrieved and reviewed by 2 authors (MN and TNP) to determine if an article met the inclusion criteria. If the authors MN and TNP differed about including an article, they discussed and resolved these differences. If authors encountered difficulties with classifying specific articles or research methodology, authors MH and MSL were consulted for guidance. After all the articles were identified, authors MN and TNP separately read each article to identify key points that addressed the study questions. After identifying key points, authors MN, TNP, and MSL reviewed the key points and resolved any differences. MH reviewed the final table for consistency and quality.

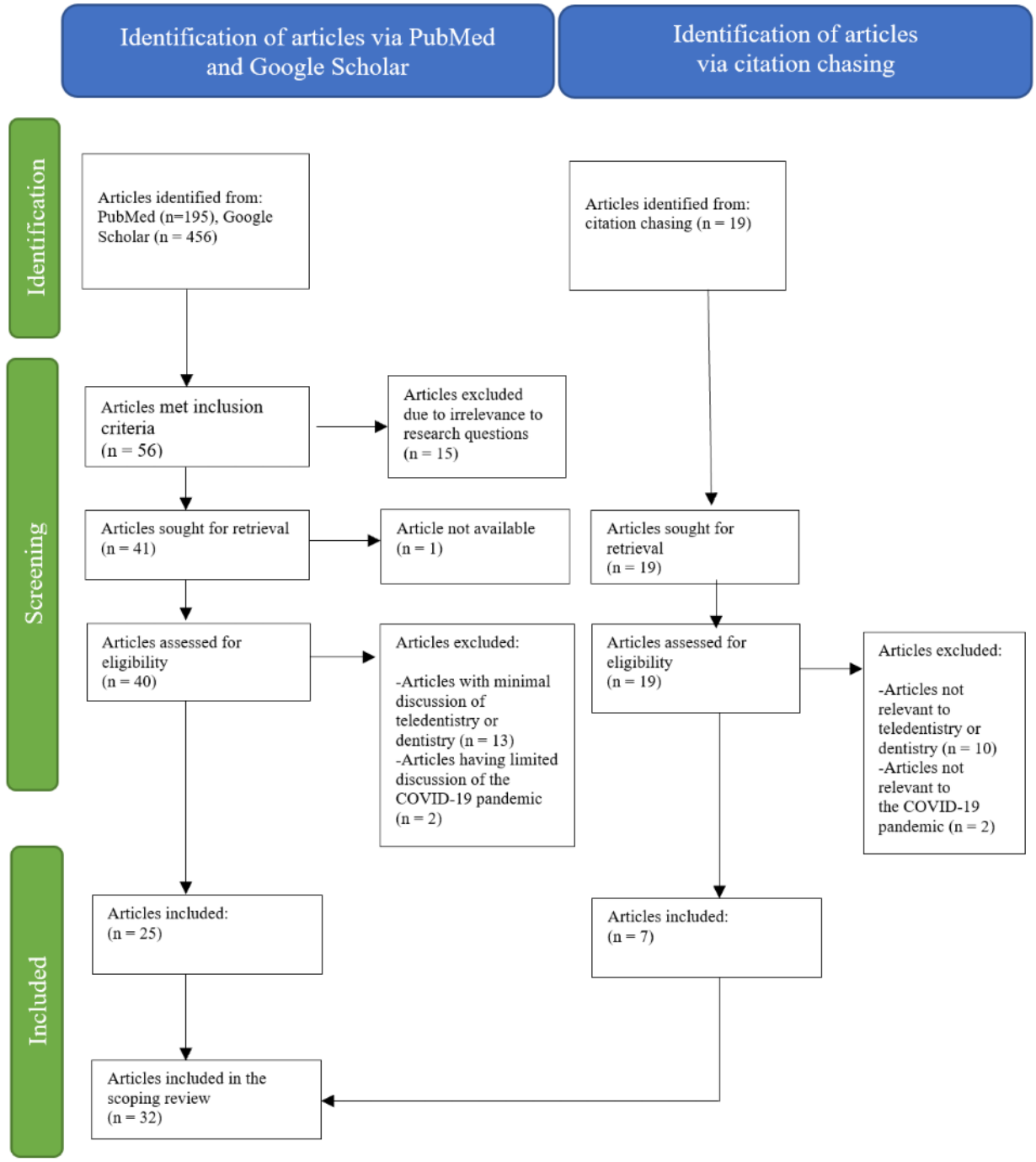
Results

Search Strategy

The flow chart in Figure 1 outlines the search strategy and reasons for excluding articles. Three reviewers (MN, TNP, and MSL) systematically appraised each article using a comprehensive form that included the full article citation, country, the type of article, a summary of key points, and, when applicable, the study population and research methodology. In addition, the authors used a checklist to ensure that each article contained key points related to one or more of the scoping review questions identified in the study aims. Following their independent review, the reviewers discussed any disagreements and achieved consensus. As part of this discussion, the authors noted that recurring key points emerged and noted the key points for each research question. For example, 3 recurring key points emerged for the question “How was teledentistry implemented during the COVID-19 pandemic?”: (1) modalities of teledentistry, (2) the applications and programs used to implement teledentistry, and (3) the reasons for using teledentistry. Articles addressing multiple study aims were reported for each aim they addressed.

Multimedia Appendix 2 details the 32 articles that met the selection criteria. Of the 32 articles, 10 were opinion pieces, 9 were narrative review articles, 4 were descriptive studies, 3 were surveys, 2 were integrative literature reviews, and there was 1 each of the following: observational study, systematic review, case report, and practice brief. The papers represented several countries including 8 from the United States, 5 from the United Kingdom, 4 from Italy and India, and 2 each from Brazil, the Kingdom of Saudi Arabia, and Canada. The remaining articles came from Pakistan, Iran, Hong Kong, Romania, and Malaysia.

Figure 1. PRISMA flowchart for article selection. PRISMA: Preferred Reporting Items for Systematic Reviews and Meta-Analyses.



How Was Teledentistry Implemented During the COVID-19 Pandemic?

Many dental offices and institutions temporarily halted elective treatment to reduce COVID-19 spread and to preserve the supply of personal protective equipment. From the review, 3 groups of recurring items for teledentistry implementation emerged: (1) modalities such as synchronous and asynchronous, (2) the applications and programs used to implement teledentistry, and (3) the reasons for using teledentistry.

Live consultations (synchronous) or store-and-forward (asynchronous) use were discussed by 15 articles. Live consultations provided patients with the opportunity to interact with clinicians in real time, while in the store-and-forward option, patients provided photos, videos, texts, or voice messages that allowed clinicians to evaluate a patient's concern at a convenient time and the ability to share images or radiographs with colleagues [5,16-25]. Radiographs used for teledentistry visits were prepandemic radiographs, and the inability to obtain new or additional images via virtual appointments was noted as a barrier to teledentistry [17,26]. If new or additional radiographs were required, patients scheduled an in-person visit for radiographic imaging [20,23].

The second recurrent item category was the type of applications and programs used to implement teledentistry. The most mentioned applications were WhatsApp, Skype, Zoom, and

Google-related services [16,17,19,24,26-35]. Less common were Mobile Mouth Screening Anywhere, a program specifically designed to detect oral cancer via photos uploaded by patients; a video platform called Video 4 Health used in conjunction with a teletrailer program, Telegram; Attend Anywhere; Facetime; and Health Insurance Portability and Accountability Act (HIPAA)–compliant programs such as Mailgate SC, Doxy.me, WebEx, Virtru, MD Office Mail, and LuxSci [5,27,36,37]. Teledentistry for orthodontics used programs that tracked the progress of orthodontic treatment. Dental Monitoring, which applies artificial intelligence to monitor patients' progress remotely, was used in Italy and the United States [22,29]. Other telecommunication platforms included GoToMeeting, BlueJeans, Microsoft Teams, and ReadyTalk [22]; Dentulu and Toothpick were used for scheduling orthodontic consultations [22]. Other applications mentioned included Smile Virtual, Review Tool, Smile Snap, and Rhinogram, all of which provide different features while allowing the clinicians to recruit patients asynchronously [22]. Teledentistry applications for patient management included TeleDent, Teledentix, and Carstack programs [22]. Features among these applications ranged from allowing clinicians to upload hygiene and health instructions, uploading documents for signatures, sending messages to patients, allowing patients to schedule appointments, and facilitating both synchronous and asynchronous consultations [22].

The third recurring item category was reasons for implementing teledentistry and included treatment, maintaining dental services, and triage. Two articles specifically focused on treating patients. In a pilot study based in Italy, Giudice et al [16] followed 2 groups of patients, one with urgent needs and a posttreatment group following a head and neck procedure, using teledentistry for initial consultations and WhatsApp to view pre- and postoperative radiographs and photographs. In Italy, Barca et al [31] used teledentistry for postoperative follow-up of precancerous lesions and for those with suspected oncological pathology or urgent head and neck concerns. These authors utilized WhatsApp or Telegram for text messaging and for transmitting images to assist in diagnosing, developing treatment plans, monitoring postoperative sites, and following suspicious lesions [31].

Other authors highlighted the integration of teledentistry into their existing systems to help maintain dental services during the COVID-19 pandemic. In the United Kingdom, Crawford and Taylor [5] described Attend Anywhere, a hospital-based teledentistry program, as a "virtual clinical system" supported by the National Health Service with YouTube tutorials to assist users. They provided video consultations for emergency clinics, new patient clinics, and multidisciplinary team clinics [5]. During a consultation, the dental professionals verified the patient's identity, took a history, and, when needed, asked patients to email pictures to a secure account [5]. The dental professionals either managed the patient virtually or triaged the patient for an in-person appointment with an appropriate provider [5]. Gleeson and Kalsi [37] discussed Attend Anywhere's ability to provide remote clinical consultation for patients with complex restorative needsf and patient satisfaction. In Brazil, physicians used telemedicine networks to provide coverage for all State municipalities. One network was Tele(oral)medicine [23], which had a goal of collecting data and communicating with dental professionals, who could make care recommendations and, for urgent issues, expedite referrals [23].

In India, the Armed Forces utilized teledentistry to triage patients [17], provide advice, and prescribe analgesics and antibiotics [17]. Patients contacted dental professionals using either the WhatsApp messenger application or email [17]. Dental professionals evaluated the patient's concern and triaged the patient into either "Emergency Dental Treatment," "Dependent Dental Centre," or "Advice & Self Help" [17]. For example, if a patient reported difficulty swallowing or uncontrolled bleeding, the patient was referred for "Emergency Dental Treatment" [17], while those with less severe pain or dental trauma could be referred to a "Dependent Dental Centre." Milder symptoms might be managed virtually through advice and self-help [17]. At the University of California San Francisco, a retrospective chart review found Tele(oral)medicine via Zoom helpful for pain management after an initial visit [26]. A United States study discussed integrating teledentistry into everyday private practice to mitigate pandemic-imposed restrictions using teledentistry both synchronously and asynchronously. The integration of teledentistry into the practice provided triage, some limited care, and hygiene assessments, as well as facilitating consultations with specialists [20]. Another pediatric and orthodontic practice separated dental professionals and staff members into 3 rotating teams [33] to answer calls and emails from patients. Patients could send photos and be followed up by phone, email, or video consultation using Zoom or FaceTime [33]. Researchers from Malaysia implemented Mobile Mouth Screening Anywhere, a web-based application that helps assess oral lesions. The app allows patients to upload photos of oral lesions and ask clinical questions; dental professionals review the data and provide recommendations [36].

Pediatric teledentistry applications and implementation were discussed by 3 articles [19,21,38]. Nuvvula and Mallineni [19] proposed using applications such as Facebook Messenger, Instagram, Skype, and WhatsApp to assess urgency and the appropriate response. One author in the United Kingdom used teledentistry to determine whether a patient required urgent or routine in-person care and if the case merited referral to other departments [21]. Parents could schedule appointments for their children, provide information regarding the child (pre- and postappointment), send images to a designated email address, and, if necessary, access BigWorld for interpretive services [21]. Kumar Mallineni et al [38] coined the term "telepediatric dentistry" for preventive services that gave parents advice and oral hygiene instructions to help maintain a child's oral health.

Academic institutions, such as Oregon Health and Science University (OHSU), University of Washington (UW), and New York University (NYU) implemented teledentistry systems during the COVID-19 pandemic. OHSU and UW used HIPAA-compliant messaging and virtual consultation platforms and noted the importance of having appropriate audiovisual technology [35]. Staff members first triaged teledental patients, including COVID-19 screening for current symptoms, travel history, and recent exposures to those who tested positive [35].

Staff members followed an onboarding protocol using a HIPAA-compliant temporary account [35] and scheduled appointments during which patients logged in and received a teledental examination [35]. Dental professionals used a decision tree to guide next steps and follow-ups [35]. At NYU, patients could make an appointment for either a telephone or video consultation [39]. Teledentistry service agents triaged calls to the appropriate dental professionals or other specialist [39] who contacted patients either by phone or video call to discuss their concerns [39]. After hours or during weekends, patients left voicemails, and clinic personnel returned calls on the following day [39]. Findings for implementing teledentistry are summarized in Table 1.

Table 1. Article summary for scoping review research question 1 (implementation).

Key points	Article sources
Synchronous and asynchronous teledentistry implementation	1. Alsafwani et al (2022) [26] 2. Chopra and Sahoo (2020) [17] 3. Crawford and Taylor (2020) [5] 4. Deshpande et al (2021) [18] 5. Giudice et al (2020) [16] 6. Meurer et al (2022) [23] 7. Nuvvula and Mallineni (2021) [19] 8. Park et al (2021) [22] 9. Patel and Wong (2020) [24] 10. Suter (2020) [20] 11. Tonkaboni et al (2021) [25] 12. Wallace et al (2021) [21]
Applications and programs used to implement teledentistry	1. Abbas et al (2020) [28] 2. Alsafwani et al (2022) [26] 3. Barca et al (2020) [31] 4. Brecher et al (2021) [33] 5. Caprioglio et al (2020) [32] 6. Chopra and Sahoo (2020) [17] 7. Chung et el (2022) [35] 8. Crawford and Taylor (2020) [5] 9. da Silva et al (2021) [30] 10. Ghai (2020) [27] 11. Giudice et al (2020) [16] 12. Gleeson and Kalsi (2022) [37] 13. Goriuc et al (2022) [34] 14. Kumar Mallineni et al (2021) [38] 15. Maspero et al (2020) [29] 16. Nuvvula and Mallineni (2021) [19] 17. Park et al (2021) [22] 18. Patel and Wong (2020) [24] 19. Rajendran et al (2022) [36] 20. Torosyan et al (2021) [39] 21. Wallace et al (2021) [21]
Reasons for implementing teledentistry	1. Alsafwani et al (2022) [26] 2. Barca et al (2020) [31] 3. Brecher et al (2021) [33] 4. Chopra and Sahoo (2020) [17] 5. Crawford and Taylor (2020) [5] 6. Giudice et al (2020) [16] 7. Gleeson and Kalsi (2022) [37] 8. Meurer et al (2022) [23] 9. Rajendran et al (2022) [36] 10. Suter (2020) [20]

What Challenges Occurred When Implementing Teledentistry During the COVID-19 Pandemic?

There were 4 major types of challenges: acceptance by dental professionals or staff, acceptance by patients, confidentiality, and reimbursement. The lack of acceptance of teledentistry by dental professionals or staff members was addressed by 8 articles. A common reason for not embracing teledentistry was a perceived difficulty in providing an accurate diagnosis based on videos or static images without being able to perform important diagnostic maneuvers such as percussion and palpation [18,19,24,27,30,31,40,41]. Additionally, images or videos may fail to fully visualize lesions and lesion borders or fail to capture 3-dimensionality and other pertinent information that might limit dental professionals' ability to establish the correct diagnosis [16,18,24,30,34,36,41]. As a result, dental professionals were apprehensive about the potential for

misdiagnosis, mismanagement, and litigation due to unfavorable treatment outcomes [21,24,29].

Other challenges included a lack of patient acceptance of teledentistry. Some patients may be unreceptive to video consultations due to an unfamiliarity with devices, and those with difficulty communicating, either because of language barriers or disabilities, may find it challenging to adapt to teledentistry [17,21,25,27,30,42,43]. Parents may be hesitant to use online consultations for their children because of unfamiliarity with teledentistry [19]. Teledentistry may also trigger anxiety and apprehension for proposed treatments and erode prepandemic patient-clinician relationships [19,21,24,30].

Protecting patient information such as photos, videos, or an electronic health history, was a common concern [5,6,18,24,25,29,30,42]. Many dental professionals utilized WhatsApp because of its end-to-end encryption. Park et al [22] noted WhatsApp, Apple FaceTime, and Facebook Messenger video chat are not HIPAA-compliant and may compromise patient information, while Zoom, Skype, and Google Meet offer HIPAA-compliant versions for dental professionals [22]. Moreover, for utilization of software that stores patient information, there should be a Business Associate Agreement (BAA) between the company providing the service and the dental professionals [22].

Several studies mentioned payment concerns and the need to discuss with insurance companies how to properly code virtual visits to ensure payment [5,18,27,41,42,44]. Most articles did not address how payment was made (whether it was by the patient or insurance companies) or how much the payment was but instead focused on the challenge of properly coding and billing for virtual visits. One article noted that teledentistry was often billed by using the code for the service provided such as D0140 (limited exam code) [7] and not teledentistry. However, this varied among different insurance carriers or states, and the authors advocated for more clarity regarding teledental visit reimbursement [7]. Additionally, many noted the cost of investing in the necessary technology infrastructure and the importance of having sufficient internet bandwidth to accommodate teledentistry transmission [5,6,17,19,21,24,27,30,34,35,41] since an inadequate internet connection may result in dropped service and a break in continuous treatment [5,6,17,28,30,31,34,41,44]. Lapses with the Attend Anywhere, which occurred during times of peak internet demand, was an example of dropped service [5]. Few guidelines for dispensing medications [17], a lack of appropriate scheduling software, and an insufficient number of trained staff were also identified as challenges [20,22]. Table 2 summarizes the challenges encountered in teledentistry.

Table 2. Article summary for scoping review research question 2 (challenges).

Key points	Article sources
Difficulties with acceptance by dental professional or staff	1. Barca et al (2020) [31] 2. da Silva et al (2021) [30] 3. Deshpande et al (2021) [18] 4. Ghai (2020) [27] 5. Giudice et al (2020) [16] 6. Goriuc et al (2022) [34] 7. Jajeh et al (2022) [40] 8. Kumar et al (2022) [41] 9. Maspero et al (2020) [29] 10. Nuvvula and Mallineni (2021) [19] 11. Patel and Wong (2020) [24] 12. Rajendran et al (2022) [36] 13. Wallace et al (2021) [21]
Difficulties with acceptance by patients	1. Chopra and Sahoo (2020) [17] 2. da Silva et al (2021) [30] 3. Ghai (2020) [27] 4. Nuvvula and Mallineni (2021) [19] 5. Patel and Wong (2020) [24] 6. Samaranayake and Fakhruddin (2021) [43] 7. Talla et al (2020) [42] 8. Tonkaboni et al (2021) [25] 9. Wallace et al (2021) [21]
Confidentiality	1. Crawford and Taylor (2020) [5] 2. da Silva et al (2021) [30] 3. Deshpande et al (2021) [18] 4. Farooq et al (2020) [6] 5. Maspero et al (2020) [29] 6. Park et al (2021) [22] 7. Patel and Wong (2020) [24] 8. Talla et al (2020) [42] 9. Tonkaboni et al (2021) [25]
Reimbursement	1. Abbas et al (2020) [28] 2. Barca et al (2020) [31] 3. Chopra and Sahoo (2020) [17] 4. Chung et al (2022) [35] 5. Crawford and Taylor (2020) [5] 6. da Silva et al (2021) [30] 7. Deshpande et al (2021) [18] 8. Farooq et al (2020) [6] 9. Ghai (2020) [27] 10. Goriuc et al (2022) [34] 11. Kumar et al (2022) [41] 12. Nuvvula and Mallineni (2021) [19] 13. Park et al (2021) [22] 14. Patel and Wong (2020) [24] 15. Singhal et al (2021) [44] 16. Suter (2020) [20] 17. Talla et al (2020) [42] 18. Wallace et al (2021) [21] 19. Wu et al (2020) [7]

What Strategies Were Used to Overcome These Challenges?

Table 3 summarizes the 20 articles that discussed strategies to address challenges. These strategies included educating dental professionals, orienting patients, providing proper compensation, and updating technologies. To improve teledentistry acceptance, researchers suggested more education and dental professional training about teledentistry [27,36,42]. Kumar et al [41] proposed webinars and continuing education provided by the American Dental Association to improve dental professionals' comfort with using newer technologies. Rajendran et al [36] required that dental professionals using Mobile Mouth Screening Anywhere review a refresher video about teleconsultation etiquette and regulatory requirements. Equally important may be training and education for patients and parents about how to transmit useful images and participate in video consultations [19]. To promote teledentistry, dental professionals and other

specialists can spread awareness among patients about this option [36]. To alleviate apprehension, some suggested an introductory call or video tour to introduce the patient to the dental professionals and the environment or to allow patients more time to prepare for a consultation or a procedure [21,24,42]. For patients who speak a foreign language, translation services can create a more welcoming environment for patients [21,42]. To ensure dental professionals are properly compensated, authors from the United States and Canada shared specific codes that successfully resulted in compensation [33,41,44]. To prevent litigation, several authors emphasized the need to obtain informed consent that details the potential risks associated with online consultations [18,29,31,42]. Articles from the United States and Canada highlighted the importance of having a system in place to verify patient identity at the time of service to prevent disclosing sensitive information to someone other than the patient [35,41,42]. In a literature review, da Silva et al [30] recommended using Zoom accounts that require passwords to enter meetings and the ability to lock meetings once all parties are present. Several authors suggested using end-to-end encryption applications or devices, confirming that an application is HIPAA-compliant, and executing a BAA to maintain proper use of patient health information [16,22,29-31]. To improve diagnostic abilities, one author recommended that an iPhone 4S or later model is needed to make an adequate assessment [5]. However, dental professionals should be mindful that up-to-date technology incurs a financial burden on patients who may already be financially challenged by the pandemic [5]. Lapses in connection can occur, and a UK-based study found that they needed a more advanced server to manage virtual dental visits [5]. To address the lack of scheduling software, Suter et al [20] turned to project management software outside of dentistry. Strategies used to overcome challenges are summarized in Table 3.

Table 3. Article summary for scoping review research question 3 (strategies to overcome challenges).

Key points	Article sources
Educating dental professionals	1. Barca et al (2020) [31] 2. Chung et al (2022) [35] 3. Deshpande et al (2021) [18] 4. Ghai (2020) [27] 5. Kumar et al (2022) [41] 6. Maspero et al (2020) [29] 7. Rajendran et al (2022) [36] 8. Talla et al (2020) [42]
Orienting patients	1. Nuvvula and Mallineni (2021) [19] 2. Patel and Wong (2020) [24] 3. Rajendran et al (2022) [36] 4. Talla et al (2020) [42] 5. Wallace et al (2021) [21]
Providing proper compensation	1. Brecher et al (2021) [33] 2. Kumar et al (2022) [41] 3. Singhal et al (2021) [44]
Updating technologies	1. Barca et al (2020) [31] 2. Crawford and Taylor (2020) [5] 3. da Silva et al (2021) [30] 4. Giudice et al (2020) [16] 5. Maspero et al (2020) [29] 6. Park et al (2021) [22] 7. Suter (2020) [20]

Were There Innovative Ideas That Resulted From the Implementation of Teledentistry?

A major innovation was adapting commonly available programs and applications to teledentistry services. Applications such as WhatsApp or communication services such as Zoom were mentioned in several articles [16,17,19,24,27-32,35]. Other platforms mentioned included Telegram, Microsoft Network, Skype, and FaceTime [24,29,31,33]. These applications helped establish communication and played a role in reducing travel, especially in regions with travel restrictions or those that were difficult to access. With certain orthodontic emergencies, teledentistry provided a platform to advise patients about home remedies such as using a pencil eraser to push on metal ligatures causing soft tissue trauma or using sterilized nail clippers to remove protruding archwire [32]. As an ancillary benefit, telemedicine led to shorter wait times for pre- and postoperative evaluations and specialty consultations [16,18,19,28,29,31,33,37] and mitigated COVID-19 spread by reducing clinic overcrowding [17]. A Saudi Arabian clinic successfully used a questionnaire to triage patients and determine whether a pediatric patient needed in-person treatment [38]. They also provided previsit videos about COVID-19 protocols to protect all parties present in the dental office [38]. The implementation of virtual waiting areas was another teledentistry innovation [35,37,38]. For patients with concerns about oral pathology and who are uncomfortable with

teledentistry, Goriuc et al [34] suggested home saliva testing to assess oncologic pathology.

Education is an important tool for maintaining oral health, and several authors suggested that teledentistry offers opportunities for education and community outreach to schools, nursing homes, rural residents, and those who are housebound as a result of age-related frailty or physical or mental disabilities [20,21,24]. Using teledentistry before a domiciliary visit can determine what materials dental professionals may need before making the visit [24]. Additionally, the synchronous and asynchronous capabilities of teledentistry helped dental institutions minimize pandemic-related lapses in dental education [6] and use virtual patients for dental students' education [6]. Project management software outside the field of dentistry represented a possible solution to fill the gap in dental scheduling software [20]. The same article described virtual operatories and hybrid clinics that integrate in-person, synchronous, and asynchronous patient visits [20]. Teleorthodontic innovations included programs such as Dental Monitoring to scan a patient's oral cavity and artificial intelligence to monitor treatment [22,29]. Others created their own programs. For example, Fazio et al [45] developed LinguAPP, which incorporated a patient questionnaire and the ability to upload photos to determine appropriate treatment.

Teledentistry was divided into subcategories such as teleconsultation, telediagnosis, teletriage, and telemonitoring services by 8 articles [17,19,21,22,27,28,30,43,44]. Through teleconsultation, dental professionals can address nonurgent concerns and use teletriage to prioritize patients needing urgent or emergency care so that they can be seen promptly [19,27,28,30,36]. Telediagnosis uses specific applications, such as Mobile Mouth Screening Anywhere, to help diagnose and share patient information, photos, videos, or radiographs with colleagues [19,27-29]. Telemonitoring can be utilized to follow patients who received advice or for follow-up of treatment [5,19,27,28,31]. However, the main role of teledentistry during the COVID-19 pandemic was to help bridge gaps in care, assure essential care for both new and existing patients, and broaden its scope to include dental specialties [17-20,28,30]. Teledentistry also expanded its use to include prescribing medications, such as antibiotics, pain medications, high-strength fluoride, and anti-inflammatory mouth rinses, which could temporarily address conditions such as swelling and pain until further treatment could be arranged [16-18,21]. Innovations are summarized in Table 4.

Table 4. Article summary for scoping review research question 4 (innovation).

Key points	Article sources
Adapting commonly available programs and applications to teledentistry	1. Abbas et al (2020) [28] 2. Barca et al (2020) [31] 3. Brecher et al (2021) [33] 4. Caprioglio et al (2020) [32] 5. Chopra and Sahoo (2020) [17] 6. Chung et al (2022) [35] 7. da Silva et al (2021) [30] 8. Deshpande et al (2021) [18] 9. Farooq et al (2020) [6] 10. Ghai (2020) [27] 11. Giudice et al (2020) [16] 12. Gleeson and Kalsi (2022) [37] 13. Goriuc et al (2022) [34] 14. Kumar Mallineni et al (2021) [38] 15. Maspero et al (2020) [29] 16. Nuvvula and Mallineni (2021) [19] 17. Patel and Wong (2020) [24] 18. Suter (2020) [20]
Education and community outreach	1. Suter (2020) [20] 2. Wallace et al (2021) [21] 3. Patel and Wong (2020) [24]
Developing new teledentistry programs and applications	1. Park et al (2021) [22] 2. Maspero et al (2020) [29] 3. Fazio et al (2022) [45]
Separating teledentistry into subcategories of services (teleconsultation, telediagnosis, teletriage, and telemonitoring)	1. Crawford and Taylor (2020) [5] 2. Chopra and Sahoo (2020) [17] 3. Nuvvula and Mallineni (2021) [19] 4. Suter (2020) [20] 5. Wallace et al (2021) [21] 6. Ghai (2020) [27] 7. Abbas et al (2020) [28] 8. Maspero et al (2020) [29] 9. da Silva et al (2021) [30] 10. Barca et al (2020) [31] 11. Rajendran et al (2022) [36] 12. Samaranayake and Fakhruddin (2021) [43] 13. Singhal et al (2021) [44]
Expanding teledentistry to include prescribing medications	1. Giudice et al (2020) [16] 2. Chopra and Sahoo (2020) [17] 3. Deshpande et al (2021) [18] 4. Wallace et al (2021) [21]

Discussion

The purpose of this scoping review was to enhance the understanding of teledentistry use during the COVID-19 pandemic and examine challenges associated with expanded services and strategies to address these challenges. The COVID-19 pandemic also presented opportunities to enhance teledentistry's scope, and this review explored innovative ideas that emerged from the expansion of teledentistry.

Principal Findings

The results indicate that teledentistry offered important services to help maintain the continuity of dental care during the pandemic. Through the utilization of different applications, patients were able to communicate their concerns to dental professionals who could analyze photos, videos, and radiographs to triage those patients needing urgent or emergent care for an in-person visit. Several programs noted that teledentistry worked well for follow-up visits and, by reducing face-to-face visits, lowered the risk of viral transmission for patients, dentists, and office staff [5,16-25].

One unexpected benefit was improved access to specialists through teledentistry triage, enhanced communication, and the use of asynchronous data transmission. In addition to mitigating the pandemic's impact on staff exposure and reducing in-person visits, teledentistry decongested clinics, which may be useful for improving patient flow postpandemic. Another benefit of teledentistry was its ability to reduce travel and the financial burdens associated with travel and improve access for patients with disabilities or other barriers to in-person visits [16,18,19,29]. Teledentistry was identified as effectively

addressing concerns such as identifying clearly benign growths and providing reassurance, removing the need for an in-person visit. Although articles on teledentistry implementation reported favorably on its role in bridging gaps in care caused by the pandemic, its implementation elicited several concerns. Acceptance by both dental professionals and patients may prove to be an obstacle that hinders future expansion, and security concerns about patient health information may also impede the acceptance of teledentistry [16,18,19,24,27,30,31].

A consistent and clear barrier to teledentistry implementation was the inability to perform diagnostic tests such as percussion, palpation, and thermal testing. The variation in image and video quality and the potential for misdiagnosis, mismanagement, and litigation were also identified as issues that may jeopardize widespread acceptance [21,24,29]. These results highlight the need for guidelines and an accepted scope of services that make teledentistry a safe and reliable platform for both dental professionals and patients. Although this review identified roles for triage, diagnosis, monitoring, and prevention, examples of conditions that might be included in a defined scope of teledentistry services include temporomandibular joints, pain management, and prescribing antibiotics. The need for advocacy with governing dental regulatory bodies is important to support and endorse protocols for teledentistry, including guidelines for dispensing medications and treatment [17,42]. Clear guidelines and protocols recommended by governing dental bodies for treatment, prescriptions, and dental codes can facilitate the process for those interested in implementing teledentistry and continuing programs beyond the pandemic. Having dental regulatory agencies certify applications and platforms for dental services as HIPAA-compliant may accelerate teledentistry acceptance by dental professionals [5]. Despite the recent adoption of dental procedure codes for teledentistry for both synchronous and asynchronous delivery of dental services, reimbursement remained a commonly mentioned concern. Codes alone may not be sufficient, since Singhal et al [44] mentioned reimbursement as an issue in Canada even though the Canadian Dental Association published insurance codes for teledentistry. In the United States, some states including California endorsed Medicaid reimbursement for teledentistry services, and although this likely helped reimbursement, no paper evaluated the impact of these legislative acts during the study period.

One outcome from the enhanced use of teledentistry during the pandemic is that it will likely contribute to an enduring and broader role in the future. In 2020, about one-third of United States adults used teledentistry, and over 80% of patients reported being satisfied with their teledental visit and indicated a willingness to use the modality again [46]. Almost three-quarters of dentists who used teledentistry anticipated maintaining or even increasing their virtual visits [47]. However, many emergency regulations, such as relaxing licensing requirements and HIPAA compliance, will be expiring, and there is debate on how to proceed moving forward. This review supports the value of teledentistry and suggests that further development of this modality can contribute to improved oral health postpandemic.

Limitations

A limitation of this scoping review was the exclusion of articles outside of PubMed and Google Scholar. Though the review included opinions and letters to the editor, it excluded government reports, conference proceedings, and policy statements. However, “grey” literature does not undergo the same rigorous peer review as more traditional academic literature. Selection bias of articles on oral surgery may also be present since several retrieved articles were identified by the search term of telemedicine. These articles met the inclusion criteria because they incorporated the oral maxillofacial surgery specialty but no other dental specialties. Finally, this review focused on teledentistry and its implementation and uses during the lockdown period. By excluding articles that did not incorporate teledentistry and its connection to COVID-19, extrapolating the results beyond the pandemic or applying the finding to future pandemics is speculative.

Conclusions

The COVID-19 pandemic lockdowns led to new teledentistry implementations, most commonly for triage but also for follow-up and nonprocedural care. Teledentistry improved access to dental services and reduced in-person visits. However, significant challenges remain. These challenges include insufficient technology infrastructure, inadequate provider skill, and a lack of established protocols to manage billing issues and privacy concerns. As pandemic restrictions ease, these barriers will need to be addressed to sustain and expand teledentistry.

Acknowledgments

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Conflicts of Interest

None declared.

Multimedia Appendix 1
PRISMA checklist for scoping review. PRISMA: Preferred Reporting Items for Systematic Reviews and Meta-Analyses.
[DOCX File , 23 KB - ijmr_v11i2e39955_app1.docx]

Multimedia Appendix 2

Article summaries.
[DOCX File , 24 KB - ijmr_v11i2e39955_app2.docx]

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Abbreviations

BAA: Business Associate Agreement
HIPAA: Health Insurance Portability and Accountability Act
NYU: New York University
OHSU: Oregon Health and Science University
PRISMA-ScR: Preferred Reporting Items for Systematic reviews and Meta-Analyses for Scoping Reviews
UW: University of Washington

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Short Paper

Knowledge Translation and Implementation Planning to Promote Research Governance in Nongovernment Organizations in the Torres Strait: Descriptive Study

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Abstract

Background: Aboriginal and Torres Strait Islander people in Australia have participated in Western research for decades. When done well, research has resulted in significant benefits and positive impacts on society. However, the primary benefactor of this research has and continues to be researchers, with limited or no research knowledge mobilized for uptake and beneficial use by end users, such as individuals and communities. In 2021, the Torres Strait Islanders Research to Policy and Practice Hub (the Hub) at James Cook University designed and implemented several strategies, including a games-based interactive workshop with representatives from nongovernment organizations (NGOs). Feedback suggests the workshop and associated activities were a success.

Objective: We describe knowledge translation (KT) and implementation planning to design and implement strategies to increase awareness and understanding of NGOs in research governance.

Methods: This descriptive study involved representatives from NGOs on Thursday Island in the Torres Strait. We collected data from a literature review and informal discussions. We used several models and frameworks to guide our approach and underpin data collection and analysis.

Results: Designing and implementing strategies to increase awareness and understanding of NGOs in the Torres Strait to govern research involved several key steps: (1) identifying and defining what needed to change and who needed to change, (2) identifying and mapping barriers and facilitators, (3) selecting the most appropriate strategies to support change, (4) implementing activities, and (5) monitoring and evaluating our approach. We developed a program logic to understand and communicate to others how we would implement activities and what resources would be required to support this process. We drew on several evidence-based KT and implementation models and frameworks to do this. First, a KT planning template was used to inform what evidence we wanted to mobilize, to whom, and for what purpose. Based on this step, we recognized we wanted to bring about change with the target audience, and as such, we drew on the previously mentioned implementation planning models and frameworks. We collated the outcomes from these initial steps.

Conclusions: Our KT and implementation practice experience were successful. Encouraging researchers and end users to adopt similar practices requires investment in training and development of KT and implementation practice. This also entails modifying research standards and guidelines to include KT and implementation practice when working with Aboriginal and Torres Strait Islander people and other vulnerable groups, creating incentives for researchers and end users to embed KT and implementation practice in research, and recognizing and rewarding the benefits and impact beyond publication and presentation.

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KEYWORDS

knowledge translation; implementation planning; research governance; nongovernment organizations; nongovernment organisations; Aboriginal and Torres Strait Islander

Introduction

When done well, research has resulted in significant benefits and positive impacts on society [1]. In Australia, Aboriginal and Torres Strait Islander people have participated in Western research for decades [2-4]. However, the primary benefactor of this research has and continues to be researchers, with limited or no research knowledge mobilized for uptake and beneficial use by end users like individuals and communities [5-7]. Our ongoing work with nongovernment organizations (NGOs) in the Torres Strait suggests the following: continued distrust; limited awareness, skills, and experience in research best practices; and little evidence describing the practical application of knowledge translation (KT) and implementation practice by researchers [8,9].

In 2021, the Torres Strait Islanders Research to Policy and Practice Hub (the Hub) at James Cook University designed and implemented several activities, including a games-based interactive workshop with representatives from NGOs in the Torres Strait. Our success is described by a workshop participant: “as a Board member, I can see the importance and why Board members or management committee members or directors should do this training. This is important for us to sit down and get our heads around and understand research, especially when you’re going to be entering into contractual agreements.”

This paper describes KT and implementation planning to design and implement strategies to increase awareness and understanding of NGOs in research governance. Effective KT centers on Aboriginal and Torres Strait Islander communities and their wisdom to achieve maximum research impact through a carefully designed process that minimizes power dynamics and privileges Aboriginal and Torres Strait Islander perspectives. Drawing on other definitions, KT is the reciprocal process of combining experiential wisdom with academic research. It involves a complex series of interactions between knowledge holders, producers, and users to achieve positive and sustainable long-term benefits for Aboriginal and Torres Strait Islander people [10,11]. Implementation is the process of putting to use or integrating new practices within a setting—it is about identifying and defining who needs to change and what individuals need to do differently, understanding and mapping barriers and facilitators, and selecting the most appropriate strategies to support change [12].

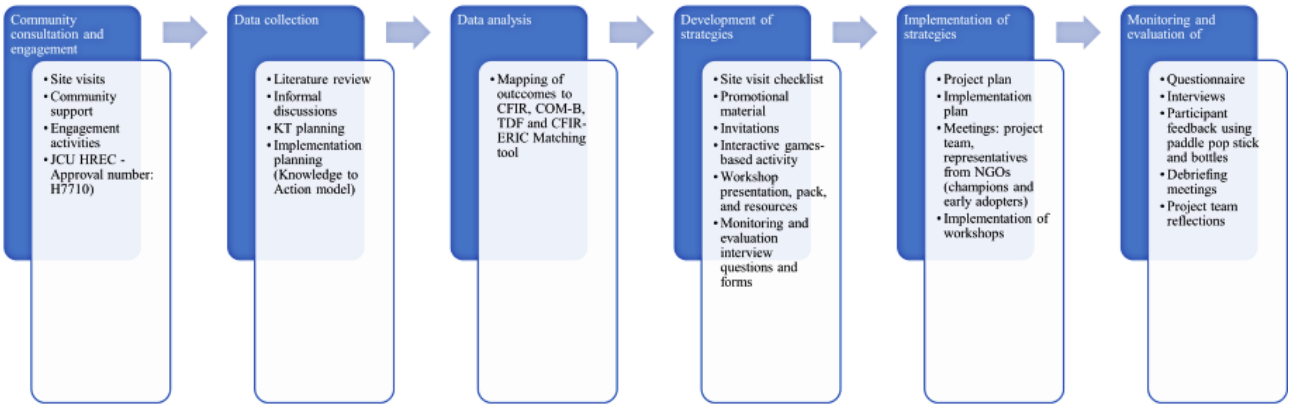
Methods

Data Collection

Figure 1 shows the methods used in this descriptive study. This paper will focus on the KT and implementation planning activities listed in the boxes titled data collection and analysis in Figure 1.

The study site was Thursday Island in the Torres Strait. The study participants were representatives from NGOs. We adopted the Knowledge to Action process model to guide our KT and implementation planning approach. We collected data from a literature review and informal discussions. The literature review focused on nationally endorsed research guidelines. Representatives from NGOs and project team members participated in informal discussions. We used a KT planning template to identify the evidence to mobilize, who were the intended users of this evidence, what key messages we wanted to share with the specified groups, and what goals we wanted to achieve with each group [13].

Figure 1. Study approach and methods. CFIR: Consolidated Framework for Implementation Research; CFIR-ERIC: CFIR-Expert Recommendations for Implementing Change; COM-B: Capability, Opportunity, Motivation, Behaviour; JCU HREC: James Cook University Human Research Ethics Committee; KT: knowledge translation; NGO: nongovernment organization; TDF: Theoretical Domains Framework.



Data Analysis

As shown in Figure 1, we used several frameworks to organize and analyze the data: the Consolidated Framework for Implementation Research (CFIR) [14], the Capability, Opportunity, Motivation, Behaviour (COM-B) [15], the Theoretical Domains Framework (TDF), and the CFIR-ERIC (CFIR-Expert Recommendations for Implementing Change) Implementation Strategy Matching tool, version 1.0 [16].

CFIR described factors to consider in planning for implementation, such as the NGO's internal and external operating environments. COM-B identified what needed to change for a behavior change intervention to be effective and described barriers to change at the individual level. TDF was used to determine the specific influences on an individual's behavior. The CFIR-ERIC Matching tool identified the evidence-based strategy that was best suited to address known barriers.

Ethics Approval

The project obtained ethics approval from the James Cook University Human Research Ethics Committee (approval number: H7710).

Results

The CFIR factors deemed influential to our approach were (1) outer setting (ongoing demand for research, distrust, limited networking and routine communication between local NGOs, increase demand for NGOs to report on outcomes and impact, limited local research workforce capacity and capability, cultural expectations and requirements about research practice) and (2) inner setting (NGOs are small to medium enterprises [20 to 50 staff], organizations 10 to 20 years of age, governed by a voluntary Aboriginal and Torres Strait Islander board of directors, limited funding and resources for NGOs to do or engage in research, NGOs provide a range of services and may be the only service provider for the region [competing interests and demands], NGOs share similar goals to improve the health and well-being of the local community).

As shown in Table 1, the barriers to research at the individual level were as follows: distrust of researchers and the research process, limited time, limited support to backfill staff to attend training, little or no awareness of research guidelines such as the Keeping Research on Track II, lack of interest, and resistance to change.

Textbox 1 displays the types of intervention strategies that can be used to address these barriers.

The program logic in Figure 2 presents our approach to implementing the strategies above.

Table 1. Mapping of identified barriers to implementation strategies to implement a set of research guidelines in nongovernment organizations in the Torres Strait.

Barriers, COM-B[a] domain, and TDF[b] construct	Implementation strategy characteristics
Limited or no awareness of research guidelines such as the Keeping Research on Track II	
Capability	
Knowledge	• Deliver educational workshops • Dynamic training • Develop and distribute educational resources • Tailor approaches to the local context and practice
Distrust of researchers and the research process	
Motivation	
Emotion: fear, anxiety, and stress	• Capture and share local knowledge
Lack of familiarity with facilitators	
Motivation	
Emotion: fear, anxiety, and stress	• Capture and share local knowledge • Regular visits to organizations • Facilitator-supported activities • Identify and co-opt champions
Limited time	
Opportunity	
Environmental stressors	• Invite board members and senior executives
Resources	• Host events in the local community • Reduce participant costs through, for example, free events with catered meals
Limited to no support to backfill staff attending training	
Opportunity	
Organization culture and climate	• Invite board members and senior executives • Identify and co-opt champions
Resistance to change	
Motivation	
Optimism	• Identify and co-opt support from local opinion leaders
Intentions	• Assess readiness • Identify environmental and individual barriers and facilitators
Goals	• Collate outcomes from stakeholder meetings, discussions, and feedback (informal needs assessment)
Beliefs about consequences	• Same as above
Lack of interest	
Capability	
Knowledge	• Capture and share local knowledge
Opportunity	
Social influences	• Identify early adopters • Identify and co-opt support from local opinion leaders
Motivation	
Optimism	• Identify and co-opt champions

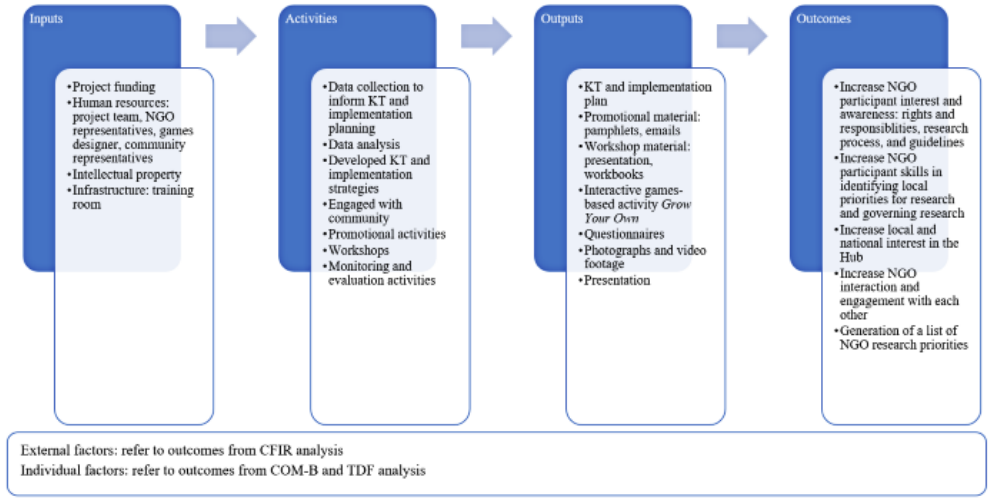
Barriers, COM-B[a] domain, and TDF[b] construct	Implementation strategy characteristics
Beliefs about consequences: outcome expectancies	• Same as above

[a]CFIR: Consolidated Framework for Implementation Research.
[b]COM-B: Capability, Opportunity, Motivation, Behaviour.

Textbox 1. Intervention strategies to address barriers.

- Needs assessment about what needs to change and readiness to change
  - Assess readiness
  - Identify environmental and individual barriers and facilitators
  - Collate outcomes from stakeholder meetings, discussions, and feedback
- Recognizing and embedding environmental barriers and enablers into approaches
  - Tailor approaches to the local context and practice
  - Capture and share local knowledge
  - Invite board members and senior executives
  - Host events in the local community
  - Reduce participant costs through free events with catered meals
- Developing and implementing strategies based on target audience needs
  - Develop and distribute educational resources
  - Deliver educational workshops
  - Dynamic training
  - Facilitator-supported activities
- Gaining target audience and community trust
  - Regular visits to organizations
  - Identify and co-opt champions, local opinion leaders, and early adopters

Figure 2. Program logic of study inputs, activities, outputs, and outcomes. CFIR: Consolidated Framework for Implementation Research; COM-B: Capability, Opportunity, Motivation, Behaviour; KT: knowledge translation; NGO: nongovernment organization; TDF: Theoretical Domains Framework.



Discussion

Principal Results

Our approach to designing and implementing strategies to increase awareness and understanding of NGOs in the Torres Strait to govern research involved several steps: (1) identifying and defining what needed to change and who needed to change, (2) identifying and mapping barriers and facilitators, (3) selecting the most appropriate strategies to support change, (4) developing and implementing activities, and (5) monitoring and evaluating our approach.

A KT planning template was used to inform what evidence we wanted to mobilize, to whom, and for what purpose. Based on this step, we recognized we wanted to initiate change with the target audience. We drew on several evidence-based KT and implementation models and frameworks to do this. We drew on the previously mentioned implementation planning models and frameworks. We collated outcomes from these initial steps and developed a program logic to understand how we would implement the strategies and what resources we required to support this process.

The approach we took in this study is not new [14,17,18]. However, there is limited but growing evidence describing the successful use and application of KT and implementation planning practices in NGOs in Aboriginal and Torres Strait Islander communities in Australia [19-21]. By supporting and strengthening these practices, we ensure evidence is mobilized effectively from research to end users. We also enhance end-user capacity and capability to draw on evidence to inform the design and implementation of programs and services in their communities for local benefit and impact. Finally, we demonstrate a systematic approach to inform the decision making of funding authorities and policy makers.

Strengths and Limitations

Strengths included having Torres Strait Islander researchers and project team members lead and implement the research, a strong level of trust and engagement between researchers and NGOs, and the presence of team capability in KT and implementation planning. The limitations of the project relate to the sample size and study site (all NGOs were in the same remote community). As such, the findings from this project are not generalizable to the broader NGO audience. Timing and time frames were also a limitation. The project timeline was 6 months during COVID-19 restrictions when travel restrictions were in place. The project team could not travel to other parts of Australia to collect data. Furthermore, there were limited project resources to fund an expansion of the project.

Conclusion

Based on our individual and collective experiences, we know programs, services, and practices are designed and implemented from what we think we know and expect. We have participated in various meetings, forums, and workshops that provided opportunities for participants to catch up and network but were unsuccessful in initiating and sustaining change. We have written journal publications and presented at conferences to enhance our track record but did little to improve investment in local communities. We wanted to disrupt this status quo and embark on an approach to increase awareness and understanding and initiate behavior change. Our KT and implementation practice experience were successful. Encouraging researchers and end users to adopt similar practices will require the following: (1) investment in training and development on KT and implementation practice, (2) modifying research standards and guidelines to include KT and implementation practice when working with Aboriginal and Torres Strait Islander people and other vulnerable groups, (3) creating incentives for researchers and end users to embed KT and implementation practice in research, and (4) recognizing and rewarding benefits and impact beyond the publication and presentation.

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Data Availability

This paper includes all data generated or analyzed in this study.

Conflicts of Interest

None declared.

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Abbreviations

CFIR: Consolidated Framework for Implementation Research
CFIR-ERIC: CFIR-Expert Recommendations for Implementing Change
COM-B: Capability, Opportunity, Motivation, Behaviour

KT: knowledge translation
NGO: nongovernment organization
TDF: Theoretical Domains Framework

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Review

Examining how Ethics in Relation to Health Technology is Described in the Research Literature: Scoping Review

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Abstract

Background: Given the increased use of technology in health care, both in extent and application, the importance of understanding the ethical implications of new health technologies increases. Profound insight into the possible ethical implications of new health technologies enhances the research and development of such technologies and the likelihood of eventual successful implementation in clinical practice.

Objective: This study aimed to gain an understanding of how and if researchers focused on health technologies describe the actual or possible ethical aspects of their research findings.

Methods: An established framework for scoping reviews was used to guide the methodology. Studies published in PubMed over the last 10 years were included if they study or refer to ethics in relation to health technology as defined by established frameworks. In total, 14,532 articles were screened, 692 were retained for full-text evaluation, and 227 were included for data extraction.

Results: In total, 250 (80.9%, N=309) studies were conducted in North America and Europe; literature review studies were dominant. Most studies (52.9%, 120/227) had no direct reference to any of the 4 basic ethical principles: beneficence, nonmaleficence, autonomy, and justice. In cases where studies referenced ethical theory, consequentialism dominated.

Conclusions: When research about technology and ethics is published, the predominant focus is on its intent rather than its actual effect on patients. This lack of insight is problematic considering the vast advancement of technology in which ethics cannot keep up with understanding and offer insights on addressing ethical issues. This finding has implications for practice, research, and education.

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KEYWORDS

ethics; ethical principles; ethical theory; health technology; eHealth; digital health; telehealth; mHealth; health care; scoping review

Introduction

Health technology is increasingly being used in various areas of health care. It provides ample options to meet societal needs in improving quality, optimizing resource use, and the coproduction of care within the health care system [1]. As health technology has moved beyond supporting the treatment of life-threatening or congenital diseases and into genomics, diagnosis, surveillance and big data, and artificial intelligence, the central ethical questions have shifted to issues around integrity and equity on both individual and system levels [2]. Such issues are concerned with challenges relating to the risk

that technology is biased, builds on or even reinforces inequalities, and overturns the principles for how care has traditionally been practiced and the logical setup for structuring the care system [3].

Health technology has traditionally been regarded as neutral [4], and bioethics is dominated by developer perspectives on the application in clinical practice [5]. However, health technology is increasingly spanning beyond the traditional organization of health care; use in contexts outside of the health care organization, such as in-home environments and workplaces; and the active role of the patient in operating and providing the functionality of the technology [6]. This overturns the traditional relationship between physicians and patients as an essential component of current health care practice [7]. Furthermore, technology's mediation of human-to-human relations may result in ethical dilemmas [8]. Therefore, a broader perspective is needed where both the context and future implications for human life are considered [9].

Given the increased use of technology in health care, both in extent and application, the importance of understanding the ethical implications of new health technologies increases [2]. Profound insight into the possible ethical implications of new health technologies enhances the research and development of such technologies and the likelihood of eventual successful implementation in clinical practice [10]. Due to the rate at which technology advances, bioethics is falling further behind in staying current with new, evolving ethical issues [11]. This is mainly due to a tradition of retrospective approaches examining ethical issues [12,13]. To address and learn from such studies, we propose that researchers and developers of new health technologies integrate ethical analysis early on in the research and development process.

Much has been written, discussed, and taught about the importance of performing health research involving human subjects ethically and by strict guidelines [14-16]. In addition, medical and health journals no longer publish research that has not gone through an ethical review by an independent ethics board [17]. These ethical review boards limit their evaluation to the ethics of the study itself by reviewing issues such as informed consent, coercion, and risks or benefits to study participants. Research ethics and the role of the ethical review boards limit themselves exclusively to the ethical nature of research studies. They do not consider the possible ethical and unintended effects of the research findings after the study has been completed [18]. This study's objective was to understand if and how researchers focused on health technologies describe the actual or potential ethical aspects of their research findings.

Methods

The methodology for this scoping review followed the methodological framework put forward by Arksey and O'Malley [19] and a previously described protocol [20]. In total, 4 stages were applied to map current knowledge and identify gaps: (1) identification of relevant literature, (2) selection of studies, (3) charting of data, and (4) synthesizing results.

Identifying Relevant Literature

To ensure the research team adequately explored a broad array of health-related aspects unbiased without using specific predetermined health-related search terms, all articles were located through Pubmed, the major database for biomedical literature in life science journals and digital books. PubMed was selected as the sole source due to the large number of interdisciplinary and mainly health-related publications located in this database and the extensive and time-consuming search strategy using individual terms of technologies based on a nomenclature rather than a single or few broad and less precise terms such as "health technology." The database search was conducted from September to October 2020. The health technologies, which were used as primary search terms, were identified through the Global Medical Device Nomenclature [21] and the nomenclature used in the World Health Organization (WHO) [22] report "Human Resources for Medical Devices, the Role of Biomedical Engineers." The list included devices and techniques used to manage health care delivery, which parallels the definitions of technology and technique [23]. Searches were conducted using 181 search terms for *technologies* AND *ethic**, allowing any of the suffixes of *ethic* (ie, ethic[s], ethic[al], ethic[ally], ethic[ist], ethic[ism], and ethic[ality]) to be included in a search of titles and abstracts. A time delimiter was set to include only articles published in PubMed in the last 10 years (2010-2020) from the date of the searches. The reason for including only recent literature is that the research field in health technology is constantly and rapidly developing and that we intended for this study to be based on current research in the field. Upon completing each search, all records were saved to a shared file and imported into the Covidence software (Veritas Health Innovation) for further analysis.

Selecting Studies

Only studies that specifically mentioned ethics concerning a health technology or technique were included. The screening was conducted in collaboration with all 6 authors. All authors participated in regular meetings to discuss the inclusion and exclusion criteria interpretations. In the initial screening, the titles and abstracts were independently examined by 2 authors, who independently determined whether the article appeared to meet the inclusion criteria. A third author was included to resolve the conflict if a disagreement was apparent.

Studies were excluded if they met the following exclusion criteria: ethics concerning human health was not mentioned; ethics concerning technology was not mentioned; the authors did not elaborate on ethics; the authors referred to research ethics only; the study was not in English; not a research article; not a peer-review article; not a retrievable article; duplicate article; or animal research ethics. After that, the studies were assessed for eligibility based on the full text. Again, 2 authors independently reviewed each study, and in cases of disagreement or uncertainties, conflicts were resolved by a third author. The Covidence software allowed several authors to code and analyze the same data set simultaneously. The average interrater reliability in screening both records and full-text articles was satisfactory (κ=0.23 and κ=0.52, respectively). The authors

followed the PRISMA (Preferred Reporting Items for Systematic Reviews and Meta-Analyses) reporting guidelines for systematic reviews to report the screening process [24].

Charting the Data

A data extraction form was designed in the Covidence software to chart critical items from the final set of studies that made it through the extensive and rigorous screening process. Data extracted using the questionnaire form included the bibliographic details of the study; geographical location where the studies were carried out; type of research methodology used; types of technologies investigated; aims of the study; and ethical principles and theory referred to in the study.

Synthesizing Results

The intention of the scoping review was not to synthesize evidence or aggregate findings from different studies but to map their characteristics. A 3-step process collated and summarized the data and presented a narrative account of existing literature. Each included article's data were independently extracted by 2 authors, and a third author confirmed a consensus of each article's extracted data. First, data extraction forms were used to report descriptive numerical analysis of the studies' extent, nature, and distribution. Second, the Bloom taxonomy of measurable verbs was used to classify the level of critical thinking in the studies as determined by the verbs used in the aims of the studies. The taxonomy comprises 6 categories describing learning progression, including knowledge, comprehension, application, analysis, synthesis, and evaluation [25] (Table 1). Third, the ethical analysis was based upon Beauchamp and Childress' [26] 4 principles approach, which inform the ethical decision-making in health care, and the 3 ethical theories—consequentialism, deontology, and virtue. Finally, a template for the extraction was developed with brief descriptions of the concepts used: beneficence—the duty to do good; nonmaleficence—avoiding causing harm to a person; autonomy—respecting the individual's right to decide for him/herself; justice—fairness and duty to protect human dignity; consequentialism—the consequences of the chosen action determine whether the action is right or wrong; deontology—there are allowed, forbidden actions (eg, Kantian duty-based ethics); and virtue ethics—the moral actor is in the center. The analysis was carried out by searching for references to the ethical principles in the studies first. Next, the description and discussion were assessed to see if the ethical theories were referred to.

Table 1. Bloom taxonomy.

Category	Description	Example verbs
Knowledge	Remember: remember basic concepts and facts	List, name, recall, record, relate, repeat, state, tell, and underline
Comprehension	Understand: explain ideas or concepts	Compare, describe, discuss, explain, express, identify, recognize, restate, tell, and translate
Application	Apply: use information in new situations	Apply, complete, construct, demonstrate, dramatize, employ, illustrate, interpret, operate, practice, schedule, and sketch
Analysis	Analyze: see connection and pattern	Analyze, appraise, categorize, compare, contrast, debate, diagram, differentiate, distinguish, examine, experiment, inspect, inventory, question, and test
Synthesis	Evaluate or assess: justify opinion and decision	Arrange, assemble, collect, combine, comply, compose, construct, create, design, devise, formulate, manage, organize, plan, prepare, propose, and setup
Evaluation	Create: create new or innovative	Appraise, argue, assess, choose, compare, conclude, estimate, interpret, judge, justify, measure, rate, revise, score, select, support, and value

Results

A total of 18,166 potentially relevant articles were identified in PubMed using the a priori medical technologies and techniques outlined in the Global Medical Device Nomenclature and WHO. Of these articles, 3534 were removed by the Covidence software because they were identified as duplicates.

After the initial screening of titles and abstracts, 13,840 articles were excluded because they refer to non–technology-based ethics, non–health-related ethics, ethics concerning research methodology, or an ethical review board reviewed the research. The second-round screening of full-text articles included 692 articles and excluded 465 articles (Figure 1). The remaining 227 articles were deemed adequate for data extraction. A complete bibliographic list of included studies can be found in Multimedia Appendix 1.

The data extraction results indicated that 80.9% (250/309) of the articles originated from researchers from North America and Europe; empirical studies were also primarily based on data collected in these countries (Table 2). In addition, 81.9% (186/227) of the studies were literature and primarily narrative reviews with limited or no descriptions of the methodological approach of the review and little distinction between references to the literature versus the assumptions from the authors.

Of the empirical studies, qualitative studies dominated. Only 7 studies used pure quantitative and objective methodologies. None of the quantitative studies focused their research on developing or using validated measures for assessing ethics (Table 2). The articles were grouped based on the different health technologies or techniques central to the research. Based on the meaning units taken from the articles' description of the respective technologies and techniques, 12 groups were initially formed and then merged into 6 groups describing the different types of technology areas with limited overlap between the areas (Table 2).

Of the 227 studies, 52.9% (n=120) had no direct reference to the 4 basic ethical principles: beneficence, nonmaleficence,

autonomy, and justice. Among the 107 studies referring to 1 or more of the ethical principles, 244 references were made, of which 33.2% (n=81) only mentioned them in passing, without linking them to an ethical theory. The references referring to an ethical principle and an ethical reasoning around ethical theory (n=163) did so mainly in relation to consequentialism (69.3%, n=113), followed by deontology (26.4%, n=43) and virtue (4.3%, n=7; Table 3).

To understand the type of approach that the research on health technology and techniques had and thus provide an understanding of the conceptual level the technologies and techniques were studied and the connection to ethics that could be made, the formulations of the aims in the articles were studied. The specific aims of each article were examined to understand the research approach, which was used to determine the conceptual level of each study and provided clarity on the connection to ethics. Based on Bloom taxonomy, most studies (80.6%, 183/227) aim to use verbs at the conceptual levels of knowledge, comprehension, and analysis. In contrast, studies that investigated application, synthesis, and evaluation were sparse (Table 4).

Figure 1. Flow diagram of the study selection process.

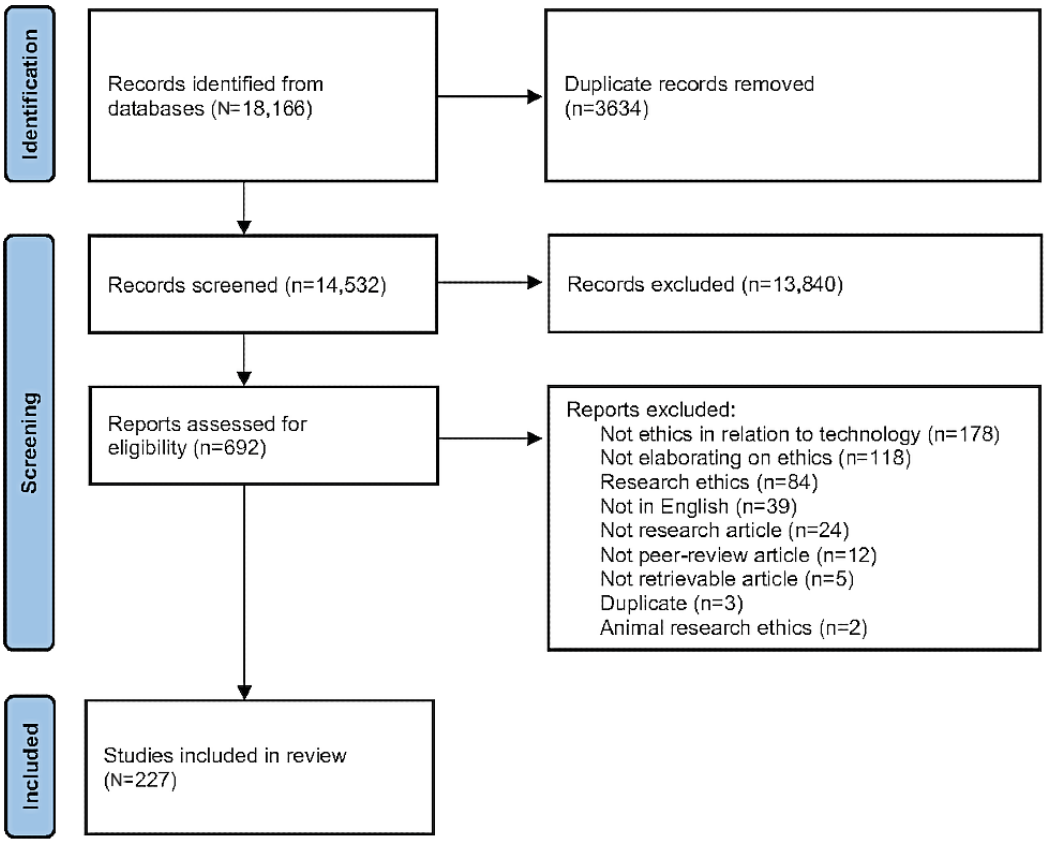

Table 2. General characteristics of included articles (n=227).

Characteristic	Article, n (%)
Country[a] (n=309)	
Africa	6 (1.9)
Asia	17 (5.5)
Europe	127 (41.1)
North America	123 (39.8)
Oceania	30 (9.7)
South America	6 (1.9)
Research design (n=227)	
Narrative literature reviews	170 (74.9)
Qualitative	30 (13.2)
Systematic literature reviews	16 (7)
Quantitative	7 (3.1)
Mixed method	4 (1.8)
Technology and technique (n=227)	
Big data, information systems, and artificial intelligence	65 (28.6)
Technologies for treatment	58 (25.6)
Internet of things, eHealth, and mobile health	41 (18.1)
Gene editing and sequencing	28 (12.3)
Gene screening, testing, and diagnosis	23 (10.1)
Technologies for assistance	12 (5.3)

[a]An article may have multiple countries of origin.

Table 3. Distribution of references to ethical principles and ethical reasoning around ethical theory (N=244).

Ethical principal	Virtue (n=7), n (%)	Deontology (n=43), n (%)	Consequentialism (n=113), n (%)	No references to ethical theory (n=81), n (%)
Beneficence	1 (14.3)	9 (20.9)	21 (18.6)	20 (24.7)
Nonmaleficence	1 (14.3)	5 (11.6)	18 (15.9)	17 (21)
Autonomy	4 (57.1)	18 (41.9)	56 (49.6)	22 (27.2)
Justice	1 (14.3)	11 (25.6)	18 (15.9)	22 (27.2)

Table 4. Distribution of verbs used in the study aims according to Bloom taxonomy.

Category, verb	Usage (N=227), n (%)
Evaluation	
Assess	7 (3.1)
Consider	3 (1.3)
Compare	2 (0.9)
Reflect	1 (0.4)
Evaluate	1 (0.4)
Synthesis	
Propose	4 (1.8)
Categorize	1 (0.4)
Point out	1 (0.4)
Develop	1 (0.4)
Speculate	1 (0.4)
Analysis	
Explore	27 (11.9)
Examine	20 (8.8)
Analyse	7 (3.1)
Investigate	6 (2.6)
Focus	3 (1.3)
Encourage	2 (0.9)
Study	1 (0.4)
Stimulate	1 (0.4)
Inquire	1 (0.4)
Inventory	1 (0.4)
Application	
Present	10 (4.4)
Offer	3 (1.3)
Contribute	3 (1.3)
Show	2 (0.9)
Determine	2 (0.9)
Assist	1 (0.4)
Inform	1 (0.4)
Comprehension	
Discuss	24 (10.6)
Review	13 (5.7)
Identify	13 (5.7)
Highlight	8 (3.5)
Understand	4 (1.8)
Summarize	4 (1.8)
Illuminate	3 (1.3)
Give	2 (0.9)
Classify	1 (0.4)
Orient	1 (0.4)

Category, verb	Usage (N=227), n (%)
Knownledge	
Provide	14 (6.2)
Address	11 (4.8)
Outline	8 (3.5)
Describe	4 (1.8)
Introduce	1 (0.4)
Underline	1 (0.4)
Lay out	1 (0.4)
Gather	1 (0.4)

Discussion

Principal Findings

Ethics and health care are closely intertwined, and it is not easy to discuss the moral principles presented in health care and the technologies used within its practice without considering the ethics involved. The findings show that more than 80% of the studies were conducted in North America and Europe and few in Africa and South America. These results are in line with research suggesting that although there is increasing research on digital health implementation in low- and middle-income countries, there is a lack of in-depth discussions of the ethical implications of health technologies in these settings [27]. The findings also show that more than 80% of the studies were literature reviews and that very few studies based their research on empirical data. In addition, primarily objective quantitative methodologies were sparse. These findings indicate the lack of discussion of the ethical issues concerning health technologies and that the limited discussions available have a poor grounding in empirical data. More then 50% of the included studies researched big data, information systems, artificial intelligence, and technologies used to provide various forms of treatment. This could reflect a tendency to raise more ethical concerns regarding implications within these technology areas instead of genetics and gene technology, gene-based screening, and technologies used for assistance during illness and rehabilitation. It could also reflect the current hype of applying health technologies based on health care data and artificial intelligence and that these technologies are more studied in general and with low reference to actual application and empirical grounding [28].

It is beneficial for the field of ethics in research and health care education to receive more measurable data in terms of the verbiage and principles surrounding ethics concerning health technology [2]. To understand how ethics have been analyzed, we looked at the usage and dichotomy of ethical principles in studying and discussing health technologies. Evaluating ethical principlism created a dynamic framework for addressing ethical dilemmas witnessed in medical practice and thus reflected in the literature [29]. The peer-reviewed research articles' content was labeled using Beauchamp and Childress' [26] 4 principles approach and the ethical theories describing virtue, deontology, and consequentialism. Either one, several, or none of the 4 principles were used to describe either or none of the 3 ethical theories. The findings in this study echo the concept that principlism itself does not set out a single consistent or coherent moral theory [29]. Therefore, viewing the dimensions and intricacies of ethics in patient care and clinical medicine is vital to understanding the complexity of ethics in health technology. The studies were further analyzed using Bloom taxonomy of measurable verbs [25]. Observing the arrangement of measurable verbs beginning with knowledge, the most basic level, and progressing through evaluation, the most complex level, provides valuable insight into the dimensions that ethics takes on in medical technology literature [30,31]. Understanding the broadness of the term ethics provided a greater scope behind how and why it is researched. Identifying ethics verbiage through this additional taxonomy enhances our understanding of the complexity of the research in which ethical issues are researched [31,32]. Unfortunately, the framing of the research, given the formulation of the research aims of the studies, had uneven conceptual distribution and was primarily of lower complexity.

Ethics informs education and professional standards, and changes in ethics are becoming increasingly apparent through the growing overlap between medicine and technology. The appreciation for the impact of ethics on the field of medicine increases as conversations about health technology application in health care continues to grow [31,33]. By summarizing the term "ethics" in health technology research, this study indirectly contributes to both health technology and ethics and informs practice and clinical decisions made every day [29]. In practice, it is evident that little work is being done proactively in identifying issues that might have unwanted or adverse results on patients. Thus, practitioners need to be trained and practice identifying and addressing ethical issues [34]. This practice needs to be a part of implementing and assessing new technologies as part of the evaluation process [35]. In addition, practitioners need to expand their curiosity beyond understanding what technologies do and understand what it does not do or does that is unwanted. Ethical committees and university centers for bioethics should be essential in helping practitioners obtain the needed skill set [36]. Examining the ethical and unintended effects as part of the research process must be required. Similar to addressing the study's limitations and ensuring the following of ethical guidelines and regulations, the researchers should consider the possible unintended effects

and ethical issues of their research regardless of the type of health technology [37]. This consideration will lead to a higher level of transparency and allow for guidance to practitioners as they implement and evaluate new technologies. Finally, regarding education, all researchers of new health technologies and techniques should have adequate training in ethics and how to evaluate unintended and ethical effects resulting from their work [36,37]. This thinking needs to transcend beyond the study's research ethics review to evaluate the impact of their work. A study of whether a new technology is carried out ethically does not necessarily mean that the technology itself will not have ethical or undesirable effects. To integrate this as a standard in research on health technologies, supervisors and committees involved in doctoral education have a crucial role in ensuring that this education is an essential part of doctoral training to establish it as a natural skill set for the next generation of researchers, supervisors, and research leaders [38].

Limitations

The selection of the sample in this study has both strengths and limitations. To avoid difficulties in defining the health relevance of different techniques and their application, the search for articles was limited to PubMed, the primary medical and health science research database. The combination of searching using keywords for ethics and technology based on WHO- and Global Medical Device Nomenclature–predetermined terminologies in this database gave a search result including records with high relevance to health technology in relation to human health. The strength of this approach is that the inclusion of studies concerning the technology's relevance to human health was not limited based on search terms but based on screening a large number of records. The weakness of the approach is that research with the same focus but found in other databases was not included in the study. All screening and data extraction was done in pairs, and the definitions and interpretations of the inclusion and exclusion criteria were discussed in regular meetings. The study focused on ethics in relation to health technology in general, which gave an overview of how the field relates to issues regarding ethics. However, a more precise and applicable result would have been obtained if the study had been limited to a more precise technology area, such as big data and artificial intelligence. Due to limitations in the authors' language skills, only articles written in English were sought, which is a limitation for the study.

Conclusion

This study shows that research about technology and ethics predominantly focuses on intent rather than actual effect on patients. This lack of insight is problematic considering the vast advancement of technology in which ethics cannot keep up with understanding and offer insights on addressing ethical issues. A predominant focus on the ethical aspects of the direct consequences of health technology means that more difficult ethical considerations are overlooked, such as potentially unintended effects, researcher's approaches to ethical issues, and expectations on abiding to regulations and standards. This finding identifies a need for a broader approach to ethical issues linked to health technology, something that should continue from the training of new researchers, in the design and funding of new research studies, and in the presentation and publication of new research results.

Conflicts of Interest

None declared.

Multimedia Appendix 1
Complete bibliographic list of included articles.
[XLSX File (Microsoft Excel File), 166 KB - ijmr_v11i2e38745_app1.xlsx]

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Abbreviations

PRISMA: Preferred Reporting Items for Systematic Reviews and Meta-Analyses
WHO: World Health Organization

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Original Paper

Evolution of Interdisciplinary Approaches Among Research-Oriented Universities in Vietnam Toward a Modern Industrial Economy: Exploratory Study

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Abstract

Background: Vietnam's 2045 development plan requires thorough reforms in science and technology, which underlines the role of research-oriented universities in generating and transforming knowledge. Understanding the current research performance and productivity in Vietnam is important for exploiting future agendas.

Objective: This study aims to explore the growth patterns and collaborations in the scientific publications of Vietnam.

Methods: Data on documents in the Web of Science Core Collection database were searched and extracted to examine the research performance in Vietnam. Publication growth patterns in both quantity and quality were examined. The evolution of research disciplines and collaboration networks were also analyzed. Trends in the growth in the number of publications, citations, and average citations per publication between 1966 and 2020 were presented. Temporal tendencies of the 10 most productive research areas in each period were illustrated. VOSviewer software was used to analyze the discipline network, country network, and institution networks. The trends and the geographical distribution of the number of publications and citations were analyzed.

Results: A total of 62,752 documents in 8354 different sources from 1966 to 2020 were retrieved. A substantial growth was observed in the Vietnamese scientific output during this period, which was mainly research with international collaboration. Natural sciences such as mathematics, materials science, and physics were the top 3 most productive research fields during 1966-2020 in Vietnam, followed by experimental research fields such as multidisciplinary sciences, plant sciences, public, environmental, and occupational health. In 1966-2020, there was the emergence of multidisciplinary research–oriented universities in both public and private sectors along with a significant increase in the number of interdisciplinary and multidisciplinary publications. Although the scientific quality has improved, these publications are still of mostly medium quality as they are concentrated in middle-ranking journals.

Conclusions: Our study highlights the notable growth in research performance in terms of both quality and quantity in Vietnam from 1966 to 2020. Building multidisciplinary and interdisciplinary research agenda, developing networks of local and international researchers for addressing specific local issues, improving the participation of private sectors, and developing science and technology mechanisms are critical for boosting the research productivity in Vietnam.

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KEYWORDS

research; performance; productivity; scientometric; Vietnam; Asia; metric; pattern; journal; publication; publishing; output; science; scientific

Introduction

Investment in science and technology plays an important role in the growth of every country. The development of science and technology helps to generate new information and knowledge, leading to a change in the production scale, labor productivity, and economic growth, and thereby improving the country's competitiveness [1-3]. Since the "Doi Moi" renovation (1986) and especially after joining the Association of Southeast Asian Nations (1995), Vietnam has been increasingly paying attention to scientific research and international publications. In 2017, Vietnam spent 0.53% of the gross domestic product on research and development, which was up from 0.19% in 2011 [4]. There have been many initiatives proposed to promote scientific research and innovation activities in Vietnam, including the establishment of national scientific research support funds such as the National Foundation for Science and Technology Development and the National Technological Innovation Fund, Science and Technology Support Units in Ministries and local governing bodies and educational and research institutions, as well as the participation of private enterprises such as the Vingroup Innovation Foundation. These initiatives require publications in international journals or patents as compulsory outcomes for every research grant. In terms of policy, international publications or patents became a mandatory requirement for doctoral students and their supervisors from 2017 [5] and for promoting the national Professor title since 2018 [6]. In addition, Vietnam's extensive integration process in the global economy has enabled scientists to access financial support from abroad and strengthen cooperation with other high-income countries such as the United States of America, Europe, Japan, Korea, and Australia [7]. These reasons have contributed to the significant growth in the number of publications in international peer-reviewed journals, thereby improving Vietnam's position on the global scientific map.

However, science, technology, and innovation in Vietnam will confront many challenges in the coming time. A report "Assessment of Science, Technology, and Innovation in Vietnam," published by the World Bank pointed out the barriers for the development of science and technology in Vietnam, including (1) limited institutional support framework for science and technology, (2) shortage of high-quality knowledge resources, (3) the immaturity and fragmentation in the policy and research implementation, (4) underappreciation of research and development activities in private and state-owned enterprises, and (5) modest contribution of state universities and research institutions [8]. Although the higher education sector accounts for more than half of the human resources for science and technology (50.8%) and two-thirds of science and technology products, the role of universities in creating knowledge through science and technology activities is still limited [8].

In 2020, the government of Vietnam proposed strategic plans to actively participate in the Fourth Industrial Revolution and promote a knowledge-based economy [9]. The Vietnamese leader has also set a goal of developing the country from 2025 to 2030, with a vision extending to 2045, in which universities that are oriented to multidisciplinary research play a key role in the innovation process and improve the labor productivity of the Vietnamese people. This is a strategic transformation direction, which requires a thorough study of the development process of universities, including the science and technology capacity, to come up with long-term investment plans. Indeed, globally, the involvement of research universities is positively correlated with the economic growth of a nation [10]. It is especially true in low-income countries that the research universities can serve as a bridge in connecting domestic and international social resources, promoting interdisciplinary development and linkage between the economic regions of a country [11].

To be able to propose appropriate policies and models to help promote science and technology activities and the development of research-oriented universities, it is necessary to have assessments of the capacity in scientific research and cooperation through quantity, structure, and international publication quality in Vietnam. Evaluating the effectiveness of investment in science and technology (or the productivity of science and technology) often encounters obstacles because the process of scientific and technological research rarely produces specific commercialized products. Given that the essence of the scientific research process is to generate information and knowledge, scientific productivity can be quantified through the quantity and quality of scientific productions such as patents or publications in peer-reviewed journals. Previous research results showed that the number of scientific publications in peer-reviewed journals is an important indicator of a country's socioeconomic development status [12-14]. Therefore, this paper used a scientometric approach to explore the growth patterns and collaborations in scientific publications in Vietnam.

Methods

Database

This study analyzed the data of Vietnamese scholars' international scientific papers and publications in the Web of Science Core Collection database system. This database consists of more than 21,100 journals, which are indexed in different classification systems such as Science Citation Index Expanded, Social Sciences Citation Index, Arts & Humanities Citation Index, Emerging Sources Citation Index, and Conference Proceedings Citation Index. This database was chosen because the journals in this system are considered to be of high quality, which is important for measuring the outcomes of academic and policy applications [15,16]. Additionally, this system provides comprehensive information of the scientific papers or publications for analysis. The Web of Science system has been used by many governments and higher education research institutions to assess science and technology productivity and research quality [17,18].

Searching Strategy

We utilized the tag "CU=(Vietnam) OR CU=(Viet Nam)" for searching data of all publications in the Web of Science Core Collection until December 31, 2020 from Vietnam. These data were downloaded and extracted into the Microsoft Excel software. The criteria for selecting the papers and publications in the study included (1) publications (eg, papers, reviews, conference proceedings, abstracts, commentaries, editorials, news, other types of nonjournal publications) in the Web of Science Core Collection database, (2) published in the English language, and (3) having full information of the authors. Papers were excluded if their author information was not available. Each record contained the following information: authors, address/affiliation of each author, title, abstract, journal, number of citations, time of download, scientific category, research area, and funding. For examining collaboration networks, we categorized the papers into 3 groups: (1) papers with a single author; (2) domestic collaboration, if all authors of the paper had affiliations in Vietnam; and (3) international collaboration, if at least one author had an affiliation in a foreign country.

Data Analyses

We summarized the characteristics of the publications by using descriptive statistics. Trends in the growth of the number of publications, citations, and average citations per publication between 1966 and 2020 were presented. We also divided the study period into 4 intervals: before 1990, from 1990 to 1999, from 2000 to 2014, and from 2015 to 2020. Temporal tendencies of the 10 most productive research areas in each period were also illustrated. The VOSviewer software (Leiden University's Centre for Science and Technology Studies) was used to analyze the discipline network, country network, and institution networks. Microsoft Excel software was utilized to analyze the trend and geographical distribution of the number of publications and citations.

Results

Publication Output and Growth Trends

From 1966 to 2020, Vietnamese scientists had published 62,752 documents in 8354 different sources indexed in the Web of Science Core Collection database. Table 1 shows the general characteristics of the publications. The main type of scientific publications was original papers (58,509/62,752, 93.2%), followed by meeting abstracts (2572/62,752, 4.1%) and review papers (1992/62,752, 3.2%). There were 4791 (7.6%) single-authored documents that were written by 2120 authors. The mean numbers of authors per document, coauthors per document, and documents per author were 1.95, 12.90, and 0.51, respectively.

Figure 1 summarizes the growth tendency of the publications in Vietnam. Beginning with 6 documents from 1966, the number of publications grew gradually in the next 2 decades to reach 91 publications in 1989. The number of documents in 1966-1989 accounted for 1.5% (956/62,752) of the total publications from 1966 to 2020. The number of publications increased more rapidly in the next decade (1990-1999) and reached 296 publications in 1999. In the third period from 2000 to 2014, the number of publications remarkably increased compared to that in the second period. By the middle of the third period (2008), the number of publications exceeded 1000 and reached 2793 publications in 2014. The total number of publications in this period accounted for 27% (16,970/62,752) of the total cumulative number of publications. However, in the fourth period (2015-2020), the number of publications exploded and outperformed that in the previous periods, accounting for 68.3% (42,832/62,752) of the total number of publications. Figure 2 shows that there was a substantial increase in the number of citations and the mean citation rate per year. Although publications in 1966 had only 3 citations (for 5 publications) with a mean citation rate at 0.1 per year, in 2020, the total number of citations was 98,362 (for 13,691 publications) and the mean citation rate was 7.18.

Table 1. Main information regarding the collection and characteristics of the papers published by Vietnamese scientists.

Description	Value
Main information (n)	
Sources	8354
Documents	62,752
Mean citations per document	16.64
Mean citations per year per document	3.00
Document types (N=62,752), n (%)	
Original papers	58,509 (93.2)
Meeting abstracts	2571 (4.1)
Review papers	1992 (3.2)
Proceedings papers	1651 (2.6)
Other document types	2162 (6.9)
Authors (n)	
Authors of single-authored documents	2120
Authors of multi-authored documents	120,351
Number of authors (N=62,752), n (%)	
Single-authored documents	4791 (7.6)
Multiple-authored documents	57,961 (92.4)
Author collaboration (ratios)	
Documents per author	0.51
Authors per document	1.95
Coauthors per document	12.90
Collaboration index	2.08

Figure 1. The annual number of publications and the cumulative number of publications in Vietnam.

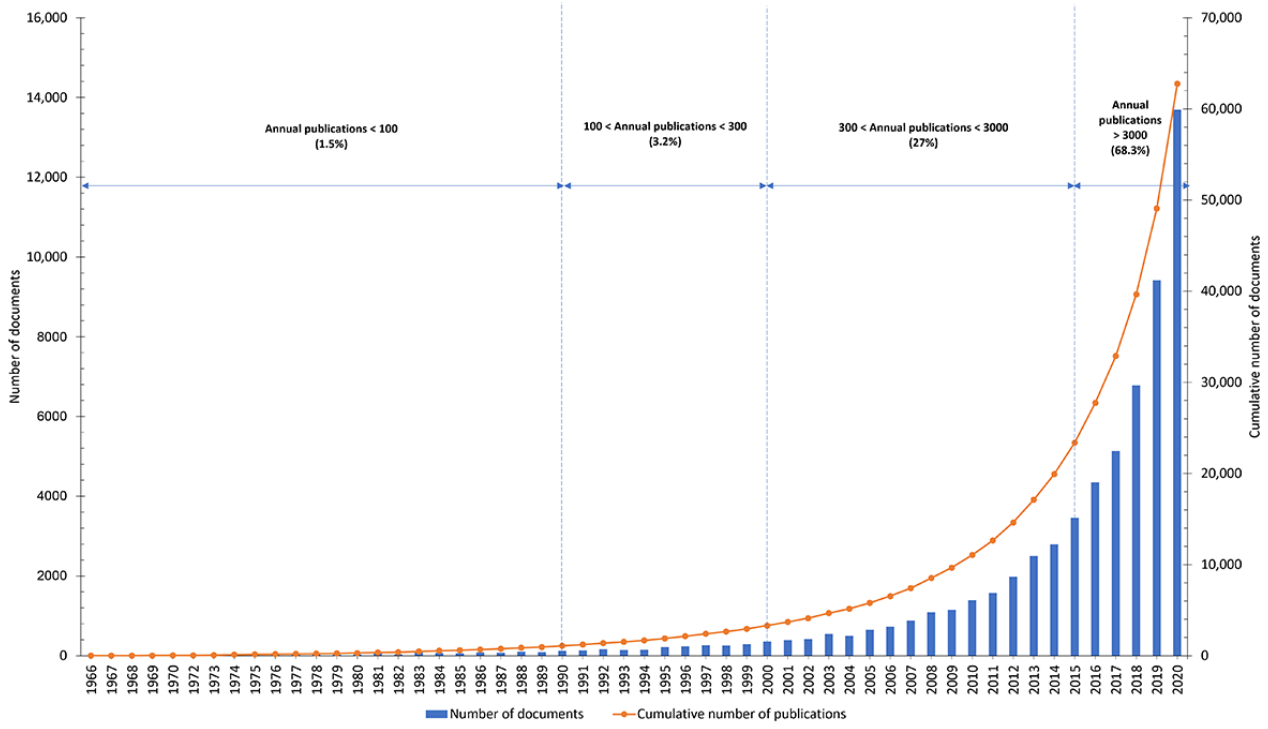
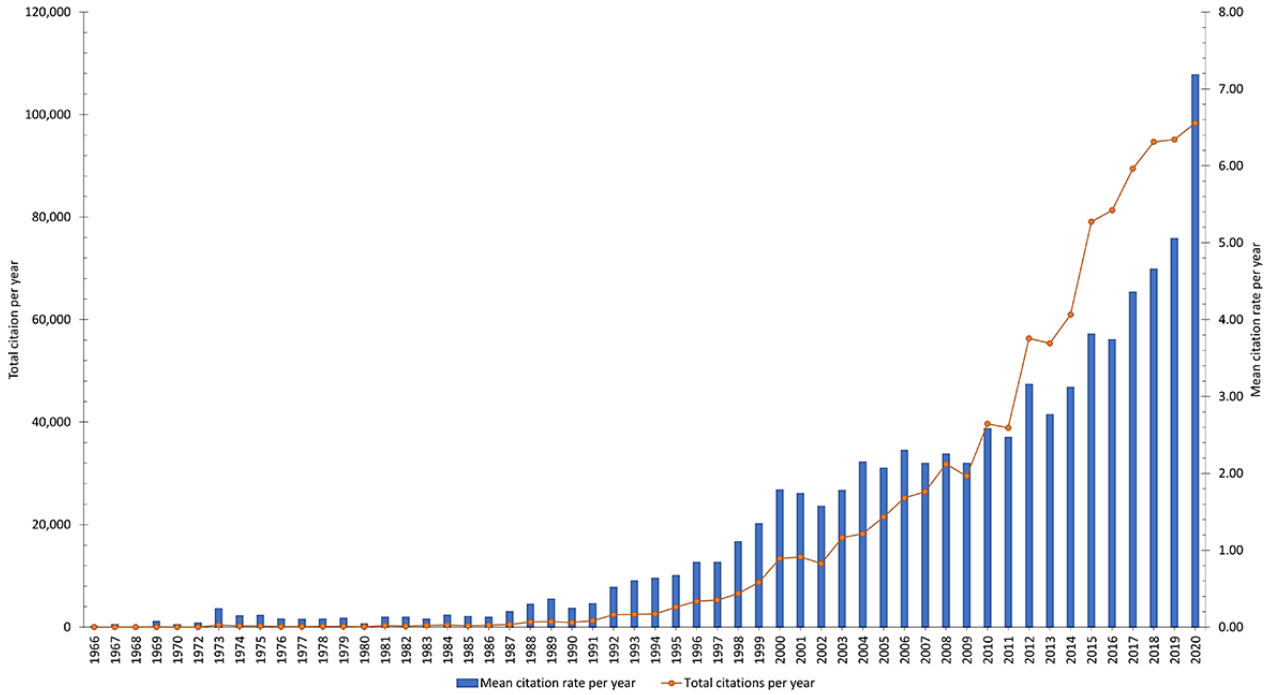


Figure 2. The annual number of citations and mean citation rate per year.



Evolution of Research Disciplines

Figure 3 illustrates the shift in the top 15 most productive research disciplines in different periods. Overall, natural sciences such as mathematics, materials science, and physics were the top 3 most productive research fields during 1966 to 2020 in Vietnam, followed by the experimental research fields such as multidisciplinary sciences, plant sciences, public, environmental, and occupational health.

Figure 4 shows the network analysis of the research disciplines. Overall, there were 6 main clusters of research fields in the international publications by Vietnam scholars: (1) clinical medicine and biomedicine (dark blue), (2) social sciences (green), (3) bioinformatics and life sciences (purple), (4) mathematics, physics, and materials science (red), (5) chemistry (light blue), and (6) earth science (yellow). Researches were mainly conducted among fields that were relatively similar (such as social sciences–clinical medicine or biomedicine-bioinformatics).

Table 2 shows that in the last 2 periods, multidisciplinary researches had a significantly higher rate of having funding compared to research studies with only 1 discipline. Moreover, the mean citation rate per document among studies with 1 discipline was lower than that in other groups in 2015-2020, but the difference was relatively small.

Figure 3. Changes in the top 15 most productive research disciplines in Vietnam. The dotted line indicates that the number of papers in that discipline reduced in the next period, while the solid line indicates that the number of papers in that discipline increased in the next period.

Figure 4. Network of the research disciplines in Vietnam.

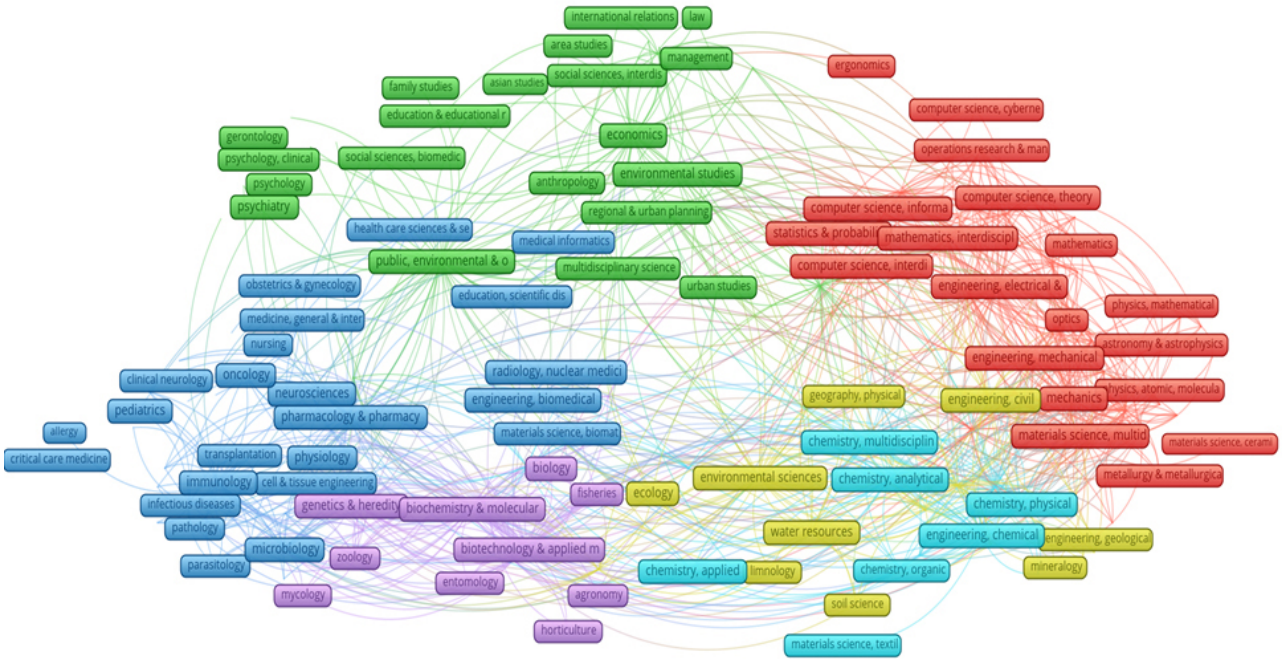


Table 2. Number of documents, documents with funding, and mean citation rate per document according to the number of research disciplines.

Characteristics	Number of research disciplines		
	1 discipline	2-3 disciplines	>3 disciplines
Documents (n)			
Before 1990	650	297	9
1990-1999	1070	863	61
2000-2014	8302	8139	529
2015-2020	22,723	18,260	1849
Documents with funding, n (%)			
Before 1990	0 (0)	0 (0)	0 (0)
1990-1999	24 (2.2)	45 (5.2)	0 (0)
2000-2014	4137 (49.8)	3993 (49.1)	289 (54.6)
2015-2020	14,305 (63)	12,498 (68.4)	1387 (75)
Mean citation rate per document			
Before 1990	5.56	8.01	9.00
1990-1999	18.82	21.34	10.28
2000-2014	28.35	26.08	24.87
2015-2020	12.43	12.69	12.92

Journals

Table S1 of Multimedia Appendix 1 shows the top 15 most active journals (of the 8354 sources of publications) in publishing researches from Vietnam based on the total number of publications. Overall, most of these journals were middle-ranking journals (second to third quartile according to the Web of Science classification). Consistent with the result above, the number of publications in these journals increased significantly from 2000 to 2020. Notably, in recent years, mega journals such as PLOS One, Scientific Reports, or Sustainability seem to be pervasive with a high number of publications from Vietnam compared to other specialized journals.

Contribution of Institutions and Localities

Table S2 in Multimedia Appendix 1 presents the top 20 most productive Vietnamese institutions. It should be noted that 1 author could have 2 or more addresses or could be affiliated with 2 or more institutions. Vietnam Academy of Science and Technology was the most productive institution (with 11,080 documents, accounting for 14.38% of the total national publications). Seventeen other institutions had more than 1000 documents published in international sources. Nine institutions were located in the northern region, while 8 institutions were located in the southern region, and 3 institutions were located in the central region of Vietnam. Among 20 institutions, only 2 universities (Ton Duc Thang University and Duy Tan University) were private institutions.

Table 3 depicts the geographical variations in the documents having Vietnamese scholars as the first author or as the corresponding author. In general, Hanoi, Ho Chi Minh City, Da Nang, Thua Thien Hue, Can Tho, and Thai Nguyen were the main cities with the highest number of publications that met this condition, and all of these cities had more than 1000 papers in total. These provinces also had the highest number of publications with Vietnamese scholars as corresponding authors. Notably, almost all provinces had lower mean citation rates among documents with Vietnamese as the first author and corresponding authors than the mean citation rate of 16.64 for all published documents in Vietnam, as shown in Table 3.

Table 3. Total number of documents and the mean citations per document in 63 provinces.

Order	Total number of documents			Vietnamese as the corresponding author			Vietnamese as the first author		
	Provinces	Documents (n)	Mean citation per document	Provinces	Documents (n)	Mean citation per document	Provinces	Documents (n)	Mean citation per document
1	Ha Noi	31,245	17.5	Ha Noi	13,929	9.6	Ha Noi	7968	7.5
2	Ho Chi Minh city	23,457	18.7	Ho Chi Minh city	12,995	13.3	Ho Chi Minh city	5527	7.3
3	Da Nang	5792	17.9	Da Nang	2449	13.0	Da Nang	543	6.6
4	Thua Thien Hue	1876	16.9	Thua Thien Hue	686	6.4	Thua Thien Hue	369	5.2
5	Can Tho	1646	16.9	Can Tho	459	7.6	Thai Nguyen	260	4.4
6	Thai Nguyen	1134	7.9	Thai Nguyen	372	6.1	Can Tho	242	5.5
7	Hai Phong	650	10.6	Nghe An	163	5.1	Nghe An	202	4.8
8	Binh Duong	465	10.2	Binh Duong	162	7.8	Thanh Hoa	155	7.3
9	Dong Thap	431	16.1	Binh Dinh	137	6.5	Binh Dinh	132	5.6
10	Khanh Hoa	411	14.9	Dong Thap	128	10.3	Binh Duong	109	4.4
11	Nghe An	400	7.6	Hai Phong	127	7.8	Lam Dong	94	6.2
12	Dong Nai	300	12.0	Bac Giang	103	8.9	Dong Thap	81	6.8
13	Binh Dinh	292	9.0	Khanh Hoa	96	11.8	Dong Nai	67	6.6
14	Thanh Hoa	279	10.4	Lam Dong	85	7.7	Hai Phong	65	2.6
15	Lam Dong	229	11.7	Dong Nai	78	8.7	Thanh Hoa	48	11.8
16	Vinh Phuc	204	7.0	Thanh Hoa	72	10.1	Quang Binh	37	6.5
17	An Giang	198	10.1	An Giang	60	5.5	Hung Yen	30	7.1
18	Hung Yen	194	8.2	Dien Bien	52	7.9	Son La	25	3.0
19	Dak Lak	174	10.7	Dak Lak	49	9.8	Dak Lak	24	9.0
20	Bac Ninh	173	16.3	Quang Binh	48	6.2	Ba Ria-Vung Tau	23	12.0
21	Phu Tho	155	12.2	Ba Ria-Vung Tau	43	13.7	An Giang	21	6.9
22	Quang Binh	138	6.4	Hung Yen	39	7.9	Phu Tho	19	4.5
23	Long An	133	6.9	Tra Vinh	38	4.6	Quang Nam	16	4.9
24	Thai Binh	132	34.2	Vinh Phuc	36	4.1	Tien Giang	14	3.0
25	Tra Vinh	132	6.5	Bac Ninh	35	16.4	Ninh Bình	10	8.3
26	Ba Ria-Vung Tau	128	11.1	Phu Tho	33	5.8	Tuyen Quang	10	3.7
27	Tien Giang	114	18.4	Son La	30	8.8	Phu Yen	8	1.3
28	Son La	113	93.0	Long An	23	6.7	Thai Binh	7	16.4
29	Hai Duong	105	6.8	Thai Binh	20	7.2	Hai Duong	6	0.5
30	Dien Bien	98	7.0	Phu Yen	19	6.5	Long An	6	4.0
31	Quang Tri	79	5.6	Quang Nam	17	5.8	Ninh Thuan	6	2.5
32	Quang Ninh	78	10.1	Hai Duong	15	6.8	Vinh Long	6	0.5
33	Ninh Binh	71	20.4	Tien Giang	14	6.9	Bac Ninh	5	18.4
34	Phu Yen	71	8.1	Tuyen Quang	13	2.4	Ha Tinh	4	0.0
35	Quang Nam	67	7.1	Kon Tum	12	6.8	Quang Ngai	4	1.5
36	Binh Thuan	50	19.2	Quang Tri	12	3.6	Quang Ninh	4	1.0

Order	Total number of documents			Vietnamese as the corresponding author			Vietnamese as the first author		
	Provinces	Documents (n)	Mean citation per document	Provinces	Documents (n)	Mean citation per document	Provinces	Documents (n)	Mean citation per document
37	Tuyen Quang	50	5.4	Vinh Long	11	0.9	Quang Tri	4	2.0
38	Vinh Long	50	7.6	Ninh Binh	10	9.9	Vinh Phuc	4	0.3
39	Quang Ngai	46	8.2	Ninh Thuan	8	2.8	Kien Giang	3	1.3
40	Kien Giang	44	11.3	Quang Ngai	7	5.4	Binh Thuan	2	1.5
41	Ninh Thuan	37	19.9	Ha Tinh	6	0.3	Ha Giang	2	2.0
42	Ha Tinh	33	8.6	Hau Giang	5	5.0	Ha Nam	2	6.5
43	Gia Lai	32	4.0	Nam Dinh	4	3.0	Kon Tum	2	24.5
44	Kon Tum	32	12.2	Ha Nam	3	7.3	Lao Cai	2	0.0
45	Nam Dinh	29	5.0	Kien Giang	3	3.3	Nam Dinh	2	0.0
46	Ha Nam	27	14.7	Quang Ninh	3	2.3	Soc Trang	2	20.5
47	Ca Mau	25	17.9	Binh Phuoc	2	2.5	Bac Giang	1	0.0
48	Lao Cai	24	5.6	Binh Thuan	2	8.0	Ben Tre	1	5.0
49	Hoa Binh	23	7.0	Hoa Binh	2	0.5	Ca Mau	1	0.0
50	Hau Giang	21	5.4	Lao Cai	2	0.0	Dien Bien	1	0.0
51	Soc Trang	19	10.7	Soc Trang	2	30.0	Gia Lai	1	0.0
52	Ben Tre	17	9.9	Yen Bai	2	3.0	Hau Giang	1	2.0
53	Bac Giang	16	6.1	Ben Tre	1	3.0	Lang Son	1	0.0
54	Binh Phuoc	16	12.3	Ca Mau	1	6.0	Tay Ninh	1	2.0
55	Lang Son	16	17.1	Gia Lai	1	1.0	Bac Kan	0	N/A[a]
56	Bac Lieu	15	6.3	Ha Giang	1	1.0	Bac Lieu	0	N/A
57	Ha Giang	11	8.5	Lang Son	1	5.0	Binh Phuoc	0	N/A
58	Tay Ninh	6	5.7	Bac Kan	0	N/A	Cao Bang	0	N/A
59	Yen Bai	6	13.7	Bac Lieu	0	N/A	Dak Nong	0	N/A
60	Lai Chau	4	1.3	Cao Bang	0	N/A	Hoa Binh	0	N/A
61	Bac Kan	2	4.0	Dak Nong	0	N/A	Lai Chau	0	N/A
62	Cao Bang	2	19.5	Lai Chau	0	N/A	Tra Vinh	0	N/A
63	Dak Nong	2	7.0	Tay Ninh	0	N/A	Yen Bai	0	N/A

[a]N/A: not applicable.

International Collaborations

According to the retrieved data set, Vietnam had collaborations with more than 200 countries and territories from 1966 to 2020. Table S3 in Multimedia Appendix 1 shows the top 15 most productive countries, which had collaborations with Vietnamese scholars. Based on the total number of publications (62,752 publication), South Korea ranked first with 3716 documents (5.9%), followed by Japan (3625/62,752, 5.8%), China (3388/62,752, 5.4%), and the United States of America (3049/62,752, 4.9%).

Figure 5 illustrates the networks of collaborations with Vietnam in research. The size of the box indicates the number of publications, while the thickness of the line shows the strength of the collaborations. The collaborations were divided into 4 clusters. The red cluster indicates strong connections with European (eg, Portugal, Greece, Turkey), African (eg, Ethiopia, Kenya), and South American countries (eg, Venezuela, Cuba). The green cluster is primarily formed by eastern and Southeast Asian countries (eg, South Korea, Japan, Singapore). The blue cluster includes countries from the Middle East (eg, Saudi Arabia, Iraq, Iran). The yellow cluster is formed by other countries (in no particular geographical grouping), including the United States of America, China, or France.

Table 4 shows the trend of the collaborative status in document publishing in Vietnam. In general, the levels of international collaboration in all 3 types, namely, first author, corresponding author, and collaborative status, have decreased significantly over time. The proportion of research with international authors being funded was significantly higher than that of studies with

only domestic authors, especially in the period of 2015-2020. Notably, studies with Vietnamese as the first or corresponding authors have a higher degree of influence (through citations) than those with foreign scholars as the first and corresponding authors.

Figure 5. Cooperation network of partner countries and Vietnam.

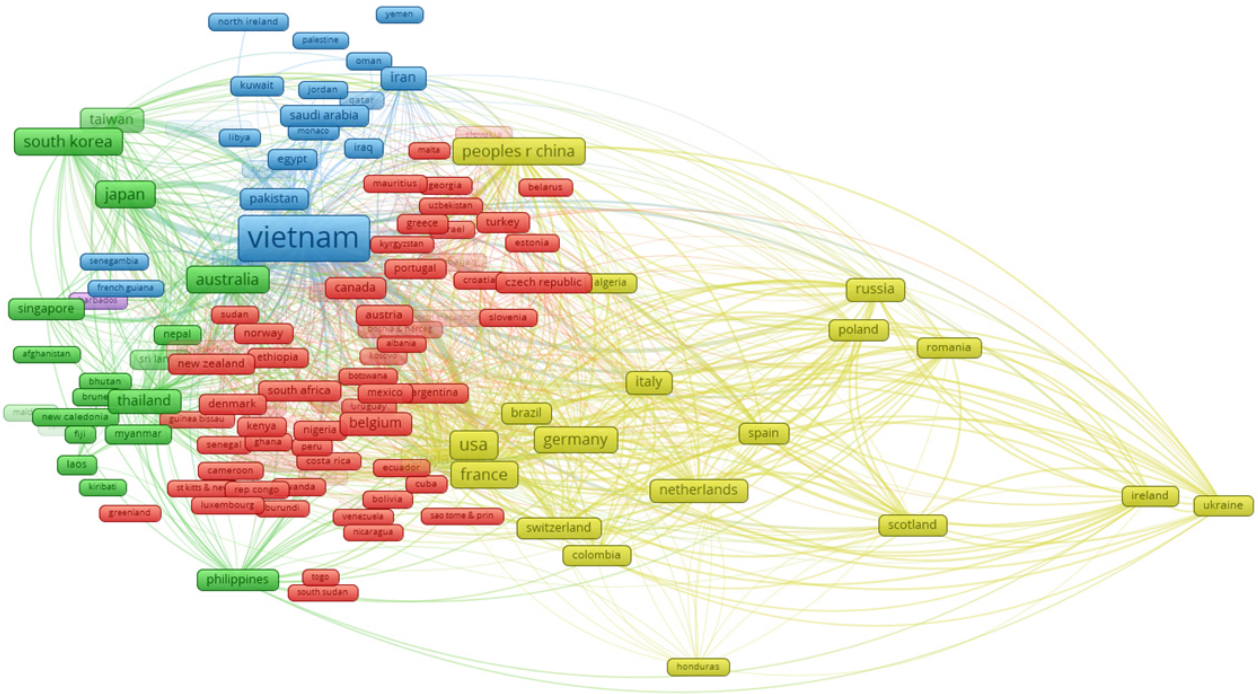


Table 4. Number of documents, number of documents with funding, and mean citation rate per document published from 1966 to 2020 in different periods.

Characteristics	First author			Corresponding author			Collaborative status		
	Domestic	International	Relative index[a]	Domestic	International	Relative index	Domestic	International	Relative index
Documents, n (%)									
Before 1990 (n=965)	4 (0.42)	952 (99.58)	238.00	513 (53.66)	443 (46.34)	0.86	20 (2.09)	936 (97.91)	46.80
1990-1999 (n=1994)	108 (5.42)	1886 (94.58)	17.46	749 (37.56)	1245 (62.44)	1.66	150 (7.52)	1844 (92.48)	12.29
2000-2014 (n=17,970)	3127 (18.43)	13,843 (81.57)	4.43	6303 (37.14)	10,667 (62.86)	1.69	3341 (19.69)	13,629 (80.31)	4.08
2015-2020 (n=42,832)	15,421 (36)	27,411 (64)	1.78	24,596 (57.42)	18,236 (42.58)	0.74	10,861 (25.36)	31,971 (74.64)	2.94
Documents with funding, n (%)									
Before 1990	0 (0)	0 (0)	N/A[b]	0 (0)	0 (0)	N/A	0 (0)	0 (0)	N/A
1990-1999	6 (5.56)	63 (3.34)	0.60	16 (2.14)	53 (4.26)	1.99	1 (0.67)	68 (3.69)	5.53
2000-2014	1739 (55.61)	6680 (48.26)	0.87	3247 (51.52)	5172 (48.49)	0.94	1609 (48.16)	6810 (49.97)	1.04
2015-2020	9713 (62.99)	18,477 (67.41)	1.07	15,177 (61.71)	13,013 (71.36)	1.16	6391 (58.84)	21,799 (68.18)	1.16
Mean citation rate per document									
Before 1990	2.25	4.10	1.82	3.96	2.39	0.60	5.80	0.55	0.10
1990-1999	13.99	5.66	0.40	10.45	9.20	0.88	8.09	11.56	1.43
2000-2014	18.82	8.34	0.44	18.45	8.70	0.47	13.33	13.82	1.04
2015-2020	8.30	4.26	0.51	9.34	3.22	0.34	5.69	6.87	1.21

[a]Relative index was calculated by dividing the proportion of documents with international collaboration to the proportion of documents with domestic collaboration or by dividing the mean citation rate per document with international collaboration to the mean citation rate per document with only domestic collaboration.

[b]N/A: not applicable.

Discussion

Overview

A knowledge-based economy requires a country to heavily invest in science and technology in addition to receiving technology transferred from other countries. Developing science and technology based on Vietnam's internal resources is an essential component for promoting economic growth and creating breakthroughs in productivity, quality, efficiency, and increasing competitiveness for sustainable socioeconomic development. This study reviewed the development of research performance in Vietnam in the period from 1966 to 2020, thereby identifying the trends in the development of science and technology in Vietnam, the contribution of research-oriented universities, and the discovering factors that need to be addressed to improve and enhance the science and technology capacity of Vietnam.

Principal Findings

Our results indicated that Vietnam's research productivity has been improving significantly, especially in the recent 5 years (from 2015 to 2020). This is reflected in the number of scientific documents in 2020 (13,691 documents), which increased by nearly 50% compared to that in 2019 (9415 documents). This can be explained by the fact that during this period, specific policies and activities aimed at promoting innovation in Vietnam from the government side as well as the formation of science funds have made significant contributions to the development of science and technology. In addition, in some research-oriented universities, policies on money rewards of universities and research institutes for scientific papers in international journals increased the motivation and research performance of Vietnamese researchers. However, despite the significant progress, the knowledge contribution of Vietnamese scholars is still modest compared to those in other countries even in the Association of Southeast Asian Nations region, such as Malaysia (24,423 documents in 2020), Thailand (16,697 documents in 2020), or Singapore (23,225 documents in 2020), according to statistics of the Web of Science database [19]. Furthermore, the number of scientific publications as of December 14, 2021 (12,783 publications) was almost equal to that in 2020, showing that science and technology activities in Vietnam are slowing down [19]. This phenomenon could be attributable to the COVID-19 pandemic; however, it might be a concerning indicator showing that current policies are being saturated. Therefore, a breakthrough in the development policy is

necessary for promoting Vietnam's science and technology and the contribution of research-oriented universities in Vietnam.

With a large population (nearly 100 million people) and large socialization resources from the private sector, Vietnam's potential for science and technology development is substantial. However, in Vietnam, the proportion of higher education (eg, undergraduate, postgraduate education) accounts for less than 30%, and the rate of the population engaged in research and development activities was only 887 people per million people in 2017, which is much lower than that in Thailand (1632 per million people in 2016) or Malaysia (2859 per million people in 2016) [8]. In addition, the results of this study showed that the role of private research institutions was not strong in the period of 1966-2020. In the top 20 research institutions with the highest scientific productivity, there were only 2 private universities. A report by the Ministry of Science and Technology showed that the innovation level of private organizations in Vietnam was lesser than expected when compared to that in other countries with similar income per capita; for example, only 53% of Vietnamese innovators informed new products in the market, while this proportion was 75% in Malaysia and 86% in Thailand [8]. This can be explained by the fact that the majority of private universities are mainly application-oriented universities, which were suitable for career guidance, while there were only few research-oriented universities [20]. However, currently, many private universities have announced the development of strong research groups with large investments. This is a model that has proven effective in other countries around the world [21-24]. Therefore, the launch of private universities in the science and technology map of Vietnam is expected to be more common in the coming period.

Findings in the analysis of journals and citations depicted those Vietnamese studies that were mainly published in middle-ranking journals. In addition, although research quality had improved with an increase in the mean number of citations per document over the years, this level is still not comparable to that in other countries in the Association of Southeast Asian Nations region [12]. Promoting interdisciplinary research is an effective way to improve research quality [25,26]. In this study, the results showed the shift in the priority research fields of Vietnam over the period of this study. In the period before 2015, research topics focused on theoretical areas such as mathematics or physics. However, in the recent period, research has been performed and published more frequently in the experimental and applied fields. Interdisciplinary and multidisciplinary research has been becoming a trend gradually in response to the increasingly complex domestic and international contexts. The involvement of multidisciplinary fields aids to solve problems from different aspects of issues, thereby significantly improving the quality of research. For example, research related to the topic of COVID-19 in 2020 involved the fields of biomedicine, bioinformatics, and mathematics to build epidemiological models for early warnings [27]. Therefore, policies that promote multidisciplinary and interdisciplinary research should also be included in science and technology policies.

International publications are contributed by major academic centers in major localities such as Hanoi, Ho Chi Minh City, Da Nang, Hue, Thai Nguyen, and Can Tho. This can be explained by the low level of English literacy of scientists in other localities [28]. However, this is mainly due to limited resources being available, and most of the resources are distributed in the provinces where strong research centers are concentrated. This may lead to a lack of science and technology development in other regions, especially in the mountainous and coastal provinces. However, these are the localities with specific scientific research problems that are valuable in contributing to global knowledge. Indeed, scientific evidence on natural and sociocultural issues in these vulnerable localities in the Web of Science Core Collection database is still limited. Therefore, developing key science programs to promote research strengths in these regions should be prioritized in national science and technology agendas. In addition, the cooperation network between strong research centers and local research units should be strongly encouraged to improve the scientific productivity and scientific research capacity of research institutions in these less developed regions.

Similar to those in previous analyses, findings in this study showed that despite a gradual decline in recent years, the contribution of international collaborations to the total number of publications is huge (through the position of the first author, corresponding authors, and fundings) [7,22,23]. This is especially true in empirical research fields, which require great investment in equipment and technology as well as technology transfer activities from countries with more advanced science. In practice, international collaborations are indispensable for promoting science and technology. These partnerships facilitate access to high-quality human, financial, and infrastructure resources for conducting research [29]. This is reflected in that documents with international collaborations had a higher mean citation per document than documents with only domestic collaborations. This result is similar to that reported in some previous studies, which showed that studies with international collaborations received more attention and had more citations [30,31]. Therefore, participating in global scientific and technological networks and calling for the participation of scientists around the world is essential. Noticeably, from 1990 onwards, documents with Vietnamese as the first author and corresponding author had higher mean citations per document in comparison with documents in which international scholars were the first or corresponding authors. This interesting result further confirms that the role of Vietnamese in leading research should be promoted.

Implications

This study had several implications for developing policies to improve science and technology not only in Vietnam but also in other low-income countries with a similar socioeconomic background. Currently, Vietnam is facing 2 major challenges. In the global context, the post–COVID-19 pandemic economic downturn and the rapid change in science and technology during the Fourth Industrial Revolution have greatly influenced the development of Vietnam owing to the country's strong participation in the global economy [8]. In the domestic context, the shortage of high-quality human resources, limited financial resources, and inappropriate policy mechanisms are the critical barriers to research and innovation. According to a report by

the Ministry of Science and Technology of Vietnam and the World Bank, in the coming years, Vietnam will spend at least 2% of gross domestic product on science and technology activities as well as increase the number of people participating in science and technology activities from 887 people per million people to 1100-1200 people per million people [8]. However, national and regional science and technology development plans need to develop strategic activities. Lessons learned from this study suggest that in Vietnam as well as in other countries with similar background, promoting multidisciplinary research and local research network to address local demands, developing rigorous and transparent mechanisms for science and technology activities to meet the international standards, improving socialization in research, as well as actively participating in the global science and technology network would be the solutions for the development of science and technology in the long run.

Strengths and Limitations

One of the strengths of this study is the detailed analysis of the characteristics of every single document, regarding authors, journals, citations, and affiliations. Besides, we analyzed the publications in Vietnam for a long period (from 1966 to 2020), which allowed us to understand the patterns of publication growth and collaborations in Vietnam. However, several limitations should be acknowledged. First, our analysis was mainly based on the Web of Science data set with English language documents. Thus, documents from sources that were not indexed in the Web of Science database were not included. Second, given the constrained English knowledge of Vietnamese scholars, our analysis might underestimate the true science and technology output in Vietnam. More rigorous studies with other databases, different languages, and other methods (such as desk review or qualitative interviews) for measuring science and technology should be performed to elucidate the status of science and technology in Vietnam as well as in other countries.

Conclusion

Our study highlights the substantial growth in the Vietnamese scientific output from 1966 to 2020. The published documents were mainly concentrated in several strong scientific research institutions in a few localities of Vietnam and were often published in middle-ranking journals. International collaborative studies played a major role in improving the quality of research, but Vietnamese-led studies were more influential than other studies led by international authors. Building networks of local and international researchers for addressing specific local issues, promoting the participation of private sectors, and developing science and technology mechanisms are critical for boosting the research productivity in Vietnam.

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Authors' Contributions

BXT, LHN, and RCMH conceptualized this study. BXT, HASN, TMTV, ALD, and NTNK curated the data for this study. BXT, HASN, TMTV, ALD, and TTHT performed the formal analysis for this study. BXT, LTKN, CL, CSHH, and RCMH conducted the investigations for this study. BXT, LHN, HASN, ALD, and NTNK contributed to the methodology of this study. BXT, CSHH, and RCMH supervised this study. BXT, TMTV, LTKN, NTNK, TTHT, and CL wrote the original draft. BXT, LHN, LTKN, TTHT, CL, and CSHH reviewed and edited this paper.

Conflicts of Interest

None declared.

Multimedia Appendix 1
Supplementary data.
[DOCX File , 24 KB - ijmr_v11i2e38591_app1.docx]

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Review

In-Home Monitoring Technology for Aging in Place: Scoping Review

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Abstract

Background: For successful aging-in-place strategy development, in-home monitoring technology is necessary as a new home modification strategy. Monitoring an older adult's daily physical activity at home can positively impact their health and well-being by providing valuable information about functional, cognitive, and social health status. However, it is questionable how these in-home monitoring technologies have changed the traditional residential environment. A comprehensive review of existing research findings should be utilized to characterize recent relative technologies and to inform design considerations.

Objective: The main purpose of this study was to classify recent smart home technologies that monitor older adults' health and to architecturally describe these technologies as they are used in older adults' homes.

Methods: The scoping review method was employed to identify key characteristics of in-home monitoring technologies for older adults. In June 2021, four databases, including Web of Science, IEEE Xplore, ACM Digital Library, and Scopus, were searched for peer-reviewed articles pertaining to smart home technologies used to monitor older adults' health in their homes. We used two search strings to retrieve articles: types of technology and types of users. For the title, abstract, and full-text screening, the inclusion criteria were original and peer-reviewed research written in English, and research on monitoring, detecting, recognizing, analyzing, or tracking human physical, emotional, and social behavior. The exclusion criteria included theoretical, conceptual, or review papers; studies on wearable systems; and qualitative research.

Results: This scoping review identified 30 studies published between June 2016 and 2021 providing overviews of in-home monitoring technologies, including (1) features of smart home technologies and (2) sensor locations and sensor data. First, we found six functions of in-home monitoring technology among the reviewed papers: daily activities, abnormal behaviors, cognitive impairment, falls, indoor person positioning, and sleep quality. Most of the research (n=27 articles) focused on functional monitoring and analysis, such as activities of daily living, instrumental activities of daily living, or falls among older adults; a few studies (n=3) covered social interaction monitoring. Second, this scoping review also found 16 types of sensor technologies. The most common data types encountered were passive infrared motion sensors (n=21) and contact sensors (n=19), which were used to monitor human behaviors such as bodily presence and time spent on activities. Specific locations for each sensor were also identified.

Conclusions: This wide-ranging synthesis demonstrates that in-home monitoring technologies within older adults' homes play an essential role in aging in place, in that the technology monitors older adults' daily activities and identifies various health-related issues. This research provides a key summarization of in-home monitoring technologies that can be applied in senior housing for successful aging in place. These findings will be significant when developing home modification strategies or new senior housing.

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KEYWORDS

in-home monitoring; aging in place; ambient assisted living; home modification; monitoring; aging; technology; intervention; older adult; wellness; independence; monitor; research; sensor; activity; behavior; cognitive; sleep

Introduction

Background

As all of the "baby boomer" generation approaches exceeding the age of 65 years, by 2030, they will proportionally expand the older population in the United States, thus becoming a super-aged society in which older individuals will comprise more than 20% of the population. The US Census Bureau data project that by 2060, the 65-and-older population will total 98 million [1]. A recent American Association of Retired Persons survey in the United States indicated that 79% of older adults want to remain in their current home and community as they age [2]. The desire of older individuals to independently and safely remain in their homes and communities is referred to as *aging in place*. Successful aging in place supports the positive experience of an individual's identity in that it helps to improve their independence and autonomy in their homes and community. Additionally, aging in place positively impacts older residents' health and well-being. According to the Center for Housing Policy [3], approximately 80% of seniors have at least one chronic health condition and 50% have at least two. Many older adults with functional or cognitive decline have difficulties in living independently when performing basic daily activities in their homes. These challenges may reduce successful aging in place because their homes might fail to support their changing needs and gradually become dangerous environments for independent living.

Home modification positively affects older adults' ability to age in place because it renders their homes safer and more accessible to both themselves and visitors, thus improving comfort and reducing accidents such as falling [4]. Home modifications, considered a promising tool for aging in place, are most beneficial when they provide tailored interventions for older adults that take into account specific health conditions such as mobility, cognitive impairment, and eye impairment, among others [5]. Thus, to support changing needs, it is important to understand how older adults interact with their residential environments.

Smart home technologies have been considered essential interventions that enable older adults to maintain wellness and independence at home [6,7]. Smart home technologies, representing a variety of sensors and devices integrated into the home infrastructure, provide a wide range of features for enhancing quality of life, from simple home automation to monitoring wellness [6]. Home automation provides remote or automatic controls for devices, appliances, or home systems that enhance an occupant's quality of life in terms of entertainment and energy-saving. In-home monitoring can be employed to monitor an occupant's health status and maintain a sense of well-being.

In particular, monitoring an older adult's daily physical activity at home can provide valuable information about their functional, cognitive, and social health status; such monitoring information can indicate the individual's ability to maintain function and independence at home [6]. With technological advancements proceeding at an unprecedented rate, smart home technologies such as the Internet of Things and ambient intelligence have become more intertwined with the fabric of everyday life and the environment. Technologies that monitor older adults' health are easily accessible at affordable prices and constitute an active research area. For the development of a successful aging-in-place strategy, in-home monitoring technology is necessary as a new home modification strategy, which can positively impact older adults' health and well-being. However, there is a huge knowledge gap between what in-home monitoring technologies are currently available and how these technologies can be incorporated into older adults' homes. Although many review papers have described existing smart home monitoring technologies for older adults, they focused on the technological perspectives of in-home monitoring technologies, such as systems, networks, and computational frameworks. There are limited resources available that architects and designers can use for developing a smart home for successful aging in place. Moreover, it is questionable how these smart technologies have changed the traditional residential environment. Thus, to ultimately enable older adults to achieve successful aging in place, a comprehensive review of existing research findings is needed to characterize recent relative technologies and to inform design considerations.

Aim of the Study

The main purpose of this study was to classify recent smart home technologies that monitor older adults' health and to architecturally describe these technologies as they are used in older adults' homes. The following research questions served as a guide for the study: (1) What in-home monitoring technologies are currently available for older adults? (2) Where can in-home monitoring technologies be installed and why are they used?

The findings of this research will provide empirical evidence of smart technology's impact on aging in place, and help designers transform and tailor older adults' living environments appropriately for the implementation of various technologies. This research will benefit various aging-in-place stakeholders, including older adults, family caregivers, clinicians, designers, public health practitioners, and policymakers.

Methods

Overview

The scoping review method was employed to identify key characteristics of in-home monitoring technologies for older adults. This method can be used to summarize underexplored research areas and determine the nature of specific topics, identifying research gaps that remain after previous studies. This study was developed according to the methodological guideline for scoping reviews [7]: identifying relevant studies;

study selection; charting the data; and collating, summarizing, and reporting results.

Identifying Relevant Studies

In June 2021, four databases, including the Web of Science, IEEE Xplore, ACM Digital Library, and Scopus, were searched for peer-reviewed articles pertaining to smart home technologies used to monitor older adults' health in their homes. The following keywords were applied when searching: ("Smart home" OR "gerontechnology" OR "monitoring" OR "ambient assisted living" OR "unobtrusive sensors" OR "in-home monitoring") and ("Older adults" OR "Aging" OR "Ageing" OR "Elderly" OR "Senior" OR "Aging in Place"). To ensure the retrieved articles were up to date, the publishing span was limited to articles bearing dates between June 2016 and 2021.

Study Selection

This scoping review was performed according to the PRISMA-ScR (Preferred Reporting Items for Systematic Reviews and Meta-Analyses extension for Scoping Reviews) guidelines [7,8], and involved a wide-ranging literature search for information on in-home monitoring technologies for older adults, employing multiple search strategies. For the title, abstract, and full-text screening, the inclusion and exclusion criteria were developed as shown in Textbox 1. This review excluded wearable sensors even though they are an important part of the monitoring strategy for older adults. This exclusion criterion was established owing to the usability barriers of these devices. For example, older adults with cognitive impairment may have difficulty in using a wearable sensor because these devices must be worn on a regular basis.

Textbox 1. Inclusion and exclusion criteria.

Inclusion criteria

- Original and peer-reviewed research
- Paper written in English
- Research on monitoring, detecting, recognizing, analyzing, or tracking human physical, emotional, and social behavior
- Research with human subjects

Exclusion criteria

- Theoretical, conceptual, or review papers without empirical data or demonstrations
- Wearable systems
- Qualitative research

Charting the Data

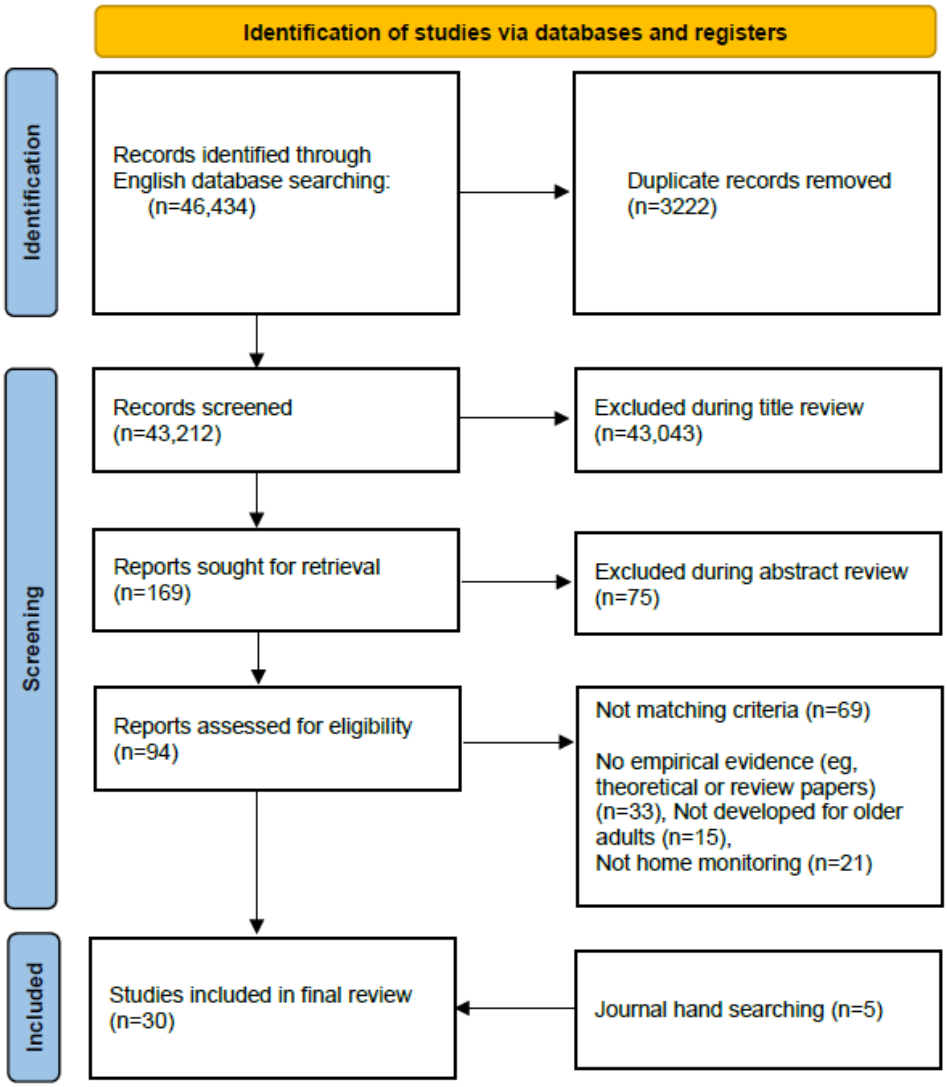
In response to the two research questions, (1) types of in-home monitoring technologies for older adults and (2) specifications of the sensors (eg, location and data), deductive thematic analysis was employed. Two authors (DK and HB) extracted data from the identified articles using an Excel file. The form included the following six factors: (1) purpose, (2) sample, (3) settings, (4) technologies, (5) technology type, and (6) outcome.

Results

Overview

As illustrated in the PRISMA flow diagram in Figure 1, the literature search found 43,212 titles on four databases after removing 3222 duplicates; 94 papers remained after titles and abstracts were reviewed, and those that were not germane to the study were eliminated. Subsequently, the 94 full texts were reviewed and an additional 69 were excluded based on the inclusion and exclusion criteria. Five additional articles were found through a manual search. A total of 30 research articles were finally included and used in the review. The overview of the 30 included articles is provided in Multimedia Appendix 1.

Figure 1. Flow diagram for the systematic scoping review.

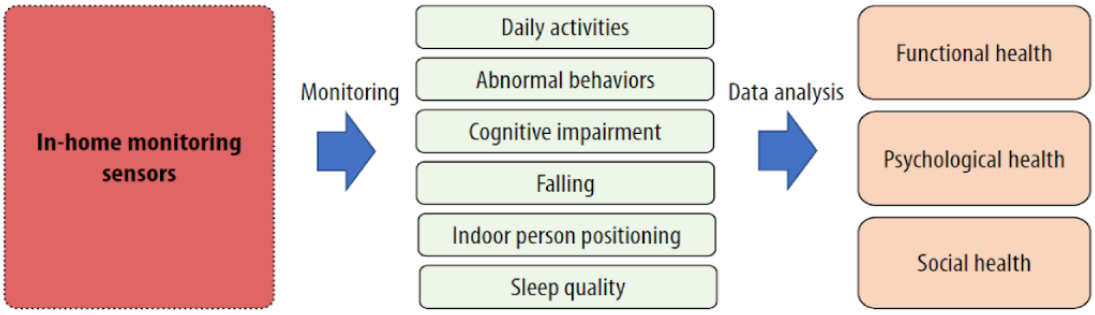


Features of Smart Home Technologies

First, to identify currently available in-home monitoring technology for older adults, it is important to understand the types and functions of in-home monitoring technology. Demiris et al [9] classified smart home technology types and functions for an aging society as follows: (1) physiological monitoring, involving data collection and analysis of physiological measurement data such as blood pressure and pulse; (2) functional monitoring/emergency detection and response, involving data collection and analysis of functional measurement data such as those associated with daily activities; (3) safety monitoring and assistance, involving data collection and analysis of environmental hazards such as flooding and fire; (4) security monitoring and assistance, involving data collection and analysis of human threats such as those associated with security alarms; (5) social interaction monitoring and assistance, involving data collection and analysis of social interactions such as those associated with computer (online) or phone usage; and (6) cognitive and sensory assistance, involving assistive technologies to compensate for memory deficits such as reminders or task instructions.

All of the reports reviewed (N=30) discussed how in-home monitoring technologies can be used to monitor older adults' activities, as well as how to analyze and detect daily activity anomalies through machine-learning algorithms. Most of the research (n=27) focused on functional monitoring and analysis, such as activities of daily living (ADLs), instrumental activities of daily living (IADLs), or falls among older adults; a few (n=3) covered social interaction monitoring. This scoping review found six functions of in-home monitoring technology among the reviewed papers: daily activities, abnormal behaviors, cognitive impairment, falls, indoor person positioning, and sleep quality (Figure 2).

Figure 2. Features of smart home technologies.



Monitoring Daily Activities

Six of the examined investigations monitored and observed older adults' daily activities in their homes using sensor technologies, and demonstrated the feasibility and reliability of ambient home-sensing platforms in older adults' residences [10-15]. One case study reviewed had installed sensors in older adults' homes and analyzed the participants' behaviors (eg, sleeping, cooking, water usage) by advanced models and algorithms for 3 months. The smartphone and computer application system used was capable of reminding the older residents to take their medications if they forgot. A contact sensor installed near the medicine box made this possible [14]. Another reviewed study monitored older adults' activities in their homes and asked them to confirm their activities using a mobile app to validate sensor data analysis [11]. The findings showed that sensor data accurately matched the self-survey.

Monitoring Abnormal Behaviors

Seven studies were included that identified older adults' functional, psychological, and social abnormal activities such as unexpected and irregular behaviors using in-home monitoring technologies and machine-learning algorithms [16-22]. For example, movement at 3 AM in a living room can be considered abnormal behavior if monitoring data showed that older residents usually wake up at 6 AM every morning.

Two studies examined a unique methodology to detect the functional health decline of older adults using a public data set from smart home testbeds at the Center for Advanced Studies in Adaptive Systems (CASAS) [19,22]. The machine-learning algorithms developed in these studies successfully detected deviations from the long-term activity patterns of older adults living alone, and demonstrated the feasibility of detecting functional decline, singular deviation, and slow-deviating trends away from a previous activity routine. Another study detected anomaly behavior from learned ADL patterns and sent a push-button indicator to older adults when abnormal behaviors were detected. The investigation results validated the success of the model [21]. This type of in-home monitoring technology was also shown to be beneficial to caregivers caring for older adults who are living alone [20]. The home care monitoring system warned caregivers if an unusual behavior was detected based on learned behavioral patterns (eg, no motion was detected in the living room until 8:30 AM).

The common assumption in abnormal behavior detection research is that older adults follow regular routines in their homes and that irregularities are abnormal. However, routine-based anomaly detection fails if monitored older adults have irregular daily routines. To address this issue, another research team [17] assumed that illness can cause changes in activity levels, time, and locations of older adults. For example, those who feel unwell may spend an unusual amount of time watching television or they may walk more slowly than normal. Research findings have shown that heatmap analysis effectively detects unusual behavior determined by activity trajectories, and that it successfully distinguishes between normal and abnormal days with 88% accuracy [17].

Previous research has demonstrated the possibility of assessing psychological and social health conditions such as depression, emotional states, and even loneliness through a unique data analysis using sensor data of older adults' home activities. In-home monitoring sensors were used to measure daily out-of-home hours, number of phone calls, computer use, walking speed, and mobility, and loneliness was also assessed during four separate periods [16]. The investigators found a significant relationship between predicted loneliness and observed loneliness, demonstrating that it is possible to estimate older adults' loneliness by analyzing sensor data. Other studies [18] have estimated older adults' depression levels by analyzing daily activities, demonstrating that proposed algorithms can effectively detect depression with up to 96% accuracy.

Monitoring Cognitive Impairment

Many investigations have introduced unique sensor technology and machine-learning algorithms to detect older adults' cognitive impairments by analyzing daily activities at home [23-27]. Researchers at an ambient assisted living lab invited two older adult groups—healthy older adults and older adults with mild cognitive impairment (MCI)—to participate in the study and monitored their behaviors [26]. Participants were asked to complete five tasks in different areas of their homes; sensor technology measured the total amount of time used to perform each task. Sensor-based observation showed that the MCI group spent more time in the kitchen looking into the refrigerator and cabinets than the healthy group. This observation provides a possible means for detecting age-related cognitive decline by monitoring performance and comparing it to IADLs. Various machine-learning models have been developed to identify older adults' cognitive decline by utilizing a public data set from CASAS and the Oregon Center for Aging and Technology (ORCATECH) [23,25,27]. Employing various statistical models, the developers demonstrated the possibility of detecting

cognitive impairments and identifying early signs of dementia with a high degree of accuracy using in-home behavior data.

Other researchers [24] developed simple nonpharmacological interventions for older adults with MCI to address abnormal behaviors related to problems such as sleep disturbance and medication interference, and demonstrated the usability and effectiveness of monitoring technology. For example, a 12-week pilot study with five older adults with dementia introduced sensor-based technology designed to guide or redirect their participants prone to nighttime wandering toward the bedroom or bathroom using smart lighting and speakers. The results demonstrated that the technology employed improved the nighttime safety of people with dementia, and also showed that depression and anxiety among caregivers had been significantly reduced.

Monitoring Falling

In-home monitoring technology has also been designed to detect older adults' falls in their homes [28-35]. We found two types of fall detection technology: vision-based and nonvision-based technologies.

Lotfe et al [32] utilized computer vision–based fall detection technology with a Kinect sensor, and found the approach to be highly reliable and accurate after analyzing recorded images of falls taken by older adults and their daily activities [32]. Other researchers developed a low-cost fall detector system composed of a camera and artificial vision algorithms, which also detected falls with a high degree of accuracy (>96%) [33]. Yet another study employed a Kinect sensor that effectively identifies the human skeleton, which can be used to monitor the gestures and posture of the human body [35]. The researchers placed two Kinect sensors in a bedroom and recorded various video images, including falling. The proposed algorithms were highly accurate in detecting falls and could predict falling risk after analyzing the posture and movement of a participant.

In addition to the aforementioned image-based falling detection strategies, many investigations have explored nonimage-based means to accomplish the same goal while addressing privacy concerns. Since older adults' gait levels are significantly related to fall risk, Muleidat and Tawalbeh [31] developed a 128-sensor "smart carpet" to monitor gait parameters and detect falls. They demonstrated that their algorithm can successfully detect older adults' falling risk as well as monitor functional decline in real time. Recently, radar-based human motion–detecting technologies have gained the attention of researchers owing to their capacity to detect postures off micro-Doppler signatures reflected by the human body. Utilizing this technology, a fall detection system was developed based on a millimeter-wave radar sensor used in conjunction with the line kernel convolutional neural network deep-learning model [30]. The system could identify a falling sequence using passive baseband data collected directly by the radar sensor with 98.74% accuracy and an average prediction time of 51.4 milliseconds. Similarly, Ding et al [28] proposed a fall detection method based on a millimeter-wave radar sensor with a k-nearest neighbor algorithm, demonstrating a high (90.83%) accuracy rate.

Fall detection systems that utilize existing in-home infrastructures such as WiFi networks have been reported. Hu et al [29] proposed an environment-independent passive fall detection system called "DeFall." Their strategy was to analyze WiFi signal interference patterns created when a falling motion occurs. After extracting such signal patterns from the channel state information of the WiFi packets, augmented dynamic time warping algorithms were embedded to identify the acceleration patterns for a typical human fall. Their prototype achieved a detection rate of 95% in either a line-of-sight or a nonline-of-sight case using only a couple of WiFi transceivers. In addition, a few studies have focused on specific risks such as staircase and bed fall risks and detections. A bed monitoring system was developed based on infrared and pressure sensors that were preinstalled on the bed frame [34]. The sensor system successfully detected specific transitions of five typical movements associated with bed use at home (lying, sitting, standing, and exiting), and was shown to be highly effective with a detection accuracy rate of nearly 90%.

Indoor Person Localization

One essential feature of in-home monitoring is the ability to locate the end user in a real-time manner [36,37]. In most scenarios, especially in digital health settings, location information helps the ADL recognition system infer a human subject's activity based on their most recent activity. Additionally, based on the user's current location, this feature enables the entire smart ecosystem to react and provide corresponding services that are available within the setting. Studies have utilized numerous technologies to provide an indoor localization service.

A multisensor human subject localization solution was proposed to incorporate various combinations of sensing devices, including radiofrequency identification transceivers, infrared, touch, and light sensors, that are mounted on furniture and appliances in the environment [36]. This unobstructed system is leveraged by adopting probabilistic models such as Bayesian network and k-nearest neighbors to infer the likelihood of the human subject's presence within the monitoring space given the context values provided by the sensory combinations. Experimental results have shown that the system can achieve submeter localization accuracy and further provide indoor tracking capability. Alternatively, as an extended feature of the smart carpet approach mentioned above, studies have also been utilizing the concept of "smart floors," which are embedded with pressure-sensing devices to perform indoor localization and tracking. Lan et al [37] recently proposed implementing such a feature with advanced pressure-sensing technologies and they constructed a complete smart floor prototype for indoor localization demonstration. The system was modeled with a Bayesian inference–based decoding scheme and could perform mutisubject real-time localization under submeter accuracy.

Monitoring Sleep Quality

One reviewed study assessed and predicted older adults' sleep quality using behavioral data. Since sleep quality plays an essential role in older adults' health and well-being, early sleep disorder detection can be very important when addressing sleep-related issues. It has been demonstrated that a simple

sensing technology and data analysis algorithm can effectively monitor older adults' sleep-wake conditions and assess sleep quality [38]. The proposed sensing environment could monitor sleep duration, sleep latency, and awakenings during the night, and found a strong correlation between surveyed data about older adults' sleep quality provided by social workers and the investigators' proposed sleep quality data.

Sensor Data and Sensor Locations

This review identified 16 types of sensor technologies and the specific location of each technology. Table 1 provides an overview of the sensor data and sensor locations.

Table 1. Overview of sensor data and locations.

Sensors	Number of articles	Data	Location
PIR[a] motion sensor	21	Duration of specific activities and walk speed	Room areas (ceiling or walls of rooms)
Contact sensor	19	Occupancy of rooms or usage of items	Doors/windows, drawers, cabinets, medical boxes, refrigerators, etc
Pressure sensor	13	Duration of specific activities (eg, sleeping, resting)	Chairs, couches, floor, and beds
Light sensor	11	Lighting usage	Room areas (walls of rooms)
Temperature sensor	9	Indoor temperature	Bedroom, living room, kitchen
Electric sensor	9	Electricity usage, use of electrical appliances	Televisions, heaters, air conditioners, and lights/switchboard
Water sensor	6	Water usage	Kitchen and bathroom (water channels, kitchen floors, toilet bowls, sinks, and bathtubs)
Humidity sensor	5	Indoor humidity	Rooms (close to air conditioners)
Depth camera	3	Body image (gestures and postures) and presence	Rooms (corners of rooms)
Kinect motion sensor/infrared camera	2	Body image (gestures and postures) and presence	Rooms (walls of rooms)
Millimeter-wave frequency modulated continuous wave radar (FMCW)	2	Body posture and motion	Rooms (walls or static furniture)
Smart carpet	2	Falling, gait, positioning, and sociability	Room areas (floor)
Computer monitor	1	Daily computer use	Computer monitoring
Phone monitor	1	Daily phone use	Each phone

[a]PIR: passive infrared.

The most common data types encountered were passive infrared (PIR) motion sensors (n=20) and contact sensors (n=19), which were used to monitor human behaviors such as bodily presence and time spent on activities. The presence of PIR motion sensor monitors in each area captured the duration of specific activities such as cooking, eating, nighttime toileting activities, and similar. Four sensors arranged in a straight line 2 feet apart also monitored older adults' mobility [16]. They were usually installed on the walls or ceilings. The range of the sensors varied, but on average, a single detector ranged up to 30 feet.

Contact sensors, also called magnetic switch or reed sensors, use magnetic flow to monitor a particular activity such as opening and closing a door, cabinet, window, or refrigerator. A signal is generated when two magnets near each other are distanced. Sensors are placed on doors, windows, drawers, or cabinets, and they monitor room occupancy or use of items such as medical boxes and refrigerators. Both PIR motion sensors and contact sensors provide information about older adults' specific activities within their home, allowing machine-learning analysis to better understand older adults' physical, psychological, and social health within their homes. Pressure sensors (n=12) monitor residents' use of specific furniture pieces such as chairs and beds by detecting transitional movement. Sensors discussed in the reports were installed under beds, chairs, or couches to monitor specific behaviors such as sleeping and sitting.

Many investigations also used a variety of environmental sensors to detect and measure light (n=10), temperature (n=9), electricity (n=9), water (n=6), and humidity (n=5). For example, light sensors captured lighting usage and were installed in each room. Electric sensors connected to electrical outlets were used to monitor electricity consumption and electrical appliance usage such as televisions, heaters, and air conditioners. A water sensor was used to measure the frequency of water usage in a kitchen and bathroom water channel.

Depth cameras (n=3), Kinect motion sensors (n=2), and radar sensors (n=2) installed on a wall or corner of each room were also used to capture specific body images such as gestures and postures. Depth cameras have several advantages compared to PIR motion sensors when monitoring older adults' activities. Since a depth camera can detect specific information such as

movement, it can handle the presence of several individuals within a space, whereas a motion sensor can detect only one individual at a time. In addition, depth cameras can distinguish animals from humans. Depth camera use for human motion analysis has become an active area of research; it can recognize particular actions, falls, and other useful behaviors. Similarly, a radar sensor can be used to detect falls and can be attached to an indoor wall or piece of static furniture at a height of around 1.5 meters. One study used computer and phone monitor sensors to monitor daily computer and phone use; the information was then used to understand the social health of older adults [16]. A smart carpet was introduced to monitor older adults' gait levels and falling episodes [31].

Discussion

Principal Findings

The aim of this investigation was to identify recent smart home technologies that monitor older adults' health and to architecturally describe these technologies as they are used in older adults' homes. This scoping review identified 30 studies focusing on in-home monitoring technology for older adults and identified key factors: types and functions of in-home monitoring technologies, the usefulness of in-home monitoring technologies, types of activity and behavior monitored by in-home monitoring technologies, and specific locations of sensing technologies. Here, we aim to extend the research findings into the implications of the identified in-home monitoring technologies to older adults' homes.

First, this review found that in-home monitoring technologies can play a pivotal role in establishing successful aging in place, and that these technologies should be considered when developing home modification plans for older adults. Understanding an older adult's daily activities at home is particularly critical for aging in place because changes in health status are usually determined through changes in ADLs or IADLs. Health assessments are important for older adults because they provide a basis for health professionals and caregivers to address unique health-related needs. Although health assessments generally need to be provided by highly skilled professionals, this study shows that many assessments have been accomplished via older adults' self-reports or those of their caregivers. Nevertheless, accurately measuring older adults' functional, psychological, and social health conditions through a self-survey has limitations [39], especially those completed by older adults with MCI.

In-home monitoring technology can be beneficial to both older adults needing help with daily living and their care providers. Various sensor technologies are capable of monitoring older adults' activities with a high degree of accuracy and reliability. Furthermore, the collected sensor data provide a machine-learning analysis that can offer a comprehensive overview of the older adult's health condition and ability to function independently within the home. Sensor technologies and unique data analysis methods can automatically identify older adults' hidden wellness parameters such as abnormal behavior, cognitive impairment, falling, and sleep quality. Health abnormality identification is of paramount importance in that the early identification of change enables older adults to receive early intervention that can play a pivotal role in minimizing the risk of further health decline. Much of the published research reviewed for this study demonstrated that in-home monitoring technologies can predict risks to older adults' physical, cognitive, psychological, and social health.

One of the critical issues in aging in place is the lack of formal support caused by the current professional caregiver shortage. Family members who bear the heavy burden of care for older adults often experience physical, emotional, social, and financial challenges. It is difficult to care for an older adult who has a cognitive impairment, especially those who wander at night, which is a major cause of caregiver burnout. Sensor-based technology has the capacity to monitor older adults' daily activities, falls, nocturnal restlessness, and eating behavior, thereby reducing caretakers' burden of care as well as accompanying stress and anxiety [40].

Second, it is essential to help older adults accept the aforementioned technologies' presence in their homes through appropriate design strategies. According to previous reviews, older adults' perceptions of usefulness, ease of use, privacy, and affordability are significantly related to their attitude and intention to use smart home products [41]. There are two implementations of in-home monitoring technologies: (1) sensors worn by older adults and (2) sensors embedded in the built environment (eg, wall, door) or attached to products such as furniture and kitchen appliances. To support ease of use, in-home monitoring technology should be developed as an ambient sensor system located in stationary home areas. Even though individual wearable sensors are commonly utilized in smart home technology, some older adults are reluctant to use them because they must constantly be worn somewhere on the body to be useful and the battery status must be checked on a regular basis. This is a particularly negative factor among older adults with MCI.

As described in Table 1, in-home technologies can be implemented into each area of senior housing for a specific purpose. For example, PIR motion sensors can be installed in room areas to monitor older adults' activities. Previous research highlighted that most older adults are positively motivated to use a sensor monitoring system; however, privacy is a critical concern for many [39]. How aware individuals are of a sensor being present in their immediate environment varies from one user to another. Some older residents quickly forget about their monitoring equipment, while others consider sensors irritating and therefore change their behavior or activity routines. For example, contact sensors attached between a door and door frame are readily noticeable and bother some residents. PIR motion sensors are usually installed high on a wall corner in a high-traffic area for a wide view. Some older adults may feel uncomfortable because they feel as if someone is observing them. Moreover, monitoring devices might be considered a stigma or a symbol of dependence. Thus, it is critical to address both privacy concerns and make sensor technology less obvious when incorporating in-home technologies into the home environment. That is, creative design solutions are needed to address these issues. An ambient sensor system should be placed above the typical human field of view, and a concealed sensor

system would help address the privacy issue. For example, magnets used in contact sensors can be concealed within the door frame, but they should be easily accessible for maintenance. Smart home technologies should be considered during the early stages of home design or home modification plans instead of adding them after the design or construction process is complete.

Limitations

The aim of this investigation was to identify recent in-home monitoring technologies, which can be applied in older adults' homes. To ensure that the research reports were up to date, the publishing span was limited to articles bearing dates between June 2016 and 2021. Furthermore, this research aimed to identify in-home monitoring technology that can be applied in older adults' homes. However, since there is no clear definition of in-home monitoring technology, the review included sensing technology designed to monitor or track human behavior or activity. Our search string included two different terms used in previous research, although other terms may also be available. Thus, this process may not have found all of the research on in-home monitoring technology for older adults. This review included only studies written in English. Therefore, we may have missed other articles written in other languages. After consultation among the authors, only one author (DK) analyzed the included studies. Thus, this might have introduced bias and impacted the results. However, the identified research and main key characteristics were thoroughly discussed among all authors.

Even though wearable devices offer a huge opportunity to monitor and track older adults' activities and behavior, this review excluded wearable sensing technology because of its acceptability and feasibility issues for older adults [42]. For example, older adults with MCI may forget to wear or charge these devices.

Conclusion

This review provides a key summarization of in-home monitoring technologies, an underexplored research area in the field of aging in place. This wide-ranging synthesis demonstrates that in-home monitoring technologies within older adults' homes play an essential role in aging in place, in that the technology monitors older adults' daily activities and identifies various health-related issues. These findings will be beneficial for architects and designers when developing home modification strategies or senior housing for successful aging in place, in that this research provides key characteristics of in-home monitoring technologies for older adults residing in their own homes. Utilizing this technology, older adults can be more proactive in terms of their health rather than reactive; they can receive early intervention after early identification. This research also highlights the importance of appropriate strategies for smart home design. The emergence of telehealth and online communication can play an essential role in successful aging in place, in that this telemedicine is an effective way to address many societal issues of older adults, such as overcrowding, driving a car, and mitigating infection risks [43]. A smart home with in-home monitoring technology can provide significant information to care providers, which will be helpful for maintaining health and well-being.

Conflicts of Interest

None declared.

Multimedia Appendix 1
Overview of 30 included studies.
[DOCX File , 35 KB - ijmr_v11i2e39005_app1.docx]

Multimedia Appendix 2
PRISMA-ScR checklist. PRISMA-ScR: Preferred Reporting Items for Systematic Reviews and Meta-Analyses extension for Scoping Reviews.
[DOCX File , 84 KB - ijmr_v11i2e39005_app2.docx]

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Abbreviations

ADL: activity of daily living
CASAS: Center for Advanced Studies in Adaptive Systems
IADL: instrumental activity of daily living
MCI: mild cognitive impairment
ORCATECH: Oregon Center for Aging and Technology
PIR: passive infrared
PRISMA-ScR: Preferred Reporting Items of Systematic Reviews and Meta-Analysis extension for Scoping Reviews

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Review

Synthesis of the Evidence on What Works for Whom in Telemental Health: Rapid Realist Review

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Abstract

Background: Telemental health (delivering mental health care via video calls, telephone calls, or SMS text messages) is becoming increasingly widespread. Telemental health appears to be useful and effective in providing care to some service users in some settings, especially during an emergency restricting face-to-face contact, such as the COVID-19 pandemic. However, important limitations have been reported, and telemental health implementation risks the reinforcement of pre-existing inequalities in service provision. If it is to be widely incorporated into routine care, a clear understanding is needed of when and for whom it is an acceptable and effective approach and when face-to-face care is needed.

Objective: This rapid realist review aims to develop a theory about which telemental health approaches work (or do not work), for whom, in which contexts, and through what mechanisms.

Methods: Rapid realist reviewing involves synthesizing relevant evidence and stakeholder expertise to allow timely development of context-mechanism-outcome (CMO) configurations in areas where evidence is urgently needed to inform policy and practice.

The CMO configurations encapsulate theories about what works for whom and by what mechanisms. Sources included eligible papers from 2 previous systematic reviews conducted by our team on telemental health; an updated search using the strategy from these reviews; a call for relevant evidence, including "gray literature," to the public and key experts; and website searches of relevant voluntary and statutory organizations. CMO configurations formulated from these sources were iteratively refined, including through discussions with an expert reference group, including researchers with relevant lived experience and frontline clinicians, and consultation with experts focused on three priority groups: children and young people, users of inpatient and crisis care services, and digitally excluded groups.

Results: A total of 108 scientific and gray literature sources were included. From our initial CMO configurations, we derived 30 overarching CMO configurations within four domains: connecting effectively; flexibility and personalization; safety, privacy, and confidentiality; and therapeutic quality and relationship. Reports and stakeholder input emphasized the importance of personal choice, privacy and safety, and therapeutic relationships in telemental health care. The review also identified particular service users likely to be disadvantaged by telemental health implementation and a need to ensure that face-to-face care of equivalent timeliness remains available. Mechanisms underlying the successful and unsuccessful application of telemental health are discussed.

Conclusions: Service user choice, privacy and safety, the ability to connect effectively, and fostering strong therapeutic relationships need to be prioritized in delivering telemental health care. Guidelines and strategies coproduced with service users and frontline staff are needed to optimize telemental health implementation in real-world settings.

Trial Registration: International Prospective Register of Systematic Reviews (PROSPERO); CRD42021260910; https://www.crd.york.ac.uk/prospero/display_record.php?ID=CRD42021260910

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KEYWORDS

telemental health; remote care; telemedicine; mental health; COVID-19; digital exclusion; realist review; telemedicine; virtual care; rapid realist review; gray literature; therapy; health care staff; digital consultation; frontline staff; children; inpatient; mobile phone

Introduction

Background

Telehealth is defined as "the delivery of health-related services and information via telecommunications technologies in the support of patient care, administrative activities, and health education" [1]. Telemental health refers to such approaches within mental health care settings. It can include care delivered by means such as SMS text messaging and chat functions but most commonly refers to telephone calls and video calls, which are central to telemental health care.

Before the COVID-19 pandemic, there was interest in many countries and settings in integrating new technologies, including telemental health approaches, more widely and effectively in mental health care services. This was of particular interest in countries where face-to-face (ie, in-person) mental health care was largely inaccessible to remote communities [2]. Research has demonstrated that telemental health can be successful in various contexts, although studies before the pandemic tended to relate to relatively small-scale and well-planned applications of telemental health with volunteer participants, rather than large-scale implementations across whole service systems. Telemental health has been found to be effective in reducing treatment gaps and improving access to mental health care for some service users [3-5]. This includes those who live far from services or where caring responsibilities affect their ability to travel [6-8]. Positive outcomes and experiences have been reported across a range of populations (including adult, child and adolescent, older people, and ethnic minority groups) and settings (including hospital, primary care, and community) [9-11]. Some evidence has suggested that telemental health modalities such as videoconferencing are equivalent to, or even better than, face-to-face modalities for some service users in terms of quality of care, reliability of clinical assessments, treatment outcomes, or adherence [9,10,12,13]. High levels of service user acceptance and satisfaction with telemental health services have also been reported in research samples [4] and for certain populations, including those with physical mobility difficulties, social anxiety, or severe anxiety disorders [6,7]. However, conversely, telemental health services are not appropriate for or favored by all service users, and there is no one-size-fits-all approach. In particular, service users experiencing social and economic disadvantages, cognitive difficulties, auditory or visual impairments, or severe mental health problems (such as psychosis) have benefited less from telemental health interventions [14,15]. Digitally excluded service users tend to be people who are already experiencing other forms of disadvantage and are already at risk of poorer access to services and less good quality care; thus, a switch to telemental health may exacerbate existing inequalities [16,17]. In addition, concerns have been raised around the impacts of telemental health on privacy and confidentiality of clinical contacts, especially for the many service users who do not have the appropriate space and facilities for its use, as well as its appropriateness for certain purposes, such as conducting assessments or risk management [14].

Encouraging evidence of telemental health acceptability and effectiveness from prepandemic research tended to relate to limited populations who had opted into well-planned remote services [18]. However, during the COVID-19 pandemic, the use of telemental health around the world greatly accelerated,

and telemental health became a routine approach for maintaining and delivering mental health services. Telemental health initiatives were central to delivering mental health services in the context of this emergency. Technological initiatives have also helped to address social isolation, which worsened throughout the pandemic [6,19]. In the United Kingdom, there were large increases in remote consultations in National Health Service (NHS) primary care [20], and national data reported that most contacts in NHS mental health settings were delivered remotely in 2020 [21], particularly during the first UK lockdown (March to July 2020).

Following the rapid adoption of telemental health at the start of the crisis, service planners, clinicians, and service users have expressed interest in the greater use of telemental health in the long term [14,19,22,23]. However, several challenges have been identified as arising from this widespread implementation [14,16,19,24,25]. These include (1) reaching digitally excluded populations, who may, for example, have limited technological access or expertise or both, thus compounding existing inequalities experienced by disadvantaged groups; (2) a lack of staff competence in using telemental health devices and confidence in delivering telemental health care; (3) a lack of technological infrastructure within health services; (4) challenges in managing clinical and technological risks in remotely delivered care; (5) developing and maintaining strong therapeutic relationships online, especially when the first contact is remote rather than face-to-face; (6) maintaining service user safety and privacy; and (7) delivering high-quality mental health assessments without being able to see or speak to the service user face-to-face. It is also more difficult to undertake physical assessments, including for physical signs linked to mental health, and side effect monitoring.

Both for future emergency responses and to establish a basis for the integration of telemental health into routine service delivery (where appropriate) beyond the pandemic, evidence is needed on how to optimize telemental health care, given the unique relational challenges associated with mental health care, and identify what works best and for whom in telemental health care delivery and in which contexts. It is also important to identify contexts in which telemental health is unlikely to be safe and effective, where face-to-face delivery should remain the default.

A methodological approach developed to address questions of which interventions work, for whom, and in which contexts in a timely way is the rapid realist review (RRR) [26]. This methodology has been developed to rapidly produce policy-relevant and actionable recommendations through a synthesis of peer-reviewed evidence and stakeholder consultation. A key characteristic of realist methodology is the focus on interactions between contextual factors (eg, a certain population, geographical location, service setting, or situation) and relevant mechanisms (eg, behavioral reactions, participants' reasoning, or resources), which affect the outcomes of interest, such as intervention adherence or service user satisfaction [26-28]. Together, these are used to develop context-mechanism-outcome (CMO) configurations, which comprise the fundamental building blocks of realist synthesis approaches. Evidence from the wider literature is also drawn upon to develop midrange theories. Midrange theories are program theories that aim to describe how certain mechanisms in specific contexts result in specific outcomes [29]; the use of the wider literature to develop midrange theories helps to elaborate and refine the developed CMO configurations by shedding further light on how their mechanisms operate [26,30-32]. Additional information on realist terminology can be found in Multimedia Appendix 1.

Objective

This is a unique opportunity to establish the characteristics of high-quality telemental health services and use these findings to identify key mechanisms for acceptable, effective, and efficient integration of telemental health services into routine mental health care. Using a realist methodology, in this RRR, we aimed to answer the question of what telemental health approaches work, for whom, in which contexts, and how? Specifically, we investigated the following questions in this review:

1. What factors or interventions improve or reduce adoption, reach, quality, acceptability, or other relevant outcomes in the use of telemental health in any setting?
2. Which approaches to telemental health work best for which staff and service users in which contexts?
3. In what contexts are phone calls, video calls, or SMS text messages preferable, and in which contexts should mental health care be delivered face-to-face instead?

We focus particularly on groups and contexts identified as high priority by policy makers (the process is described in detail in the *Methods* section), including children and young people, crisis care and inpatient settings, and groups at high risk of digital exclusion; examples from these groups are included wherever possible.

Methods

Overview

The RRR was conducted by the National Institute for Health Research Mental Health Policy Research Unit (MHPRU), a team established to deliver evidence rapidly to inform policy making, especially by the Department of Health and Social Care in England, associated government departments, and NHS policy leadership bodies. The project constitutes the final stage in a program of work on telemental health delivery conducted to meet urgent policy needs, which included an umbrella review of pre–COVID-19 evidence [18], a qualitative investigation of service user experiences of telemental health [24], a systematic review of literature on telemental health adoption conducted during the early phase of the pandemic [14], and a systematic review on the cost-effectiveness of telemental health approaches (personal communication by Clark et al, 2022). This RRR was registered on PROSPERO (International Prospective Register of Systematic Reviews; CRD42021260910).

We conducted the RRR during the COVID-19 pandemic, with videoconferencing via Zoom (Zoom Video Communications) as the primary means of communication among the research team.

Study Design

An expert reference group of 28 people, including 16 (57%) university-employed academics, 7 (25%) experts by experience (lived experience researchers from the MHPRU Lived Experience Working Group (LEWG) with personal experiences of using mental health services or supporting others or both), and 8 (29%) experts by profession (including frontline clinicians), guided and contributed to the RRR throughout. Some members belonged to multiple groups and therefore worked from several (academic, clinical, or lived experience or multiple) perspectives.

The group met weekly throughout this process from July to November 2021. The expert reference group meetings served to develop and refine the study protocol; plan the searches for evidence (particularly the targeted additional searches supplementing the initially planned strategy); iteratively examine, refine, and validate the CMO configurations derived from our evidence synthesis, with reference to their expertise by experience or profession or both; and plan wider consultation on our emerging findings. Members of the expert reference group also contributed to the literature searches, data extraction, synthesis, and interpretation of data.

The stages of our RRR were based on the following five steps, variations of which have been described and used in previous studies [26,31,32]:

1. Developing and refining research questions
2. Literature searching and retrieving information (data/stakeholder views)
3. Screening and extracting information/data
4. Synthesizing information/data
5. Interpreting information/data

Our approach to these steps was iterative rather than linear, particularly for steps 3, 4, and 5, where there were multiple phases of extraction, synthesis, and interpretation. This is described in detail in the following section.

Developing and Refining the Research Question

We formulated the research question in response to policy maker needs. We reviewed findings from earlier stages of the MHPRU's program on COVID-19 impact on mental health care and on telemental health [6,18,19,24,33] with policy makers, including senior officials and mental health teams in the Department for Health and Social Care, NHS England, and Public Health England. We then identified questions to be addressed from their perspective to plan for future implementation and delivery of telemental health. This included considering how best to incorporate telemental health in routine practice once the need for its emergency deployment passes. Early in these discussions, three priority groups regarding the evidence that is currently lacking were identified as especially important for policy and planning: children and young people, users of inpatient and crisis care services, and digitally excluded groups. Digitally excluded groups include those who have no or reduced access to the digital world because of a lack of digital skills (eg, using computers or smartphones), connectivity (eg, access to the internet or phone signal), and accessibility (eg, those who may require assistive technology or do not have access to digital devices or connectivity because of, eg, costs). Our primary question of which telemental health approaches work, for whom, and in what context originated in these discussions and was further refined by the MHPRU core research team who identified a RRR methodology as appropriate and further refined the primary and secondary questions and methodology with the expert reference group before registering the protocol.

Selection Criteria

Sources were included if they met the criteria described in the following sections.

Participants

Participants included staff working in the field of mental health, people receiving care from mental health services, family members, and other supporters of people receiving mental health care.

Interventions

Interventions included any form of remote (spoken or written) communication between mental health professionals, or among mental health professionals and service users, family members, and other supporters, using video calls, telephone calls, SMS text messaging services, or hybrid approaches combining face-to-face and web-based modalities. Peer support communications were also included alongside any strategies or training programs to support the implementation of the abovementioned interventions. Self-guided web-based support and therapy programs were excluded.

Types of Evidence

This included qualitative or quantitative evidence on (1) what improves or reduces adoption, reach, quality, acceptability, or clinical outcomes in the use of telemental health; (2) impacts of introducing interventions or strategies intended to improve adoption, reach, quality, acceptability, or clinical outcomes; (3) interventions or strategies intended to help mental health staff make more effective use of telemental health technologies; (4) impacts of telemental health on specific service user groups and settings, including people who are digitally excluded, users of inpatient and crisis care services, and children and young people; and (5) the appropriateness of the use of telemental health versus face-to-face care in particular contexts. In addition to outcomes, sources were required to include information on mechanisms (ie, what works, for whom, and how).

Study Design

This included any qualitative, quantitative, or mixed methods study design, including relevant service evaluations, audits, and case series. Gray literature and other sources, such as websites, stakeholder feedback, and testimonies from provider organizations and service user and carer groups were also included. Sources were also included if the focus was not solely on remote working, but the results contained substantial data relevant to our research questions. Substantial data had to provide relevant and sufficient information on context, mechanisms, and outcomes and contribute to the development of overarching CMO configurations. Editorials, commentaries,

letters, conference abstracts, and theoretical studies were excluded.

Search Strategy

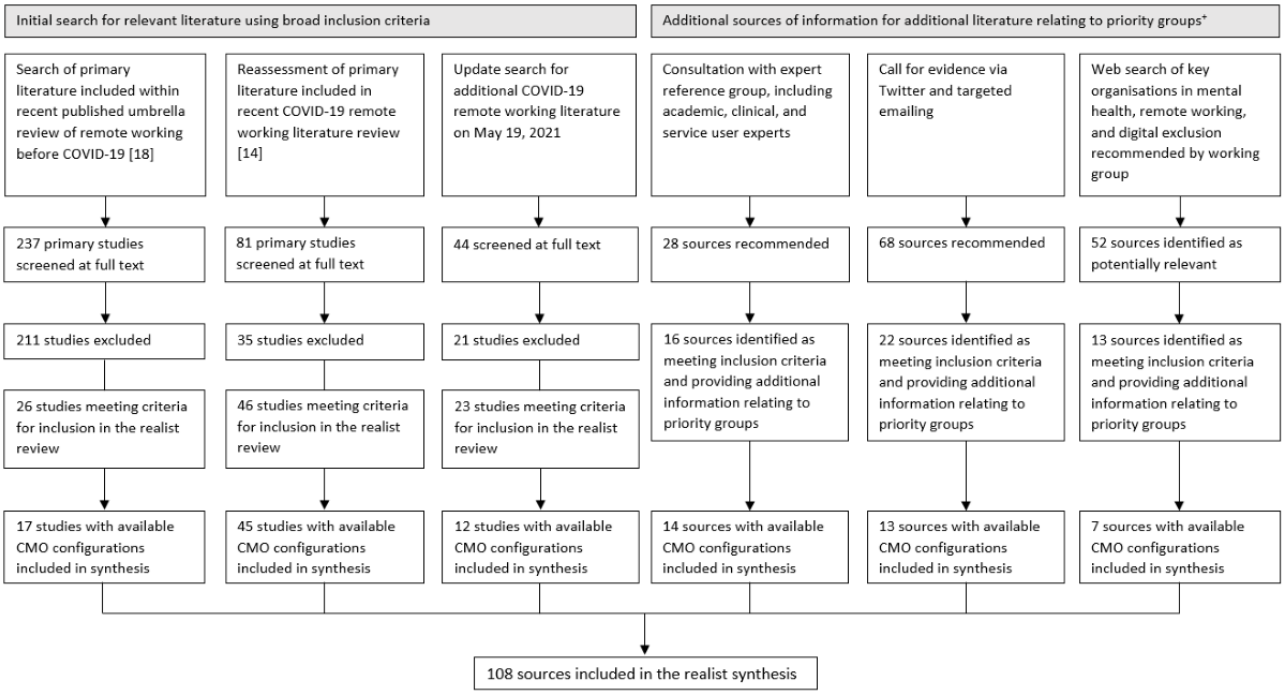
The search strategy was in accordance with PRISMA (Preferred Reporting Item for Systematic Reviews and Meta-Analyses) guidelines (Figure 1) [34]. Resources and literature were identified through the sources described in the following paragraphs.

First, we screened peer-reviewed studies included in 2 previous reviews on telemental health conducted by the MHPRU. The umbrella review by Barnett et al [18] included systematic reviews, realist reviews, and qualitative meta-syntheses on remote working before the onset of the COVID-19 pandemic [18]. The systematic review by Appleton et al [14] synthesized primary research on the adoption and impacts of telemental health approaches during the pandemic [14]. An updated search of the latter review was conducted on May 19, 2021.

Second, we worked with our expert reference group to identify additional peer-reviewed and gray literature. Searches were conducted on the websites of relevant national and international voluntary and statutory organizations identified by the expert reference group and by internet searches (eg, Mind and the Royal College of Psychiatrists). Identified literature was noted on a shared Microsoft Excel spreadsheet. This process was supported using Slack, a web-based messaging application, to coordinate this complex and rapidly changing process.

Finally, the MHPRU disseminated a call for evidence via Twitter and email to relevant organizations and individuals (such as charities supporting digital inclusion, chief information officers, and telehealth leads within NHS Trusts) inviting them to submit relevant evidence, including evaluations, audits, surveys, stakeholder feedback, and testimonies from provider organizations and service user and carer groups.

Figure 1. PRISMA (Preferred Reporting Items for Systematic Reviews and Meta-Analyses) diagram. *Inpatient and crisis service users, children and young people, people who are digitally excluded, and items from a service user viewpoint [14,18]. CMO: context-mechanism-outcome.



Study Selection

References included in the umbrella and systematic review were downloaded and screened for inclusion in the RRR using EPPI-Reviewer (version 4.0) [35]. One of the reviewers screened abstracts and titles of the references identified through the updated searches of the umbrella review and systematic review. Full texts were reviewed for inclusion, with included and *unsure* sources checked by another reviewer. Sources were included in the final review if they met our inclusion criteria and provided relevant information for the development of CMO configurations. Disagreements were resolved through discussion with the wider research team.

Process of Data Extraction, Synthesis, and Interpretation

Data Extraction

The source characteristics were extracted and inputted on EPPI-Reviewer (version 4.0) [35]. Extracted characteristics included study aim and design (if applicable), type of service, telemental health modalities used, mental health diagnosis of service users, and staff occupation. MHPRU researchers screened each included source for information that could be assembled into CMO configurations related to telemental health (ie, information on contexts, outcomes, and underlying mechanisms). Underlying CMO configurations were extracted by MHPRU researchers and LEWG members. Underlying CMO extraction involved reading each source before identifying contexts, mechanisms, and outcome configurations that were

either (1) identified by the authors in the paper or (2) identified by extractors by linking them together from the data, descriptions, and discussion in the paper. Each week, samples of the extracted CMO configurations were reviewed by the expert reference group to ensure coherence, relevance, validity, and format consistency.

Data Synthesis

The research team then began the process of synthesizing the underlying CMO configurations by reviewing the extracted CMO configurations and identifying emerging themes. We developed four domains to encapsulate key aspects of the evidence: (1) connecting effectively; (2) flexibility and personalization; (3) safety, privacy, and confidentiality; and (4) therapeutic quality and relationship. Each of the 4 identified domains was allocated to an MHPRU researcher to lead the synthesis, with input from LEWG members, clinicians, and MHPRU senior researchers.

To develop content for each of these 4 domains, underlying CMO configurations were, in essence, synthesized based on similarities to create a single overarching CMO (discussed in full detail in Multimedia Appendix 1). Underlying CMO configurations extracted from individual sources were reviewed in terms of their similarities and differences (eg, CMO configurations related to the convenience of telemental health) and then grouped together based on similar mechanisms (eg, flexibility, which reduces practical barriers to accessing mental health care) and outcomes (eg, increasing attendance and reducing missed appointments). Each similar group of underlying CMO configurations was then synthesized and refined to create a single overarching CMO, which reflected key content across the underlying CMO configurations, as well as input from the expert reference group. Each overarching CMO was assigned to 1 of the 4 domains.

Realist work does not conduct a traditional quality appraisal, as it values evidence from all sources in a nonhierarchical manner [27,29]. Our overarching CMO configurations were also significantly developed throughout the synthesis process based on stakeholder input, and thus, quality appraisal of individual study sources would not have reflected the quality of the final overarching CMO configurations.

Interpretation

An iterative process of revising and refining overarching CMO configurations from the perspective of stakeholder experience followed. Revisions, refinements, and additions were first made through discussion with the expert reference group. Summaries were then also discussed at three 2-hour stakeholder webinars, each focusing on one of our priority groups: children and young people, inpatient and crisis care services, and digitally excluded groups. The webinars were primarily attended by groups representing these constituencies and services who work with them, including experts and stakeholder representatives from research, policy, and clinical settings (nationally and internationally); the voluntary sector; lived experience groups and community organizations working with marginalized groups; and telehealth technology initiatives. There were between 30 and 40 participants at each webinar. During the webinars, participants were divided into breakout rooms, with a facilitator and a note taker from the core research team. High-level summaries of preliminary data were presented by domain, and attendees were asked to discuss the following questions: (1) whether the preliminary summaries captured their own knowledge and experience of telemental health, (2) whether the summaries applied to and how the summaries were relevant for the priority group at hand, and whether they were aware of any additional challenges or recommendations related to delivering telemental health to the priority group.

On the basis of the feedback from these webinars, the overarching CMO configurations within each of the 4 domains were then further revised and refined. We actively sought additional information related to each overarching CMO, including relevant contexts, further detail about mechanisms, real-life examples of strategies and solutions (such as for overcoming barriers identified within the CMO), and points of particular importance or concern, from the webinar notes, the expert reference group meetings, and related literature. We noted this information alongside the relevant overarching CMO and used it to refine the CMO configurations. In addition, we drew upon midrange theories (evidence-based theories derived from the wider literature) to provide more theoretically informed explanations of mechanisms (eg, the digital inverse care law [16], which theorizes that those most in need of care via telemental health are least likely to engage with it and existing inequalities will widen, helped to strengthen the mechanisms around digital exclusion). Throughout this process, the core research team and the expert reference group were iteratively consulted, and their feedback was integrated into the overarching CMO configurations. The revised theories were shared for a final email consultation with the stakeholders who were invited to our webinars. Their feedback was incorporated and resulted in the final overarching CMO models presented under each domain in this paper.

Results

Overview

Underlying CMO configurations were extracted from 17 studies included in the previous umbrella review [18] and from 45 studies included in the systematic review [14]. The updated search yielded 44 potentially relevant studies, of which 21 (48%) were excluded (either as they did not contain data on context, mechanisms, and outcomes or they added no additional information as data saturation had been reached). CMO configurations were extracted from 52% (12/23) of the remaining studies that met our inclusion criteria and were included in the realist synthesis. Through consultations with our expert reference group, we identified 28 sources, of which 16 (57%) met our inclusion criteria and provided additional information related to our priority groups, and 14 (50%) yielded CMO configurations that were included in the synthesis. We received 68 potential sources through the call for evidence, of which 22 (32%) met our inclusion criteria and provided relevant information on our priority groups; CMO configurations were extracted from 13 (19%) of these. Finally, website searches identified 52 potentially relevant sources, of which 13 (25%)

met our inclusion criteria and 7 (13%) provided information relevant to CMO configurations. The realist synthesis includes a total of 108 sources.

Of the 108 included sources with primary data or detailed accounts of what works, for whom, and in what context, most were primary research studies (72/108, 66.7%), followed by service descriptions/evaluations/audits (19/108, 17.6%), guidance documents (4/108, 3.7%) and briefing papers (3/108, 2.8%), commentaries/editorials/discussions (4/108, 3.7%), and letters (2/108, 1.9%), as well as a review (1/108, 0.9%), news article (1/108, 0.9%), webpage (1/108, 0.9%), and a service user–led report (1/108, 0.9%). Of the 84 sources that included primary research data, 32 (38%) used quantitative methods, 19 (23%) used qualitative methods, and 33 (39%) used mixed methods (including n=2, 2% case studies).

Most sources were published in the United States (41/108, 38%) and the United Kingdom (34/108, 31.5%). The remaining sources collected data in Canada (7/108, 6.5%), the Dominican Republic (1/108, 0.9%), Australia (7/108, 6.5%), China (2/108, 1.9%), India (3/108, 2.8%), Egypt (1/108, 0.9%), and Nigeria (1/108, 0.9%), as well as 10 European countries, including Austria (1/108, 0.9%), France (1/108, 0.9%), Germany (1/108, 0.9%), Ireland (1/108, 0.9%), Italy (2/108, 1.9%), Netherlands (1/108, 0.9%), Portugal (1/108, 0.9%), Spain (1/108, 0.9%), Sweden (1/108, 0.9%), and Switzerland (1/108, 0.9%). Details of the included sources are presented in Multimedia Appendix 2 [12,19,24,36-153].

Overarching CMO configurations for each domain are summarized in Tables 1-4, and details of the underlying CMO configurations and summary notes on stakeholder discussions, which shaped the overarching CMO configurations, are presented in Multimedia Appendix 3 [12,19,24,36-153]. For each overarching CMO, we included examples of key contexts that are relevant for the CMO and examples of strategies and solutions addressing the challenges or opportunities identified in the CMO: these were drawn from underlying CMO configurations and stakeholder discussions. In the text outlining each domain, we also identify major midrange theories that elucidate mechanisms and outcomes for overarching CMO configurations.

Domain 1: Connecting Effectively

The content of this domain relates to establishing a good web-based connection to join a video call of sufficient quality or to engage in telemental health via phone or message, with a particular focus on digital exclusion. Table 1 outlines 7 overarching CMO configurations identified in relation to this domain, addressing issues concerning device and internet access (CMO 1.1 and CMO 1.2), technology training (CMO 1.3), the impact of preparation and technological disruptions (CMO 1.4 and CMO 1.5), the familiarity and usability of the platforms (CMO 1.6), and the acceptability of telemental health as an alternative to receiving no care during emergency situations (CMO 1.7). Three of the CMO configurations were related to trying to resolve three main challenges: (1) access to a charged, up-to-date device that enables internet access (CMO 1.1); (2) an internet (Wi-Fi or data) or signal connection (CMO 1.2); and (3) the knowledge, ability, and confidence to engage on the web (CMO 1.3). Much of the content relates to challenges service users encounter in engaging with telemental health; however, the literature and stakeholder discussion also yielded significant challenges for staff and service providers in the practicalities of connecting on the web.

Theories regarding the relationship between digital exclusion and other forms of exclusion and deprivation, as well as the potential of digital exclusion to amplify inequalities, contribute to our understanding of key mechanisms and outcomes in this domain. Widening inequalities have been described as an inevitable consequence of the expansion of the role of technology in health care, with loss of access to community facilities, such as libraries, making this a still greater risk during the pandemic [154]. The “digital inverse care law” [16] describes a tendency for groups in most need of care (eg, older people or people experiencing social deprivation) to be least likely to engage with technological forms of health care. This is highly salient in mental health care, given the strong associations between experiencing mental health challenges and experiencing one or, often, many forms of disadvantage [154].

Access to devices (CMO 1.1) is a contributor to digital exclusion, and groups who are especially likely to be affected include homeless individuals and people living in poverty, those receiving inpatient or crisis care, and young children who may not have their own devices. The type of device may be important for accessing telemental health. For example, smartphones may be less suitable for video therapy because of their small screens [155], although this may be less relevant for young people who are familiar with and consistently use smartphones for connecting on the web [156]. This raises future research questions around which types of digital devices work for whom and in what context when it comes to continuing telemental health treatment. It may also have implications for the provision of suitable equipment to certain populations.

Our consultations and the wider literature revealed that lack of access to good quality Wi-Fi, including poor Wi-Fi in hospitals and offices, was a further key barrier to the successful and equitable delivery of telemental health (CMO 1.2). It was emphasized that modernization of software and hardware, particularly within the NHS, is needed in many health care sites to allow for the requirements of telemental health. Service users also reported relying on their own mobile phone data to connect to telemental health services, often depleting their data completely after or during just one video call or consultation, which is expensive to replenish and may also deter engagement. This could amplify existing inequalities, leaving some service users at risk of digital exclusion and unable to access the internet and mental health support. Disruptions to telemental health appointments because of poor connections are a significant barrier to engagement (CMO 1.4). Our consultations and the existing literature highlighted the importance of having an alternate form of communication (eg, a telephone call) as a backup plan in case of a technology or connection failure [36,37,157,158].

Table 1. Domain 1: Connecting Effectively.

CMO[a] title	References	Overarching CMO	Key contexts	Example strategies and solutions
CMO 1.1: Providing *service users* with access to digital devices	[19,39-49,59]	When service users who do not have access to digital devices are given access to up-to-date devices (and chargers), paid for or loaned to them (context), this results in improved access to and implementation of telemental health services (especially via video platforms; outcome 1), some inequalities in accessing a digital device are addressed (outcome 2), exacerbation of existing inequalities is less likely (outcome 3), and service users are more able to maintain personal contact with family and friends if they wish and access a range of web-based services (outcome 4), as this reduces the burden of having to purchase a device for the service users and provides more financially viable access to devices required for web-based connections (mechanism).	Lack of access to devices particularly affects people living in poverty or unstable living circumstances (such as homeless people or refugees), as well as other groups at risk of exclusion not only from telemental health but from a range of services and networks (such as people who are cognitively impaired or with psychosis or substance abuse disorders). It can also particularly affect inpatients, who may not have access to devices or charging facilities or both on the ward, and children and young people, who may not have access to their own devices.	• Schemes organized by bodies, including health care providers, libraries, schools and colleges, charities, and community organizations, that lend or give digital devices and chargers • Inpatient wards providing devices, such as iPads, and short cable or wireless chargers, or charging lockers • Health services providing separate and private rooms with videoconferencing capabilities • Promoting awareness among service providers about the tendency for digital exclusion to exacerbate existing disadvantages and inequalities, with the development of active strategies to mitigate this • Phone calls rather than video calls may be more appropriate for service users who do not have access to digital devices that facilitate video calls
CMO 1.2: Lack of access to stable, secure, and adequate internet connection				
Staff	[19, 39, 41, 42, 44, 47, 50-60]	When the staff deliver telemental health via video from workplaces or homes with an unstable and poor internet connection (context), teleconsultations are difficult (or impossible) to conduct with service users (outcome 1), fewer teleconsultations are conducted (outcome 2), and telemental health is viewed less positively (outcome 3), as staff experience frustration, and there is reduced motivation to arrange web-based appointments (mechanism).	This is particularly relevant for staff working within health care providers that frequently have insufficient Wi-Fi or internet connection to deliver sessions smoothly. It also affects staff who do not have adequate Wi-Fi connectivity in their own homes or when working in the community.	• Investing in high-quality IT infrastructure to ensure disruptions to calls do not originate from poor provider connections • Providing devices with access to data, or data/Wi-Fi allowances, for use by staff when working away from health service premises (at home or in community settings)
Service users	[19, 39, 41, 42, 44, 47, 50-60]	When service users only have access to an insecure, unstable, and poor-quality internet connection or consistent technological problems (context), it is difficult for telemental health to be viewed positively (outcome 1), they are able or willing to accept fewer web-based consultations (outcome 2), they may continue to struggle with their mental health (if face-to-face consultations are unavailable; outcome 3), and this may result in digital exclusion that could exacerbate existing inequalities (outcome 4), as the service users struggle to engage in sessions with sufficient clarity and mutual comprehension and experience frustration (mechanism).	This is especially relevant for service users on low incomes or from socially marginalized groups (such as homeless people), those living in multiple occupancy households where Wi-Fi is overstretched, and people from low-to-middle income countries. Lack of access to reliable internet or even electricity also differentially affects people in rural and remote areas. People in marginalized groups may also lack the means to pay for a telephone service.	• Signposting to low-cost plans for people on low incomes • Providing free access to Wi-Fi, data, and phone connections (may be included with devices that are lent or given) • Providing or signposting to community hubs with access to data • Providing face-to-face appointments where the above problems cannot be resolved
CMO 1.3: Benefits of providing support and guidance for using technology				

CMO[a] title	References	Overarching CMO	Key contexts	Example strategies and solutions
Staff	[19, 24, 38, 42-44, 46, 53, 59, 61-75]	When staff who lack the confidence or knowledge to deliver mental health care online (particularly via video calls) receive practical instruction and guidance on how to use technology to deliver mental health services (including clear information about how to operate within local policies, procedures, and platforms; troubleshoot issues during telemental health sessions; and formulate and implement backup plans; context), they feel an increased sense of confidence in managing and delivering telemental health services (mechanism), which leads to increased use of telemental health services (outcome 1) and fewer delays, resulting in more appointments being completed on time (outcome 2).	This is especially relevant for staff who are new to delivering mental health care remotely or who are unclear or unfamiliar with using locally recommended platforms and procedures.	• Provision of training sessions relevant to the local context, including information on troubleshooting technology and maintaining privacy, safety, and confidentiality • Access to guidance on video calls, including clear information on processes and policies for providing telemental health in the organizations where the staff work • Peer support and group or team sessions for practicing technology • Refresher training sessions and rolling training for new joining staff
Service users	[19, 24, 38, 42-44, 46, 53, 61-75]	When service users with access to a technology device who struggle with the confidence, knowledge, or the ability to use telemental health receive guidance, reassurance, and instruction (tailored to their health care provider and their language, reading ability, and any sensory disability) on how to use technology (particularly video calls) to access mental health care, engage with backup plans, and receive timely technical support and troubleshooting during treatment sessions (context), they feel an increased sense of confidence in accessing telemental health (mechanism), which reduces anxiety in using telemental health and digital technologies (including in their personal lives; outcome 1), facilitates the adoption of and adherence to telemental health (outcome 2), improves service users' ability to adjust to remote care (outcome 3), reduces interruptions in care delivered via telemental health (outcome 4), and increases satisfaction with telemental health (outcome 5).	Receiving guidance tailored to local policies and procedures for telemental health access is relevant to all service users. It is likely to be particularly relevant to groups identified as at high risk of digital exclusion through lack of confidence in using technology, including older people, people with severe mental health problems, and people with intellectual disabilities or cognitive impairments. Production of accessible guidance is especially relevant for people with cognitive impairments or intellectual disabilities, children, people with sensory disabilities, and people who do not understand English well.	• One-to-one training or support from a digital facilitator/champion/mentor, peer supporters, family, friends, or a dedicated member of staff who can provide guidance • Written or video information about how to access telemental health, including material tailored to age, cognitive abilities, sensory impairments, and language, and to the platforms that are in local use (eg, guidance in other languages, easy-to-read material with pictures, and personalized workbooks sent to children before a telemental health contact) • Opportunities for practice and repetition of training as needed • Written guides for different technology platforms that give step-by-step instructions, including how to set up IDs and passwords, sent out with appointment letters • Brief and direct training sessions offered to service users before their web-based appointment, performing a trial run of using the technology beforehand or increasing web-based contact duration to accommodate learning
CMO 1.4: Impact of technology-related disruptions	[36, 45, 56, 76-82]	When technological issues (including connection problems and device issues) lead to disruptions in web-based sessions and there is no prearranged backup method of contact (eg, a plan to connect by telephone instead of video call if needed; context), the quality of the intervention is diminished (outcome 1), there is a loss of empathic connection between client and therapist (outcome 2), and the sessions may not be able to continue (outcome 3), as the flow of the conversation is interrupted and session time reduced, for example, when having to ask the other person to repeat what has been said or when cut off completely, leaving staff and service users potentially feeling distracted, frustrated, awkward, and upset (particularly if there is a threat of therapy withdrawal because of missed sessions; mechanism).	This is particularly relevant for the use of videoconferencing, where phone backup can reduce the risk of abandoning appointments because of failure to make a stable connection.	• Agree to a backup method of connecting (eg, reverting to telephone calls in the event of a disruption) • Where connection issues cannot be readily resolved, and backup methods are not sufficient, strategies to address connection problems (as mentioned previously) are required, or moves to face-to-face care should be facilitated

CMO[a] title	References	Overarching CMO	Key contexts	Example strategies and solutions
CMO 1.5: Preparing *service users* for telemental health	[83-85]	When staff prepare service users for telemental health appointments and communicate clearly with service users about what to expect (context), this leads to more accepted calls and fewer missed service user contacts (outcome), as service users have more relevant knowledge of the process, including when to expect contacts and from what number, and feel more comfortable engaging with telemental health services (mechanism).	This is relevant across telemental health contexts but may be particularly relevant for service users who have not used telemental health before or are anxious or worried about telemental health.	• Informing service users when they are going to be contacted and via what platform • Sending texts to remind a service user that a call is scheduled for a specific time • Informing service users about when phones are manned and how long they can expect to wait for a call back • Routing staff telemental health calls to service users through unblocked, local, and familiar clinic or hospital numbers or, if a private number must be used, ensuring that service users are expecting this
CMO 1.6: *Service users'* familiarity with the platform and ease of use	[41,66,86-90]	Where service users already use remote technologies for social, educational, or work purposes, or where the web-based platforms are relatively easy to use (context), offering a choice of familiar and accessible technology platforms that may be less difficult and time-consuming for staff and service users to understand or learn (mechanism) may increase the likelihood of engagement with services via telemental health, especially video calls (outcome).	This is especially relevant to service users who are already making some use of technology, for example, for social, educational, or work purposes.	• Service providers prioritizing allowing the use of a variety of platforms, especially those likely to be widely familiar (eg, Zoom and WhatsApp video) • Attempting to address governance concerns and provide guidance for safe use, balancing web-based safety and other risks such as disengagement from services
CMO 1.7: Telemental health may be a better alternative to receiving no care for *service users* during an emergency, such as the COVID-19 pandemic	[36, 43, 60, 90-92]	When service users are offered telemental health appointments as face-to-face appointments are restricted (eg, because of COVID-19 or another emergency; context); these appointments are likely to be accepted by some service users on the basis that they are the main way by which mental health care can continue (outcome 1), and there is a reduced risk of infection from COVID-19 (outcome 2), as telemental health is seen as preferable to receiving no support at all and as an alternative to canceling appointments entirely (mechanism).	This is applicable across mental health services in the context of any emergency which restricts face-to-face meetings, especially in services where all face-to-face contacts have been discontinued or where they are limited to immediate crises. It is especially relevant for service users who need to self-isolate because of high personal risk, or where clinicians need to self-isolate after contact with others.	• Widespread implementation of telemental health has proved a successful strategy for maintaining contact with many (but not all) mental health service users during an emergency that restricts face-to-face contact, with some service users accepting telemental health in this situation, but who would otherwise be reluctant or unable to do so if not in a relatively short-term emergency • Some continuing face-to-face contacts are still required if care is to be offered to all who need it

[a]CMO: context-mechanism-outcome.

We identified the importance of technology training and sustained formal and informal support for service users (CMO 1.3). Variations in the ability to use telemental health are likely to disproportionately affect certain service user populations, often groups who also experience high levels of need for mental health care and inequalities in its provision. This includes people living in deprived circumstances, people with cognitive difficulties, people with paranoia, or those who do not speak the same language as service providers. Understanding how to use technology is also important for service users' social engagement and connection, which is relevant for wider recovery and citizenship [159-161]. Young children may also be disproportionately affected as they may not be able to resolve difficulties they experience during telemental health sessions without the help of their parents or other supporters.

For staff (CMO 1.3), our evidence suggests that staff training provided more widely and accessibly on using technology for telehealth would be helpful to ensure high-quality service provision and overcome barriers around staff not having time allocated to training or being reluctant to ask for support. Evidence suggests that there are also benefits of having access to technical support to troubleshoot issues during sessions [38], as well as of practicing new skills and learning with colleagues and peers [162].

The importance of the familiarity and usability of platforms was highlighted throughout our stakeholder consultations and weekly reference group meetings, as well as in the published literature (CMO 1.6), in keeping with previous research on the acceptability of telemedicine by service users [163]. Many of the platforms and devices commonly used for telemental health services, for example, during the COVID-19 pandemic, were

not designed for use in health care settings and, therefore, may be less user-friendly. The importance of usability is emphasized by Nielsen and Landauer [164]; 3 of 5 main usability attributes of a program are that it should be easy to learn, efficient to use, and easy to remember. This is in keeping with our findings related to familiarity and usability in telemental health.

Finally, preparing service users for telemental health sessions was key (CMO 1.5). This was relevant across telemental health contexts; however, information tailored to individual communication needs may be especially helpful for service users who may experience additional challenges connecting on the web (eg, those who are inexperienced with technology or anxious about using telemental health, young children, older people, and people with cognitive difficulties). For people with significant sensory impairments, specialist adaptations will need to be available if telemental health is to be a viable modality (eg, mobile phones that flash when receiving a call or providing guidance in Braille or sign languages).

Domain 2: Flexibility and Personalization

Table 2 presents the CMO configurations, key contexts, and example strategies and solutions for the domain of flexibility and personalization. The need for flexibility and personalization was a key theme identified in both the literature and stakeholder consultations when considering using telemental health in place of (or in conjunction with) face-to-face mental health support. A total of eight overarching CMO configurations were identified in this domain, which can be divided into three main categories: taking individual preferences into account (CMO 2.1, CMO 2.5, and CMO 2.7), convenience (CMO 2.2), and allowing for more collaborative and potentially specialized care (eg, involving specialists, family, or friends in care; CMO 2.3, CMO 2.4, CMO 2.6, and CMO 2.8).

Our findings emphasize the importance of taking individual service user preferences into account when deciding whether to make use of telemental health, in selecting the modality of digital communication used (including the type of technology platform), and in decisions about involving others (clinicians or family members) in care. This finding underpins all other CMO configurations in this theme and coheres with theories regarding the importance of shared decision-making, collaborative care planning, and personalization in mental health care [165-167]. Involving service users and carers in decisions and care planning as part of a collaborative approach to mental health care has been identified as central to best practice [168]; for example, a review of collaborative care for depression and anxiety found this approach to be more effective than usual care in improving treatment outcomes [169].

Flexible use of telemental health was also identified as being beneficial in reducing barriers to accessing mental health support for some service users, particularly those who may struggle to access face-to-face services for reasons such as caring or work commitments, problems traveling (eg, because of a physical disability, anxiety, or lack of transport) or a reluctance to attend the stigmatizing places. Telemental health can also facilitate connections between clinicians, especially across different services or specialties, which can improve multidisciplinary working and collaboration across teams and agencies and provide service users with a wider range of specialists or support for specific groups. This approach has been identified as having salience in a mental health setting [170-172]. In some cases, telemental health was viewed by both service users and clinicians as more convenient, as it reduced the need for (and cost of) traveling to face-to-face appointments.

Telemental health was also seen as an important tool in inpatient wards, especially during the COVID-19 pandemic when visiting was restricted, as it allowed service users to stay in touch with family and friends and for them to be involved in their care. It also allowed staff supporting inpatients in the community to remain involved.

However, instances were identified where telemental health was not appropriate, and face-to-face care needs to be available. For example, some service users do not wish or feel able to receive care by remote means or do not wish to have all appointments by this means, whereas others may struggle with telemental health because of sensory or psychological factors or a lack of access to appropriate technology and internet connectivity.

Table 2. Domain 2: Flexibility and personalization.

CMO[a] title	References	Overarching CMO	Key contexts	Example strategies and solutions
CMO 2.1: Taking *service users'* individual preferences into account—offering alternatives	[24, 36, 48, 50, 65, 67, 75, 77, 90, 91, 93-104, Eagle et al (email, August 31, 2022)]	When services using remote mental health care allow service users to choose the modality of telemental health and a choice of remote versus face-to-face care and regularly check their preferences (context), this allows service users to have greater autonomy and choice (mechanism), leading to them feeling more satisfied and able to engage with the type of care received (outcome 1), leading to improved uptake (outcome 2) and improved therapeutic relationships with their clinician (outcome 3).	Allowing service user choice and delivering services flexibly is a key principle across settings and populations, with the overall aim that care of equivalent quality should be available in a timely way whatever modality is chosen. Hybrid care, with a flexible mixture of face-to-face and telemental health care based on the purpose or function of appointment (eg, prescription review versus the first visit to see a clinician), preference, and circumstances, is especially relevant to service users receiving relatively complex care with multiple types of appointments, for example, from multidisciplinary community teams. Children and young people may particularly benefit from being offered a choice as it increases their feelings of autonomy and improves engagement in care.	• Initial conversations about telemental health with all service users, in which their preferences regarding the mode of appointments and their access to and expertise and interest in using technology are explored (a shared decision-making tool could be used to structure this) • Ensuring that clinicians making collaborative plans with service users for telemental health use are aware of risk factors for difficulties engaging with telemental health and digital exclusion, including individual difficulties and wider contextual factors, such as poverty and poor or shared housing • Ensuring equal access to timely care of good quality regardless of choice of modality • Regularly revisiting preferences and collaboratively planning how care will be delivered • Ensuring that service users engaging in group therapies and activities have understood and consented to the ways of working of the group and that face-to-face alternatives are of equivalent quality
CMO 2.2: Removing barriers—greater convenience for *service users and family/friends*	[19, 24, 36, 38, 40, 42, 45, 54, 55, 67, 70, 75, 76, 79, 81, 82, 84, 90-92, 95, 97, 105-112]	Among some service users, family, and other supporters experiencing specific practical barriers to attending face-to-face services (childcare or other caring responsibilities; location, work, and mobility limitations; travel difficulties/costs, and work commitments) and those who have good access to telemental health (context), telemental health may provide increased flexibility that addresses individual practical barriers (mechanism), which can lead to telemental health being viewed by some service users and carers as more convenient and accessible than face-to-face care (outcome 1), easing attendance (outcome 2), increasing uptake (outcome 3), and reducing missed appointments (outcome 4).	This may be relevant for parents with young children, people with caring responsibilities, and people who struggle to travel because of work commitments/disability/costs; children and young people in school or higher education (so they can access mental health care without having to leave their place of education); people who live in remote areas or a long distance away from a specialist service; and people for whom travel is challenging because of impaired mobility or sensory impairments or mental health difficulties such as agoraphobia. There may be more advantages to treatments that involve the support of family and friends.	• Offering explicit choice wherever possible between telemental health and face-to-face care, including home visits where services are able to provide this, also considering that different modalities may be used for different purposes • Identification of people for whom attendance at office appointments is challenging so that telemental health (or home visits) can be considered • Continuing to offer choice and checking preferences throughout the duration of care (ie, not just asking once) • Avoiding missed appointments by offering a switch to telemental health as an option when a service user is unable at short notice to attend a face-to-face appointment

CMO[a] title	References	Overarching CMO	Key contexts	Example strategies and solutions
CMO 2.3: Involvement and support for *family and friends*	[79, 91, 113-115]	When family and other supporters are invited (with service user agreement) to join telemental health sessions (context), this may result in more holistic treatment planning and greater engagement of family and others in supporting service users (outcome 1); may help improve therapeutic relationships and treatment success (outcome 2), increase engagement (outcome 3), and reduce some uncertainty and anxiety around treatment (outcome 4); and may increase the satisfaction of and support for family and friends (outcome 5), as family and other supporters may be able to participate in care planning meetings and assessments that they would have found difficult to attend face-to-face, increasing their engagement in supporting service users and their understanding of their difficulties and care plans (mechanism).	This is especially helpful for those living in locations different from their family and friends or where family and friends have caring or work commitments preventing them from attending meetings face-to-face, children and young people (as this may allow their parents to be more involved in their care), and service users in inpatient settings where family and friends cannot visit (eg, because of epidemic-related restrictions) or as the hospital is in a remote location.	• Working with service users to identify any family and friends whose attendance at care planning and other clinical meetings (including on inpatient wards) would be helpful, including those for whom telemental health would facilitate access, such as people in distant locations or whose commitments would make it difficult to attend face-to-face meetings • Using strategies for service users to provide guidance on using telemental health to family and friends and prepare them for appointments • Offering children and their families the opportunity to have telemental health appointments (or, if feasible, home visits) if they find it easier to participate as a family without having to travel to an appointment and to be seen in a clinical setting • In inpatient wards, providing charged iPads, short cables, or charging lockers to allow service users to charge their own devices so that they can use technology to connect with family or other supporters
CMO 2.4: Widening the range of available mental health services and treatments for *service users* via telemental health	[49, 116-118]	For service users who may benefit from services that they cannot readily access locally and that provide specialized forms of treatment and support regionally or nationally (context), telemental health can widen the range of specialist assessment, treatment, and support available (mechanism), which potentially leads to improved access to services tailored to individual needs and culturally appropriate or specialist services (outcome 1) and improved satisfaction and treatment outcomes (outcome 2), although an impoverished range of local face-to-face provision may be a risk if referral to distant specialist care via telemental health becomes routine (outcome 3).	People to whom this is relevant may include people who have complex clinical needs or rarer conditions such that they would potentially benefit from assessment, treatment, and support from specialist services provided at regional and national rather than local levels; people who may be able to access distant therapists who speak their own language or interpreters of rare languages not available locally; people who would benefit from support from voluntary organizations that meet specific needs that are not catered for locally (eg, that support particular cultural groups; lesbian, gay, bisexual, transgender, and queer groups; or people with sensory impairments); and people who would benefit from a wider choice of therapies and support (including peer support) than is available locally.	• Development (including of funding arrangements) and dissemination of information about specialist services accessible via telemental health • Access for service users, their family and friends, and clinicians to information and signposting regarding community and voluntary sector organizations beyond their catchment area, which are accessible via telemental health • Development of safeguards against the erosion of local and in-person national specialist services in favor of routine specialist telemental health, in line with public-sector equality duty to anticipate and provide for the needs of groups with protected characteristics under the Equality Act (eg, pregnant people who are at increased risk of domestic violence, people whose disabilities cause sensory hypersensitivity, and people who struggle with screen time)
CMO 2.5: Adaptations for *service users* with sensory or psychological barriers to telemental health	[40, 50, 77, 119]	Offering face-to-face (or telephone) appointments to people who struggle to cope with sensory (visual or auditory) aspects of telemental health or have symptoms that are exacerbated by it (context) may help to improve engagement with mental health care (outcome) as the adverse effects of the switch to telemental health for these symptoms and sensory or cognitive impairments may be avoided and service users are able to access their preferred modality of care (mechanism).	This may be relevant for people with symptoms that may interfere with or be exacerbated by engaging with telemental health, such as persecutory ideas or hearing voices; autism; sensory or cognitive impairments; and migraines.	• Ensuring that face-to-face appointments (including home visits if there are impediments to office appointments) remain available • Making clinicians aware of the types of clients who may find it particularly difficult to engage with telemental health • Adapting telemental health where helpful, for example, through switching off cameras, using telephone rather than video calls, or communicating via SMS text message

CMO[a] title	References	Overarching CMO	Key contexts	Example strategies and solutions
CMO 2.6: Inclusion of multidisciplinary and interagency teams in *service users'* care	[89,115]	When mental health consultations are conducted using telemental health (context), it enables the inclusion of staff in appointments who are based geographically far away or who have schedules that would not have allowed them to join a face-to-face session (outcome 1), meaning care and support has potential to be more holistic and integrated (outcome 2), as it is possible for staff from different services and sectors to provide perspectives and contribute to plans (mechanism).	Key contexts include hospital inpatients, where telemental health may enable staff who work with them in community settings to join reviews and ward rounds (especially in pandemic conditions where they cannot attend in person), and people with complex treatment and support, who are receiving support from >1 team or sector.	• Working with service users to identify staff whom it would be helpful to involve in consultations such as review and care planning meetings, including in social care, housing, and the voluntary sector • Facilitating the involvement of such staff in reviews via telemental health, especially where face-to-face attendance is not feasible
CMO 2.7: Continuing to offer face-to-face care to *service users*	[53, 81, 92, 116, 120]	When service providers offer care of equivalent quality and timeliness face-to-face (including home visits where needed) rather than via telemental health to service users who do not wish or do not feel able to receive their care remotely (context), it ensures that care can continue and that inequalities in provision are not created or exacerbated (outcome), as it provides a choice to service users and avoids the negative impacts of digital exclusion (mechanism).	People for whom face-to-face options may be preferable, and choice is especially important, include those who do not have access to private spaces, live with people they do not wish to be overheard by in their appointments (including perpetrators of domestic abuse), do not feel comfortable communicating via remote means, and do not want therapy to intrude on their private lives should be included. In addition, some service users who value the time spent traveling to and from face-to-face appointments to process emotions may find face-to-face options particularly useful.	• Ensuring services are able to offer a choice between telemental health and equivalent care delivered face-to-face (especially when telemental health is part of routine care rather than a means of managing a national emergency) • Ensuring (as in CMO 2.1) that clinicians are fully aware of service user preferences and circumstances (which may be elicited via a shared decision-making tool) and continue to monitor these over time • That clinicians are alert for any changing circumstances during telemental health where a service user does not feel comfortable to speak and make alternative arrangements accordingly (eg, using text functions on videoconferencing platforms or arranging face-to-face appointments)
CMO 2.8: Communication between *staff*	[19, 85, 121]	When remote technology platforms are used to facilitate real-time communication between staff members, including managers or clinicians working in different teams (context), it can lead to improved efficiency, more convenient working and staff management (outcome 1), improved communication and collaborative planning (outcome 2), and process improvement opportunities (outcome 3), as staff have the ability to rapidly share information, keep track of evolving telemental health procedures (eg, during emergencies), and make collaborative decisions (mechanism).	Contexts in which this is relevant include multidisciplinary teams who are not working on the same site; complex provider organizations with management teams and clinicians working on multiple sites; situations in which people may be receiving care from multiple teams, for example, from an inpatient or crisis service, as well as a continuing care service.	• Making use of telemental health platforms to strengthen liaison and collaboration between teams and professionals on different sites (eg, through increased enhanced liaison between managers across an organization) or provide better access to a range of educational events • Using telemental health platforms to facilitate multidisciplinary team meetings between staff on different sites (especially if some are working from home) • However, awareness is needed that perceived pressure for staff to provide an immediate response may also negatively affect their work-life balance

[a]CMO: context-mechanism-outcome.

Domain 3: Safety, Privacy, and Confidentiality

Table 3 presents the four overarching CMO configurations, key contexts, and example strategies and solutions for the domain of safety, privacy, and confidentiality. Key messages were the importance of ensuring the availability of a private space for both service users and clinicians (CMO 3.1), the potential for telemental health to provide privacy to some service users experiencing stigma (CMO 3.2), the importance of considering how to manage risk when using telemental health and the limits to how far this is possible (CMO 3.3), and data security and staff training (CMO 3.4).

Table 3. Domain 3: Safety, privacy, and confidentiality.

CMO[a] title	References	Overarching CMO	Key contexts	Example strategies and solutions
CMO 3.1: Lack of privacy	[39, 42, 45, 48, 54, 55, 58, 60, 77, 79-82, 90, 91, 97, 101, 102, 104, 111, 120, 122-127]	When accessing telemental health sessions without access to a private space or secure private connection (context), service users and staff are at an increased risk of being overheard (mechanism 1), potentially leading to breaches of privacy and confidentiality (outcome 1), risk of harm to those in unsafe domestic situations (outcome 2), and reluctance to speak openly about sensitive topics (outcome 3). It may also cause some service users to experience frustration, distress, and anxiety (mechanism 2), leading to impacts on service user engagement and interactions (outcome 4) and reduced willingness to use telemental health and continue therapy (outcome 5).	Issues related to lack of privacy at home are especially relevant for young people who are distracted by their home environment, may not feel safe in their own home, or have siblings/parents/other family members unexpectedly appearing in the room; parents with children at home; those experiencing domestic abuse who are not able to be honest about symptoms, risk, or violence experienced; people who may be living with/caring for extended family or in households that are crowded; inpatients who may not have a space where they feel *psychologically safe*; people living in houses of multiple occupation; staff members who are not able to work in a private environment when providing remote therapy; and service users who experience cultural stigma in the home from their families relating to their mental health.	• Brainstorming with the service user whether there are potential options for private places or times when privacy is more likely • Offering face-to-face sessions when a private space is not available for telemental health, especially if there is any possibility that the person is at risk from someone in their home environment • Regular, discreet checking that the service user (and therapist) is in a private space (eg, using the chat function in video calls) and taking steps to provide alternative locations if not • Being flexible regarding the time of appointments • Allowing people to turn off their camera or use virtual or blurred backgrounds (as well as ensuring that the option is available and they are aware of how to do this) • Working with schools to provide safe spaces away from home for children (although young people may not want to alert teachers/other pupils to their need for a space to use for therapy) • Attention to clinicians' access to a private space and disclosure to service users if they are not in a completely private environment (eg, a shared office or a private home with other family members on the premises) • Use of headsets with microphones
CMO 3.2: Privacy, anonymity, and reduced stigma (*service users*)	[40, 43, 92, 103, 105, 128-131]	For some service users who feel stigmatized when attending a mental health service in person and who have access to a private and secure space to receive therapy remotely (context), being provided with the option of telemental health as an alternative means there is an option to receive care with more anonymity (mechanism), which helps ensure their privacy and safety (outcome 1), thereby increasing the accessibility of services (outcome 2).	Some groups may be more likely to feel there is a stigma associated with attending mental health premises or reluctant to have contact with others doing so, for example, young people not previously in contact with services.	• Offering telemental health (or home visits) to avoid missed appointments to people who are reluctant to attend mental health premises because of perceived stigma or as they find them intimidating

CMO[a] title	References	Overarching CMO	Key contexts	Example strategies and solutions
CMO 3.3: Managing risk	[24, 43, 85, 91, 111, 112, 119, 124, 132-136]	When services incorporate tailored risk management procedures in the delivery of remote care (context), it encourages consideration of the risks associated with remote care specific to each individual, including the risk of self-harm or suicide and risk from others in situations of domestic abuse, and ensures the staff are aware of the procedures to try to assess and respond to risk or safeguarding concerns despite challenges associated with remote care (mechanism), which has the potential to improve the safety and well-being of service users and others (outcome 1). However, a disadvantage of telemental health is that real-time risk assessment limits an immediate response to be organized when someone is at imminent risk of harm and some distance away (outcome 2).	This may be relevant to people who are currently unwell or in a crisis, situations where someone is remote from the assessing clinician or at a location unknown to them, situations where technological difficulties occur during an assessment of someone who is at high risk, people with eating disorders or who are physically unwell and where there are practical impediments to assessing risk remotely, and when a service user suddenly exits during a telemental health consultation and it is not clear why. In substance misuse services, it may be harder to detect whether someone is under the influence of drugs or alcohol.	• Establishing a call back number before the commencement of the session in the case of disconnection when discussing distressing or sensitive topics • Increased coordination with service users/families to facilitate safe transport to emergency departments if needed • Setting clear protocols regarding when staff can be contacted via digital means, including who to contact instead in the case of an emergency • Identification of where the service user is located at the start of the session to enable a faster response of in-person support if needed • Development of a “telehealth manual” containing information on what to do in the event of a sudden ending of the call and who to contact • Codevelopment of a crisis plan with the service user • Offering 24/7 helplines and continued availability of face-to-face crisis response, including capacity for home visits • Ensuring adequate device battery or connecting to a charger at the start of the session to reduce the risk of disconnection
CMO 3.4: Technological support and information security	[85]	When services provide technology support, software with appropriate security, and devices (including mobile phones and headphones) to staff specifically for work use (context), it helps ensure privacy and confidentiality for both service users and staff (outcome), as staff can store information securely on devices that are not shared with others (mechanism 1) and are able to ensure that service users are aware of when they will have access to their work devices (mechanism 2).	This may be relevant in services where staff share office space and devices, or where a shortage of devices may lead to the use of personal devices, for example, for home working; when balancing service user preference with risk from using less secure software or software with which the staff are less familiar; where software has a particular set of settings that must be enabled to ensure secure, private connections.	• Providing data safeguarding and other technology-based training to all staff (as knowledge cannot be assumed) • Providing information on which software is encrypted/secure • Providing funding to staff for the purchase of equipment • Setting recommended boundaries for both service users and clinicians in relation to the privacy of personal life and maintaining a work-life balance, for example, by not being contacted outside working hours or using a personal phone

[a]CMO: context-mechanism-outcome.

With the most supporting literature, CMO 3.1 highlights the need for appropriate private space to receive telemental health and that many service users may not have consistent access to such a space. As a lack of privacy can risk breaches in confidentiality and safety for some, a key message was that alternatives such as face-to-face modalities or alternative times/locations to receive telemental health should be provided. The importance of privacy for effective mental health care has been frequently cited in the literature and is likely to be especially important in ensuring high-quality telemental health [91]. Although some literature indicated that some service users feel an increased sense of privacy and a reduction in stigma when not having to attend mental health clinics in person (CMO 3.2), a key message lies in providing a choice so that each individual can work with their clinicians to find ways of receiving care that they are happy with, a message highlighted in CMO configurations throughout this paper.

CMO configurations in this domain also make it clear that telemental health can result in greater risks, both directly as it may be more difficult for clinicians to assess and respond to risks (CMO 3.3) and indirectly if data security is impaired (CMO 3.4). In both cases, proactive steps to assess and limit risk before the use of telemental health, as well as preplanned strategies to respond to events that threaten safety, are important. Data security knowledge should not be assumed, and training to help staff keep service users’ personal information secure will also mitigate telemental health–specific risks. However, evidence from both the literature and the stakeholder consultations made it clear that it is difficult to fully overcome the obstacles to effective risk assessment and management that result from staff and service users being in different places, meaning that the continuing availability of an in-person community crisis response is also important.

Domain 4: Therapeutic Quality and Relationships

Table 4 displays the overarching CMO configurations, key contexts, strategies, and solutions for the final domain of therapeutic quality and relationships. Therapeutic relationships have been identified as pivotal for the successful delivery of telemental health across the literature and stakeholder consultations. The domain addresses barriers (CMO 4.1 and CMO 4.2) to and facilitators (CMO 4.3, CMO 4.4, CMO 4.5, and CMO 4.6) to the development of therapeutic relationships and delivery of quality care and discusses the impact of telemental health on staff well-being (CMO 4.7).

Trust and therapeutic relationships are important across health care, and relational aspects of care are especially crucial in mental health [173-178]. However, the reliance on telemental health platforms, particularly telephone and text-based communication, may affect communication and subsequently therapeutic relationships (CMO 4.1). Our CMO configurations, particularly their mechanisms, were informed by general theories regarding the role and development of therapeutic relationships in mental health care.

CMO 4.1. highlights that telemental health is likely to lead to a change or reduction in visual and nonverbal cues, including active listening and back channels, facial expressions, gestures, posture, and eye contact, which makes aspects of communication, such as pauses, difficult to interpret. In addition, time delays in video calls may create silences and lead to talking over each other and delayed visual responses, which negatively affect communication and nonverbal synchrony [179,180]. As a result, not only therapeutic relationships but also the staff's ability to conduct accurate assessments are compromised (CMO 4.1 and CMO 4.2). However, conversely, good quality video contacts with well-trained clinicians may mitigate some of the therapeutic challenges when delivering telemental health. Those making first contact with mental health services appear to be particularly affected by the potentially impersonal nature of telemental health and thus benefit not only from an initial face-to-face session but also from more frequent subsequent telemental health sessions to establish stability and trust (CMO 4.1 and CMO 4.5). In addition, our findings indicate that staff confidence and ability to deliver good quality care and develop therapeutic relationships via telemental health can be fostered through training sessions provided by services (CMO 4.3).

The literature and stakeholder consultations identified no telemental health modality that is consistently superior for developing therapeutic relationships (CMO 4.4). Rather, whether telephone calls, video calls, or face-to-face meetings are most appropriate seems to depend on the purpose of the sessions and on an individual's preferences based on their personal experiences and circumstances and whether they are new to the service, as well as the nature of their mental or physical health problems. Video calls seem to be preferred for more substantial and in-depth sessions than other telemental health modalities [24]. Providing service users with choice regarding the frequency, duration, and telemental health modality is crucial for therapeutic relationships and quality of care.

Despite its limitations, flexible use of different telemental health modalities can provide significant opportunities to foster therapeutic relationships and increase the quality of care, such as checking in, sending reminders via SMS text messages, and using features such as chat functions to increase engagement among service users (CMO 4.6).

Finally, taking breaks in between telemental health sessions and fostering positive telemental health working environments is key for staff well-being and the delivery of high-quality care (CMO 4.7).

Table 4. Domain 4: Therapeutic quality and relationship.

CMO[a] title	References	Overarching CMO	Key contexts	Example strategies and solutions
CMO 4.1: Change in nonverbal cues and informal chat, affecting the therapeutic relationship	[12, 19, 24, 36, 37, 40, 45, 49, 54, 55, 60, 67, 76, 77, 79, 81, 90-92, 96, 103, 137 - 142]	When switching from face-to-face to telemental health care (context), staff and some service users perceived the relationship between staff and service users (and other service user group members) to be negatively affected or found it more difficult to develop a therapeutic relationship (outcome 1) and, thus, were less willing to take up or use telemental health (outcome 2), more likely to be dissatisfied (outcome 3), and viewed care as less effective compared with previously received face-to-face care (outcome 4). This was because they perceived telemental health to be impersonal and found it more difficult to discuss personal information because of a lack of nonverbal feedback, eye contact, and social cues, as well as informal chat before, after, and during sessions (mechanism).	This may be relevant during rapid switches to telemental health because of emergency situations such as the COVID-19 pandemic in which staff training and structured telemental health implementation are limited because of time constraints; for staff with limited training and experience generally and those with limited experience of using telemental health specifically, who may lack the confidence to navigate the change in visual cues, which, in turn, can affect the therapeutic relationship; for staff and service users who are new to a specific service, staff/service user, or to mental health care generally; for service users who are apprehensive of technology use or who are concerned about the violation of their privacy; and in telemental health group sessions in which the flow of conversation is affected or people find it less easy to establish relationships and be at ease with the whole group.	• Offering new service users the option to receive their first appointment face-to-face when starting telemental health, depending on their preference • Under pandemic conditions, exploring whether service users prefer telemental health sessions over face-to-face sessions, which require wearing masks • Checking in with service users about their experiences and preferences regularly while trying to use a particular telemental health platform consistently • Allocating additional time to address service user concerns about technology use and privacy • Using high-quality equipment and ensuring good camera placement during video calls • Making greater efforts to communicate clearly, enhance gestures, and provide verbal and nonverbal reinforcement, such as active listening and backchanneling (ie, nonverbal or verbal responses) • Focusing on service user–centered communication, such as being reassuring and supportive • Taking more time to informally chat and get to know new service users one-to-one when delivering the initial appointment via telemental health • Providing training to staff to increase their comfort with technology and training to interpret social cues when using telemental health • Providing reassurance to staff that service users often perceive the therapeutic relationship to be less affected by telemental health than staff believe • Facilitating relationships between service user group members by keeping the video call open after the main session to allow follow-up conversations
CMO 4.2: Assessment via telemental health versus face-to-face (*staff*)	[40, 82, 92, 111, 121, 133, 137, 138, 143 - 145]	When using telemental health for assessments (context), staff report finding it more difficult to assess mental health problems, care needs, and risk, and make diagnoses (outcome), as they are less able to observe nonverbal and visual cues (depending on the telemental health modality used), and some service users may find it more difficult to have in-depth conversations about their problems and experiences (mechanism).	Cues can include extrapyramidal symptoms from antipsychotics, hygiene, gait, direct eye contact, mannerism, and linguistic nuances. Conducting assessments might be particularly difficult over the phone because of the lack of visual cues; with service users who experience domestic violence and abuse and thus cannot be honest about their well-being and current situation in the presence of their abuser; with young children; with service users who find it difficult to speak directly about their difficulties and experiences; and when the staff make incorrect assumptions about service users' mental states based on behavioral indicators and without considering service user reports, especially of neurodivergent service users.	• Offering service users the option to receive face-to-face care for first assessments and in crisis situations • Taking both service user reports and nonverbal and visual cues into account for assessments • Offering service users experiencing domestic violence and abuse the option to use text-based communication in addition to face-to-face care or other telemental health modalities to avoid being overheard • Providing training to staff in conducting assessments using telemental health

CMO[a] title	References	Overarching CMO	Key contexts	Example strategies and solutions
CMO 4.3: *Staff* support and training	[49, 63, 102, 146]	When staff receive specific instructions and training, for example, on how to build rapport using telemental health and support from colleagues with prior telemental health experience (context), it facilitates quality of care (outcome 1), building therapeutic relationships (outcome 2), and increased engagement (outcome 3), as staff are able to ask questions and acquire new skills and knowledge about the interventions and thus build confidence in delivering telemental health (mechanism).	This is likely to be especially relevant to staff who have little or no previous experience of delivering telemental health.	• Offering staff training on aspects of good care that go beyond technical skills and issues • Staff training should ideally be co-designed and codelivered with service users
CMO 4.4: *Service users* who find it easier to establish a therapeutic relationship				

CMO[a] title	References	Overarching CMO	Key contexts	Example strategies and solutions
On the web	[39, 60, 79, 96, 99, 119, 136, 137, 147, 148]	When delivering telemental health to some services users who feel uncomfortable in clinical settings and social situations (context), these service users find it easier to build a therapeutic relationship and are more willing to use telemental health (outcome), as they feel safer, are more relaxed and less anxious being in their own environment or outside of clinical settings and in-person social situations, or both, and, thus, feel more empowered and comfortable to open up and speak freely (mechanism).	This may be especially relevant for some children and young people, including those with special needs and neurodivergent children, who find clinical settings and having to travel upsetting, and some service users with social anxiety. However, it is important that using telemental health does not reinforce potentially detrimental safety behaviors that may maintain and potentially exacerbate their social anxiety.	• Offering service users the option of receiving care by telemental health rather than face-to-face, especially if they neither wish to attend clinical settings nor to be visited by professionals at home
Via video versus phone	[24, 36, 50, 52, 55, 78, 105]	When service users and staff who prefer video calls use them (instead of telephone calls or text-based chats) for telemental health (context), it can facilitate a stronger therapeutic relationship (outcome 1), satisfaction (outcome 2), and engagement (outcome 3), as it is easier to see visual and nonverbal cues, gauge the therapist's reaction, and connect with the service user/staff member than with other telemental health modalities (mechanism).	This applies to service users across age groups and may be especially the case for new service users.	• Encouraging clinicians to offer video calls rather than relying on phone calls and SMS text messaging and providing the relevant infrastructure and guidance to support this
Via the phone versus face-to-face or video calls	[50, 65, 80, 111]	When services offer phone calls and SMS text messages instead of video calls (context), some service users are more satisfied with their care (outcome) as they do not have to sit still and see themselves on screen, are less conscious of their body language and facial gestures, are less distracted by the clinician's nonverbal cues, are able to move around freely, and are thus less inhibited and able to open up more quickly (mechanism).	This might be especially relevant for service users who are neurodivergent, socially anxious, and self-conscious about their appearance.	• Informing service users about the option to turn off their camera during video calls or using the phone if they are uncomfortable • Offering a telephone call or text service instead, if the service user prefers this
CMO 4.5: More frequent telemental health sessions plus SMS text messages	[39, 40, 99, 104, 149]	When services adapt flexibly to service users' preferences regarding the pattern and frequency of telemental health sessions, including offering more frequent, shorter rather than infrequent, long sessions, and additional asynchronous SMS text messages and calls to check in between sessions (context), it may lead to stronger therapeutic relationships (outcome 1), increased engagement (outcome 2), and improved quality of care (outcome 3), as service users receive regular and more frequent support depending on their preference (mechanism).	Lack of a need to travel means that more frequent shorter sessions may be particularly feasible with telemental health: they are potentially less tiring and thus might better maintain concentration and engagement, especially for children. Frequent sessions might help new service users to build trust and reduce anxiety around the treatment. Frequent sessions may also help support and monitor less stable service users, for example, following a crisis.	• Considering offering shorter and more frequent sessions when telemental health is a primary modality for delivering care
CMO 4.6: Enhancing the quality of care through the use of telemental health enhancements	[24, 74, 101, 150-152]		Additional telemental health features might be particularly helpful for young children (who overall find it difficult to engage on the web). Adolescents who experience social anxiety or are autistic may benefit from and prefer the chat function.	• Using SMS text messaging (including apps) to maintain communication in a flexible way between appointments, especially for younger people for whom this may be a preferred method of communication • Using screen sharing to facilitate psychoeducation or working together on assessment or therapeutic tools • Using telemental health sessions to introduce apps and websites that support self-management or therapy or to collaboratively complete measures and questionnaires

CMO[a] title	References	Overarching CMO	Key contexts	Example strategies and solutions
		When clinicians make appropriate and personalized use of enhancements and extensions of telemental health (such as using chat, voice activation to instruct phones, SMS text messaging and other text-based messaging, web-based appointment schedules, screen sharing, and apps accessed during sessions; context); it can lead to success engaging in telemental health (outcome 1) and broadening the range of strategies and interventions available during clinical meetings (outcome 2), as these features make engaging with services easier and provide a functional method useful for exchanging practical information, such as reminding service users about the date and purpose of an appointment, with less room for ambiguity and more creative methods of engagement (mechanism).		
CMO 4.7: *Staff* well-being and quality of care	[51-53, 80, 88, 91, 101, 107, 112, 153]	When the staff use the time saved on travel to take breaks in between telemental health sessions (context), it may increase staff well-being (outcome 1) and improve quality of care (outcome 2), as it provides the opportunity to reflect and recharge after telemental health sessions, which are often experienced as tiring and thus reduces fatigue, tension, and anxiety among staff (mechanism 1), and staff can use some of the time on clinical work, catch up on administrative tasks, or engage in professional developmental activities (mechanism 2).	This may be relevant for clinicians who can work wholly or partly at home and teams working across different sites or who visit service users at home or in other community settings.	• Supporting clinicians in planning their time so that they can work from home and save travel time on some days • Considering appointing some interested professionals to fully remote roles in which they can develop skills and make efficient use of time • Ensuring that when time is saved because travel is not needed, clinicians still have suitable breaks between on-screen appointments and are able to dedicate some of the time saved to their own professional development • Fostering a working culture in which staff are encouraged to take breaks between telemental health sessions to reflect and recharge

[a]CMO: context-mechanism-outcome.

Discussion

Principal Findings

Our RRR identified CMO configurations within four key domains, each with a range of practical implications regarding what works and for whom in telemental health: connecting effectively; flexibility and personalization; safety, privacy, and confidentiality; and therapeutic quality and relationship. Potentially, the most important finding of this realist review is the significance of personal choice and that one size does not fit all for telemental health. This includes choice of modality (eg, video, telephone, and text-based chat functions), platform, frequency or duration of sessions, and the option to revert to face-to-face sessions if preferred or required by the service user based on their current context or to vary modality from contact to contact. This review has highlighted that there are many contexts where face-to-face care is preferred or needed by service users, and this should be accessible and available to them and should be of equivalent timeliness to remote care (especially when delivered as part of routine care rather than as a response to a national emergency). However, the use of telemental health is a convenient and potentially advantageous option for some people in many contexts; thus, it is beneficial for mental health clinicians to have the skills and resources to offer telemental health as an option. When service users' choices about what works for them are respected and decisions about care planning are made collaboratively, it is likely to be conducive to a stronger therapeutic relationship where the service user feels heard and respected [178].

Access to a device with a stable internet connection, as well as the confidence and ability to use a device to access telemental health, were identified as minimum requirements for both staff and service users to access telemental health, without which face-to-face appointments would be necessary. The devices and platforms used for delivering telemental health needed to be user-friendly [163,164], and preferably familiar, to easily facilitate sessions. Telemental health seemed to reduce some barriers to receiving mental health support experienced by some service users, such as those who were unable to travel or in inpatient wards, making it an acceptable alternative to

face-to-face sessions for some people under these circumstances. It may also potentially allow service users greater access to out-of-area specialist services and support that is focused on specific groups (eg, cultural or lesbian, gay, bisexual, transgender, and queer groups). Issues of privacy, including data protection and confidentiality, or staff and service user access to a private space were emphasized throughout the literature and our consultations; this is likely to disproportionately affect disadvantaged groups of service users, such as those experiencing poverty, those in multi-occupancy households, children and young people, or people living with controlling or abusive partners or other family members. Already disadvantaged groups are similarly at particularly high risk of inequalities being exacerbated through digital exclusion. The "inverse digital care law," stating that the use of digital technologies can make health inequalities worse [154], may well apply to the widespread implementation of telemental health [16]. Service planning and delivery must be based on a strong awareness of these risks and the need to overcome these barriers. There is also a duty to ensure that in-person care of equivalent quality remains readily available.

The impact on therapeutic relationships for both staff and service users has also been highlighted, with difficulties interpreting visual or nonverbal cues being cited as a barrier to establishing a good therapeutic relationship that enables service users to disclose sensitive information and staff are able to conduct valid clinical assessments. Adapting to service user preferences flexibly and giving weight to self-reports during assessments is likely to increase the quality of care and foster strong therapeutic relationships.

Strengths and Limitations

The use of the RRR methodology to rapidly establish a set of theories about what works, for whom, and in which circumstances in telemental health has several strengths. The breadth of screened written evidence extends beyond published academic literature to nonacademic (including policy, third sector, and lived experience) sources. The targeted call for evidence sent directly to expert stakeholders from research, policy, and clinical settings (nationally and internationally), the voluntary sector, lived experience groups, minority groups, and representatives from health tech initiatives identified resources that would otherwise have been missed. Through these procedures, we rapidly identified literature from a wide range of key perspectives to contribute to the development of the CMO configurations.

The analysis process was rigorous and valued both published literature and stakeholder views, with the use of rapid realist methods allowing a range of stakeholder perspectives to be incorporated beyond what is normally possible in reviews. Our expert reference group (including clinical, academic, and lived experience experts) fed into the review process and theory development throughout, iteratively reviewing the plausibility, relevance, and usefulness of our individual and overarching CMO configurations. A wider group of expert stakeholders provided further input to identifying sources and reviewing overarching CMO configurations, especially regarding our priority groups: children and young people, users of inpatient and crisis care services, and digitally excluded populations. Continuous detailed feedback from the lived experience researchers and frontline clinicians helped to reduce bias toward academic perspectives; ensured the inclusion of a breadth of real-life experiences; and supported the iterative development of our methods, results, and interpretation of the findings.

A final key benefit of the RRR methodology is that we could rapidly investigate not only outcomes of telemental health use but also the mechanisms underlying what works and for whom, which most methodologies do not allow. We could also explore the contexts in which telemental health was implemented, as well as the telemental health resources that are available. This approach should be considered for future evaluation of telemental health.

Some limitations should be noted. The first relates to generalizations made in the process of developing overarching CMO configurations. These tended to combine underlying CMO configurations that related to a range of service user and clinician groups, service settings and types, and social and national contexts. We looked for important themes that appeared of general relevance and were validated through stakeholder consultation. However, it is likely that in some areas, we lost a more nuanced understanding of the relationship between particular CMO configurations and particular contexts. We also used a broad definition of telemental health to capture as much richness (and data) as possible from the available sources. However, we have merged heterogeneous forms of telemental health within most of our overarching CMO configurations, which may differ in their effectiveness and underlying mechanisms. Therefore, the conclusions are limited regarding mechanisms; outcomes for specific types of telemental health; and the impact on service users, staff, and carers. We also included literature that draws on the experiences of service users and clinicians both before and during the pandemic. However, technologies and approaches to implementation have changed substantially, with prepandemic evidence tending to focus on the planned and relatively small-scale implementation of tools specifically designed for mental health. Studies from the pandemic tend to relate to a range of phone and video call technologies implemented at scale with limited strategic planning. During the pandemic, staff and service users may also have been more willing to trial telemental health, given the extraordinary circumstances. The available technologies, and clinicians' and service users' skills in applying them, are also likely to have changed over time and are likely to continue to change.

The nature and strength of evidence drawn on for the review also need to be noted. Most sources were qualitative studies, service evaluations, or cross-sectional studies of associations; we found few relevant trials or longitudinal studies. We tried to maximize the value of this body of evidence by combining findings from multiple studies with expert stakeholder input to obtain theories with multiple sources of support about what works and for whom, illustrating them with example contexts and strategies. However, the lack of testing through traditionally robust methods in testing intervention strategies, such as trials and other longitudinal forms of evaluation, still needs to be noted, as discussed further in the *Implications for Research*

section. In line with realist methodology [27,29], we did not appraise the sources we identified using traditional methods. However, sources were only included if they provided sufficient information on context, mechanism, and outcomes and contributed to the development of our overarching CMO configurations. Our extracted data were reviewed for their validity and coherence by our expert reference group.

Despite the inclusive search strategy and specific efforts to gain a wide range of perspectives, digitally excluded groups remain underrepresented in this study. This is partly because of the lack of literature focused on digital exclusion and the web-based methods used to conduct our review during the COVID-19 pandemic. Efforts were made to gain perspectives on digitally excluded groups by involving charities and staff and service user advocates working with people in such groups, including in projects aimed at addressing digital exclusion, in our stakeholder consultation. However, people experiencing severe digital exclusion did not participate in our web-based consultations, and the extent to which others can advocate for them is limited. Similarly, this study identified a lack of evidence in the literature about how to make telemental health engaging and effective for young children, nor were we able to find many people with relevant expertise to participate in our consultations. Data were also limited on group therapy and the role or experiences of families and other supporters of service users. Most available literature focused exclusively on staff perspectives of telemental health and crucially neglected to include the views or experiences of service users and their families or other supporters. Therefore, we were unable to incorporate these groups and their perspectives in our analysis and synthesis.

This study was initially planned and commissioned through discussions between policy makers in the Department of Health and Social Care and the MHPRU leads; lived experience researchers did not have the opportunity to contribute during the early stages of formulating research questions and identifying the methodology to be used.

Implications

Implications for Clinical Practice

A range of implications for clinical practice and service planning can be drawn from our CMO configurations. The challenge for the future will be to find sustainable ways of implementing them in clinical practice and finding an appropriate balance between telemental health and traditional face-to-face care in future service delivery. In the context of a recent emergency (the COVID-19 pandemic), telemental health has been used with some degree of success to maintain care for at least some service users. Evidence and experiences from this widespread emergency implementation are helpful, both to inform future responses to such emergencies and allow a preliminary assessment of potential opportunities and pitfalls in implementing telemental health beyond an emergency context.

Some clear principles to guide practice emerge from our CMO configurations. Offering choice, planning care collaboratively, and listening to personal preferences regarding whether to use telemental health need to be embedded within services in which there is continuous use of telemental health as we move through and out of the COVID-19 pandemic. How choice is negotiated, enabled, and communicated is crucial. For choice to be real, options need to be clearly explained and discussed at every stage; face-to-face care of equal quality should be delivered as promptly as telemental health; and choice should be seen as dynamic, especially when a service user is in crisis. Preferences should be reconfirmed regularly and hybrid forms of care made available if appropriate. Choices may also be different after the COVID-19 pandemic, when the risk of infection traveling to and at appointments may no longer be a concern and consultations are no longer masked; mask-wearing at most face-to-face appointments during the pandemic may undermine some advantages of in-person care. Ideally, service user and clinician choices and resources should be balanced through shared decision-making. Use of telemental health cannot be assumed to be a permanent switch; thus, preferences should be revisited regularly. In planning services, it may be easier to switch from in-person appointments to digital appointments than vice versa, and this needs to be considered in staffing and working space arrangements. Traditional inpatient and community services are limited in their ability to collaborate and provide choice in their established processes, such as care planning and risk assessment or management [177,178,181-183]. Therefore, it may be unrealistic to expect improvements in these areas when delivering telemental health.

Lack of access to digital devices or data, or of expertise in connecting to telemental health services, is a problem that service providers may be able to address for some people. For example, opportunities to develop skills and clear guidance and opportunities to practice may be relatively straightforward ways of alleviating problems with connecting effectively for some people who may find telemental health a convenient way of receiving care if they are supported to engage. At best, obtaining access to telemental health may be a skill acquired along with developing the skills to access a variety of other significant parts of the digital world. In other instances, clinicians and service providers should be aware that digital exclusion tends to be rooted in other forms of disadvantage and that they can most readily avoid exacerbating such disadvantages by offering face-to-face care. Persevering with telemental health when service users do not want to receive care by this means and are not in the habit of using digital technologies may prove futile in everyday clinical care. There is also likely to be scope for improving the extent to which service providers have the capacity to connect effectively, for example, through better infrastructure, clear guidance and training for staff, and clarity and flexibility regarding platforms.

Developing a therapeutic relationship is key for the quality and success of care, and offering initial appointments face-to-face may facilitate this, subject to service user choice. In addition, services and staff may need to consider how to adapt telemental health care to account for the change in visual cues, including body language and facial expressions (although visual cues in face-to-face sessions may, in any case, be compromised while infection control considerations mean most sessions are masked).

In addition, the domain of privacy, safety, and confidentiality has implications for clinical practice. Clinician awareness of potential risks associated with using telemental health is important and may steer them away from conducting some consultations in this way. Maintaining privacy and safety, for example, for people at risk within their homes, is also a significant reason to prioritize service user choice, especially choices not to accept telemental health appointments, as they may not readily be able to explain the basis for their choice. Clinicians need also to be aware of the challenges of assessing and responding to risk when using telemental health, including the advantages of face-to-face meetings; the need to give weight to service user reports where visual or verbal cues may be obscured; and the importance of backup plans, such as for disconnection or when an urgent response is needed. Clinicians and care coordinators could also helpfully ensure that service users have access to and can use telemental health care adequately before the agreed web-based sessions begin, although this may be affected by staffing issues and limited resources [184,185].

Implications for Policy

Digital poverty does not exist in isolation, and the experience of poverty may be the root cause of their digital exclusion. Providing service users with access to devices and the internet, for example, serves as an adequate short-term fix but does not address the systemic welfare issues experienced by many service users [186]. Strategies to mitigate digital exclusion could include the provision of good national Wi-Fi coverage, free broadband [187], and investment in accessible and connected community hubs; implementing these would require action from the government rather than health services.

Telemental health services seem to be a viable alternative to face-to-face care for some service users, including in emergency situations, such as COVID-19. To provide good telemental health services, investment is needed, for example, in providing telemental health–specific training and guidance, high-quality infrastructure, and potentially technological devices to staff and service users. Preregistration education and training should include skills in telemental health. Further investment is likely to be needed in updating this as evidence and technologies change (eg, to cover the ongoing costs of keeping hardware and software up to date). This may need to be balanced against any savings anticipated from implementing telemental health. This study has also highlighted the importance of service user and frontline staff involvement in the planning of all telemental health services and provision.

Implications for Research

Much of the included research was based on explorations of views and experiences of people participating in telemental health in various settings. We found few studies involving systematic evaluation of planned strategies to achieve high-quality implementation of telemental health in routine settings. Primary studies of this form would be valuable, potentially using implementation research and participatory action research models to explore outcomes and experiences of strategies aimed at good quality implementation of telemental health in varying real-world settings during and after the pandemic. Our CMO configurations have the potential to inform such a primary research study: it would be helpful to develop and test coproduced strategies for implementing principles encapsulated in the CMO configurations in real-world settings. Similarly, our understanding of what works and for whom in telemental health would be improved by conducting primary research with specific groups, particularly those excluded from previous studies, such as digitally excluded groups or peer support networks, and in specific contexts, such as in group therapy sessions. Identifying methods of reaching digitally excluded populations in research studies, as well as identifying groups for whom telemental health is not appropriate, would be helpful. This is likely to be labor and time intensive and needs appropriate funding. Future research could also usefully explore the use of different telemental health modalities individually and in more depth.

Choice has been emphasized as crucial in the use of telemental health. The mechanisms behind choices and collaborative decision-making would benefit from further investigation, potentially using realist methods and drawing on principles from shared decision-making research. Investigation is warranted of the best approaches to providing the information needed to make an informed choice, holding collaborative discussions on how to personalize care for each individual, and providing staff and service users with guidance and training needed to participate effectively in telemental health. At a provider level, evidence is needed on what makes a good telemental health platform, how to balance data security with the flexibility that service users and clinicians may value in choosing platforms and using familiar tools if possible, and how to adapt risk management to a telemental health context. However, trusts may compromise their ability to offer choice and flexibility to service users when they specify the platforms that can and cannot be used to deliver telemental health services (although this may have advantages, including increasing staff familiarity). Future work could helpfully investigate whether certain combinations of features, platforms, or modalities are optimal for service users, their carers, and clinicians.

Researchers conducting evaluations of telemental health should consider that *satisfaction* tends to be evaluated as one component. However, satisfaction with telemental health comprises several components that need to be individually considered. For example, the skills of therapists may be rated highly, whereas telemental health platforms themselves may cause significant frustration and, if they were scored separately, would be poorly rated. Therefore, telemental health needs to be evaluated as several elements rather than as a singularity.

The impact of telemental health delivery on staff is a further key area of investigation. Some staff in research studies and in our stakeholder consultations reported finding prolonged screen use draining and perceived it as a contributor to burnout. The impact of telemental health on staff and ways of ensuring that it does not increase burnout or physical or psychological stress requires investigation. It may be pertinent to investigate whether services function better, and staff and service users are more satisfied, when certain staff become telemental health specialists, as opposed to asking all users to engage with it for some appointments.

A final key consideration is that any future research into telemental health should include lived experience knowledge, expertise, and views, including those from digitally excluded groups. Working remotely as a research team can facilitate the inclusion of a range of key stakeholders who might otherwise not be able to attend face-to-face meetings, promote ongoing communication, and simplify the coordination of tasks. However, similarly to telemental health care, it can also lead to the exclusion of already marginalized groups, such as digitally excluded people. There is a need to fund research designed and led by people with lived experience of mental health service use.

Lived Experience Commentary

The lived experience commentary written by KM, RRO, and PS is shown in Textbox 1.

Textbox 1. Lived experience commentary.

Commentary

We welcome the question "what works for whom, in what circumstances, and how?" At its heart, a realist review understands that each person has different needs from services, including telemental health services. The challenge is the reliance on existing knowledge and the potential to overlook gaps, especially where the world has changed rapidly because of the COVID-19 pandemic.

The digital methods used to consult a wider audience also further marginalize everyone who does not have, or want, such access. Including people who do not use telemental health would produce different research questions and answers. Similarly, including technology experts might provide some reassurance, for example, about regulation, risk, and ethics raised by practices such as the recent sharing of free text data from a UK crisis text line with third-party researchers to develop artificial intelligence–driven tools [188].

Digital technology has increased restrictive practice in mental health via surveillance [189], sometimes based on poor-quality research conducted with financial incentives from manufacturers [190]. Health data have been shared with police in programs such as Serenity Integrated Mentoring on shaky legal and ethical grounds [191]. Although these are not telemental health per se, they provide a context. In that context, we would have liked the question "What works for whom?" to consider political and financial interests.

This study's methods encouraged a discussion of choice, personalization, and flexibility, which we welcome. We highlight two reflections.

First, choice is not only about preferring one option over another: it can be life or death. Within mental health, service users are often expected to bare our souls to get our choices respected. With telemental health, this is dangerous. If the criteria for accessing a face-to-face service are harm-based, we might be forced to put ourselves at risk to obtain what we need. When someone is being abused by their partner, they may need face-to-face services but not explain why at a first assessment. We must be taken at our word without being required to explain ourselves to clinicians who have not yet earned our trust.

Second, choice is limited by the available options, which are constrained by material circumstances and power. Service users generally have relatively little power in their relationships with an overstretched system. If a wheelchair user's choice is to travel to a building with an unreliable lift versus telemental health, it is not a meaningful choice. If you have to wait 6 months for a face-to-face appointment but you can have telemental health the next week, it is not a meaningful choice. If you cannot afford to connect to the internet, you do not have a meaningful choice. The option of telemental health must not become an excuse to allow face-to-face services to become harder to access.

Many of the actions for telemental health implementation are specific applications of general principles of good care: informed consent to make meaningful choices; clarity about the use of our health data, breeding trust; and understanding and responding to the contexts in which we live our lives.

Within such contexts, we welcome a focus on digital poverty as poverty. The policy solutions to poverty lie well beyond mental health—a broader overhaul of the punitive welfare system and a society in which workers are empowered to negotiate livable wages.

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Authors' Contributions

MS, KRKS, RA, and PB contributed to the design of the manuscript; acquisition, analysis, and interpretation of data; and drafting and revision of the manuscript.
UF, RRO, KM, PS, BC, KP, MB, and KT contributed to the design of the manuscript; acquisition, analysis, and interpretation of data; and revision of the manuscript.
NL and CT contributed to the acquisition and analysis of data and revised the manuscript.
C-AB, JS, SR, TG, JG, FP, RG, and TJ contributed to the design of the manuscript; acquisition, analysis, and interpretation of data; and revision of the manuscript.

NVSJ, RMC, BL-E, AS, JJN, and SJ contributed to the conception and design of the manuscript; acquisition, analysis, and interpretation of data; and revision of the manuscript.
All authors have approved the final version of the manuscript.

Conflicts of Interest

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Multimedia Appendix 1
Glossary.
[DOCX File , 226 KB - ijmr_v11i2e38239_app1.docx]

Multimedia Appendix 2
Study characteristics.
[DOCX File , 102 KB - ijmr_v11i2e38239_app2.docx]

Multimedia Appendix 3
Overarching context-mechanism-outcome configurations.
[DOCX File , 136 KB - ijmr_v11i2e38239_app3.docx]

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Abbreviations

CMO: context-mechanism-outcome
LEWG: Lived Experience Working Group
MHPRU: Mental Health Policy Research Unit
NHS: National Health Service
NIHR: National Institute for Health Research
PRISMA: Preferred Reporting Items for Systematic Reviews and Meta-Analyses
PROSPERO: International Prospective Register of Systematic Reviews
RRR: rapid realist review

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Review

Trends in Health Quality–Related Publications Over the Past Three Decades: Systematic Review

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Abstract

Background: Quality assessment in health care is a process of planned activities with the ultimate goal of achieving a continuous improvement of medical care through the evaluation of structure, process, and outcome measures. Physicians and health care specialists involved with quality issues are faced with an enormous and nearly always increasing amount of literature to read and integrate. Nevertheless, the novelty and quality of these articles (in terms of evidence-based medicine) has not been systematically assessed and described.

Objective: The objective of this study was to test the hypothesis that the number of high-evidence journal articles (according to the pyramid of evidence), such as randomized control trials, systematic reviews, and ultimately, practice guidelines, increases over time, relative to lower-evidence journal articles, such as editorials, reviews, and letters to the editors.

Methods: We used PubMed database to retrieve relevant articles published during the 31-year period between January 1, 1989, and December 31, 2021. The search was conducted in April 2022. We used the keywords “quality care,” “quality management,” “quality indicators,” and “quality improvement” and limited the search fields to title and abstract in order to limit our search results to articles nearly exclusively related to health care quality.

Results: During this 31-year evaluation period, there was a significant cubic increase in the total number of publications, reviews, clinical trials (peaking in 2017, with a sharp decline until 2021), controlled trials (peaking in 2016, with a sharp drop until 2021), randomized controlled trials (peaking in 2017, with a sharp drop until 2021), systematic reviews (nearly nonexistent in the 1980s through 1990s to a peak of 222 in 2021), and meta-analyses (from nearly none in the 1980s through 1990s to a peak of approximately 40 per year in 2020). There was a linear increase in practice guidelines from none during 1989-1991 to approximately 25 per year during 2019-2021, including a cubic increase in editorials, peaking in 2021 at 125 per year, and in letters to the editor, peaking at 50-78 per year in the last 4 years (ie, 2018-2021).

Conclusions: Over the past 31 years, the field of quality in health care has seen a significant yearly increase of published original studies with a relative stagnation since 2015. We suggest that contributors to this dynamic field of research should focus on producing more evidence-based publications and guidelines.

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KEYWORDS

health quality; publication; medline; quality assessmnet; healthcare quality

Introduction

Overview

Quality assessment in health care is a process of planned activities with the ultimate goal of achieving a continuous improvement of medical care through the evaluation of structure, process, and outcome measures [1-4].

Practicing physicians and health care administrators dealing with quality issues face a formidable challenge in following the developments of their fields of expertise, especially in view of

the ever-increasing number of medical publications [5]. The number of medical journals have increased over the years and internet makes them readily accessible [5]. Several effective engines allow rapid searches for medical articles. The National library of Medicine offers PubMed as a free service. PubMed classifies publications by type, including clinical trials, editorials, letters, systematic reviews, meta-analyses, practice guidelines, randomized controlled trials, and reviews, among others. This classification is particularly important for researchers, as it provides the reader with some kind of 'quality' assessment in terms of evidence-based medicine. Evidence-based medicine classifies article as a pyramid that has articles of the lowest level of evidence (eg, expert opinions or background information) at its basis, and at its top, it has articles with the highest level of evidence (ie, systematic reviews) [6]. This pyramid is modified from time to time, as many suggestions are offered in order to improve it [7].

The number of publications in the field of health care quality predictably increases over time, in view of the constantly increasing number of journals, researchers, funding, the appearance of open access publications, and the technologic improvements in publication procedures and speed. It is important, however, to verify whether the quality of articles published in this field of medicine improves over time, as compared to their quantity. Physicians and health care specialists involved with quality issues are faced with an enormous and nearly always increasing amount of literature to read and integrate, but it is not clear whether the quality of these articles has also increased. To the best of our knowledge, novelty and quality of these articles (in terms of evidence-based medicine) has not been systematically assessed and described, and the objective of our systematic review of articles published in this field of medicine was to fill this gap. We, therefore, aimed to verify the hypothesis that there is a relative significant increase in the number of high-evidence journal articles, such as randomized control trials, systematic reviews, and ultimately, practice guidelines, in particular, as compared with 'lower-quality' (in terms of evidence-based classification) articles.

Methods

Digital Database

We used PubMed [8] to retrieve relevant articles published between January 1, 1989, and December 31, 2021. We followed the PRISMA (Preferred Reporting Items for Systematic Reviews and Meta-Analyses) requirements for a systematic literature review [9]. The search was conducted in April 2022. We focused on the field of health care quality in a manner similar to previous studies performed by us [10]. In order to do so, we attempted to retrieve as many health care quality–related articles as possible. We did not use additional databases, such as Embase or Google Scholar, because of the considerable amount of 'noise' added, that is, mostly articles published in nonprofessional journals. As a threshold of quality, we aimed to only look at articles published in journals registered in MEDLINE.

Search Strategy

We searched for the following keywords: "quality care" OR "quality management" OR "quality indicators" OR "quality improvement." A preliminary search conducted in this fashion returned a huge number of articles unrelated to health care quality, in which the word "quality" appeared several times in the body of the article, for example in the expression "quality of life." Similarly, the addition of the search terms "quality control," "quality assessment," and "quality assurance" retrieved even more articles, and the vast majority of these articles were not related to health care quality. Thus, in the final search, we used the keywords "quality care," "quality management," "quality indicators," and "quality improvement" and limited the search field to title and abstract only, which allowed us to limit our search results to articles nearly exclusively related to health care quality.

Inclusion and Exclusion Criteria

We aimed to include all articles related to quality in health care and exclude all those that were retrieved by the search but were not related to health care. In view of our systematic review of all titles and abstracts, 2 of the authors (JM and FBM) were able to verify that the keywords and search strategy allowed us to include all the articles retrieved without exclusion. We also limited the search to articles written in English and dealing with humans (as opposed to animals). We repeated the search by each time using one limit according to publication types as classified by PubMed, and we noted the total number of publications per year for the 31 years of the specified period. As mentioned in the introduction section, we used PubMed's own classification of articles such as relatively 'low-evidence articles' (eg, case reports, editorials, letters, and reviews), and higher-evidence ones (eg, clinical trials, controlled trials, randomized controlled trials, meta-analyses, systematic reviews, and practice guidelines) [10,11]. In order to verify that the classification and tagging offered automatically by PubMed was accurate, we used a random sample of 5 articles each year, and in 100% of the cases, PubMed's classification was accurate. There are, however, obvious overlaps; for instance, all randomized controlled trials are also classified as clinical trials; some papers, based on a case report and a review of the literature, are classified both as reviews and case reports; systematic reviews are also classified as reviews. Some but not all meta-analyses are part of systematic reviews.

Statistical Analyses

The Minitab Statistical package (version 16.0; Penn State University) was used for statistical analyses. We used regression analysis (ie, linear and best-fit nonlinear) to determine the effect of year of publication on the number of publications of each type. A P value <.05 was considered significant.

Results

Table 1 depicts the number of each type of publication retrieved using the stratification of 7 different research and publication methods selected by year. There was a significant cubic increase over the study period in the total number of publications (R^2=0.997; P<.001; Figure 1) ; reviews (R^2= 0.961; P<.001;

Figure 2); clinical trials (R^2=0.822; P<.001), peaking in 2017, with a sharp decline until 2021 (Figure 3); controlled trials (R^2=0.829; P<.001), peaking in 2016, with a sharp drop until 2021 (Figure 4); randomized controlled trials (R^2=0.888; P<.001), peaking in 2017, with a sharp drop until 2021 (Figure 5); systematic reviews (R^2=0.993; P<.001), from nearly none in the 1980s through 1990s to a peak of 222 in 2021 (Figure 6); and meta-analyses (R^2=0.920; P<.001), from nearly none in the 1980s through 1990s to a peak of approximately 40 in 2020 (Figure 7); There was a linear increase in practice guidelines from none in 1989-1991 to approximately 25 per year during 2019-2021 (R^2=0.692; P<.001; Figure 8); there was a cubic increase in editorials (R^2=0.961; P<.001; Figure 9), peaking in 2021 at 125 per year, and in letters to the editor (R^2=0.858; P<.001; Figure 10), peaking at 50-78 per year in the last 4 years prior to this study, from 2018 until 2021.

Table 1. Types of publication retrieved in this study.

Year	Case reports	Clinical trials	Controlled trials	Editorials	Letters	Meta-analyses	Practice guidelines	Randomized controlled trials	Reviews	Systematic Reviews	Total publications
2021	36	105	38	125	63	36	24	72	674	222	8543
2020	34	124	76	101	78	40	26	86	662	198	7773
2019	17	118	95	82	52	33	13	81	560	181	6738
2018	26	105	88	69	63	27	23	83	586	170	6158
2017	20	147	86	66	45	24	20	122	593	114	5622
2016	16	118	128	74	48	25	15	92	610	123	5095
2015	12	113	94	71	43	24	16	78	559	93	4647
2014	16	115	84	67	29	24	20	89	435	83	4033
2013	17	87	91	44	24	24	19	67	361	67	3396
2012	13	72	71	52	12	29	26	53	291	61	2798
2011	12	72	58	43	22	9	8	59	264	41	2407
2010	16	51	63	36	16	8	16	42	218	37	2110
2009	15	40	45	30	12	5	12	29	222	38	1793
2008	7	36	32	32	17	2	10	28	234	20	1577
2007	8	27	31	27	11	7	4	21	230	18	1408
2006	4	24	23	28	10	6	19	15	215	14	1357
2005	5	43	17	23	12	2	9	27	153	9	1120
2004	6	39	31	25	10	1	14	28	158	13	1064
2003	7	31	34	9	4	0	23	23	127	4	900
2002	4	21	24	16	12	1	5	15	111	4	865
2001	5	32	17	15	3	3	7	23	107	5	820
2000	6	21	28	15	7	2	6	12	107	3	774
1999	6	18	16	16	9	0	8	8	111	1	774
1998	4	15	12	15	3	1	1	5	120	1	747
1997	13	13	6	7	7	1	7	8	113	0	717
1996	8	12	10	16	5	0	4	9	91	0	677
1995	0	9	11	16	3	0	5	6	68	0	686
1994	8	5	7	6	4	0	5	2	55	0	655
1993	5	2	3	10	2	1	3	2	46	0	594
1992	2	2	2	10	12	0	2	1	28	0	447
1991	2	0	1	8	0	0	0	0	23	0	342
1990	1	0	0	1	2	0	0	0	14	0	197
1989	2	1	0	3	1	0	0		11	0	147

Figure 1. Total yearly number of publications (y-axis) versus year of publication (x-axis).

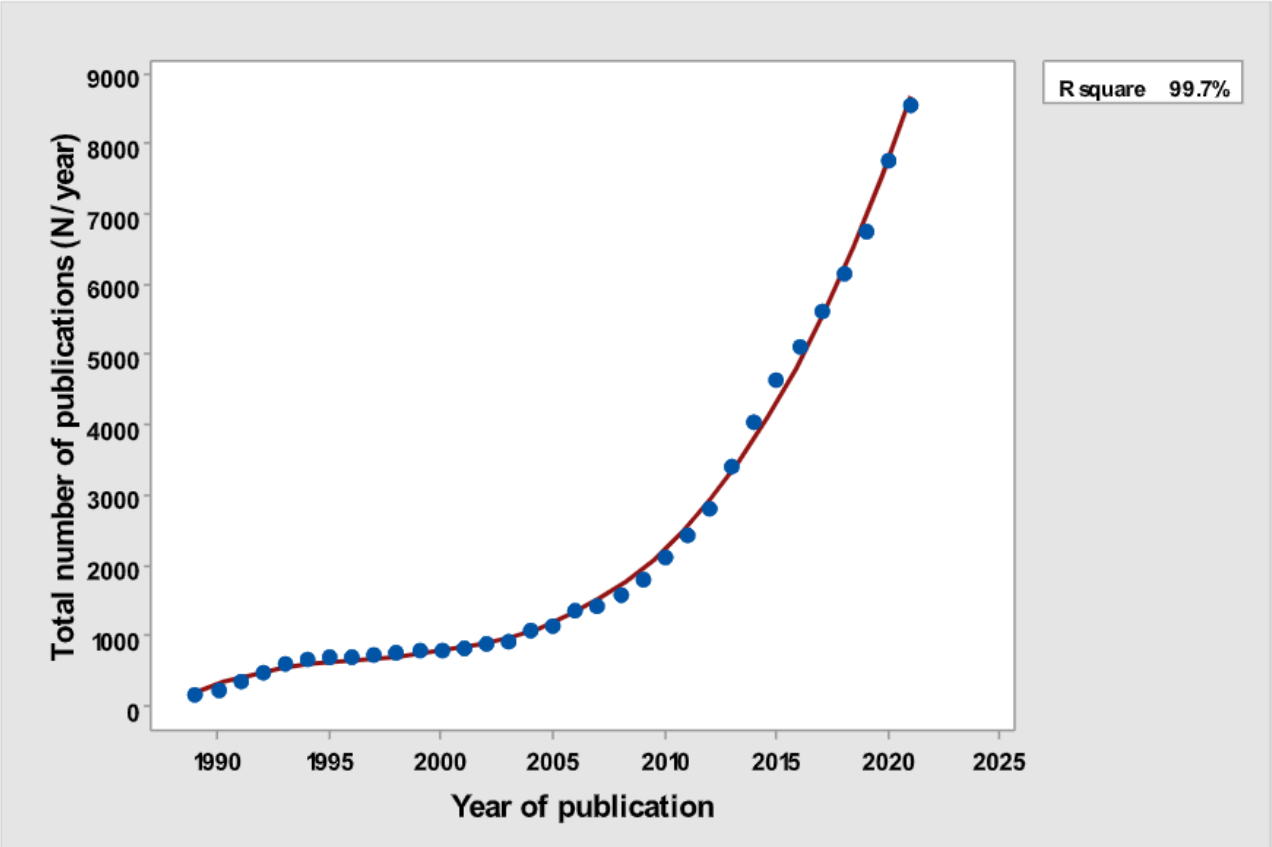


Figure 2. Yearly number of reviews (y-axis) versus year of publication (x-axis).

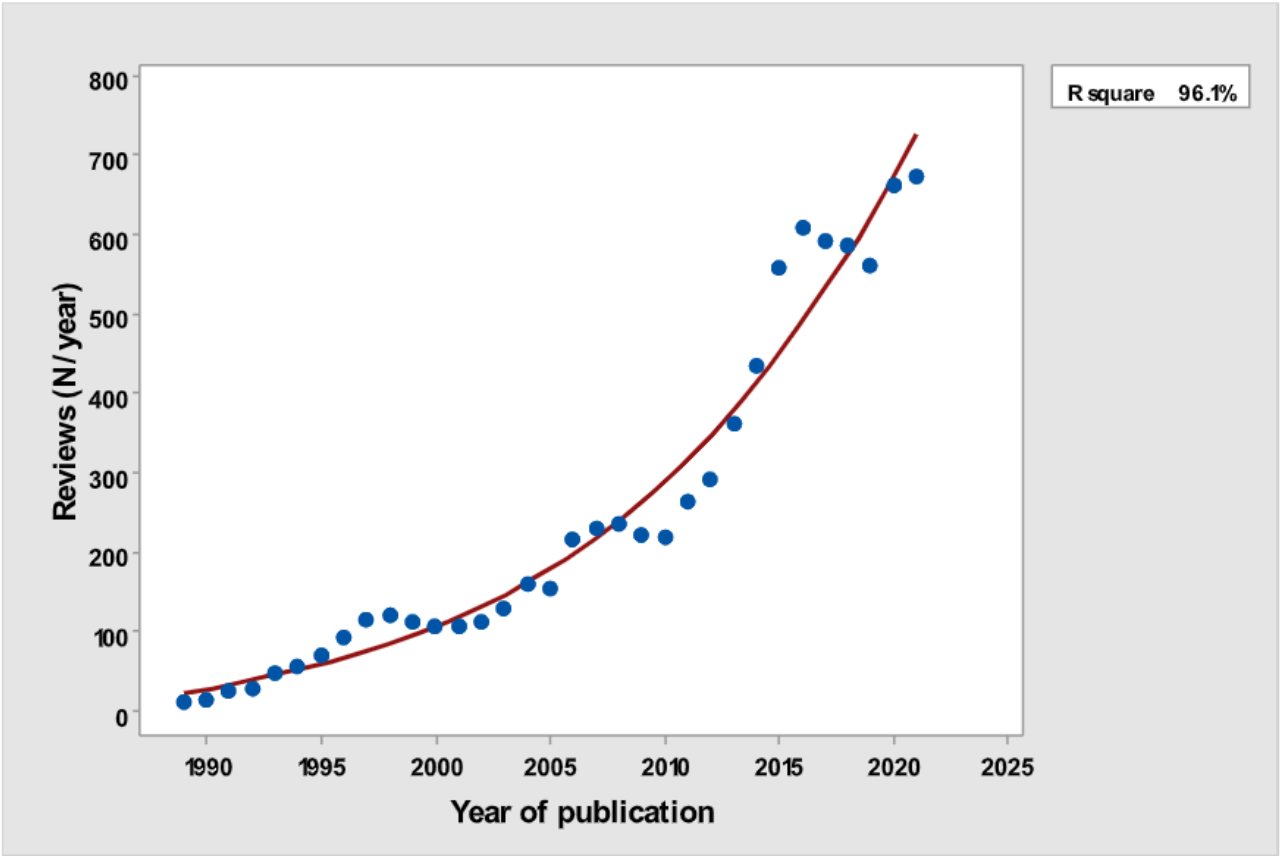


Figure 3. Yearly number of clinical trials (y-axis) versus year of publication (x-axis).

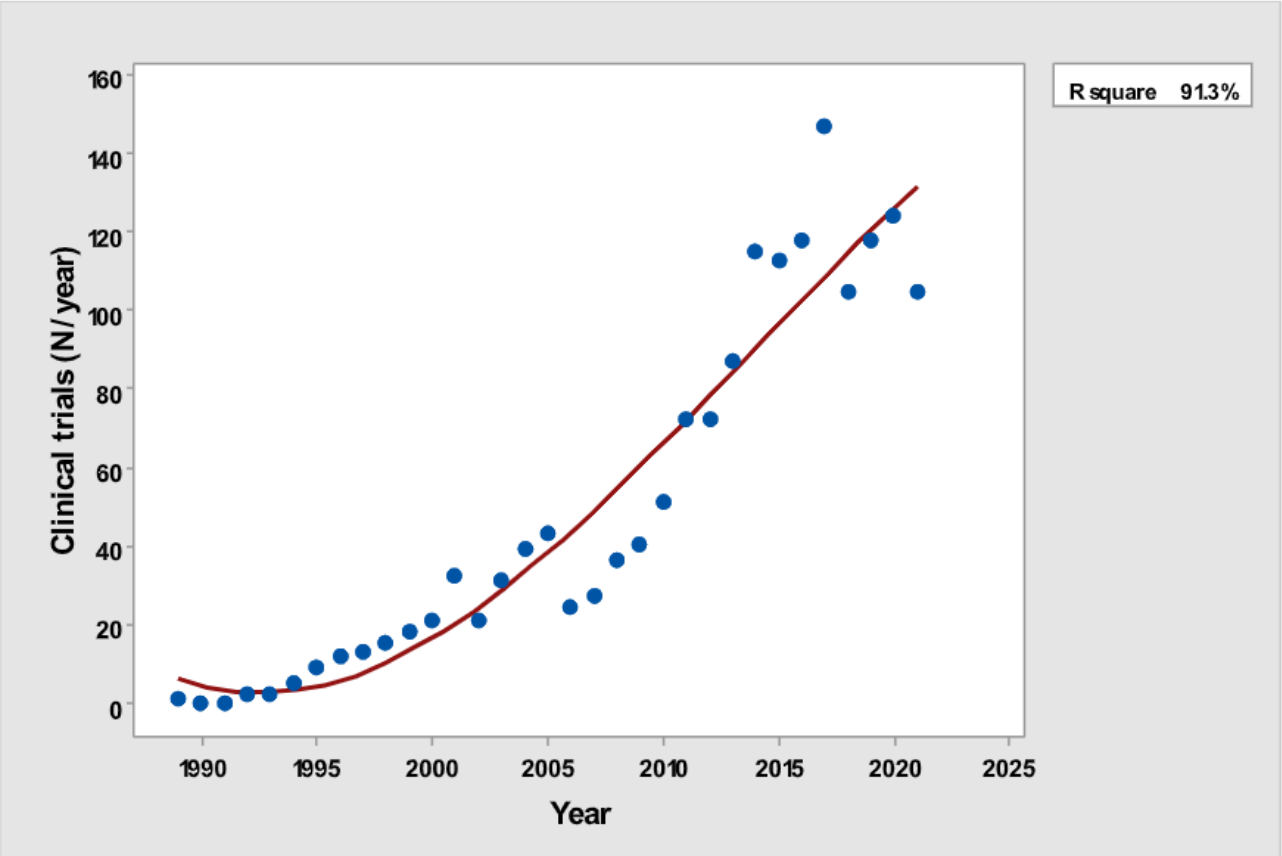


Figure 4. Yearly number of controlled trials (y-axis) versus year of publication (x-axis).

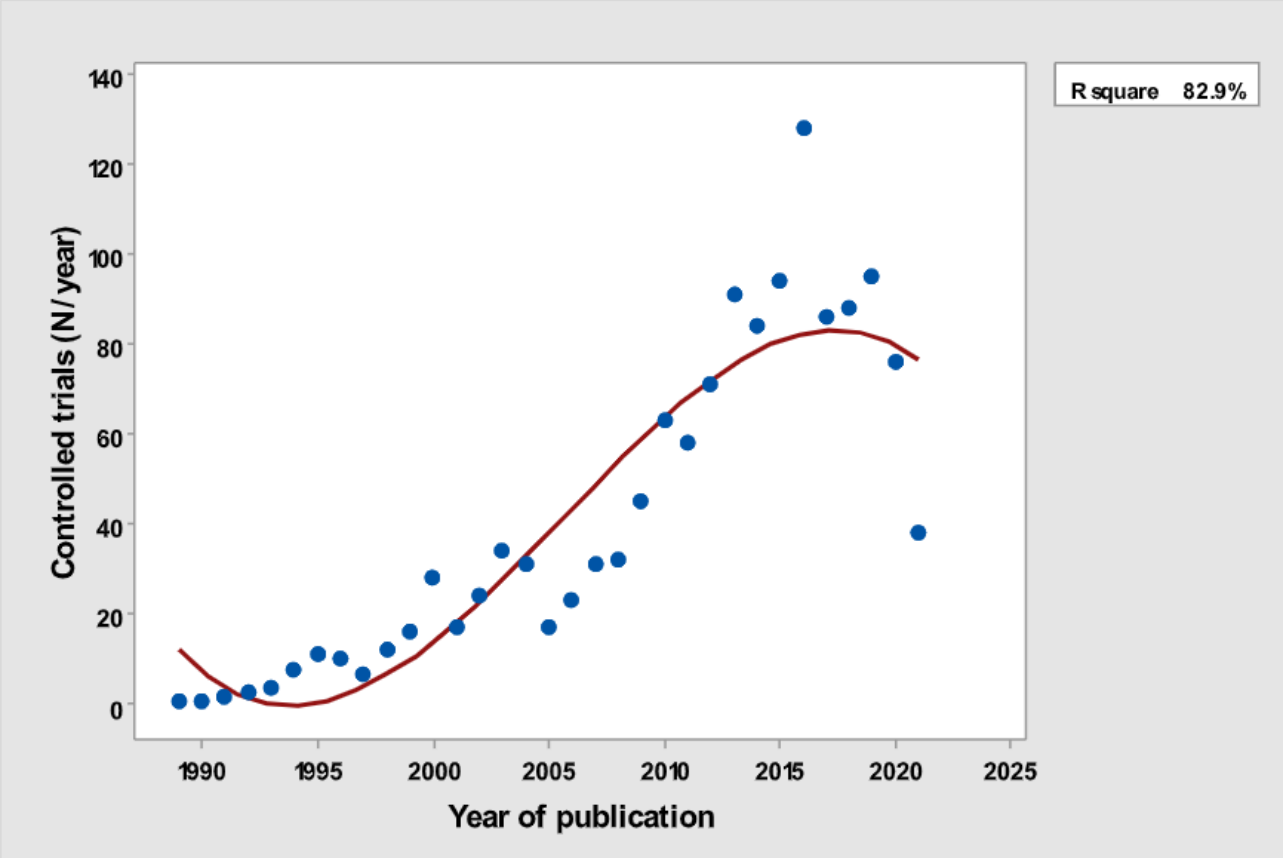


Figure 5. Yearly number of randomized controlled trials (y-axis) versus year of publication (x-axis). RCT: randomized controlled trial.

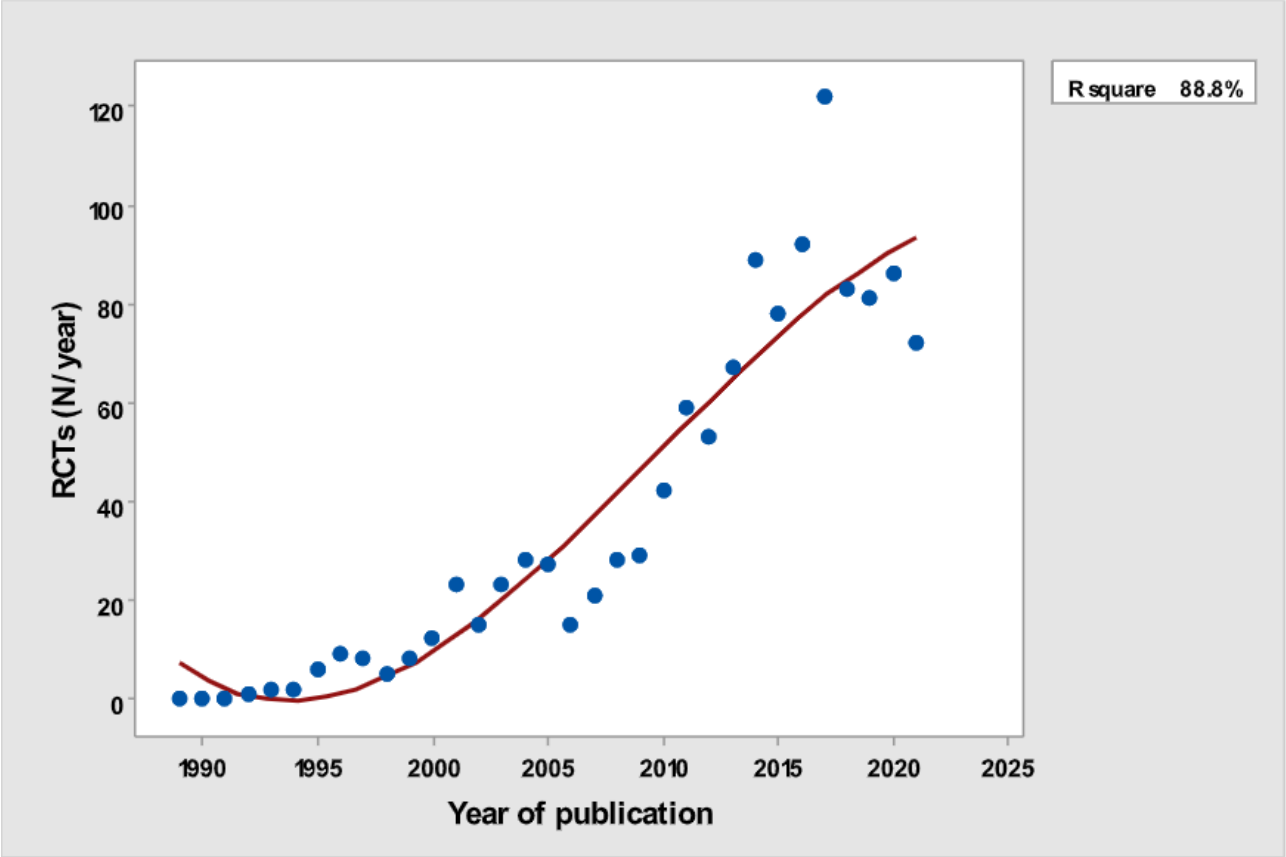


Figure 6. Number of Systematic reviews (y-axis) per year (x-axis).

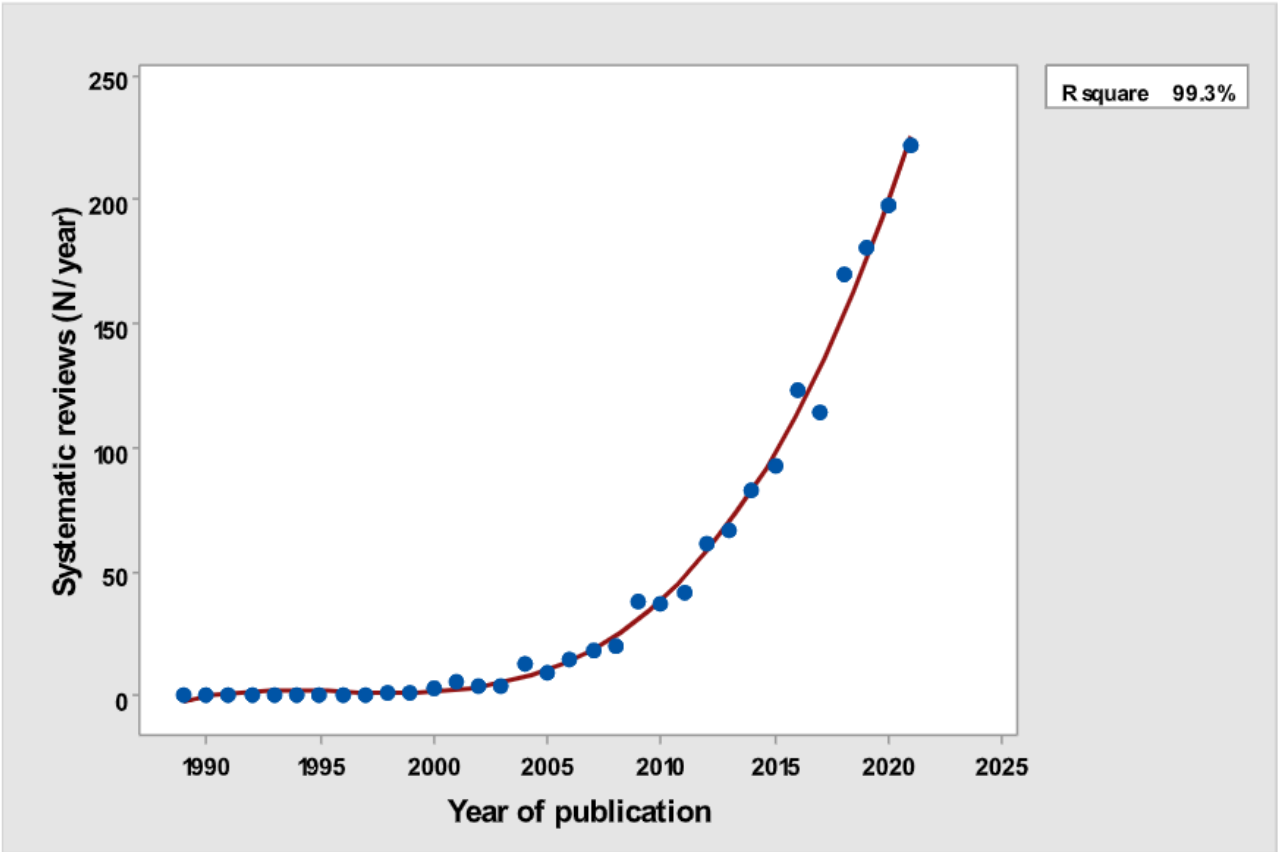


Figure 7. Number of Meta-analyses (y-axis) per year (x-axis).

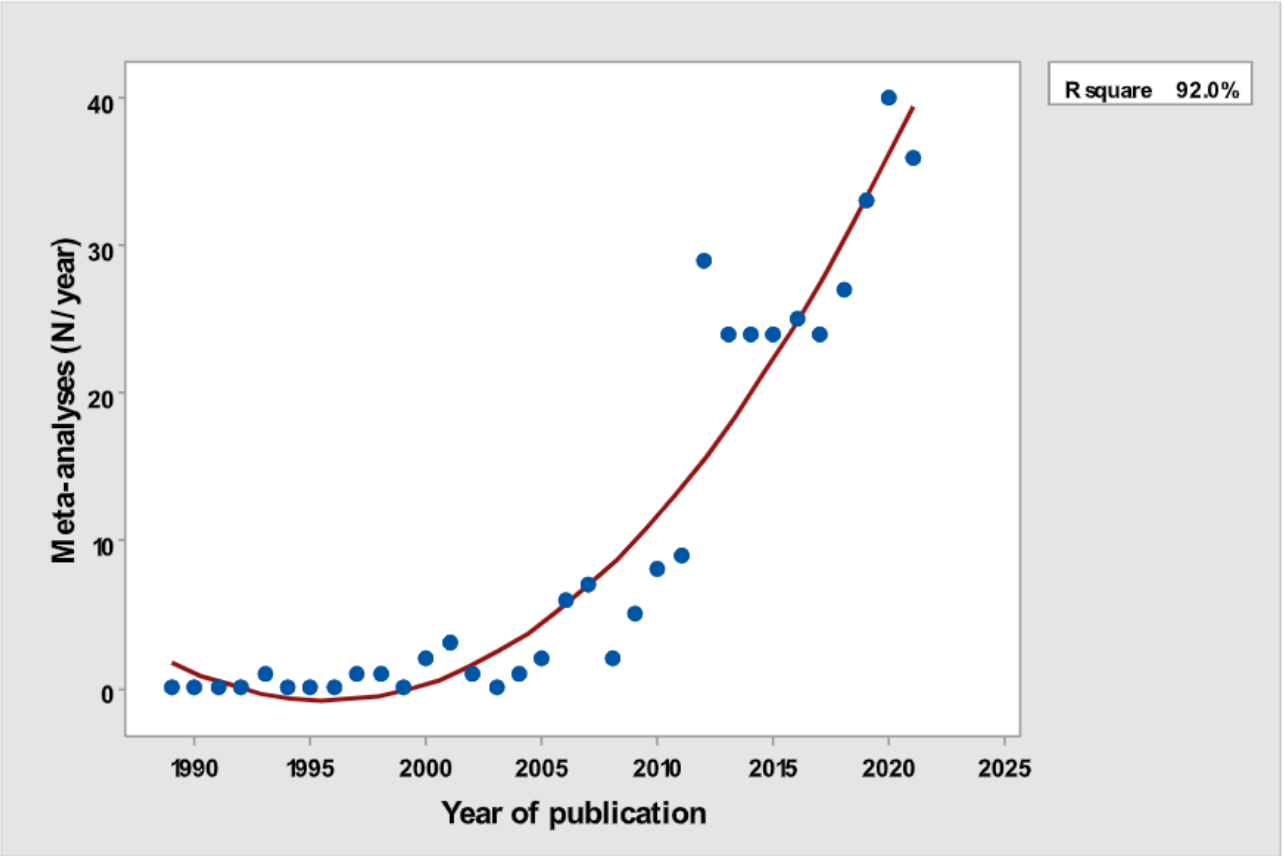


Figure 8. Number of practice guidelines (y-axis) per year (x-axis).

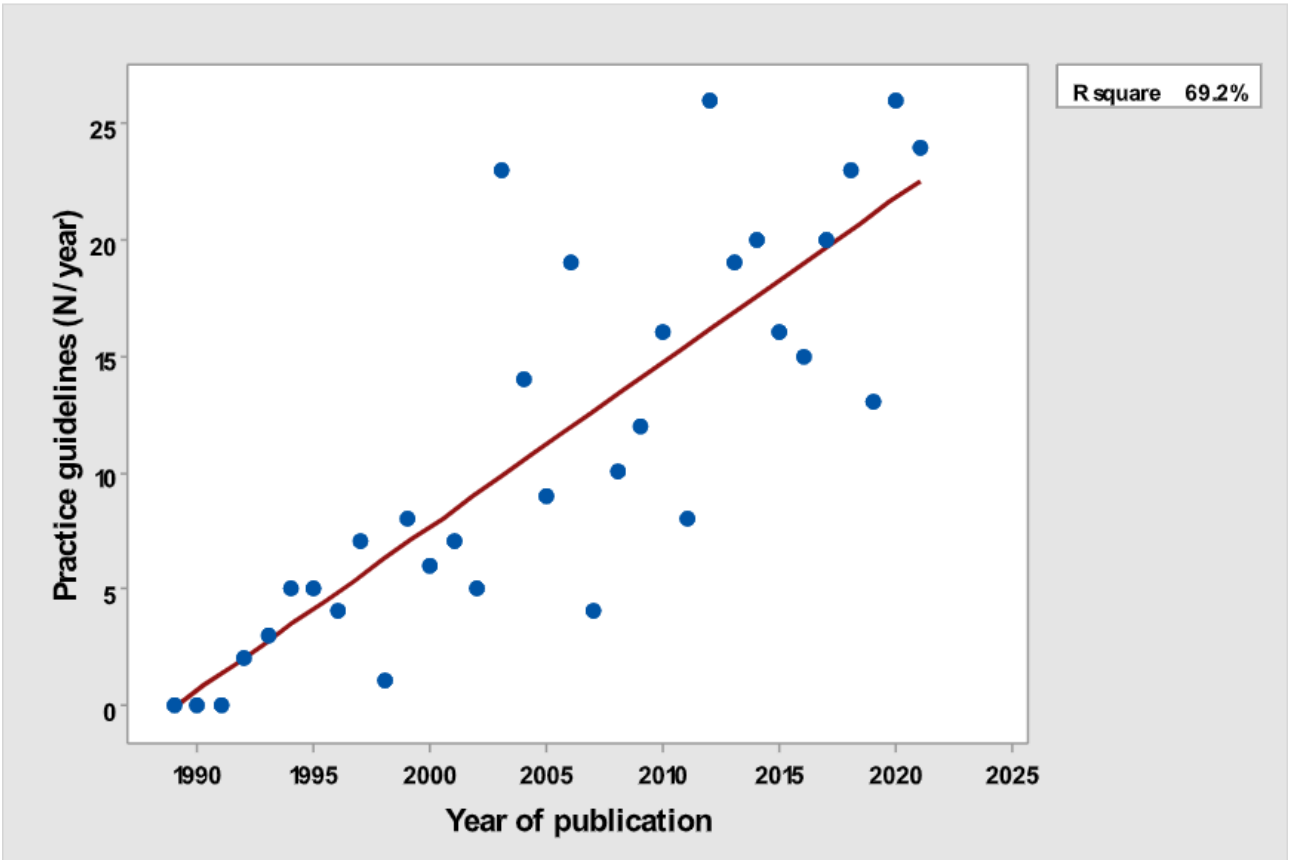


Figure 9. Number of editorials (y-axis) per year (x-axis).

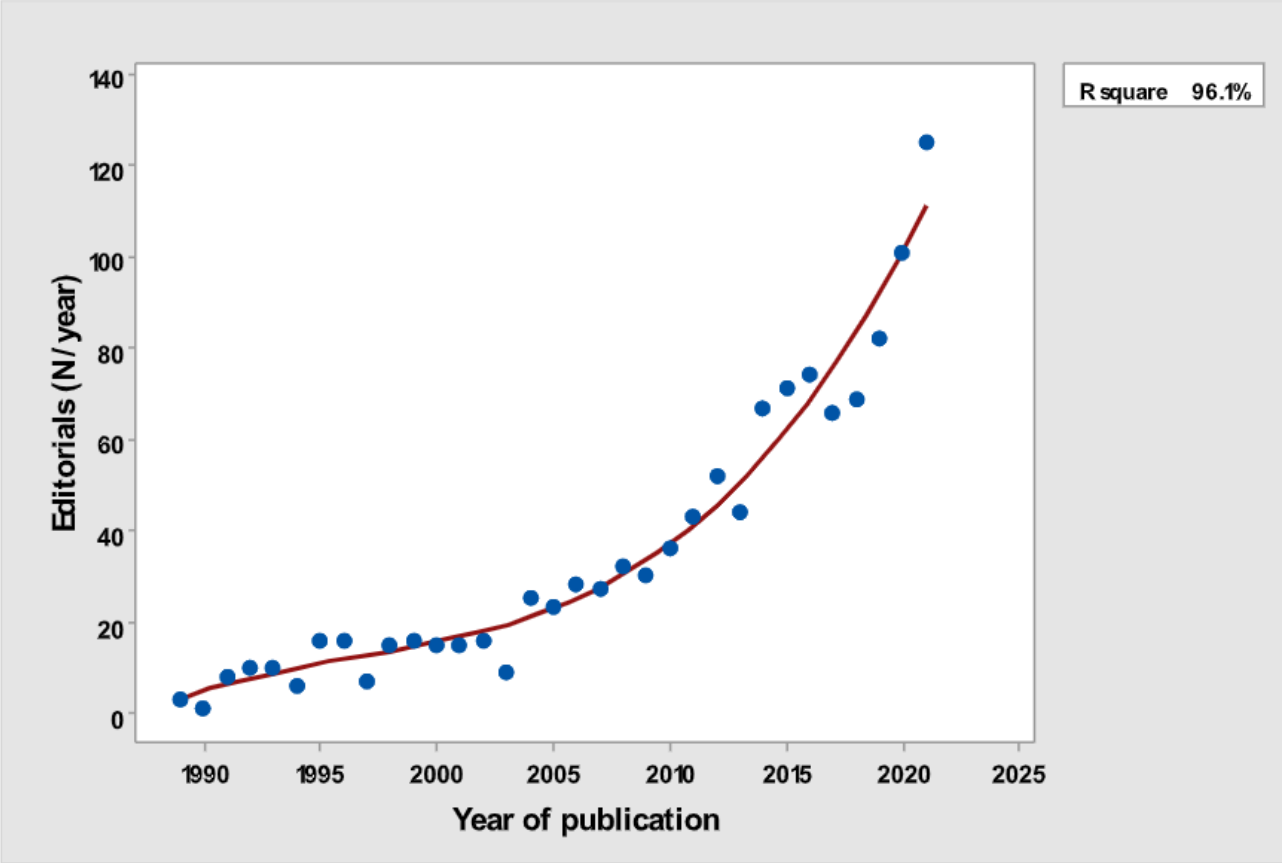
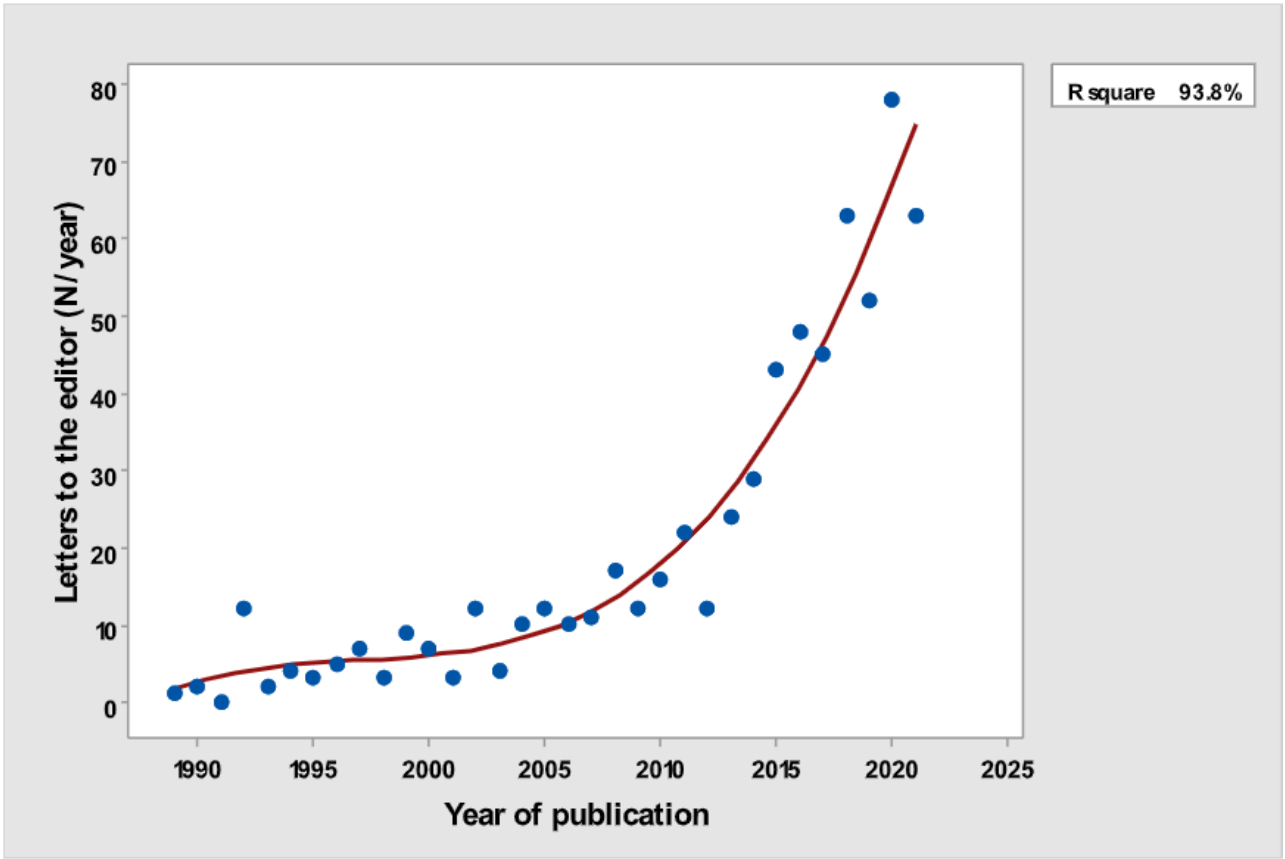


Figure 10. Yearly number of Letters to the editor (y-axis) versus Year of Publication (x-axis).



Discussion

Principal Findings

This study demonstrates that physicians and health care specialists involved with quality issues are faced with an enormous and nearly always increasing amount of literature to read and integrate. It is striking, however, that this amount may have shown a trend toward stabilization in important types of publications, such as clinical trials, controlled trials, and randomized controlled trials, or even a decrease since 2015.

The slope of the increase was not the same for each type of publication. The rate of yearly increase in the number of publications was the slowest for clinical guidelines (linear rather than cubic). The number of yearly clinical guidelines increased slowly over time, strikingly different from the quasi-exponential increase in the total yearly number of all publications. Letters to the editors and editorials continued to steadily increase over the years of the study. The greatest rate of increase was for reviews.

Comparison With Prior Work

The trend toward stabilization in important types of publications, such as clinical trials, controlled trials, and randomized controlled trials, or even a decrease in these publications since 2015 might be unique to the field of health care quality, as the number of publications reported by the National Library of Medicine and registered in PubMed has increased exponentially over the same period without any such decline since 2015 [12].

The number of yearly clinical guidelines increased slowly over time, strikingly different from the quasi-exponential increase in the total yearly number of all publications. Practice guidelines are important in every field of medicine because they are to set up a standard based upon high level of evidence, and even if such type of evidence does not exist, they are at least based upon expert opinion. Graham et al [13] recently stated:

> *The most important benefit of clinical practice guidelines is their potential to improve both the quality or process of care and patient outcomes. Increasingly, clinicians and clinical managers must choose from numerous, sometimes differing, and occasionally contradictory, guidelines.*

We can only speculate about this phenomenon. One possible explanation is that, as a rule, guidelines are to be followed. Not following them may lead to malpractice suits, and the fear for malpractice suits might be a deterrent for professional associations to publish such guidelines [14]. Guidelines also require an organizational infrastructure (eg, a professional association or academy), at a national or international level, that is capable of identifying an important and often controversial topic and will invest the necessary resources to enlist professional experts and often fund their time and travel expenses to a common meeting place, where the guidelines will be written. Such an infrastructure may not be established enough in the field of health care quality to allow for the development and subsequent publication of numerous guidelines every year [15]. Writing guidelines also requires reaching a consensus [15], and professional associations in the field of health care quality might not be organized enough to issue a large number of guidelines. Finally, there might be a limit of how many guidelines can be written in a particular field, and it is possible that the field of quality in health care might have reached some degree of ‘saturation’ in the number of potential guidelines.

Letters to the editors are usually author initiated, contrary to editorials, which are mostly invited. Nevertheless, these 2 types of articles continued to steadily increase over the years of the study, in spite of the fact that they are both unlikely to add much evidence to medical knowledge and rank very low in the evidence-based pyramid [7].

Reviews and systematic reviews are often written by invitation, and they have the potential for being highly quoted, in particular when there is a restriction in the number of references [16]. There was a fast increase in both types of articles, but we suspect that a relative stagnation in the number of randomized controlled trials will limit the ability to perform systematic reviews at increasing rates in the near future.

Limitations

One limitation of our study is that we cannot claim that our search allowed us to recall all papers published in the field of health care quality. The inclusion of additional keywords or other languages may have added a substantial number of publications. In addition, quality is a broad concept with different dimensions, frameworks, and even definitions. Quality indicators are categorized into input, process, output, outcome, and impact. Each published study can focus on any one of these indicators. Moreover, quality studies are affected in various settings, including primary care, secondary, or tertiary settings. Some terms, such as “patient satisfaction” or “health marketing,” may in fact be related to some aspects of quality. Thus, the search strategy and classification that we used in this study may not show a true picture of the volume of studies in this field. However, we do not believe that accessing those articles would have significantly modified our findings or our conclusions, in view of the very large number of publications that we were able to retrieve. Another limitation of our study is that we did not use other databases such as Embase or Google Scholar. Adding these databases would have probably helped us retrieve additional articles, but they would likely be articles published in journals not registered in PubMed [17]. Some of them may well have been published in legitimate, ‘newer’ journals not yet registered in MEDLINE, but as a threshold of quality, we aimed to only look at those registered in MEDLINE, which our methodology allowed us to do.

Another limitation of our study is that the classification and tagging offered by PubMed may not be 100% accurate. This applies mostly to the type of study. Classification errors are probable. However, a random sample of the retrieved articles revealed an excellent degree of agreement with PubMed classifications. Moreover, although the number of health quality–related papers appeared to be rising in quantity, we could not determine whether it also increased in quality, since PubMed does not classify medical articles by quality. At times, a few articles of very high quality will have a much more meaningful impact on clinical care than many other articles of lesser quality. Our study somewhat warns physicians and health

care specialists who wish to address health care quality issues that many reviews and commentaries in this field may be poorly supported by solid evidence.

Conclusions

Over the past 29 years, the field of quality in health care has seen a significant annual increase of published original studies, with a relative stagnation or decrease since 2015. As the internet has created a revolution in the availability and accessibility of scientific publications, it may yet create additional striking changes in the trends that we currently report. Moreover, secular changes in funding priorities may also create significant changes in the future. We suggest that contributors to this dynamic field of research should strive to produce more evidence-based publications and guidelines rather than commentaries and nonsystematic reviews that do not really provide much additional evidence.

As digital health includes concepts from an intersection between technology and health care, we hope that in the years to come, there will be digital transformations to the health care field that will enable researchers, practicing physicians, and health administrators to have better and faster means to find evidence-based solutions for the quality problems they face.

Conflicts of Interest

None declared.

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Abbreviations

PRISMA: Preferred Reporting Items for Systematic Reviews and Meta-Analyses

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Review

The Effect of Classroom-Based Interventions on Sedentary Behavior and Spinal Health in Schoolchildren: Systematic Review

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Abstract

Background: Multifaceted school-based interventions involving many stakeholders show promise toward the reduction of sedentary behavior (SB) and improved musculoskeletal conditions in schoolchildren. In resource-limited contexts, where schools face multiple, complex demands, broad school-based interventions may not be possible. In these settings, less complex, resource-efficient interventions are more likely to be adopted and implemented. Interventions that are limited to classrooms and that do not require broader stakeholder participation may be more appropriate to lower-resource settings.

Objective: The aim of this study was to systematically search for, identify, and summarize the literature on the effectiveness of classroom-based interventions on SB and spinal health in schoolchildren.

Methods: PubMed, EBSCOhost CINAHL, Web of Science, and Scopus were searched between January 1, 2021, and April 30, 2021. We included experimental studies conducted exclusively in school classrooms that objectively measured classroom SB and spinal health. The search terms related to SB, classroom sitting, and classroom neck and back pain. Studies that reported on objectively measured classroom physical activity and instrumented observation of healthy spinal behavior were included in the review. The included studies were critically appraised using the McMaster critical review form for quantitative studies. The study findings were summarized in tables, and a meta-analysis of homogeneous review outcome data was conducted.

Results: Overall, 12 experimental studies from high-income countries were included: 9 (75%) studies focused on SB, and 3 (25%) focused on spinal health. Of the 9 SB studies, 8 (89%) reported decreases in classroom sitting time. The pooled medium-term effects of a subset of SB interventions showed statistically significant decreases in sitting time (P=.03), whereas short-term effects and long-term effects were not significantly reduced (P=.13 and P=.23, respectively). A meta-analysis of spinal health studies demonstrated statistically significant improvements in spinal behavior during functional tasks (P=.005).

Conclusions: Classroom-based interventions aimed at reducing SB and improving spinal health may be effective without placing an additional burden on teachers and parents. SB interventions must include strategies to overcome teachers' and learners' hedonic motivation to sit during class time. Standardized outcomes for school-based SB are encouraged so that findings from various settings may be pooled to determine the overall effect across studies. The use of standardized functional outcomes in spinal health studies will aid in determining the effectiveness of spinal health interventions across studies.

Trial Registration: PROSPERO International Prospective Register of Systematic Reviews CRD42020176080; https://www.crd.york.ac.uk/prospero/display_record.php?ID=CRD42020176080

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KEYWORDS

sedentary behavior; classroom sitting; spinal health

Introduction

Background

Globally, noncommunicable disorders such as musculoskeletal conditions (eg, low back pain [LBP] and neck pain) and cardiovascular diseases (eg, stroke) are a growing cause of disability [1]. Furthermore, the need for rehabilitation services for these kinds of conditions has increased in inverse proportion to countries' income levels [2]. The prevention of noncommunicable diseases, especially in regions burdened by infectious diseases such as HIV and AIDS and tuberculosis, is an important health strategy [3]. Although the causes of back pain and cardiovascular disease are multifaceted, rehabilitation professionals have focused on the relationship between these health burdens and sedentary behavior (SB). The Sedentary Behavior Research Network defines SB as "any waking behavior characterized by an energy expenditure ≤1.5 METS [metabolic equivalents] while in a sitting or reclining posture" [4]. Epidemiological associations between SB and a range of noncommunicable diseases such as type 2 diabetes, obesity, spinal musculoskeletal injury, and even some cancers are corroborated by physiological evidence [5]. Redundant understanding (understanding that has been informed by new knowledge and is no longer useful or current) of the physiology of SB encouraged researchers to investigate remedies for the effects of SB with interventions aimed at increasing moderate to vigorous physical activity [6]. The realization that the effects of SB are not "equally and oppositely matched" by the benefits of moderate to vigorous physical activity has prompted researchers to instead trial interventions to reduce the accumulation of SB [6]. This preventive approach to addressing sedentary behavioral physiology is germane to recommended preventive measures of sitting-related back pain.

The causal relationship between SB (such as sitting) and the onset of back pain is complex, as is apparent in the contradictory findings in the literature [7]. Although the methodological weakness of studies may account for some of these equivocal findings, another important factor may be the heterogeneity of back pain. The effects of (particularly prolonged) static sitting on the structures of the spine include continuous intervertebral disk compression and resultant compromised disk nutrition. Furthermore, in vitro studies have demonstrated how intervertebral disk tissue deforms under loads comparable to the compressive loads experienced during sitting [8]. In the absence of an optimal sitting posture [7], a proposed strategy to mitigate the effects of prolonged sitting on the spinal structures is dynamic sitting [9]. The rationale of this strategy is to encourage small-range high-frequency changes in the spine, using specific chairs or equipment, to reduce continuous loading of spinal structures [9]. However, the efficacy of dynamic sitting is limited. As such, researchers turned to assessing the efficacy of strategies aimed at reducing total sitting time, particularly by breaking up prolonged periods of sitting, as a means of mitigating the effects of sitting on the spinal tissues [10]. Interrupting prolonged periods of sitting with alternative postures such as standing is purported to balance the load on musculoskeletal tissues, mitigating the onset of soft tissue strain and delaying the onset of discomfort.

Reducing the accumulation of SB by interrupting prolonged periods of sitting has also been suggested as a means of arresting harmful SB physiology [11,12]. Given that SB continues from childhood into adulthood [13], much scientific research on SB in children has been published in the last decade [14]. SB in children has consistently been associated with increased cardiometabolic disease, including insulin resistance [15] and decreased high-density lipoprotein cholesterol [16]. Developing effective preventive strategies that are designed to limit cardiometabolic health problems associated with SB during childhood seems prudent considering its effect on health-related quality of life [17,18] across the life span.

Considering that LBP also tracks across the life span from adolescence into adulthood [19] and given the association between SB and LBP, early interventions aimed at preventing SB from becoming ingrained at school-going age has the potential to address manifold health burdens. The World Health Organization has encouraged the coordination of health and education systems in health promotion for several decades [20]. SB is ubiquitous during school time, with class time being the most sedentary period [21]. The past decade has seen many studies published on strategies aimed at reducing SB in schools [22].

Hegarty et al [23], in their review of school-based studies aimed at reducing SB in children, describe the range of underpinning theoretical bases. Although the design of interventions based on various theoretical underpinnings is justified, the pragmatic challenges inherent to resource-constrained contexts hinder the feasibility of interventions that require additional resources beyond the status quo. Interventions underpinned by social cognitive theory or social frameworks [24] that burden teachers with teaching SB-related curricula in addition to the normal academic content may stretch a school's human resources to the point that the intervention becomes unfeasible [25]. Furthermore, interventions that require parents to engage with learning materials [26] are not feasible in contexts of low adult literacy, low parent-child engagement, and prevalent child-headed families, as are common in low-income countries plagued by war or epidemics. According to the capability, opportunity, and motivation behavior framework [27], school-based interventions that involve changes to the physical environment of the classroom (opportunity) and that neither depend on participants' acquisition of additional capability nor increase participants' motivation for SB are likely to succeed in reducing classroom SB [28].

Objectives

In resource-constrained contexts, it is important that public health programs are underpinned by sound theoretical frameworks that increase the likelihood of succeeding and that address multiple health burdens. Given the potential benefits of reducing SB in relation to noncommunicable diseases and spinal health across the life span, reviewing the literature on the implementation of classroom-based interventions aimed at reducing SB and improving spinal health will provide important information in deciding what strategies to implement in the South African context. This review, which aimed to identify and summarize evidence on the effectiveness of classroom-based

interventions aimed at reducing SB and improving spinal health, certainly meets these criteria.

Methods

This systematic review was registered with PROSPERO in November 2020. The review was conducted according to the PRISMA (Preferred Reporting Items for Systematic Reviews and Meta-Analyses) statement [29].

Eligibility Criteria

The following inclusion and exclusion criteria were considered for this review.

Types of Studies

Given that this review aimed to identify and summarize the effectiveness of interventions, studies with any form of experimental design were included. Studies with experimental designs include case studies and case series, uncontrolled before-and-after trials, interrupted time series trials, nonrandomized controlled trials, cluster randomized controlled trials, and randomized controlled trials. All English-language studies published until April 30, 2021, were considered.

Types of Participants

Participants enrolled at primary and high school classrooms were included in this review.

Types of Interventions

Any classroom-based interventions aimed at reducing classroom SB and improving back health were considered for this review. Examples of classroom-based interventions that were considered included, but were not limited to, education programs, movement integration, exercise or movement programs, or changes to the classroom environment. Only interventions that were conducted within the confines of the classroom were considered.

Types of Comparisons

Comparison groups had to be subject to the usual classroom conditions.

Types of Outcomes

Studies had to report on objectively measured classroom sitting time, bouts of prolonged periods of sitting, frequency of interruptions to sitting, spinal muscle strength, or instrumented observation of healthy spinal behavior.

Exclusion Criteria

Observational studies were not considered for inclusion in this review because they would not be able to infer the effectiveness of interventions. Studies with participants who required special education and mobility needs were excluded because these school classrooms are often adapted to facilitate the educational and mobility requirements of these learners and differ from mainstream school classrooms. In addition, studies that included participants with spinal pain related to injury or disease were not eligible for inclusion. Experimental studies with intervention strategies with components that go beyond the school classroom or school time were also not considered eligible for inclusion. Studies that did not apply the definition of SB as behavior that expends ≤1.5 metabolic equivalents [4] were excluded.

Search Strategy

The following electronic databases were comprehensively searched from database inception to April 30, 2021: PubMed, EBSCOhost CINAHL, Web of Science, and Scopus. Database searches included a combination of Medical Subject Headings (PubMed) and similar keywords in combination with Boolean operators such as *OR* and *AND* according to the database function. An example of the combination of keywords searched included (*school OR class OR classroom*) AND (*sedentary behavior OR sedentariness OR sitting*) for SB studies and (*school OR class OR classroom*) AND (*spine OR spine health OR posture*) for studies on spinal health. Only language filters were applied to searches. One researcher (DF) conducted all searches. Hand searches of reference lists of the included studies to identify additional studies were conducted.

Study Selection

The results from the 4 database searches were screened by study title and abstract according to the eligibility criteria by one researcher (DF). Duplicate studies were identified, exported to Microsoft Excel, and manually removed. A second researcher (QL) spot-checked the potential included studies for incorrect study retention. Thereafter, retained studies were screened by full-text reading of the papers. The second researcher (QL) repeated the spot-check once full-text screening was completed. Consensus was then reached about the inclusion of studies in the review. Study eligibility was assessed by one researcher (DF), with uncertainties discussed with the second researcher (QL).

Search results from the respective electronic databases were exported to Mendeley reference management software (Mendeley Ltd). The results were copied into a customized Microsoft Excel sheet to document the review results, identify and exclude duplicates, and track information for the PRISMA flowchart [29].

Methodological Appraisal

The included studies were critically reviewed using the McMaster critical review form for quantitative studies [30]. This review tool allows the researcher to appraise the included studies on the stated purpose of the study and relevance of the background literature, appropriateness of the study design, study sample and selection, measurement and detection bias, sample size, outcomes and results, and conclusion and implications. Studies were not excluded based on quality.

Data Extraction

Data from the included studies were extracted according to the study design, participant information, intervention description, study outcomes, and intervention effects. The information was recorded in a customized Microsoft Excel data extraction form by the first author (DF). The second author (QL) performed a spot-check on a subsample of the included studies to assess accuracy and consistency. Consensus about the extracted data was reached between the researchers before data synthesis. Data was extracted according to the following categories:

- General study information: date of extraction, author or authors, title, type of publication, and country of origin
- Study characteristics: study aims and objectives and study design
- Participants: population and setting and number of participants
- Intervention features: intervention setting and mode of intervention
- Measurement description: unit of measurement, type of measurement, frequency, and follow-up duration

Data Analysis

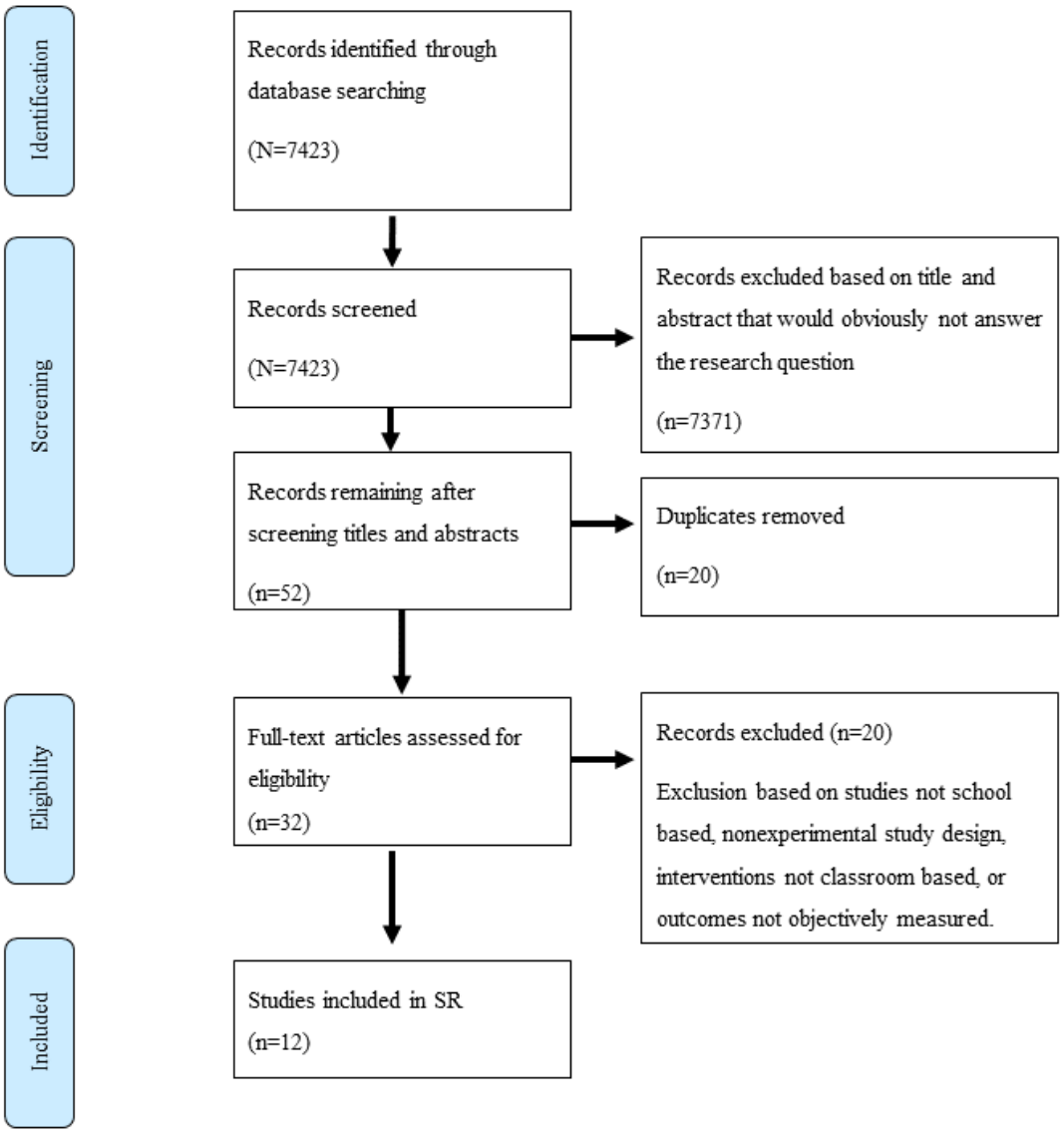
The key outcomes were SB and spinal health. We used Review Manager (version 5.4.1; The Cochrane Collaboration) [31] to conduct a meta-analysis of SB and spinal health outcomes where required data (mean and SD or SE) were available, and outcomes were similar. The data to conduct a meta-analysis were extracted from published manuscripts and supplementary files, requested from the corresponding author or derived using the calculator function in Review Manager. A random effects model for heterogenous data among studies was used. We conducted a subgroup analysis based on the follow-up period in different studies (short: <12 weeks, medium: 12-24 weeks, or long term: ≥24 weeks). The overall measure of effect (mean difference and 95% CIs) was calculated for all outcomes and subgroups, and we considered the I^2 test as the measure of subgroup heterogeneity. Effects and *P* values of SB and spinal health outcomes that were too dissimilar and not appropriate for inclusion in the meta-analysis were calculated using MedCalc (version 20.113; MedCalc Software Ltd) [32] and tabulated.

Results

Study Selection

The search results from the 4 databases used yielded 7423 studies. A total of 12 papers met the inclusion criteria, each reporting on individual studies, and were included in the review (Figure 1).

Figure 1. PRISMA (Preferred Reporting Items for Systematic Reviews and Meta-Analyses) flow diagram of search results and included studies. SR: systematic review.



Study Characteristics

Participants and Study Location

The included studies comprised 2296 participants: 1026 (44.69%) in SB studies and 1270 (55.31%) in spinal health studies (Table 1). Study sample sizes ranged from 23 to 696 participants with ages ranging from 8 to 17 years. Of the 12 studies, 2 (17%) had male-only participants [33,34], whereas the remaining studies (10/12, 83%) had male and female participants. Of the 12 studies, 6 (50%) had >100 participants, and 1 (8%) had >500 participants.

Table 1. Characteristics of included studies.

Country (setting), study	Study aim	Study design (sample size)	Sample description (age [years])
Sedentary behavior studies			
United Kingdom (2 primary school classes), Sherry et al [35]	To assess the impact of a full standing desk allocation system on sitting behavior and to explore changes in behavior-related mental health, MSK[a] health, and markers of cognitive function	Pilot controlled trial (n=55)	Year 5 students (9-11)
Australia (2 primary school classes), Contardo Ayala et al [36]	To assess the impact of an intervention incorporating height-adjustable desks and pedagogical strategies on overall volume and pattern of classroom sitting	Pilot nonrandomized trial (n=41)	Year 6 students (11-12)
Belgium (10 primary and 9 secondary schools), Verloigne et al [37]	To conduct an effect evaluation of implementing standing desks in the classroom and evaluate the process of implementing standing desks	Cluster RCT[b] (n=343)	Grade 5 students (10-11) and grade 10 students (15-16)
Portugal (1 primary school), Silva et al [38]	To investigate the impacts of a classroom standing desk intervention on classroom sitting time and verify effects of the intervention on whole-day SB[c] and PA[d] during the week and weekend	Cluster controlled trial (n=49)	Grade 6 students (11-13)
United Kingdom (10 primary schools), Norris et al [39]	To test the effect of a PA class intervention on children's PA and SB, on-task behavior, and student engagement	Cluster RCT (n=264)	Year 4 students (8-9)
Australia (2 primary schools), Ee et al [34]	To determine the effects of a classroom standing desk intervention on school sitting and standing time, waking hours PA and SB, and MSK discomfort	Within-participants crossover trial (n=47)	Grade 4 students (10-11); only male participants
Australia (1 secondary school), Sudholz et al [40]	To examine the impact of combining environmental change and classroom prompts on adolescents' classroom sitting time, prolonged sitting bouts, standing and stepping time, and sitting interruptions	Quasi-experimental design (n=105)	Grades 7, 10, and 11 students (12-17)
Australia (1 primary school), Parry et al [33]	To assess effects of yearlong intermittent use of a standing desk on sitting and standing time at school and sedentary time and PA for waking hours, as well as self-reported presence and intensity of MSK symptoms	Repeated measures within-participants crossover trial (n=23)	Grade 4 students (9-10); only male participants
United States (9 elementary schools), Swartz et al [41]	To determine the effect of stand-biased desks on PA and SB in elementary schoolchildren and examine the impact of stand-biased vs sitting desks on SB and activity during the school day	Within-classroom crossover design (n=99)	Grades 3, 4, and 6 students; age not reported
Spinal health studies			
Belgium (3 primary Schools), Cardon et al [42]	To investigate the efficacy of a back education program and examine habit changes	RCT (n=696)	Grades 4 and 5 students (9-11)
Germany (2 primary schools), Dullien et al [43]	To examine whether teacher-led intervention programs could improve back-care knowledge, back-friendly behavior, and core muscle endurance	Cluster RCT (n=176)	Grade 5 students (10-12)
Belgium (8 elementary schools), Geldhof et al [44]	To investigate the effect of an optimized multifactorial back education program on knowledge and postural behavior in children	Quasi-experimental pre-post design (n=398)	Elementary school students (9-11)

[a]MSK: musculoskeletal.

[b]RCT: randomized controlled trial.

[c]SB: sedentary behavior.

[d]PA: physical activity.

The 12 included studies were all conducted in high-income regions, namely Europe (n=5, 42%) [37,38,42-44], Australia (n=4, 33%) [33,34,36,40], the United Kingdom (n=2, 17%) [35,39], and the United States (n=1, 8%) [41]. Of the 12 studies,

9 (75%) focused on the intervention's effects on SB [33-41], and 3 (25%) focused on spinal health [42-44]. Of the 12 studies, 10 (83%) were conducted in primary schools [30,33-38,40,44], 1 (8%) in a secondary school [40], and 1 (8%) in both primary and secondary schools [37].

Description of Interventions

Of the 9 SB study interventions, 1 (11%) [39] used physically active lessons (Table 2). The remaining SB study interventions comprised either adding to [37], replacing all [35,36,38,40], or replacing a proportion of the traditional classroom desks with stand-biased desks [33,34,41]. Of the 9 studies, 5 (56%) [35-38,40] included teacher training and development as part of the intervention. All the spinal health studies used a back education program [42-44]. Of the 3 studies, 2 (67%) [43,44] added posture awareness training to the back education program, and 1 (33%) [43] included an exercise component in the intervention.

Table 2. Summary of study interventions.

Study	Intervention description	Intervention duration	Theoretical underpinning
Sedentary behavior studies			
Sherry et al [35], 2020	All usual desks replaced with height-adjustable sit-stand desks. Instructional posters in classroom demonstrating correct posture, environmental change to classroom, reflective motivation from teacher, and monthly visits from researchers	8 months	Behavior change wheel [45]; COM-B[a] model
Contardo Ayala et al [36], 2016	All usual desks replaced with height-adjustable sit-stand desks and original chairs replaced with laboratory stools; teacher development about pedagogical approaches to reduce and break sitting and how to adapt delivery of usual curriculum and safe use of desk	8 months	Not reported
Verloigne et al [37], 2018	Three standing desks introduced into class, and teachers received presentation to situate the intervention in health context based on evidence (printed presentation material provided to teachers)	6 months	Not reported
Silva et al [38], 2018	Traditional seated desks exchanged for adjustable sit-stand standing desks, teacher training sessions by physical education and psychology professionals, and family support sessions	16 weeks	Not reported
Norris et al [39], 2018	Physically active lesson intervention "Virtual Traveler" comprised three 10-minute physically active sessions per week (18 sessions)	6 weeks	BCTTv1[b] [46]
Ee et al [34], 2018	Class divided in half and rotated through use of height-adjustable stand-up desks, whereas other half used traditional desks on 21-day cycle	6 weeks	Not reported
Sudholz et al [40], 2020	Traditional classroom desks exchanged for height-adjustable desks and backless laboratory stools; 3 posters and desk stickers to provide behavioral prompts; and 1-hour teacher training on how to use desks, evidence of health benefits of breaking up sitting time, and tips and strategies for adolescents	6 months	Not reported
Parry et al [33], 2019	Class divided in half and rotated through use of standing desks for 21-day cycle throughout school year	8 months	Not reported
Swartz et al [41], 2019	Half the class allocated stand-biased desk for 9 weeks before using sitting desk for 9 weeks; other half allocated sitting desk for 9 weeks before using stand-biased desk for 9 weeks	18 weeks	Not reported
Spinal health studies			
Cardon et al [42], 2002	Six weekly 60-minute back education sessions delivered by physical therapist based on biomechanical literature and the German program of back exercises. The program made use of 10 "make your disks happy" guidelines	6 weeks	Not reported
Dullien et al [43], 2018	Teacher-delivered 5 back-care lessons (materials provided) focusing on anatomical knowledge of the spine, good and bad sitting posture, healthy backpack habits and lifting, healthy carrying, and back-friendly sport and nutrition; posture awareness training and improvement posters put up in classroom; and mandatory back and abdominal muscle exercises at the beginning of each class	1 school year (10 months)	Not reported
Geldhof et al [44], 2006	Six weekly back education lessons by physical therapist included back anatomy and pathology as well as principles of biomechanical postures during standing, sitting, lying, lifting, pushing, and bending; 10 large posters of back posture principles; and stimulation of dynamic sitting by introducing 2 Pezzi balls and a Dynair wedge for each classroom, as well as twice daily movement breaks	2 years	Not reported

[a]COM-B: capability, opportunity, and motivation behavior.

[b]BCTTv1: Behavior Change Technique Taxonomy version 1.

Critical Review of Included Studies

Table 3 provides a summary of the McMaster critical review [47] of the included studies. All included papers clearly stated the study purpose, adequately described the sample, and provided sufficient details regarding the intervention. Furthermore, all studies reported the study results in terms of statistical significance, used appropriate methods of analysis, and reported on the clinical importance of their results. Of the 12 studies, 11 (92%) provided a justification for the sample size, whereas 1 (8%) [39] did not. The spinal health studies [42-44] all showed weakness in terms of validity of the outcome measures used and lack of control of contamination as part of their design.

Table 3. McMaster critical review form for quantitative studies.

	Sedentary behavior studies									Spinal health studies		
	[35]	[36]	[37]	[38]	[39]	[34]	[40]	[33]	[41]	[42]	[43]	[44]
Study purpose: was the purpose clearly stated?	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
Literature: was relevant background literature reviewed?	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓		✓
Sample												
Was the sample described in detail?	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓		✓
Was the sample size justified?					✓							
Outcomes												
Were the outcome measures reliable?	NR[a]	✓	NR	✓	✓	✓	✓	✓	✓			
Were the outcome measures valid?	NR	✓	✓	✓	✓	✓	✓	✓	✓			
Intervention												
Was the intervention described in detail?	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
Was contamination avoided?	✓		✓		✓	N/A[b]		N/A	N/A	✓		✓
Results												
Were the results reported in terms of statistical significance?	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
Were the analysis method or methods appropriate?	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓		✓
Was the clinical importance reported?	✓	✓	✓	✓	✓		✓	✓				
Were dropouts reported?	✓		✓		✓	✓			✓	✓		✓
Conclusions and implications: were the conclusions appropriate given the study methods and results?		✓	✓	✓	✓	✓	✓	✓	✓	✓		✓

[a]NR: not reported.

[b]N/A: not applicable.

Variability of Study Outcomes in SB Studies

The SB studies reported outcomes either in relation to school time [33,34,37,38,41] or class time [35,36,39,40] (Table 4). There were also differences in the units of measurement used, namely minutes [35-37,39], minutes per 9 hours [33,38], minutes per day [34,41], and minutes per lesson [40]. Sitting was the main proxy measure used for SB, but 25% (3/12) of the studies included proxy measure variations such as frequency of 30-minute sitting bouts; sitting time accumulated in >5-minute, 10-minute, and 20-minute sitting bouts; and sitting time accumulated in >15-minute bouts [44].

Table 4. Intervention effects on sedentary behavior and spinal health in included studies.

Study	Measure of effect (units)	Value	*P* value	Direction of the effect
Sedentary behavior studies				
Sherry et al [35], 2020	Mean difference (95% CI) sitting time as percentage of wear time	–25.34 (–32.25 to –18.43)[a]; –19.99 (–27.05 to 12.94)[b]	.001[a]; .008[b]	Improved[a]; improved[b]
Contardo Ayala et al [36], 2016				
	Mean difference (95% CI) classroom time sitting bouts >5 minutes	–10.4 (–25.76 to 4.96)[b]	.19	No effect
	Mean difference (95% CI) classroom time sitting bouts >10 minutes	–17.67 (–33.78 to 1.56)[b]	.03	Improved
	Mean difference (95% CI) classroom time sitting bouts >20 minutes	–10.21 (–26.72 to 6.31)[b]	.23	No effect
Verloigne et al [37], 2018				
	Mean difference (SE) school hours frequency of sitting bouts ≥30 minutes	Primary school –0.578 (0.364)[c]; secondary school 0.463 (0.545)[c]	>.10[c]; >.10[c]	No effect[c]; no effect[c]
	Mean difference (SE) school hours time accumulated in sitting bouts ≥30 minutes	Primary school –30.518 (17.245)[c]; secondary school 26.073 (26.802)[c]	≥.05 to .10[c]; >.10[c]	No effect[c]; no effect[c]
Sudholz et al [40], 2020	Mean difference (95% CI) sitting in >15-minute bouts (minutes per lesson)	–7.7 (–17.5 to 2.0)[c]; –11.2 (–18.0 to –4.5)[a]	.14[c]; .002[a]	No effect[c]; improved[a]
Swartz et al [41], 2019				
	Mean difference (95% CI) SB[d] (minutes per day) grade 3 across-group comparison	12.9 (4.33 to 21.47)[c]; 19.3 (12.64 to 25.96)[a]	.003[c]; <.005[a]	Worsened[c]; worsened[a]
	Mean difference (95% CI) SB (minutes per day) grade 4 across-group comparison	12.4 (0.64 to 24.16)[c]; 4.3 (–5.73 to 14.33)[a]	.03[c]; .37[a]	Worsened[c]; no effect[a]
	Mean difference (95% CI) SB (minutes per day) grade 6 across-group comparison	4.2 (– 10.61 to 19.01)[c]; –14.4 (–28.69 to – 0.11)[a]	.57[c]; .04[a]	No effect[c]; improved[a]
Spinal health studies				
Cardon et al [42], 2002				
	Mean difference (95% CI) practical test score	19.47 (16.4 to 22.54)[c]; 19.20 (16.96 to 22.88)[a]	<.001[c]; <.001[a]	Improved[c]; improved[a]
	Mean difference (95% CI) candid camera score	8.23 (5.96 to 10.58)[b]	≤.001	Improved
	Percentage change weekly back or neck pain prevalence	–5.1[c]; –7.9[a]; –8.6[b]	Not reported[c]; not reported[a]; <.05[b]	Not reported[c]; not reported[a]; improved[b]
Dullien et al [43], 2018				
	Percentage reduced back pain frequency	–25.89[b]	.84	No effect
	Mean difference (95% CI) back knowledge score	2.6 (1.5 to 3.7)[b]	.001	Improved
Geldhof et al [44], 2006				

Study	Measure of effect (units)	Value	*P* value	Direction of the effect
	Mean difference (95% CI) general back posture knowledge	2.4 (1.75 to 3.05)[b]	<.001	Improved
	Mean difference (95% CI) specific back posture knowledge	1.2 (0.23 to 2.17)[b]	<.001	Improved
	Mean difference (95% CI) percentage lesson duration static sitting	5.7 (–6.72 to 18.12)[b]	Not reported	Not reported
	Mean difference (95% CI) percentage lesson duration dynamic sitting	1.9 (–1.93 to 5.73)[b]	Not reported	Not reported
	Mean difference (95% CI) percentage lesson duration trunk flexion	–7.4 (–22.80 to 8.00)[b]	<.05	Improved
	Mean difference (95% CI) percentage lesson duration trunk torsion	–0.60 (–4.9 to 3.7)[b]	.79	No effect
	Mean difference (95% CI) percentage lesson duration neck flexion	30.3 (–4.92 to 11.52)[b]	Not reported	Not reported
	Mean difference (95% CI) percentage lesson duration neck torsion	–0.60 (–4.90 to 3.70)[b]	<.05	Improved

[a]Measurement period: <24 weeks.

[b]Measurement period: ≥24 weeks.

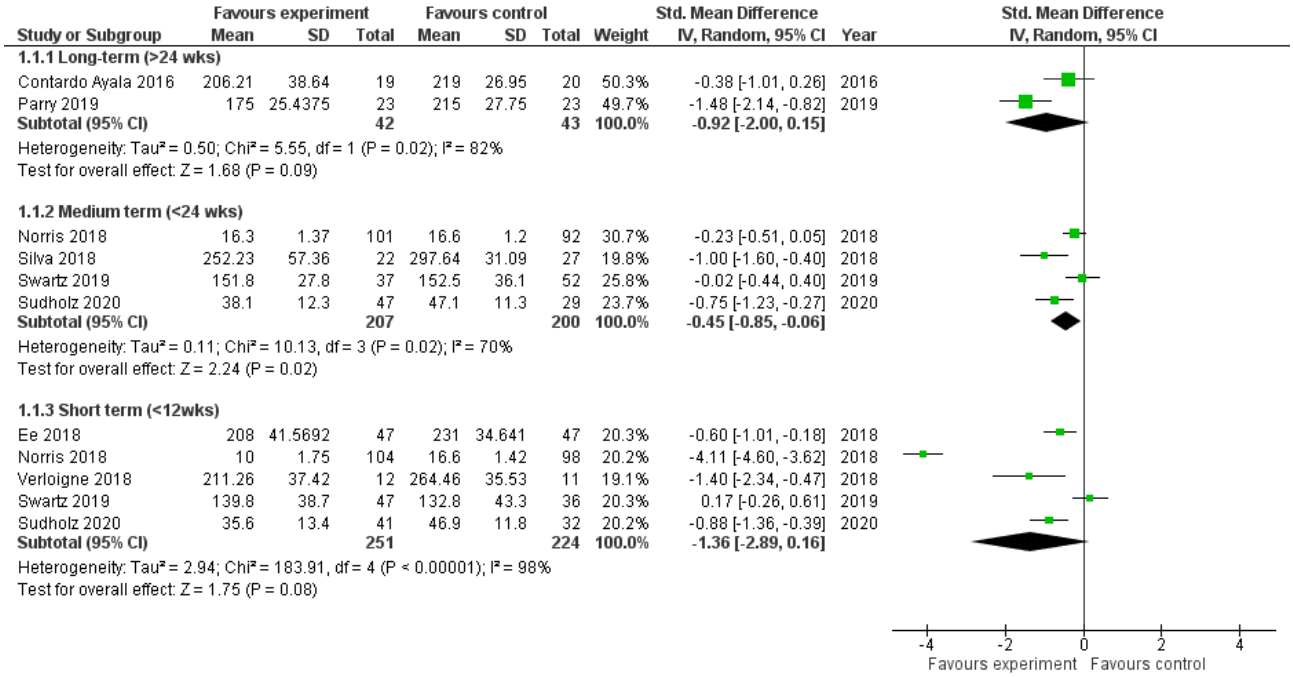
[c]Measurement period: <12 weeks.

[d]SB: sedentary behavior.

Intervention Effects

The SB study by Swartz et al [41] reported an increase in SB in the intervention group at final follow-up (Figure 2). All the other studies [33-40] reported decreased sitting time, with 75% (6/8) of these studies [33,34,37-40] reporting statistically significant differences. Statistically significant short-term SB intervention effects were reported in 44% (4/9) of the studies [34,37,39,40], whereas 22% (2/9) of the studies [38,40] reported statistically significant intervention effects in the medium term. The study by Parry et al [33] reported statistically significant long-term intervention effects to reduce SB, whereas the study by Sudholz et al [40] reported statistically significant short- and medium-term intervention effects.

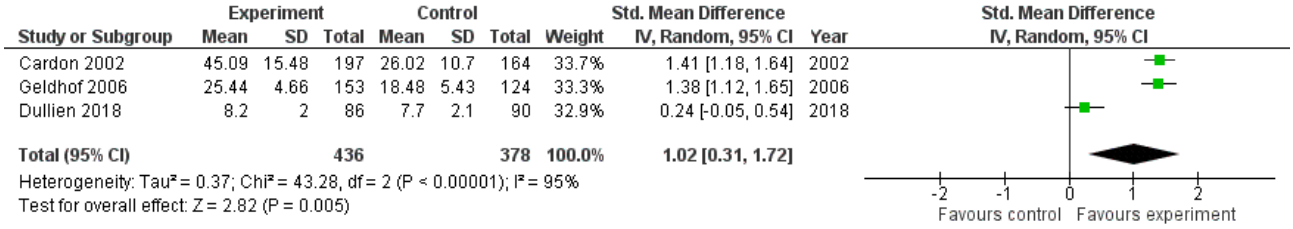
Figure 2. Forest plot of random effects of classroom sitting between intervention and control groups.



All 3 spinal health studies [42-44] showed statistically significant improvements in spinal behavior during practical or functional tasks; for example, during the practical test [42], carrying a heavy object [43], and during material handling [44] (Table 4). A random effects model analysis of the long-term effects of the spinal health interventions showed a large pooled effect in favor of back health interventions (Figure 3). Both studies that evaluated the intervention effects on back-care

knowledge reported statistically significant long-term improvements [43,44]. Of the 2 spinal health studies [42,44] reporting on weekly spinal pain prevalence, 1 (50%) [42] showed a statistically significant decrease in the long term. A statistically nonsignificant reduction in frequency of spinal pain was reported by Dullien et al [43].

Figure 3. Forest plot of random effects on spinal behavior during functional task between intervention and control groups.



Discussion

Principal Findings

Our study summarized the effects of classroom-based interventions targeting two separate but related health outcomes, namely SB and spinal health. The main finding is that classroom-based interventions yielded mixed results for SB outcomes and positive results for spinal health outcomes. The interventions used in the included studies were conducted within the classrooms, thus not requiring additional school and community resources.

In our study, it was found that SB interventions mostly aimed to reduce classroom sedentariness by altering classroom behavioral topography (ie, using combinations of teacher and learner education and sit-stand furniture strategies). The exception was the study by Norris et al [39], which used a teacher-led physical activity strategy. Although both strategies yielded positive results in reducing classroom sitting time, the teacher-led physical activity intervention by Norris et al [39] was more effective than the other interventions in the short term (Figure 2). However, the effectiveness tapered off in the medium term, which may imply that teacher-led interventions might not be sustainable after the cessation of the intervention period. The teacher-led physical activity intervention relied on the teacher administering the physical activity and was thus unable to influence the SB of learners outside of the periods in which the activity was being conducted. However, behavioral topography interventions allowed learners to reduce their SB without reliance on the teacher. The interventions based on altering behavioral topography had relatively smaller effects in the short term, but these reductions were maintained at follow-up. The reason for these interventions' relatively small reduction in SB may be that they either insufficiently addressed teachers' and learners' automatic perceptual mechanism to habitually sit during lessons [48] or were unable to alter teachers' perceptions that they are better able to maintain classroom order and control when learners are seated [49]. The teacher-led physical activity intervention required learners to participate in the physical activity without the need to overcome either of these factors. The mixed findings regarding the effectiveness of interventions on SB contrast with the definitive improvements shown by the spinal health interventions.

Spinal health interventions produced large pooled effects for improving spinal health behavior during functional tasks in the long term (Figure 3). Three distinct methods of intervention were used in the different studies, namely educational lessons [42-44] and accompanying visual aids (such as posters) [43,44], physical activity or exercise programs, and ergonomic devices [43,44]. The intervention by Dullien et al [43] resulted in smaller improvements in spinal health behavior during a functional task than the other spinal health studies. The functional outcome used by Dullien et at [43] consisted of a single carrying task. It is likely that the learners who completed the multidomain functional task used by Cardon et al [42] and Geldhof et al [44] were able to compensate for low scores attained in some of the domains with higher scores achieved in other domains. This was not possible in the single-domain functional task used by Dullien et al [43]. The nonuniformity of this functional outcome across the studies must be considered in the interpretation of this study finding.

The nonuniformity of the reported units of measurement and outcome measurement of studies hindered cross-study comparison. Units of measurement from SB studies included aggregated minutes, minutes per 9 hours, minutes per day, and minutes per lesson. Furthermore, the variability and makeup of spinal health outcome measurements are also problematic; for instance, Cardon et al [42] included sitting posture and ring-binder use at the desk in the observation of practical application of healthy spinal principles, whereas Geldhof et al [44] measured static and dynamic posture separately from other functional tasks. Furthermore, Dullien et al [43] embedded the observation of the demonstration of static and dynamic posture in a back behavioral trial. The use of standard measures of outcome and standardized measurement units is likely to facilitate cross-study comparison and must therefore be addressed by future research in the field.

The heterogeneity in study design across the included studies required the use of a generic critical appraisal tool [47]. The studies were generally well described, which is helpful to researchers planning similar intervention studies. However, the critical review revealed notable shortcomings, namely the nonreporting of clinical importance, lack of a justified sample size, and use of nonvalidated and unreliable outcome measures in the spinal health studies. The lack of reporting of sample size justification in the included studies implies that the studies were underpowered to assess the study outcomes. The use of nonstandardized and unreliable outcome measures may introduce bias into the study findings. These limitations of the included studies undermine the study findings and, by extension, the generalizability of the findings.

The burden posed by spinal health conditions and noncommunicable diseases [50] in low-resource countries matches that in high-income countries. However, the competing demands for resources as well as psychosocial and economic contextual factors in low-income countries must be considered by researchers and program planners intending to conduct similar studies in such countries; for instance, in low-income contexts and settings characterized by marked inequity in society, unequal resource distribution in communities and schools may threaten disproportionate rollout of classroom-based interventions. In addition, the interdepartmental collaboration required to roll out classroom-based health programs at sites managed by departments of education is not guaranteed in resource-scarce settings [51]. Given that all included studies were conducted in high-income countries, the generalizability of our review's findings may be limited in resource-scarce countries.

A previous systematic review of school-based SB interventions [23] included intervention programs that incorporated strategies that extended beyond the confines of the classroom. These differences are noteworthy because reducing discretionary and nondiscretionary SB may require different intervention strategies [28]. In addition, our study included classroom-based interventions aimed at improving spinal health. The common pedagogical approaches between SB and spinal health studies included in our review (ie, teacher training; the use of an education and training program delivered by the teacher, researchers, or the use of posters; and changing the physical environment of the classroom using alternative classroom furniture or dynamic sitting equipment) are strategies common to both SB and spinal health studies included in our review. Owing to their potential benefits, combining SB and spinal health intervention strategies to create an impact on both health outcomes may be a cost-effective approach for low-resource settings. The commonality between SB and spinal health studies is not surprising given the likely common root problem, namely the accrual of prolonged periods of static sitting in schools [52]. Given the pervasiveness of prolonged classroom sitting and its dual harmful associations with metabolic syndrome and adverse loading patterns of spinal structures, our review provides supportive evidence for the effectiveness of bimodal classroom-based interventions to address both these health outcomes.

All 3 spinal health studies [42-44] included a classroom-based back education program, which included information about the structure and function of the spine during sitting and standing postures as well as functional spinal movement. These back education programs proved effective in producing statistically significant improvement in functional back behavior in the long term. This once more provides evidence for the effectiveness of classroom-based spinal health interventions. Given that both SB and spinal health interventions comprised classroom-based training via teacher-delivered presentations and educational posters or stickers, there may be potential to combine the SB and spinal health messages to address these related health concerns as part of a single, combined intervention strategy. Our study shows promising findings for researchers and health program planners considering implementing school-based interventions that do not require resources beyond the confines of the classroom environment or that may be a burden to the home environment. The relatively small resource footprint of effective classroom-based interventions is preferred in resource-constrained contexts. Programs with limited resource footprint may also improve sustainability [25].

Strengths and Weaknesses of Included Studies

A strength of our review is the inclusion of objectively reported and measured SB studies, thus eliminating the risk of over- or underestimation owing to participant recall. Another strength is the long-term reporting of spinal health outcomes. A weakness of the SB studies was the variability of the units of measurement, making it difficult to pool the data and conduct a meta-analysis of the intervention effects. High levels of heterogeneity in meta-analysis limits the utility of the study findings. A weakness of the spinal health studies was that although sitting posture and spinal behavior formed part of the back education interventions, intervention effect on sitting posture and behavior made up a small component of the outcome measures used. Furthermore, the functional assessment outcomes were nonstandardized and incongruent with typical classroom behavior. The use of standardized functional assessment outcomes in future studies will improve cross-study comparison.

Study Limitations

The first limitation of our study pertains to the search strategy used for the different electronic databases. Although we made use of the PubMed database capabilities such as searching using Medical Subject Headings, the full search capabilities of the other 3 databases were not optimized. This may have resulted in missing relevant studies that may have influenced the results of our review and meta-analysis. However, a recent search of the PubMed database yielded results that were similar to those of our initial search. Second, this study is limited by the fact that all the included studies were set in high-income countries. Thus, the findings are not generalizable to low- and middle-income countries. This is particularly pertinent given the relatively expensive SB intervention of height-adjustable sit-stand desks. Third, our study is limited by the inclusion of experimental study designs, which are associated with increased risk of bias. Given the small number of studies found that conducted classroom-based interventions, studies were not excluded based on methodological quality. The need for evidence on the effectiveness of classroom-based interventions in this emerging field was prioritized over the inclusion of studies with less inherent bias.

Conclusions

The findings of our study suggest that classroom-based interventions may be effective in improving SB and spinal health outcomes without placing a burden on space, equipment, or staff beyond the classroom setting. Our findings show significant effects on spinal health outcomes and positive trends in SB outcomes, although the overall effect was only significant in the medium term. Effective classroom-based interventions can thus potentially be considered by researchers, clinicians, and program planners wanting to develop classroom-based interventions in resource-constrained environments. Future

studies to advance interventions aimed at improving SB outcomes must include strategies to overcome teachers' and learners' hedonic motivation to sit during class and use appropriate sampling methods and justified sample sizes.

Conflicts of Interest

None declared.

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Abbreviations

LBP: low back pain
PRISMA: Preferred Reporting Items for Systematic Reviews and Meta-Analyses
SB: sedentary behavior

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Review

Education During Ward Rounds: Systematic Review

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Abstract

Background: Enhancing the educational experience provided by ward rounds requires an understanding of current perceptions of the educational value of rounds.

Objective: This systematic review examines perceptions of education in ward rounds, educational activities in ward rounds, barriers to learning, and perceptions of simulation-based ward rounds.

Methods: The 2020 PRISMA (Preferred Reporting Items for Systematic Reviews and Meta-Analyses) guidelines were followed. MEDLINE (EBSCO), Cochrane, and Scopus were searched on May 29, 2022, for studies assessing learning during ward rounds. The search terms included “ward rounds,” “education,” and “trainees.” Then, the selected articles were reference searched. In total, 354 articles were retrieved. The articles were assessed for eligibility by 2 independent reviewers who screened titles, abstracts, and full-length texts. Articles addressing trainees’ education in all ward rounds were included. Articles were excluded if they were specific to certain disciplines, were reviews, were not published in scholarly journals, were published before 2015, were published in languages other than English, or did not concern human participants. Following the removal of 63 duplicates, a total of 268 articles were excluded. The risk of bias within the selected articles was also assessed via the Critical Appraisal Skills Programme checklist for qualitative research. Qualitative data were used to describe results in a narrative synthesis and in tables.

Results: A total of 23 articles were included. Perceptions of teaching in rounds were addressed by 6 studies, of which 3 showed negative perceptions among participants, 2 reported ambivalent perceptions, and 1 showed positive perceptions. Perceived barriers to teaching during rounds were assessed by 7 studies. The reported barriers included time constraints, workloads, schedules, interruptions, the service-oriented nature of rounds, the lack of feedback, hierarchies, the lack of opportunities to ask questions and be engaged in patient management, and divergent learner needs. Further, 8 studies identified types of educational activities, including observation, patient-specific teaching, and discussion. Perceptions of learning through simulated ward rounds were assessed by 8 studies, and a consensus of satisfaction was noted among learners. The interventions that were explored to improve education included using teaching frameworks, involving clinical librarians, and changing the setting of ward rounds.

Conclusions: The main limitations of this review are the predominant use of qualitative data in the included articles and the lack of standardization for the educational compositions of ward rounds among articles, which made the articles hard to compare. In conclusion, learning opportunities in ward rounds are often missed, and trainees perceive rounds to have low educational value. It is important to recognize the barriers to education during ward rounds and address them to maximize the benefits of ward rounds. Finally, there is a need to develop plans that incorporate teaching regularly during ward rounds in the inpatient setting.

Trial Registration: PROSPERO CRD42022337736; https://www.crd.york.ac.uk/prospero/display_record.php?RecordID=337736

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KEYWORDS

education; learning; rounds; trainee; ward rounds; medical education; simulation-based learning; digital health; digital learning; education intervention

Introduction

Ward rounds are conducted by teams of health care practitioners to review, assess, and manage patients in an inpatient setting, visiting each patient in order at their bedside. Ward rounds also represent an opportunity for trainees to learn and enhance their clinical and interpersonal skills [1,2]. The educational component of rounds is impacted by workloads, time constraints, and physicians' teaching attitudes and practices [3]. This has resulted in predominantly negative perceptions of the educational value of ward rounds [4,5]. The recognition of ward rounds as an educational platform has resulted in initiatives, such as simulated ward rounds, that aim to enhance the educational opportunities typically gained through ward rounds.

Enhancing the educational experience provided by ward rounds requires an understanding of current perceptions and experiences. This review examines perceptions of the educational value and content of ward rounds and the interventions that have been explored to optimize education in ward rounds.

Methods

Study Design

This systematic review followed the 2020 PRISMA (Preferred Reporting Items for Systematic Reviews and Meta-Analyses) guidelines [6]. This review was registered in PROSPERO (ID number: CRD42022337736).

Search Strategy

MEDLINE (EBSCO), Cochrane, and Scopus were searched on May 29, 2022, for studies examining the educational value of ward rounds. The search terms used included "ward rounds," "rounds," "teaching," "education," "learning," "junior," and "trainee." Search limiters were added to narrow the search; the limiters included publications in scholarly (peer-reviewed) journals, English-language articles, human studies, and a date of publication ranging from 2015 to the date of the search. The search was restricted to papers published from 2015 to the date of the search in order to ensure that recent trends in teaching and education in wards were identified. Table 1 shows details on the search terms.

Table 1. Search strategy for MEDLINE (EBSCO)[a].

String number	Search strings	Results, n
String 1	*"ward rounds" OR "rounds"*	90,462
String 2	*"teaching" OR "education" OR "learning"*	1,924,938
String 3 (strings 1 and 2)	*("ward rounds" OR "rounds") and ("teaching" OR "education" OR "learning")*	9316
String 4	*"trainee" OR "junior"*	81,722
String 5 (strings 3 and 4)	*("ward rounds" OR "rounds") AND ("teaching" OR "education" OR "learning") AND ("trainee" OR "junior")*	579
String 6 (strings 3 and 4)	*("ward rounds" OR "rounds") AND ("teaching" OR "education" OR "learning") AND ("trainee" OR "junior")*	291

[a]Limiters: scholarly (peer-reviewed) journals, a date of publication ranging from 2015 to 2022, English-language articles, and human studies.

Inclusion and Exclusion Criteria

Articles addressing trainees' education in all ward rounds were included. Articles were excluded if they did not relate to education during ward rounds, were specific to certain disciplines, were reviews, were not published in scholarly journals, were published before 2015, were published in languages other than English, or did not concern human participants.

Data Extraction and Reporting

Two independent reviewers assessed articles for eligibility. In cases of disagreement, discussions were sufficient for reaching an agreement. No third-party review was needed to resolve discrepancies. After excluding articles, the number of remaining relevant articles was reduced by specifying search limiters. Articles were then excluded based on reading the abstracts and titles. A search of the references in the selected articles was also performed. Next, full texts were read to assess articles' relevance to the selected topic. Afterward, reference searching was performed to identify more articles. Qualitative data on the following themes were extracted: perceptions of the educational value of ward rounds, perceived barriers to teaching and learning, types of educational activities, perceptions of simulation-based ward rounds, the impact of trainee characteristics on the educational experience provided by rounds, and interventions and solutions that were explored to improve learning during ward rounds. The participants' views and reported outcomes were expressed as percentages.

Quality Assessment of Studies

The quality of the evidence presented in the selected articles was assessed via the Oxford Centre for Evidence-Based Medicine levels of evidence [7]. The risk of bias within the selected articles was also assessed via the Critical Appraisal Skills Programme (CASP) checklist for qualitative research [8]. For conflicts related to the quality assessment of the studies, a discussion was held between the two authors of this paper, and a final rating was determined. No third party was needed to resolve any conflicts.

Results

Search Results

A total of 354 publications were retrieved. Studies were sorted by relevance. After removing duplicates, titles and abstracts were screened to assess eligibility, which resulted in the exclusion of 261 articles. The remaining 30 full-length articles were read, and 7 additional articles were excluded. Exclusion details are outlined in Figure 1. One article was identified by reference searching the selected articles. A total of 23 articles were included in this review (Figure 1 and Table 2).

The themes pertaining to education in ward rounds were identified (Table 3).

Figure 1. PRISMA (Preferred Reporting Items for Systematic Reviews and Meta-Analyses) flow diagram.

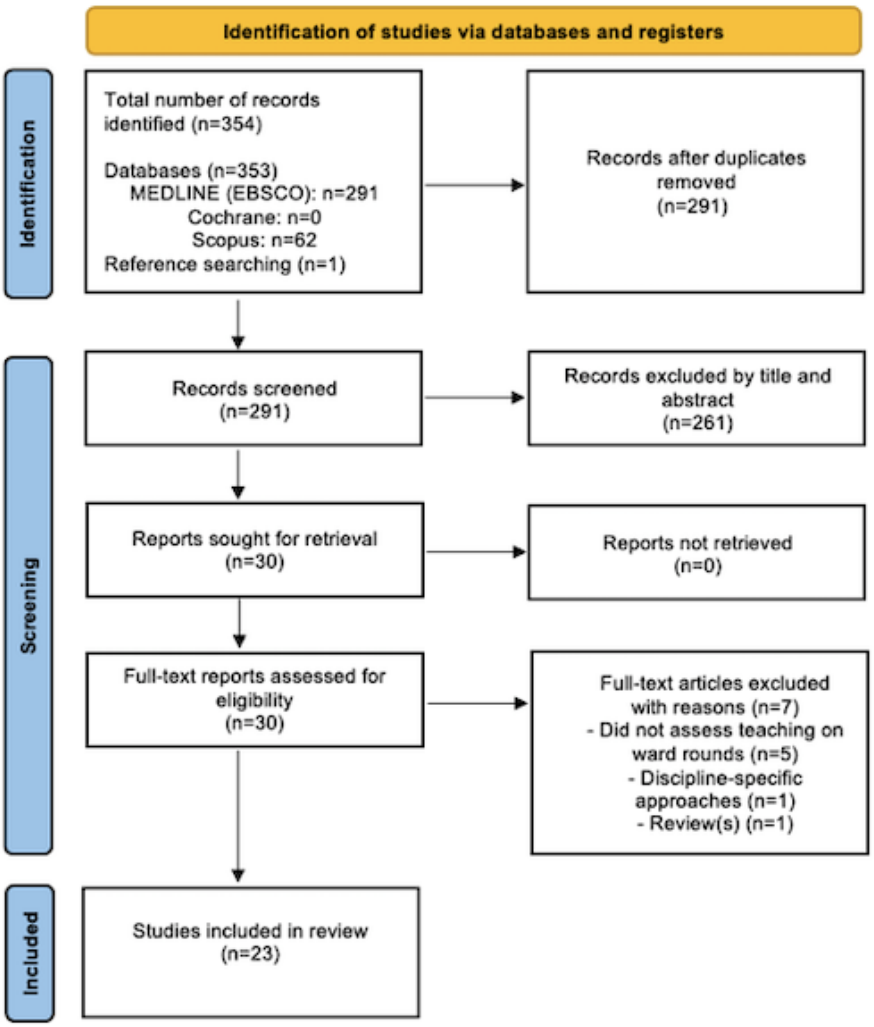


Table 2. Included studies.

Study (authors, year published)	Study type	OCEBM[a] evidence level
Gee et al [9], 2015	Audit	2C
Harvey et al [10], 2015	Nonrandomized crossover trial	2B
Laskaratos et al [11], 2015	Cross-sectional observational study	3
Piquette et al [12], 2015	Prospective observational study	2C
Powell et al [13], 2015	Pre-post study	2B
Thomas [14], 2015	Cross-sectional observational study	3
Herrmann et al [15], 2016	Observational study	4
Laskaratos et al [5], 2016	Cross-sectional observational study	3
Rabinowitz et al [16], 2016	Qualitative study	3
Merritt et al [17], 2017	Cross-sectional observational study	3
Beck et al [18], 2018	Prospective observational study	2C
Gray and Enright [19], 2018	Cross-sectional observational study	3
Morgan et al [20], 2018	Pre-post study	2B
Rao et al [21], 2018	Multiarm pre-post study	2C
Somasundram et al [22], 2018	Experimental study	2C
Goodrich et al [23], 2020	Nonrandomized trial	3
Levine et al [24], 2020	Prospective mixed methods	2C
Spence et al [25], 2020	Nonrandomized trial	3
Gray et al [26], 2020	Observational study	4
Armendariz et al [27], 2021	Prospective observational study	2C
Khan et al [28], 2021	Cross-sectional observational study	3
Modak and Gray [29], 2021	Qualitative study	3
Solomon et al [30], 2021	Randomized controlled trial	2B

[a]OCEBM: Oxford Centre for Evidence-Based Medicine.

Table 3. Themes pertaining to education during ward rounds in each article.

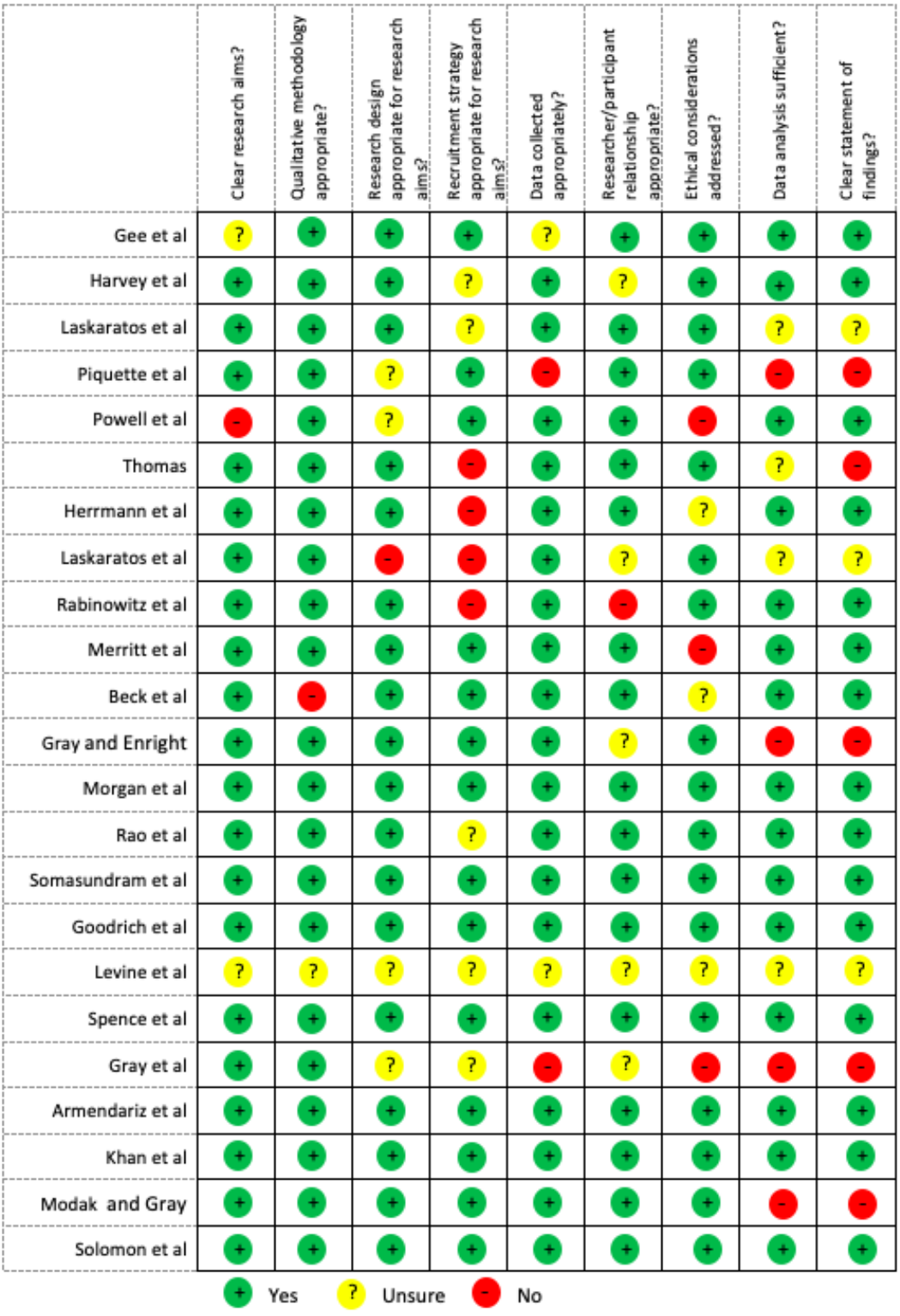
Articles (authors, year)	Perceptions of the educational value of ward rounds	Perceived barriers to teaching and learning	Types of educational activities	Perceptions of simulation-based ward rounds	Impact of trainee characteristics	Interventions explored to optimize education in ward rounds
Laskaratos et al [5], 2016	✓[a]	✓	✓			
Gee et al [9], 2015				✓		
Harvey et al [10], 2015				✓		
Laskaratos et al [11], 2015	✓	✓				
Piquette et al [12], 2015			✓			
Powell et al [13], 2015				✓		
Thomas [14], 2015				✓		
Herrmann et al [15], 2017						✓
Rabinowitz et al [16], 2016		✓	✓			
Merritt et al [17], 2017)			✓			
Beck et al [18], 2018	✓		✓			
Gray and Enright [19], 2018	✓	✓				
Morgan et al [20], 2018				✓		
Rao et al [21], 2018				✓		
Somasundram et al [22], 2018				✓		
Goodrich et al [23], 2020						✓
Levine et al [24], 2020			✓			
Spence et al [25], 2020				✓		
Gray et al [26], 2020						✓
Armendariz et al [27], 2021		✓				
Khan et al [28], 2021	✓	✓	✓			
Modak and Gray [29], 2020	✓	✓	✓		✓	
Solomon et al [30], 2021						✓

[a]✓: indicates the studies incorporated the relevant theme(s) mentioned in the header.

Quality Assessment of Studies

Of the 23 included studies, 6 were cross-sectional observational studies, 4 were prospective observational studies, 2 were pre-post studies, 1 was an audit, and 1 was a randomized controlled trial. The details of the other study types can be found in Table 2. The risk of bias was assessed based on the CASP checklist for qualitative research. In general, most papers (19/23, 83%) had a low risk of bias, per our assessment. The findings of this assessment can be found in Figure 2.

Figure 2. Risk of bias assessment [5,9-30].



Perceptions of the Educational Value of Ward Rounds

A total of 6 studies assessed perceptions of teaching in rounds [5,11,18,26,28,29] (Table 3). For this review, perceptions of education in rounds were considered positive, ambivalent, and negative if such education was considered acceptable by at least 55% of the respondents, by 50% to 54% of respondents, and by less than 50% of the respondents, respectively. In 3 of the 6 studies, participants had negative perceptions of the educational value of rounds [5,11,18]. Beck et al [18] conducted an observational study that objectively demonstrated that teaching only occurred in 29% of patient encounters. In addition, 2 of the 6 studies reported an ambivalent perception of education. However, Gray and Enright [19] reported a discrepancy between the education received and the education desired by trainees; this study relied on a mixed methods approach, using questionnaire-based perceptions as well as observations. Similarly, Khan et al [28] found that trainees perceived rounds

as service oriented and considered them to be "business rounds." One study reported positive perceptions of educational opportunities among participants. Their perceptions of the educational value of rounds were congruent with consultants' engagement in education, trainees' initiative in seeking feedback, and organizational constraints [29].

Perceived Barriers to Teaching and Learning

A total of 7 studies assessed perceived barriers to teaching during rounds [5,11,16,19,27-29]. Textbox 1 provides details on the perceived barriers in each study. There were many barriers mentioned; however, a recurring theme was noted—time constraints [11,16,28,29]. Although ward rounds are recognized as educational opportunities, teaching during rounds may increase the time needed to conduct rounds. Moreover, interruptions [11,27] have been noted as another common barrier to effective ward rounds. The potential educational aspect of ward rounds is why they are beneficial to trainees; however, it has been noted multiple times that the service-oriented nature of rounds [5,11,28] diminishes this educational element.

Textbox 1. Perceived barriers to teaching and learning during rounds.

Laskaratos et al [11], 2015

- Time constraints
- Workload
- Interruptions
- Service-oriented nature of rounds (competing administrative tasks)
- Sparsity of feedback

Laskaratos et al [5], 2016

- Service-oriented nature of rounds

Gray and Enright [19], 2018

- Hierarchal nature of rounds (consultant-led rounds)
- Limited opportunities for trainees to be involved in setting management plans
- Limited opportunities to ask questions

Khan et al [28], 2021

- Time constraints
- The number of patients (workload)
- Service-oriented rounds

Modak and Gray [29], 2020

- Time restrictions
- Workload
- Schedules
- Clerical duties
- Hesitancy to provide feedback
- Consultants' willingness to teach
- Trainees' initiative to ask for feedback

Armendariz et al [27], 2021

- Interruptions during rounds (eg, interruptions by nurses, consultants, and workers from other disciplines; phone calls; and personal interruptions)

Rabinowitz et al [16], 2016

- Time restraints
- Limited working hours
- Variations in participants' needs

Impact of Trainee Characteristics

One study addressed the impact of trainees' characteristics on their perceptions of the educational value of rounds. Modak and Gray [29] found that trainees' traits influenced their learning; these included the initiative to seek feedback, ask consultants questions, and self-reflect. However, trainees' willingness to take initiative was influenced by their concerns about consultants' expectations for their knowledge. Furthermore, the trainees' states also impacted their learning; the trainees' states reflected their uncertainty about their knowledge baseline and clinical assessments, as well as their preexisting workloads (clerical responsibilities) and cognitive overload. In addition to the trainees, some registrars were also unwilling to teach residents due to their lack of confidence in their knowledge.

Types of Educational Activities

A total of 8 studies mentioned learning activities during ward rounds [5,12,17,18,24,28,29] (Table 3). In Laskaratos et al's [5] 2016 study, senior trainees found rounds useful for learning higher-order skills, such as difficult decision-making. However, senior trainees thought that there were limited opportunities to learn about clinical assessments and gain medical knowledge. Beck et al's [18] study emphasized medical discussions during rounds as a method of teaching through modeling and observation. The most discussed topic was "cancelling low-value laboratory investigations, therapies, or limiting parameters monitored," followed by "developing a patient-centered plan." These topics were discussed in 8% and 7% of encounters, respectively. Merritt et al [17] examined the teaching methods that have been used during rounds and ranked physicians as teachers. Physicians with better teaching ratings performed more patient-specific teaching, discussed general medical topics, and provided trainees with feedback. In Khan et al's [28] study, participants identified the elements that can be best learned during rounds in descending order, as follows: investigation, management, patient history taking, and patient examination. Furthermore, Modak and Gray [29] identified different didactic strategies, which included ceasing teaching opportunities, performing case-specific reflections, highlighting important information, teaching while having a casual coffee break following rounds, and having consultants explain their rationales and guide residents in making decisions. Levine et al [24] analyzed teaching points related to patient safety; the points were taught through verbal conversations pertaining to inpatient and discharge safety, diagnostic safety and the prevention of errors, medication and procedure safety, communication, and hospital-acquired infections. The verbal patient safety messages were presented as statements (medical orders), inquiries, or factual reaffirmations and reminders. Additionally, Piquette et al [12] explored 2 approaches for teaching in rounds. The first approach was "in series" teaching, which involved a structured session that focused on education that was not interrupted by providing care to patients, whereas the second approach involved highlighting quick learning points for residents "in parallel" with caring for a patient. The advantages of the "in series" approach included providing structured teaching and an opportunity to focus on trainees' individual learning needs, whereas the "in parallel" approach allowed the educational focus to revolve around the cases encountered. Finally, in a study by Rabinowitz et al [16], residents identified different learning points from rounds, as follows: deriving differential diagnoses and management plans, conducting physical examinations, practicing presenting patients' conditions to colleagues, communicating plans to patients, and understanding the importance of professionalism.

Perceptions of Simulation-Based Ward Rounds

Perceptions of learning through simulated ward rounds were assessed by 8 studies [9,10,13,14,20-22,25] (Table 3). All studies reported good perceptions and a general consensus of satisfaction with simulated ward rounds among learners. The use of simulation was useful in highlighting skills that learners can improve [10,14,21,22,25], as well as improving learners' perceived preparedness and confidence [9,13,14,20,25]. Spence et al [25] reported that participants noticed that simulation sessions helped them recognize the importance of clinical handover and improve their communication, situational awareness, teamwork skills, and ability to make decisions. Furthermore, simulation-based practice has been proposed to train residents when novel round approaches, such as family-centered rounds, are used in some pediatric departments [21].

Interventions Explored to Optimize Education in Ward Rounds

A total of 4 studies addressed different interventions that were attempted to optimize residents' educational experiences during ward rounds [15,23,26,30]. Of these, 2 studies attempted to use frameworks that involved the following four stages: planning, implementing a teaching strategy (this can involve asking questions, prompting reasoning, identifying themes, encouraging evidence-based learning, and observing), observing, and ending sessions by reinforcing learning points and participants' understanding. The aforementioned frameworks were referred to as "set, target, inspect and close" by Gray et al [26] and "plan, do, study, act cycles" by Herrmann et al [15]. The teaching strategy explored by Herrmann et al [15] involved incorporating a clinical librarian in rounds to promote information seeking and encourage trainees to raise relevant clinical questions and use evidence-based practices. These frameworks were well perceived by consultants and rendered educational activities that were explicit and engaging for team members. These strategies were also advantageous because they were congruent with usual rounds and did not consume additional time [15,26]. Furthermore, 2 of the 4 studies investigated the impact of changing the setting of ward rounds on residents' educational experiences [23,30]. Solomon et al [30] compared rounds conducted at patients' bedsides with hallway rounds; they found that hallway rounds were perceived to be superior in terms of efficacy and the education rendered. Moreover, Goodrich et al [23] compared hallway rounds to a novel "conference room rounding style." Conference room rounds were rounds that were performed while sitting in a conference room and involved all of the concerned interdisciplinary stakeholders (eg, physicians, nurses, pharmacists, dietitians, and social workers). Goodrich et al [23] found that conference rounds were associated with greater efficacy, education, and family involvement when compared with hallway rounds.

Discussion

Overview

Daily ward rounds are conducted to assess patients' status and progress throughout their hospital stay and devise management plans accordingly. They provide a great opportunity for trainee doctors to learn. However, the educational component of ward rounds remains an underresearched field; this review was conducted to explore the existing research on this topic.

During rounds, attending physicians can highlight elements of clinical assessments, communication, management, general and evidence-based medical knowledge, and the decision-making process. They may explain rationales for selected approaches, emphasize cost-efficient options or alternatives, and tackle patient-centered approaches. They can also involve learners, answer their questions, and provide feedback [17,19].

Principal Findings

This review showed that trainees' views on the educational value of rounds are predominantly negative [5,11,18]. Speculations have risen about the impact of trainee characteristics on residents' educational attainment in ward rounds; Modak and Gray [29] found that trainees' willingness to seek feedback, ask questions, and self-reflect impacted their learning. However, trainees' willingness to take such initiatives was impacted by their concerns about not meeting basic knowledge expectations. There are many factors impeding the teaching process during ward rounds, including time pressures, competing administrative tasks, physicians' teaching practices, and the consultant-led hierarchal structure of rounds [5,19]. To address time restrictions, Eraut [31] proposed using didactic approaches that are reactive in nature and pertain to the educational encounters that occur at the workplace. Another approach to teaching at the workplace was proposed by Hoffman et al [32], who presented the following options: reflecting during the encounter itself ("reflection-in-action") and reflecting after the encounter ("reflection-on-action"). Theoretically, considering these options can help learners and educators overcome the system-related barriers to education during rounds. Moreover, simulated ward rounds also present alternate learning opportunities. These simulations have been shown to increase confidence, preparedness, and the awareness of potential hospital-based challenges among learners [9,10,13,14,20]. Other interventions have also been explored, including using frameworks that involve planning, doing activities, receiving feedback, and identifying learning points. In 2 studies, the use of frameworks helped consultants incorporate teaching into rounds and not consume additional time that could have interfered with their schedules [15,26]. Furthermore, a study that compared residents' educational experiences in bedside rounds to those experiences in hallway rounds found that hallway rounds were associated with better learning experiences [30]. Another study compared hallway rounds to conference rounds. Conference rounds were conducted while sitting in a conference room; they were multidisciplinary rounds that involved a clinical librarian to encourage evidence-based learning. Conference rounds had a higher degree of efficacy and provided a better educational experience [23].

Comparison to Prior Work

Over the years, the educational value of teaching at the bedside has been commended, as it has been linked to increased information retention [33]; a better understanding of individualized patient management [34]; and more precise differential diagnoses following clinical assessments, which result in fewer unnecessary services [34,35]. The types of educational activities that have been performed at patients' bedsides include activities for eliciting physical findings based on patient histories and physical examinations [33,34], demonstrating skills under supervision [36], and enhancing communication skills as well as professionalism [34]. Moreover, older studies identified barriers to bedside teaching, such as time constraints, the fear of causing discomfort to patients, distractions, [33,34,36], obstacles to infection control, increased reliance on investigations [34], and the lack of educator training for physicians [35]. Some solutions that were previously proposed by the literature are preparing patients and trainees prior to commencing rounds, assessing junior trainees' educational needs, changing clinicians' attitudes toward teaching, and allocating educational tasks among team members [33,36,37].

An article by Kim et al [38] compiled different educational strategies that can be used to improve bedside teaching; 4 of these strategies can be applied to ward rounds. The first strategy was creating a learning culture through role modeling by more senior physicians, rewarding teaching, and encouraging teaching by nurturing leadership development skills. As a part of role modeling, more senior physicians can role model features of humility, the acknowledgement of knowledge deficiencies, the act of asking colleagues for help, self-correction, and the act of apologizing when a mistake is made. The second strategy Kim et al [38] suggested was scaffolding, which means providing trainees with the assistance they need to perform a task and gradually withdrawing the assistance provided until trainees no longer need help performing the task. The third suggested strategy was using the 1-minute preceptor model, which is composed of the following components: committing to a diagnosis, providing reasoning, providing feedback about what was done well, and guiding learners on how to handle mistakes and omissions. Through this model, a teacher can tailor teaching content to the gaps identified in learners' approaches [38,39]. The fourth strategy that can be used is identifying learning points from encounters and encouraging further reading on these points by assigning short, casual, 5-minute mini-presentations [38]. Another article by Ratnani et al [40] emphasized the importance of bridging the gap between superficial book-learned knowledge and conceptual practical knowledge. Some of the strategies they brought up were aiming to gradually build up trainees' knowledge, simplifying principles, simplifying knowledge, and comparing and contrasting knowledge.

It is important to recognize ward rounds as missed educational opportunities. This could be addressed by setting plans to incorporate teaching during rounds to make them more learner centered. This would involve physicians planning to engage trainees in the assessment and management of patients while also providing trainees with feedback. This can be followed up by assessing learners' perceptions of the teaching methods used

and the aspects they find most useful via anonymous surveys or quality assessment audits.

Strengths and Limitations

One of the strengths of this review is that it sought the most recent information on teaching during ward rounds. This is because trainees' current perspectives would not be masked by the changes in the educational content of ward rounds over time. Furthermore, this review addresses an underresearched topic in the literature and highlights this topic's importance. This review also has limitations. The content that this review assesses, which includes perceptions, is mainly qualitative in nature, and some of the included articles derived results from a qualitative synthesis, which is suboptimal. Furthermore, there has been no aggregation or standardization for the educational composition of ward rounds, which made the articles difficult to compare. Finally, many of the interventions that have been attempted have not been studied further to adequately assess their efficacy and reliability.

Conclusion

Despite the potential that ward rounds demonstrate for providing education, learning opportunities are often missed. In many articles (3/6, 50%), trainees perceived rounds to have low educational value. The perceived barriers to teaching during rounds were time constraints and the hierarchal structure and service-oriented nature of rounds. However, simulated ward rounds have been associated with improvements in the confidence and preparedness of learners. There is a need to develop plans that incorporate teaching regularly during ward rounds in the inpatient setting.

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Conflicts of Interest

None declared.

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Abbreviations

CASP: Critical Appraisal Skills Programme
PRISMA: Preferred Reporting Items for Systematic Reviews and Meta-Analyses

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Review

Scientific Publication Patterns of Systematic Reviews on Psychosocial Interventions Improving Well-being: Bibliometric Analysis

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Abstract

Background: Despite numerous empirical studies and systematic reviews conducted on the effectiveness of interventions improving psychological well-being, there is no holistic overview of published systematic reviews in this field.

Objective: This bibliometric study explored the scientific patterns of the effectiveness of different psychosocial interventions improving well-being among various categories of individuals with mental and physical diseases, to synthesize well-being intervention studies, and to suggest gaps and further studies in this emerging field.

Methods: The bibliometric analysis included identifying the most productive authors, institutions, and countries; most explored fields and subjects of study; most active journals and publishers; and performing citation analysis and analyzing publication trends between 2014 and 2022. We focused on data retrieved from known databases, and the study was conducted with a proven bibliometric approach.

Results: In total, 156 studies were found concerning the research domains and retrieved using LENS software from high-ranking databases (Crossref, Microsoft Academic, PubMed, and Core). These papers were written in English by 100 authors from 24 countries, among which, the leading country was the United Kingdom. Descriptive characteristics of the publications involved an increased number of publications in 2017 (n=35) and 2019 (n=34) and a decreased number in 2021 (n=4). The top 2 leading authors by citation score are James Thomas (3 papers and 260 citations) and Chris Dickens (3 papers and 182 citations). However, the most cited study had 592 citations. *BMJ Open* (n=6 articles) is the leading journal in the field of medicine; *Clinical Psychology Review* (n=5), in psychology; and *Frontiers in Psychology*, in psychological intervention (n=5) and psychology (n=5). The top 2 publishers were Wiley (n=28) and Elsevier (n=25).

Conclusions: This study indicates an overall interest in the declared domains within the last decade. Our findings primarily indicate that psychosocial interventions (PIs) were evaluated as being effective in managing mental and physical problems and enhancing well-being. Cognitive behavioral therapy was assessed as being effective in treating anxiety, psychoeducation in relapse prevention, and gratitude interventions in improving overall health, and the mindfulness approach had a positive impact on decreasing distress and depression. Moreover, all these intervention types resulted in an overall increase in an individuals' well-being and resilience. Integrating social and cultural factors while considering individual differences increases the efficiency of PIs. Furthermore, PIs were evaluated as being effective in managing symptoms of eating disorders, dementia, and cancer. Our findings could help provide researchers an overview of the publication trends on research domains of focus for further studies, since it shows current findings and potential research needs in these fields, and would also benefit practitioners working on increasing their own and their patients' well-being.

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KEYWORDS

psychosocial intervention; well-being; systematic review; bibliometric analysis; bibliometrics; scientific research; medical research; publication; publish; citation; scientometrics; mental health

Introduction

Background

The effectiveness of available interventions for improving well-being is one of the major research questions that scientists and practitioners are exploring nowadays. Psychoeducational interventions were evaluated as effective in increasing compliance and preventing relapse among family carers of individuals with psychosis [1]. The gratitude interventions have a significant impact on individuals' physical and mental health [2]. Despite small numbers and low-quality data, some of them supported the efficiency of acceptance and commitment therapy in parenting of children with long-term conditions, seizure control in epilepsy, psychological flexibility, and self-management [3]. CBT was considered effective in the treatment of anxiety among individuals with asthma rather than treatment of the illness itself [4]. Carolan et al [5] stated no significant difference between studies using cognitive behavioral therapy and those using other psychological interventions.

A systematic review on mindfulness approach highlighted positive personal experiences and professional benefits among participants, such as reinforcement of their clinical skills and attitudes [6]. Mindfulness meditation resulted in positive outcomes in relation to distress, burnout, and depression among health care professionals [7], overall increase in staff well-being and resilience [8], along with a decrease in distress and blood pressure [9]. Evidence presented in a systematic review by Alsubaie et al [10] suggests increased effectiveness of mindfulness-based cognitive therapy. Duarte et al [11] identified and evaluated economic evidence for mindfulness meditation in improving mental health and stated inadequate data to generalize the findings.

The social and cultural factors need to be incorporated into the design and implementation of interventions to increase their efficiency [12]. In addition, possessing skills that allow attitude change, adjustment of the content to the target group, and matching the gender and ethnicity of the person delivering the intervention and the recipient are considered significant factors [13]. However, individual differences should be considered an influential determinant in a psychological intervention's efficiency [14]. A multicomponent psychosocial intervention (PI) was evaluated as being effective in improving cognitive functioning, social interaction, and well-being [15] and in decreasing pain [16] among patients with dementia. A systematic review by Shen et al [17] supports the effectiveness of PIs combined with family-based models, education, supportive services for caregivers, and abuse of older individuals. Another study suggested that physical activity is positively correlated but sedentary behaviors are negatively associated with psychosocial well-being in early childhood [18]. Delivering positive experiences, destigmatization, and use of a person-centered approach are recommended for effectively treating dementia [19]. However, a systematic review on the effectiveness of psychological interventions supporting patients with cancer in increasing their life quality stated insufficient data to claim its efficiency [20].

A combination of internal and external factors enables carers of patients with a cancer diagnosis to experience positive emotions [21]. A "Schwartz Rounds" environment [22] and interventions enhancing work engagement, including personal resource–building, job resource–building, leadership training, and health promotion [23], were all evaluated as being effective in providing support to health care staff with managing emotional challenges at work and improving their well-being. Graham et al [3] focused on exploring the life quality among health care professionals helping patients with eating disorders, while Narzisi and Simons [24] analyzed evidence of interventions preventing obesity among children. It has been stated that evidence- and theory-based interventions are more effective in promoting healthy eating habits [25]. A study on the holistic treatment of patients with obesity reported positive effects on awareness, health behavior, and physical activity and led to a decrease in drinking and an increase in well-being and self-efficacy [26]. The negative impact of stigma on psychological well-being among patients with ED was reported in a mixed methods systematic review by O'Connor et al [27].

A systematic review by Attwood et al [28] appraised the interventions for health care professionals to improve their negative attitudes toward personality disorders. Vereenooghe et al [29] investigated the effectiveness of psychological and pharmacological interventions for mental health problems among individuals with severe intellectual disabilities. Merkouris et al [30] recognized the significant predictors (eg, being employed, no gambling debt, and personality traits), unclear predictors (eg, treatment goal), and nonsignificant predictors (eg, education, income, anxiety, substance use, etc) for disordered gambling.

The multilevel parenting intervention program showed its positive impact at each level, resulting in an improvement of well-being among children, parents, and families [31]. The idea of using PIs with adoptive parents [32] and evidence-based parenting interventions [33] are effective for enhancing children's well-being. Peters et al [34] suggested that the areas related to the parents' perception of infants' mental health are important. It has been shown that parental interventions decrease maternal depressive symptoms [35] and can be positively associated with educational, health, and well-being effects as well as economic benefits [36].

To sum up, many recent studies suggested that psychological, social, digital, and other interventions are effective approaches in increasing an individuals' well-being. However, there is no overview of available systematic reviews and meta-analyses, which synthesized the analyzed qualitative and quantitative studies in the indicated research domains. This bibliometric study is aimed to analyze the objectives and synthesize the findings of identified systematic reviews on the effectiveness

of different PIs directed on increasing well-being among children, adults, and professional staff experiencing a physical or a mental illness.

Purpose of the Study and Research Questions

The primary purpose of this study is to explore scientific publication patterns in systematic reviews encompassing research domains of PIs and well-being. This study also aims to reveal the contribution of scientific knowledge by highlighting the contributions, gaps, and direct potential further studies. Based on the research objectives and scope, the following research questions have been formulated: (1) What are the descriptive characteristics of publication results? (2) Who are the most productive authors or coauthors, and what are their institutions and fields of study? What are the citation results of those authors? (3) Which organizations, countries, sources, and publishers contribute to the research area? (4) What are the results of keyword analysis of the publications?

Methods

Bibliometric Study

The bibliometric study provides the opportunity for researchers to investigate existing scientific patterns, trends, and associations in searched domains and interrelated fields over identified publication data. For bibliometric analysis to be successful, it requires a structured database with the appropriate data that will allow the researchers to answer the aforementioned research questions [37-43].

Bibliometrics uses statistical methods to analyze scholarly publications in a wide spectrum such as peer-reviewed journal articles, e-books, conference proceedings, periodicals, reviews, and reports. The bibliometric study, as a method, offers a range of tools for analyzing both, empirical studies and literature reviews [39-45]. In this study, the author employed descriptive publication results, author or coauthor, institutions and country productivity, source and publisher productivity, and most common MeSH (Medical Subject Headings) and keyword analysis [40,43,44].

Data Collection and Extraction

An efficient bibliometric study requires a well-structured database to analyze available and relevant publication data. The main bibliometric databases available for this paper are Crossref (n=156 papers), Microsoft Academic (n=151), PubMed (n=156), Core (n=147), and PubMed Central (n=79). All databases have their citation count categories. Thus, publication data were retrieved from the aforementioned reputed databases with the following search strategy. The search time frame was 2014 to 2022, since there were no relevant publications indicated before 2014. We included only systematic reviews (n=156) with the following search query: *positive AND (psychology AND (interventions AND well-being))*.

The abovementioned search criteria were conducted, and the data were retrieved as plain .txt and excel .csv file formats for further analysis. The Microsoft Excel and Lens platform (version 7.4) software with the “bibliometrix” package was used for descriptive and bibliometric data analysis.

Bibliometric data were obtained by first identifying all extracted articles in the Lens databases [46]. To ensure accuracy, results from a comprehensive Lens search of all papers published from 2014 to 2022 were cross-referenced and matched between the highly ranked databases (Crossref, Microsoft Academic, PubMed, PubMed Central, and Core). The discrepancy between the total numbers in each database was checked manually. No duplication or missing studies were identified; thus, accurate matching was accomplished. The resultant list from Lens software was exported into a Microsoft Excel spreadsheet, and the visualized data were saved as images.

Validation of the search query was based on reviewing the top 156 cited documents about PIs and well-being to ensure that they fit within the scope of the research field. This approach was adopted to eliminate false positive results by excluding documents focusing on the impact of other approaches or any document irrelevant to the explored subject.

Results

Publication Profile and Descriptive Publication Results

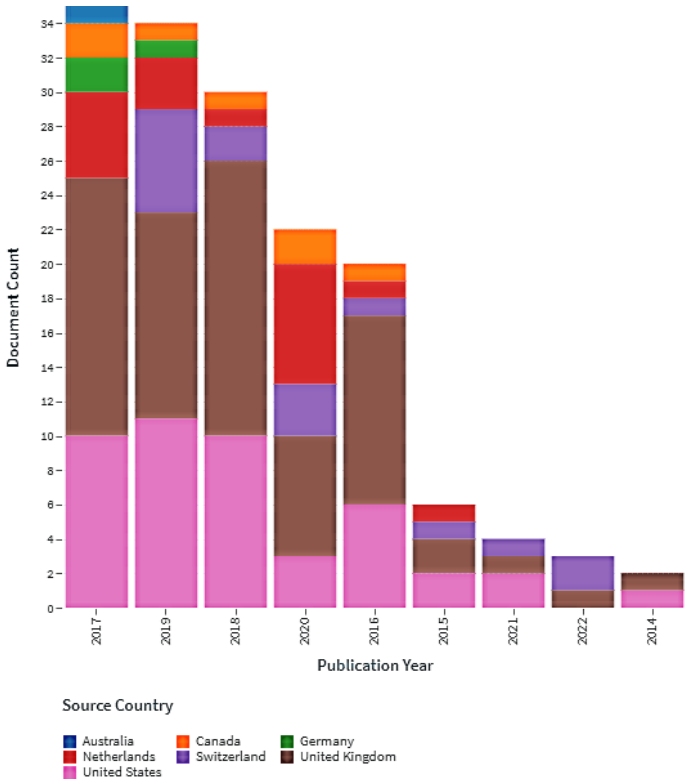
A total of 156 relevant publications for the identified research domain were retrieved from the Lens database. The papers were written in English by 100 corresponding authors or coauthors from 24 different countries, where the leading country is the United Kingdom, followed by Australia and the United States. Descriptive characteristics of the publications show an increase in the number of studies in 2017 (n=35) and 2019 (n=34) and a decrease in 2021 (n=4). The top 4 fields to which the published papers belong are medicine (n=84), psychological intervention (n=80), psychology (n=62), and clinical psychology (n=43).

Distribution of Publications by Date

Figure 1 shows the dynamics of publishing papers about PIs and well-being in different countries in 2014-2022.

Records include 2 papers in 2014, which then significantly increased in 2016 (n=20) and 2017 (n=35). In 2018, this number slightly decreased (n=30), again increased in 2019 (n=34), and decreased in 2021 (n=4) and 2022 (n=3). In 2017 (one of the most productive years), the most productive countries were the United Kingdom (n=15) and the United States (n=10), followed by the Netherlands (n=5). In 2019, the United States was leading in publishing papers within the studied domain (n=11), followed by the United Kingdom (n=12), Switzerland (n=6), and the Netherlands (n=3). The United Kingdom and the United States were productive in publishing papers on PIs and well-being during 2014-2022. Canada was one of the most productive countries in 2017 (n=2) and 2020 (n=2), with a total of 7 papers published during the studied period.

Figure 1. Publication records by date of publishing and most productive country (2014-2022).



Field and Subject of Study

This research domain is categorized by the top 10 major fields of study (out of 100 in total) with the number of published studies. According to our results, most published papers in PI and well-being are related to the following fields of study: medicine (n=84), psychological intervention (n=80), psychology (n=62), and clinical psychology (n=43). Obviously, some of the papers were qualified to a few fields of study (see Multimedia Appendix 1). The most often explored subjects among published papers on PIs and well-being are psychiatry and mental health (n=45), general medicine (n=26), clinical psychology (n=20), general psychology (n=13), developmental and educational psychology (n=12), and health informatics (n=12) (see Multimedia Appendix 1).

Most Productive Authors or Coauthors and Institutions

Table 1 presents the top 10 most productive authors by the total number of cited papers; it also presents the number of publications and author productivity measured by the average citations per published paper. The top 4 leading authors are as follows: James Thomas with 3 published papers and 260 citations, followed by Chris Dickens with 3 papers and 182 citations, Brendon Stubbs with 2 papers and 72 citations, and Catherine Meads with 2 papers and 53 citations. Other authors wrote 2-4 papers and received 20 citations.

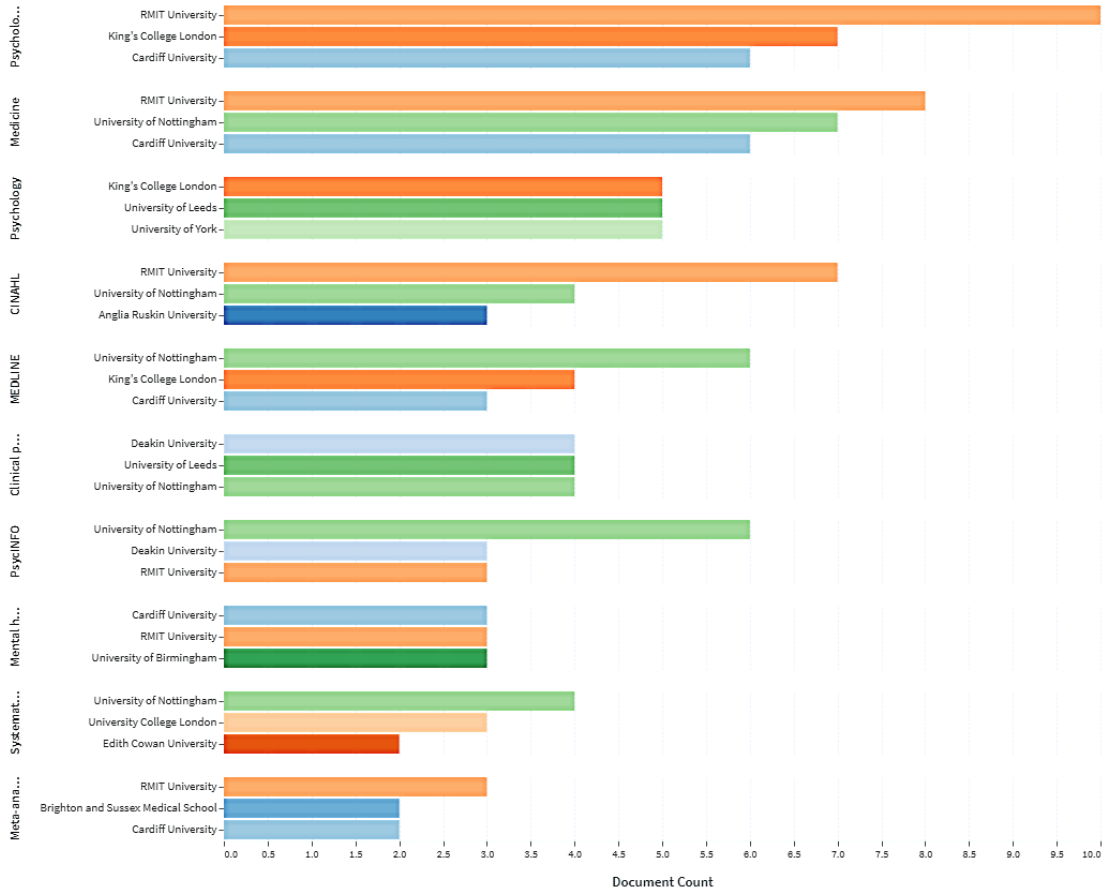
According to the obtained results, the top 10 cited articles in the studied domain, Sanders et al [31] was the leading paper and has the highest citation score (592/6847, 8.6% counts) (see Multimedia Appendix 1).

Figure 2 shows the most productive (top 10) institutions by field of study and year of publication. The Royal Melbourne Institute of Technology is one of the leading institutions in publishing papers in psychological intervention (n=10), medicine (n=8), and mental health (n=3) and in CINAHL (n=7) and PsycINFO (n=3); King's College London, in the field of psychological intervention (n=7) and psychology (n=5) and in MEDLINE (n=4); and Cardiff University, in psychological intervention (n=6), medicine (n=6), and mental health (n=3) and in MEDLINE (n=3). Another leading institution is the University of Nottingham in the fields of medicine (n=7), clinical psychology (n=4), and mental health (n=3) and in MEDLINE (n=6) and PsycINFO (n=6).

Table 1. Top 10 authors by document count, sum, and average citing of scholarly works.

Author	Sum of cited scholarly works, n	Publications, n	Productivity (average citation per paper), mean
James Thomas	260	3	87
Chris Dickens	182	3	61
Brendon Stubbs	143	2	72
Catherine Meads	105	2	53
Chris Bonell	85	3	28
Ruth Garside	85	3	28
Colette Joy Browning	85	2	42
Claudio Di Lorito	71	4	17
Andrew Thompson	64	2	32
Alessandro Bosco	60	3	20

Figure 2. Publication records by institutions and field of study. RMIT: Royal Melbourne Institute of Technology.



Most Productive Journals and Publishers

Figure 3 shows the top 5 productive journals belonging to each of the top 10 fields of study. According to our results, *BMJ Open* (n=6) and *Journal of Medical Internet Research* (n=4) are leading in the field of medicine. In the field of psychology, the most productive journal is *Clinical Psychology Review* (n=5), while *Frontiers in Psychology* is one of leading journals in psychology (n=5) and psychological intervention (n=5). The field of clinical psychology was represented by *Clinical Psychology Review* (n=4) and *Journal of Clinical Child & Adolescent Psychology* (n=4). *BMC Psychiatry*, *BMJ Open*, *Journal of Mental Health*, and *Social Psychiatry and Psychiatric Epidemiology* are the most productive journals in the field of mental health with 2 published papers each.

Table 2 provides data on the most productive publishers by document count, sum, and average citing of scholarly works. According to our results, the top 3 publishers in the domain of PI and well-being are Wiley (n=28), Elsevier (n=25), and BioMed Central (n=15). However, the most cited papers were published by Elsevier (n=2560). The 3 least productive publishers in these domains are Multidisciplinary Digital Publishing Institute (8 published papers and 105 citations in

total), Frontiers Media SA (6 published papers and 101 citations in total), and SAGE Publications (7 published papers and 168 citations in total).

According to our results, the most productive journals are *International Journal of Environmental Research and Public Health* (7 papers; Multidisciplinary Digital Publishing Institute), followed by *BMJ Open* (6 papers; PubMed), and *Frontiers in Psychology* (6 papers; Frontiers Media SA). *Child: Care, Health and Development* and *Journal of Advanced Nursing* are the most productive journal (4 papers; Wiley). *BMC Psychiatry* and *BMC Public Health* (3 papers; BioMed Central) are leading in publishing papers, while *Clinical Psychology Review* (6 papers; Elsevier) is the most productive journal (see Multimedia Appendix 1).

Table 3 shows the top 10 productive countries by document count, average author count, and the sum and average of scholarly citations.

According to our results, the top 3 productive countries by document count are the United Kingdom (n=126), Australia (n=30), and the United States (n=14). The top 3 countries by average author or coauthor count are Australia (n=78), Germany (n=65), and the United States (n=63). The 3 leading countries by the sum of citations are the United Kingdom (n=5700), Australia (n=2350), and the United States (n=880). The most productive countries by average citation score are Switzerland (n=130), Australia (n=78), and Germany (n=65). New Zealand (n=15) is the least productive country with 4 publications and 60 citations in total.

Figure 3. Most productive journals by publication count and field of study.

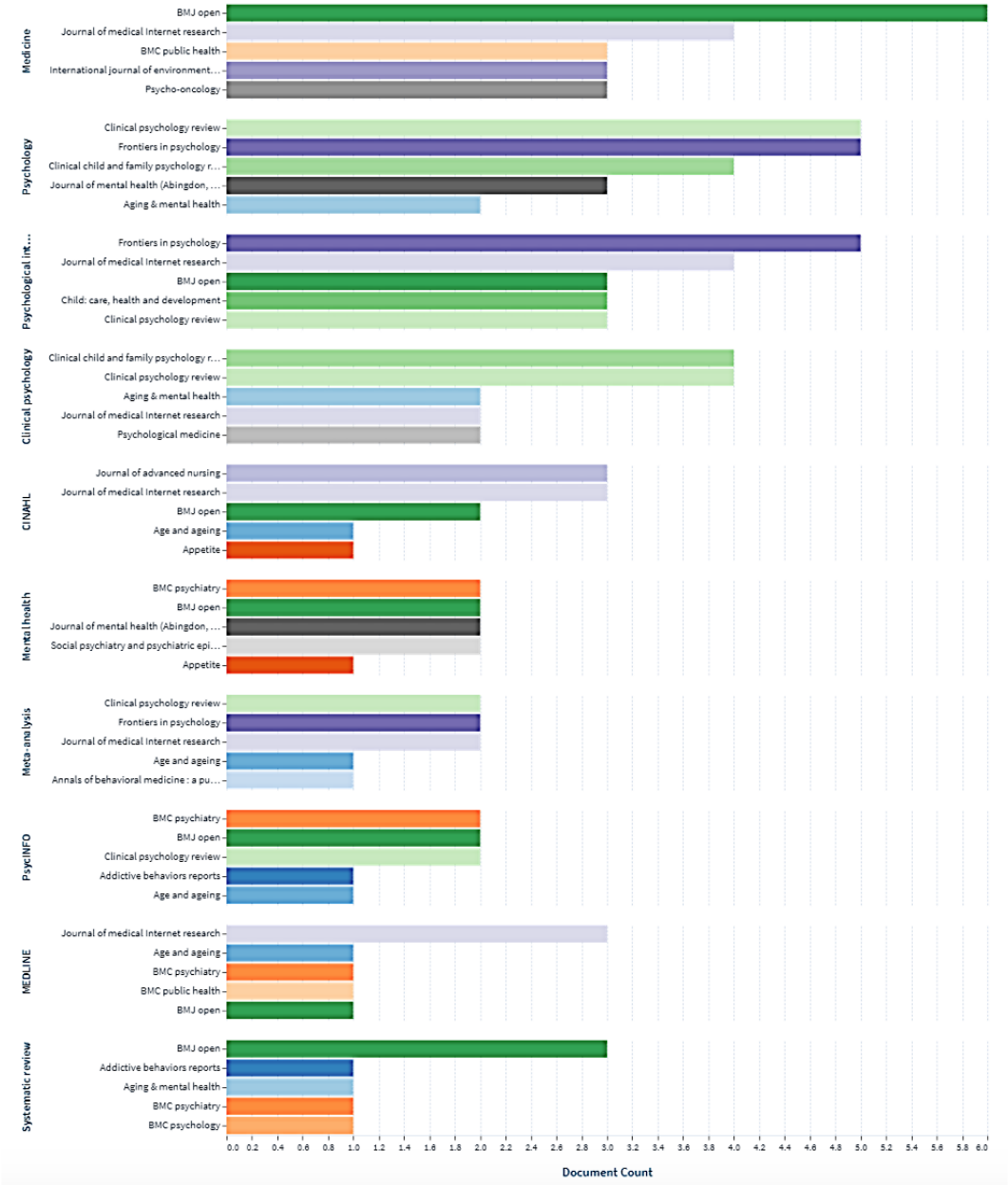


Table 2. Top 10 publishers by document count, sum, and average citing of scholarly works.

Publisher	Publications, n	Sum of cited scholarly works, n	Productivity (average citation per papers), mean
Wiley	28	710	25
Elsevier	25	2560	102
BioMed Central	15	602	40
Multidisciplinary Digital Publishing Institute	8	105	13
SAGE Publications	7	168	24
BMJ Publishing Group	6	169	28
Frontiers Media SA	6	101	17
Oxford University Press	6	215	35
JMIR Publications	5	444	89
Academic Press	4	203	51

Table 3. Top 10 countries by document count, author average count, and the sum and average of scholarly citations.

Country	Publication, n	Average authors count, n	Sum of scholarly citations, n	Productivity (average citation per paper), mean
United Kingdom	126	45	5700	45
Australia	30	78	2350	78
United States	14	63	880	62
Germany	6	65	390	65
New Zealand	4	15	60	15
Switzerland	3	13	390	130
Spain	3	58	175	58
Ireland	3	57	170	57
Netherlands	3	27	80	27
China	2	40	80	40

Keyword Analysis and MeSH

MeSH terms are assigned to PubMed entries by the National Library of Medicine at the National Institutes of Health. This analysis reveals the frequency of the MeSH terms used in analyzed publications. Table 4 shows the most frequently used MeSH terms in the publications associated with PIs for well-being. The first column represents MeSH terms and the second one shows article counts.

Multimedia Appendix 2 illustrates two different word cloud–based data distributions. The left side shows a word cloud of keywords by document count, whereas the right side represents keywords by the sum of citations. According to the obtained results, the top 3 cited keywords are “meta-analysis” (n=1740, average citation score=66.9), “well-being” (n=1218, average citation score=76.1), and “public health” (n=897, average citation score=112.1). The least cited keywords are “intervention” (n=183, average citation score=22.8) and “behavioral change” (n=207, average citation score=51.7).

Table 4. Most relevant top 10 MeSH (Medical Subject Headings) terms according to PubMed.

MeSH terms	Article count, n
Humans	132
Adult	28
Females	28
Male	23
Child	21
Adolescent	21
Quality of life	16
Aged	14
Mental health	13
Qualitative research	11

Discussion

Principal Findings

This bibliometric analysis was conducted to investigate existing scientific patterns, trends, and associations in extracted systematic reviews on the effectiveness of PIs aimed to improve well-being among children, adults, and professional staff experiencing physical or mental illness. The text analysis highlighted the most frequent subject categories and fields along with the keywords and MeSH terms.

By analyzing the results of the data set regarding PIs improving the well-being of individuals with various psychological and physical problems published in well-known databases, the rapid increase in research interest in this subject was clearly indicated. The trend sharply increased in recent years between 2016 and 2020. This growth in interest could reflect the decrease in psychological and physical well-being among health care professionals, adults, and youths; therefore, the need for effective PIs supporting individuals in improving their overall well-being has become crucial.

The wide range of available PIs (including the psychological, psychoeducational, and parental interventions and the mindfulness approach) were recognized as effective in managing mental health and physical problems and in increasing overall well-being [1,3,6]. Cognitive behavioral therapy was evaluated as effective in the treatment of anxiety [4]; psychoeducational interventions, in relapse prevention [1]; and gratitude interventions, in the improvement of overall health [2].

Mindfulness training had a positive impact on decreasing burnout, distress, and depression among health care staff [7], improving their clinical skills and attitudes [6] and increasing their resilience overall [8]. Integrating social and cultural factors [12], considering individual differences [14] and skills for change and adjustment to the group target [13], increases the efficiency of interventions, especially for cognitive functioning, social interaction, and well-being [15]. Work engagement, personal resources, and leadership skills increase the probability of experiencing positive emotions [21,22] and managing emotional challenges at work more effectively [23]. PIs that help increase self-awareness and self-efficacy are effective in managing eating disorders and improve an individuals' well-being overall [24,26,47]. PIs for parents were evaluated as effective for adopted children [32], parents of infants [34], and mothers with maternal depressive symptoms [35], resulting in an improvement of well-being among children, parents, and whole families [31].

Even though there is increasing interest in the research domains explored in this study, no publication using a bibliometric approach has been found to analyze the PIs for improving individuals' well-being. Therefore, the uniqueness of this study could itself be considered its strength. This study reveals scientific patterns and future research gaps to academics and practitioners. Text analysis also highlighted and supported popular subject areas to clarify the research scope and directions.

One of the limitations of this study is that the number of relevant studies made precise content analysis more challenging; however, this was beyond the scope and aim of this study. Although the various bibliometric analysis methods exist in the literature, the scope and size of the research led authors to concentrate on more specific analysis such as descriptive statistics with this data set of studies from 2014 to 2022.

Gaps and Future Scope

According to our findings, the aforementioned research domains are prevalent, and an upward trend in interest can be seen for publication records since 2016. Besides, the majority of the subject category records were found in the fields of medicine, PIs, psychology, and clinical psychology. Further research would be conducted with various aspects of bibliometric analysis including systematic reviews, meta-analysis, and empirical studies. Moreover, the studies assessed here indicate the importance of further explorations and analyses to develop appropriate and feasible PIs for the improvement of well-being and managing mental and physical health problems.

Focus has to be directed on how to optimize intervention design to improve an individual's well-being in the long term [1,48] and how to encourage and measure the maintenance of psychological, social, and environmental changes [47,49].

Further research should develop criteria for the evaluation of interventions' effectiveness in improving psychological

well-being [50,51], and assess individual experiences across a range of PI [14] and treatment–response associations in particular [18].

More research on intervention type, intensity, duration, and follow-up measurement [28] is required for a more precise evaluation of the effectiveness of PI for patients with cancer [20] and those with dementia [15].

Further research is required to provide recommendations about the effectiveness of interventions with adoptive parents [32] and parents of infants to improve their mental well-being in later life [34].

More studies are needed to explore the benefits of group work interventions [52] and to design work interventions appropriate to individual conditions and expectations [23]. Exploration of the benefits of group interventions, characteristics of professionals, and impact of motivational strategies on intervention delivery and outcomes would be beneficial [53].

Future research on PIs should focus on the needs of older patients [54] and connections between intervention activities and ultimate change in behaviors related to abuse of older individuals [17].

There is a need for methodological standards in testing the mechanisms of mindfulness-based treatment [10], their cost - effectiveness for mental health conditions [11], and individual readiness for mindfulness-based interventions [6].

Conclusions

This bibliometric study aimed to explore and analyze the scientific patterns and relations of scholarly publications on the effectiveness of PIs for improving well-being among individuals with psychological or physical conditions. Therefore, various forms of bibliometric methods have been employed, and findings were illustrated with a data visualization approach. The bibliometric analysis was conducted on 156 systematic reviews published in highly ranked databases between 2014 and 2022.

Our results present the most frequent subject and field categories, popular keywords, productive authors, countries and institutions, active journals, and publishers within the chosen domain. This bibliometric study revealed the patterns of publication and critical areas in the data set and provides insights and research directions for academics, practitioners, and readers who wish to collaborate in this domain for the future.

A total of 156 relevant publications were retrieved and analyzed from highly ranked databases (eg, PubMed, Crossref, and Microsoft Academic). Among the top 3 leading authors with respect to the number of citations per paper are the following: James Thomas with 3 published papers and 260 citations, followed by Chris Dickens with 3 papers and 182 citations, and Brendon Stubbs with 2 papers and 72 citations. However, the most cited paper was that of Sanders et al [31] with 592 out of 6847 (8.6%) citations; this was followed by Johnson et al [55] with a citation record of 561 (8.2%), followed by Strauss et al [56] with a citation count of 335 (5%). According to the obtained results, the top 2 cited keywords are “well-being” (n=1218, average citation score=76.1) and “public health” (n=897, average citation score=112.1). The least cited keywords are “intervention” (n=183, average citation score=22.8) and “behavioral change” (n=207, average citation score=51.7).

According to the analyzed data, *BMJ Open* (n=6) and *Journal of Medical Internet Research* (n=4) are leading in the field of medicine; *Clinical Psychology Review* (n=5), in psychology; and *Frontiers in Psychology*, in psychology (n=5) and psychological intervention (n=5). Clinical psychology is represented by *Clinical Psychology Review* (n=4) and *Journal of Clinical Child & Adolescent Psychology* (n=4). The top 3 publishers in the domain of PIs and well-being are Wiley (n=28), Elsevier (n=25), and BioMed Central (n=15). However, the most cited papers were published by Elsevier (n=2560).

The data discussed here indicate the significance of further explorations in this field to adjust the certain positive psychology interventions to the individual and situational factors to increase their effectiveness in improving overall well-being among individuals with mental and physical problems.

Authors' Contributions

IS conceptualized the study; conducted the literature review; was responsible for the methodology and data extraction and analysis; and drafted, edited, and critically reviewed the manuscript. IS read and approved the final manuscript.

Conflicts of Interest

None declared.

Multimedia Appendix 1
Top 10 fields of study by publication count, study characteristics, and their distribution by publisher.
[DOCX File , 229 KB - ijmr_v11i2e41456_app1.docx]

Multimedia Appendix 2
Keywords by document count and sum citing scholarly work count (limited to 50).
[PNG File , 78 KB - ijmr_v11i2e41456_app2.png]

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Abbreviations

MeSH: Medical Subject Headings
PI: psychosocial intervention

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Review

Physicians' Perspectives on Inpatient Portals: Systematic Review

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Abstract

Background: Inpatient portals are online platforms that allow patients to access their personal health information and monitor their health while in the acute care setting. Despite their potential to improve quality of care and empower patients and families to participate in their treatment, adoption remains low. Outpatient portal studies have shown that physician endorsement can drive patients' adoption of these systems. Insights on physicians' perspectives on use of these platforms can help improve patient and physician satisfaction and inpatient portal uptake.

Objective: The purpose of this systematic review is to better understand physicians' perspectives toward inpatient portals.

Methods: A systematic literature review was conducted for studies published between 1994 and November 2021 using keywords for physicians' perspectives toward patient portals and personal health records. Databases included PubMed, MEDLINE, Web of Science, and Scopus. Articles solely focused on nonphysician clinicians or addressing only outpatient settings or shared notes were excluded from this review. Two reviewers performed title, abstract, and full-text screening independently. Bias assessment was performed using the JBI SUMARI Critical Appraisal Tool (Joanna Briggs Institute). Inductive thematic analysis was done based on themes reported by original authors. Data were synthesized using narrative synthesis and reported according to overarching themes.

Results: In all, 4199 articles were collected and 9 included. All but 2 of the studies were conducted in the United States. Common themes identified were communication and privacy, portal functionality and patient use, and workflow. In studies where physicians had no prior patient portal experience, concerns were expressed about communication issues created by patients' access to laboratory results and potential impact on existing workflow. Concerns about negative communication impacts were not borne out in postimplementation studies.

Conclusions: Physicians perceived inpatient portals to be beneficial to patients and saw improvement in communication as a result. This is consistent with outpatient studies and highlights the need to improve training on portal use and include physicians during the design process. Health care organizations and information technology entities can take steps to increasing clinician comfort. Physician concerns involving patient portal usage and managing patient expectations also need to be addressed. With improved clinician support, initial pessimism about communication and workload issues can be overcome. Limitations of this review include the small number of pre- and postimplementation studies found. This is also not a review of perspectives on open notes, which merits separate discussion.

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KEYWORDS

inpatient portals; personal health record; physician perspectives; patient portals; inpatients; technology

Introduction

The patient portal is defined as an online platform that allows patients to view their personal health record for personal health information such as medication lists, immunization history, laboratory results, discharge summaries, and clinical notes from recent doctor visits. Some patient portals may have additional functions that allow patients to communicate directly with their provider, request medication refills, and schedule their own appointments [1].

Many patients who actively used the portal felt the platform improved access to care and communication, increased awareness of their disease, and encouraged behavioral change [2]. Despite the benefits of portal use, many factors can prevent patients from remaining engaged in portals, such as lack of computer skills and concerns with data privacy [3].

In the United States, adoption of patient portal systems across office-based practices has been steadily growing since the passage of the Health Information Technology for Economic and Clinical Health (HITECH) Act of 2009, a federal mandate which promotes health information exchange through financial incentives [4]. The 21st Century Cures Act, passed in 2016, established rules requiring sharing of clinical information, including clinical notes, with patients [5].

Expansion from outpatient portals to inpatient portals is a more recent phenomenon. Inpatient portals can help inform patients and their caregivers about the ongoing care in the acute care setting. Features can include care team information, medication lists, laboratory results, medical history, secure messaging, educational material, and a variety of other components.

Inpatient portals have the potential to improve quality of care and patient safety through providing bedside patient education, increasing patient engagement, and streamlining communication between physicians and hospitalized patients [6]. This is especially important in the age of the COVID-19 pandemic when many hospitals have placed visitor restrictions to prevent the spread of the virus. One study reported that across 70 academic centers in North America, 17% did not allow visitors while 73% allowed only one visitor at a time [7]. With many people unable to see their loved ones in the hospital, clinicians needed to develop strategies to update families using remote platforms [8]. Patient portals can be an excellent modality for keeping caregivers abreast of treatment progress.

Although many studies have addressed factors patients consider when using these portals, less research has been done on physicians' perspectives on portals. Provider endorsement of patient portals was found to be a key factor in driving patients' interests in using the portal [9]. Thus, it is imperative to discuss physicians' attitudes toward patient portals. Prior work on outpatient portals identified several concerns related to health care professionals' experiences with web-based patient portals, including communication, privacy, workload, and patient use of portals [3,10].

The purpose of this systematic review is to better understand physicians' perspectives toward inpatient portals. As health technology continues to accelerate, it is critical that we address components that are effective and those that are barriers to use. In doing so, we can better use these platforms to increase patient and physician satisfaction while improving quality of care and connectivity for hospitalized patients.

Methods

Eligibility Criteria

We conducted a systematic review of research that discusses physicians' views on patient portals in the acute care setting. The Sample, Phenomenon of Interest, Design, Evaluation, Research (SPIDER) framework was used to define the inclusion criteria (Table 1). Studies that combined physicians' perspectives with other health care professionals, such as nurses or physician assistants, were included if physicians were explicitly included in the methods. No limitations were placed on physician specialty, geographic location, or years of practice.

Qualitative, quantitative, and mixed methods studies were included under the criteria that they addressed physician engagement or perspectives on inpatient portals, were published in the English language from 1994 through the last interim search (November 2021), and included search keywords.

Table 1. Inclusion criteria for the systematic review using the Sample, Phenomenon of Interest, Design, Evaluation, and Research type (SPIDER) framework.

	Eligibility criteria
Sample	Physicians and other clinicians if physicians were explicitly included. No limitation on specialty, location, or years of practice.
Phenomenon of interest	Factors that influence physicians' perspectives and attitudes toward inpatient portals.
Design	No limitations on study design.
Evaluation	Experiences and perceptions around use of inpatient portals.
Research type	Qualitative, quantitative, and mixed methods research from after 1994.

Exclusion Criteria

Articles focusing on nonphysician clinicians or staff were not included in this review. Outpatient portal and electronic health records discussions were also excluded from this review. Other reasons for article exclusion included not written in English, not about patient portals, focused solely on open or shared notes without addressing any other components of patient portals, and being a description of a study protocol that did not include any results.

Database Search Strategy

We performed the initial database search on February 18, 2021, on PubMed, MEDLINE, Web of Science, and Scopus. An interim literature search across all 3 databases was conducted on November 29, 2021.

The search strategy included a set of keywords relating to patient portals and physicians' perspectives of patient portals. Keywords were developed using medical subject headlines and derived from scoping articles related to the subject. Search terms included the following: "physician satisfaction" OR "physician satisfaction" OR "physician utilization" OR "physician perceptions" OR "physician attitudes" OR "physician engagement" OR "physician perspectives" OR "physician barriers" OR "physician factors" AND "Patient Portals" OR "patient portals" OR "patient web portals" OR "patient health records" OR "portal adoption" OR "personal health record" OR "online portals." The search strategy was adjusted for each database (Multimedia Appendix 1). The protocol for this study was registered with PROSPERO (The International Prospective Register of Systematic Reviews; ID #CRD42021236228).

Gray literature was not included. For opinion articles, editorials, and literature reviews discussing inpatient portals, a hand search of references was performed. This did not yield any additional studies to the primary search.

Study Selection Process

After database search and duplicate removal, articles were imported to Rayyan [11]. Title and abstract screening was done independently by 2 authors, KLB and CC. Conflicts were resolved through discussion between the 2 reviewers upon completion of the title and abstract screening stage until consensus was reached. Included articles were imported back from Rayyan to EndNote (Clarivate). This process was repeated for the interim literature search.

Full-text screening was then performed by KLB and CC. Disagreements during the study selection process were resolved by discussion to achieve consensus.

Data Extraction and Analysis

Quality of studies was assessed using the JBI SUMARI Critical Appraisal Tool (Joanna Briggs Institute) for the appropriate study type. Checklists for qualitative research and analytical cross-sectional studies were used [12,13]. This bias assessment was completed by 2 reviewers, KLB and CC, with conflicts resolved by consensus.

The JBI SUMARI data abstraction form was used for each paper. Data collected included authors, year, methods for data collection and analysis, country of origin, phenomena of interest, setting, participant characteristics and sample size, description of main results, and reported themes. Extracted data were coded by authors KLB and CC. Following initial extraction, data were exported from JBI SUMARI to Microsoft Excel for consolidation and synthesis.

Themes were identified inductively from qualitative and cross-sectional studies as reported by the original authors if available. Otherwise, themes were identified during data extraction and coding by KLB and CC. Original study themes were then categorized and simplified by discussion until consensus was reached by all authors. Data were synthesized using narrative synthesis and reported according to thematic categories.

Reporting of the results from this systematic review was guided by the PRISMA (Preferred Reporting Items for Systematic Review and Meta-Analysis) statement (Multimedia Appendix 2).

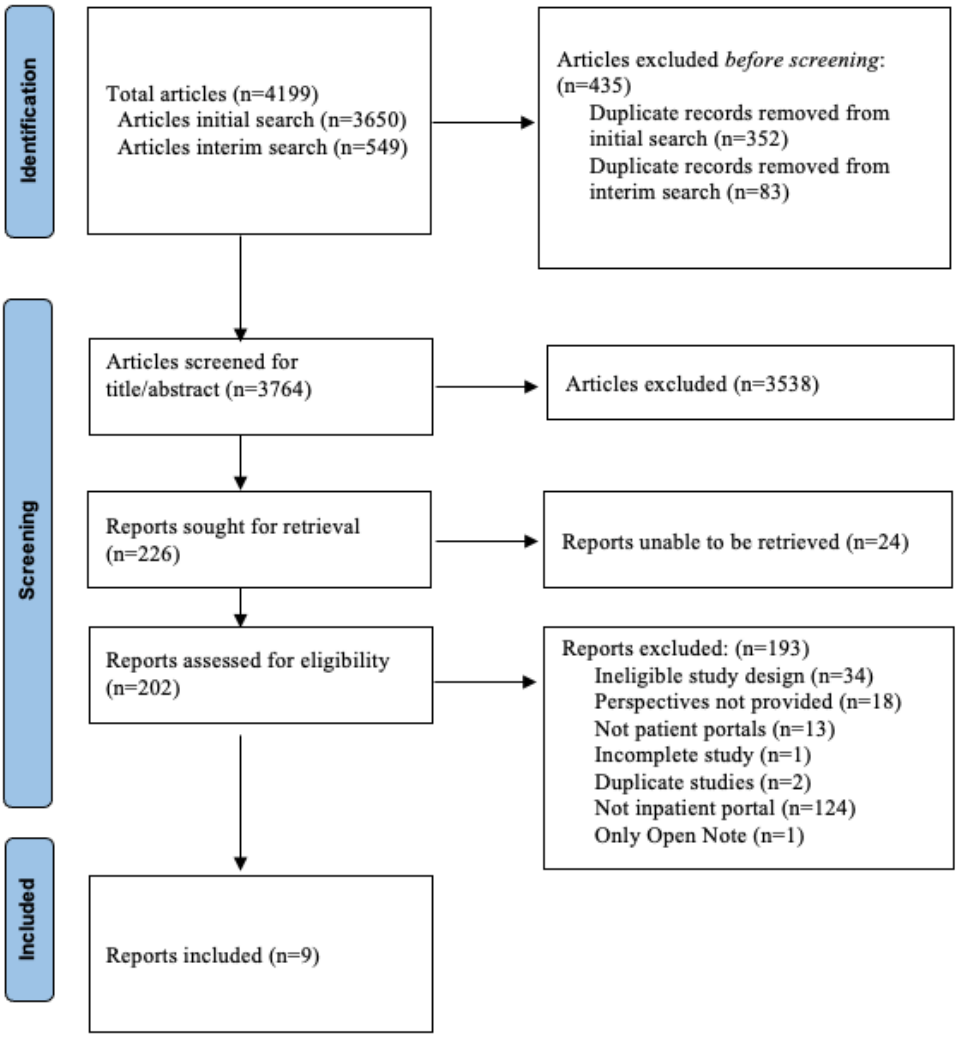
Results

Screening and Identification of Papers

From the initial literature search, a total of 3650 references were retrieved across all 3 databases and imported into EndNote 20. After 352 duplicates were removed, 3306 articles underwent screening based on the title and abstract. The interim literature search retrieved 549 new references, and 83 duplicates were removed.

A total of 226 articles were sought for full-text screening, of which 24 articles were unable to be retrieved. A total of 202 articles underwent full-text screening by KLB and CC. After screening was completed, 193 reports were excluded and 9 articles were included. Details regarding the search and selection process from the initial and second search were combined in a PRISMA flowchart (Figure 1). A κ value of 0.579 from the initial title and abstract screening showed a moderate level of agreement between the 2 reviewers [14].

Figure 1. Flowchart of the search and selection process.



Risk of Bias Assessment

Critical appraisals based on the JBI SUMARI Critical Appraisal Tool are summarized in Table 2 and Table 3. Most qualitative studies had an overall low risk of bias. Several of the cross-sectional studies did not address confounding factors and had a moderate risk of bias. All 9 articles were considered suitable for inclusion in the final review.

Table 2. JBI SUMARI critical appraisal results: analytical cross-sectional study.

Authors, year	Q[a]1[b]	Q2[c]	Q3[d]	Q4[e]	Q5[f]	Q6[g]	Q7[h]	Q8[i]	Yes, n (%) (N=8)
Grossman et al, 2018 [15]	Y[j]	Y	Y	Y	U[k]	U	Y	Y	6 (75)
Hefner et al, 2017 [16]	Y	Y	U	Y	Y	N[l]	Y	Y	6 (75)
Kelly et al, 2017 [17]	Y	Y	Y	U	U	U	Y	Y	5 (63)
Kelly et al, 2020 [18]	Y	Y	Y	Y	Y	N	Y	Y	7 (88)
Thapa et al, 2021 [19]	Y	Y	N/A[m]	Y	Y	N	Y	Y	6 (75)

[a]Q: question.
[b]Q1: Were the criteria for inclusion in the sample clearly defined?
[c]Q2: Were the study subjects and the setting described in detail?
[d]Q3: Was the exposure measured in a valid and reliable way?
[e]Q4: Were objective, standard criteria used for measurement of the condition?
[f]Q5: Were confounding factors identified?
[g]Q6: Were strategies to deal with confounding factors stated?
[h]Q7: Were the outcomes measured in a valid and reliable way?
[i]Q8: Was appropriate statistical analysis used?
[j]Y: yes.
[k]N: no.
[l]U: unclear.
[m]N/A: not applicable.

Table 3. JBI SUMARI critical appraisal results: qualitative research.

Authors, Year	Q[a]1[b]	Q2[c]	Q3[d]	Q4[e]	Q5[f]	Q6[g]	Q7[h]	Q8[i]	Q9[j]	Q10[k]	Yes, n (%) (N=10)
Bell et al, 2016 [20]	Y[l]	Y	Y	Y	Y	Y	Y	Y	Y	Y	10 (100)
Frangella et al, 2018 [21]	Y	Y	Y	Y	Y	N[m]	N	Y	N	Y	7 (70)
Fuller et al, 2020 [22]	Y	Y	Y	Y	Y	Y	N	Y	Y	Y	9 (90)
O'Leary et al, 2016 [23]	Y	Y	Y	Y	Y	U[n]	Y	Y	Y	Y	9 (90)

[a]Q: question.
[b]Q1: Congruity between stated philosophical perspective and research methodology?
[c]Q2: Congruity between research methodology and research question or objectives?
[d]Q3: Congruity between research methodology and methods used to collect data?
[e]Q4: Congruity between research methodology and representation and analysis of data?
[f]Q5: Congruity between research methodology and interpretation of results?
[g]Q6: Is there a statement locating the researcher culturally or theoretically?
[h]Q7: Is the influence of the researcher on the research, and vice-versa, addressed?
[i]Q8: Are participants and their voices adequately represented?
[j]Q9: The research is ethical according to criteria, or, for recent studies, there is evidence of ethical approval by an appropriate body?
[k]Q10: Conclusions drawn in the research report do appear to flow from the analysis or interpretation of the data?
[l]Y: yes.
[m]N: no.
[n]U: unclear.

Study Characteristics

The initial and interim search captured studies that evaluated physicians' perspectives of inpatient portals pre- (4 studies) and postimplementation (5 studies). According to country, 7 originated from the United States, 1 originated from Argentina, and 1 originated from Saudi Arabia. There were 2 studies from pediatric hospitalizations, and 1 from the intensive care unit setting. The studies collected included research categorized as quantitative (n=5) and qualitative (n=4). Table 4 shows the data extracted from the studies.

Participants in the quantitative studies included 1288 clinical team members. This included 375 physicians, among whom 34 were specified as resident physicians. The remaining included physician assistants (n=17), nurse practitioners (n=3), nurses (n=680), clinical support staff (n=205), and pharmacists (n=8). Quantitative data were collected via surveys. Participants in the

qualitative studies included a total of 59 physicians, including resident physicians (n=28) and practicing physicians (n=31), a few of whom were specified as hospitalists (n=6). Qualitative data were collected via interviews and focus groups.

Table 4. Summary of included literature and themes identified.

Reference, Year, Country	Phenomena of interest	Participants and methods	Portal description	Themes identified
Bell et al [20], 2016, United States	Clinician perspectives on how an electronic portal can affect communication deficits in the ICU[a] and quality of care	n=26 clinicians, 8 of whom were physicians; focus group discussions	Theoretical web-based communication-based portal	Communication and privacy
Kelly et al [17], 2017, United States	Health care team members interacting with parents during their child's hospitalization and participating in portal training during implementation	n=94 clinicians (pre) and 70 clinicians (post) for survey; 11 (pre) and 10 (post) of whom were attending physicians, 34 pediatric residents (pre) and 23 residents (post)	Pre- and postimplementation MyChart Bedside portal available on tablet; features including vital signs, daily schedule, lab/test results, vital signs, secure messaging, note-taking, education materials, and nonurgent requests	Workflow, communication
Frangella et al [21], 2018, Argentina	PHR[b] benefits, potential problems, how PHRs might be used in everyday practice	n=29 physicians, 9 of whom were attending physicians and 20 residents; focus group; personal interviews	Theoretical web-based inpatient portal	Portal functionality and patient use, communication, and privacy
Thapa et al [19], 2021, Saudi Arabia	Health care professionals' willingness to use digital health tools including patient portals	n=218 health care professionals, including 78 physicians; quantitative survey	Theoretical inpatient portal	Workflow, communication
O'Leary et al [23], 2016, United States	Challenges and benefits of portal based on physicians' perspectives, how new portal features may affect patients and providers	n=14 physicians, including 6 hospitalists and 8 residents; focus groups and thematic analysis	Mobile app portal with features such as care team information, scheduled tests, and medication list. Features not yet implemented included secure messaging and lab results.	Workflow, communication
Fuller et al [22], 2020, United States	Clinicians' perspectives on the value and utility of tools available on the patient-centered discharge toolkit on the portal	n=22 clinicians including 8 physicians; thematic analysis, focus groups	Discharge portal available on tablet/iPad that included a safety dashboard, secure messaging, discharge checklist, and bedside display	Portal functionality, workflow
Grossman et al [15], 2018, United States	Providers' perceptions of portal's usefulness to patients and its impact on care	n=63 providers including 12 physicians; quantitative survey	Acute care portal used in randomized clinical trial available on tablet; features including test results, medications, provider information, vital signs and weights, prescribed diet, comments, and pain level	Portal functionality and patient use, workflow
Hefner et al [16], 2017, United States	Physicians' attitudes and perceptions about portal technology and training	n=193 physicians; quantitative survey	MyChart Bedside portal available on tablet; features including daily schedule, lab/test results, secure messaging, note-taking, education materials, and Dining on Demand (request for food)	Portal functionality and patient use
Kelly et al [18], 2020, United States	Provider experiences with inpatient portal for hospitalized patients and parents on bedside tablet computers	n=96 inpatient providers including 47 physicians; quantitative survey	MyChart Bedside on tablet (as above)	Workflow, communication, portal functionality and patient use

[a]ICU: intensive care unit.

[b]PHR: personal health record.

Common Themes Across Physicians' Perspectives on Inpatient Portals

Common themes were addressed by participants in both quantitative and qualitative studies. These included perspectives on communication and privacy, portal functionality and patient use, and workflow.

Impact on Communication and Privacy

Physicians believed that the inpatient portal has enhanced their communication with patients [19,20,23] and has even improved the quality of discussion during rounds [18,23]. However, they also noted concerns regarding how information uploaded to the portal could be misinterpreted by patients and highlighted that patient literacy is a barrier [20]. Additionally, physicians worried that using the patient portal as a communication tool may cause anxiety and distress among patients [20,21,23]. If patients were to access lab results or a diagnosis before thoroughly discussing the information with their treatment team, it could cause unnecessary stress for the patient [20,23].

Participants also noted that the volume of information would be another stress contributor for patients [20]. Setting expectations was mentioned as a communication tool used to decrease anxiety associated with notifications and improved the quality of patient communications [20]. Engaging patients and families early in hospitalization can improve the understanding of what information is available and can be a way to identify their preferences for information sharing [20].

Concerns With Privacy

Privacy and caregiver access were mentioned with concern that family may receive sensitive information before the care team had a chance to speak with the patient [20,23]. One of the preimplementation studies expressed concern that the family may disengage from care if information was seen first on the portal instead of delivered by the team [21]. On the other hand, caregiver and family access was mentioned as one of the benefits of portal systems [18,23] to decrease the barrier to staying abreast of information especially for results that are expected. Data safety was also of concern [19].

Physicians' Perceptions on Inpatient Portal Functionality and Patient Use

When physicians were surveyed regarding the inpatient portal's usefulness to patients, most agreed that their patients found the acute care patient portal easy to use and trustworthy [15]. A majority also agreed that the portal helped patients comprehend their medical problems and was a convenient avenue for information to be delivered to patients without negatively impacting communication [15,18].

Compared to patients, physicians underestimated the importance of features such as entering comments and recording pain level [15]. In one hospital using MyChart Bedside, physicians believed the most useful feature for patients was Dining on Demand, a feature that allowed patients to place an electronic meal order.

Interestingly, physicians from one study believed the education features to be less likely to be used by the patients [16], which contrasts with the opinions of physicians across other studies, who recommended including more educational resources [20,21]. It was suggested that patients would benefit from this feature through improving health literacy [20] and providing information suitable to a patient's specific needs [21].

Useful features consistently noted by physicians included medication lists and viewing the daily schedule [16]. The perceived value of medication lists was high across several studies [15,16,18,21,23] with some physicians ranking it as the most useful along with laboratory results [15]. These features not only help patients engage in their care, but also augment identification of errors in medication documentation and improve medication reconciliation with implications for patient safety [16,18,21-23].

Feature Recommendations

Although inpatient portals can vary in which functions are available to patients, physicians interviewed prior to portal usage offered suggestions they believed would increase patient use and address adoption barriers. Recommendations included allowing patients and families to customize what type of information they would receive to prevent information overload [20], creating a note-taking space for patients to write questions or concerns for the physician to review, and involving more physicians in the design process of inpatient portals [21]. Communication tools for other physicians and care team members used to document what has already been told to the patient could also decrease mixed messaging [20].

Inpatient Portals' Impact on Workflow

Physicians' perspectives regarding the inpatient portal's impact on workflow varied. Those who were using a mobile app portal believed that their workflow was only minimally impacted with the current features they were using, such as care team information, scheduled tests, and medication lists, but feared that the addition of other features, such as secure messaging and laboratory results, would impact workflow [16,23]. Physicians who felt they did not receive sufficient training on portal use were not as optimistic about incorporating the portal into their current workflow compared to nurses and clinical staff [16]. Variable uptake by attending physicians was cited by some residents to be a barrier to portal usage [22].

In another study, only 11% of providers believed that the portal increased their workload, and only 8% perceived they spent more time answering questions related to the portal [18].

Physicians interviewed prior to portal implementation appeared to be more concerned that workload would increase [17], noting concerns over features such as note sharing [16] and information delivery leading to an increased number of questions from patients [17,21]. Physicians were also concerned that digital health tools in general would lead to increased work-related stress [19]. These concerns did not seem to be borne out in the postimplementation studies.

Discussion

Principal Findings

This review identified various themes that emerged from studies of physicians' perspectives on inpatient portals that were generally consistent with studies of outpatient portals. Recurrent themes included communication and privacy, portal functionality and patient use, and impact on workflow (Table 4). Consistent with other patient portal studies, physicians who have already experienced patient portal use in practice held more positive views, while those without experience of the portal appeared more hesitant about its implementation.

Both qualitative and cross-sectional studies showed that physicians, like other clinical team members, believed the inpatient portal helped patients access information more readily and could promote patient autonomy as well as patient safety, as some patients identified errors in the medication lists and documentation. Managing patients and families' expectations about information and communication are important to ensuring patient preferences are respected and privacy is maintained.

Comparison With Prior Work

Physicians without prior experience noted communication concerns about allowing patients to view their laboratory results or notes because it may cause unnecessary stress for patients [20,21,23]. Care team workers, such as nurses, nurse managers, and unit clerks shared similar sentiment toward providing patient access to such information, noting enhanced communication because of portal usage [24].

Postimplementation, physicians appeared to be less concerned about causing patient anxiety that would negatively impacting their workflow in turn [17,19,21]. This complements studies showing that patients are amenable to receiving laboratory and other information through patient portals [25,26]. Some patients prefer to receive information before discussing with the inpatient care team, so that they have an opportunity to formulate more cogent questions for their physicians [25].

This dichotomy was also seen in workload impacts. Inpatient portals ultimately did not seem to negatively impact physician workflow [18] or increase the workload as feared [17]. Some of the increase in workflow was due to needing to ask for help with technical support for patients. Technology concerns were also noted by studies of other clinical team members [24]. Physicians who felt they did not receive sufficient training on portal use themselves were not as optimistic about incorporating the inpatient portal into their current workflow compared to nurses and clinical staff [16]. As noted by other members of the care team, increased hands-on training would be beneficial, as it would highlight the value of the portal and encourage portal usage [24]. In the outpatient setting, physicians and other health care providers have brought up similar concerns over the lack of training and issues with portal usability as a barrier to portal usage [27].

Practical Implications

As a result of the COVID-19 pandemic, medical services have become more accessible online as practices implement telemedicine appointments [28]. With such services becoming more broadly available, comfort with virtual health management and patient portal use is expected to increase. The surge in popularity of tools like patient portals requires consideration of physician and provider perspectives. Inpatient needs are more acute, and the availability of nearly real-time information including medication schedule's effect on patient participation should be explored further. Benefits of both expected features, like medication reconciliation, and unexpected features, like meal ordering, should be considered in future portal development.

Patient adoption of portals is heavily influenced by physician endorsement. When physicians are concerned about increasing work burden from integrating patient portals, they are less likely to encourage use or discuss these platforms with patients, thus reducing patient enrollment and usage [29]. The findings of this review suggest that most of these concerns came from physicians who had no prior experience with patient portals [19,21,30], while physicians with hands-on experience found the portal had little impact on their workload [18]. This effect merits direct study, as it was not explicitly addressed and has implications for how physicians are educated about anticipated portal workflow.

Addressing preconceived notions about portal usage, by providing better training for instance, may help curb pessimism about these digital tools. Improving physician understanding of patient preferences for receiving information can be helpful. Involving physicians during the portal design and implementation process may also allay some of the concerns about workflow and usability.

Future Directions

As inpatient portal research continues to evolve, further research is needed to address how inpatient portals impact quality of care, existing health disparities, and patient engagement. Evidence has shown lower patient portal use among economically disadvantaged populations due to a lack of technology skills, lack of health literacy, lack of English proficiency, preference for in-person communication with providers, and security concerns [31,32]. One study found that patients with higher educational attainment and higher health literacy were more likely to register for the patient portal. After registration, however, health literacy did not seem to affect frequency of accessing the portal [33]. Acute care episodes may be an opportunity to increase health literacy using inpatient portals through assisted registration processes and education. Research on the continuum of outpatient to inpatient portal use is important to identify other factors that may increase portal use [25,34].

Furthermore, since this review identified conflicting perspectives regarding the significance of educational resources for patients through the portal, more research should be done on the types of educational resources that may be valuable to patients and physicians alike.

It is also important to highlight the accessibility of these portals in both inpatient and outpatient settings, and how privacy concerns carry over to patients who have a caregiver. Patients

have reported that while certain features of the portal, such as medication information and appointment scheduling, have helped their caregiver to provide better care for the patient, they would like to control what information is shared [35]. To better cater to this population, further studies are needed to inform development of features, such as creating proxy accounts, and how that may affect communication with clinicians. Training on portals among patients and caregivers can encourage use and dispel concerns about technology and security risks. Allowing patients to set boundaries on what information can be accessed by caregivers will also be important for protecting patient privacy [36].

As systems within the hospital become better integrated and more interoperable, there may be opportunities to provide patients with anticipated testing and procedure information to inform their plan as orders are placed, scheduled, or delayed. This may also improve patient satisfaction related to undefined wait times and perioperative delays.

Limitations

First, although a comprehensive search was performed, this review is limited by the fact that there is only a small number of studies included. There were nearly the same number of pre- and postimplementation studies. With further development and maturation of inpatient portal systems, future postimplementation studies will be able to provide broader practical understanding of issues related to workload and communication.

Second, this study also did not ask questions specific to open notes. Open note–specific studies, such as a survey conducted by Ralston et al [37], demonstrate that clinicians' attitudes toward open notes changed drastically pre- and postimplementation, as the percentage of physicians perceiving open notes to be beneficial changed from 29% to 71% after implementation [30,37,38]. Studies have also reported that allowing access to notes and clinical data in practice alleviated stress among parents with children who are hospitalized [30,39], and thus physician fears of causing confusion were unrealized [40]. In the outpatient setting, it was found that primary care physicians who shared the same concern about patient access to notes and results ultimately believed that the benefits outweighed their fears, citing increased patient engagement and vigilance, and improved patient awareness [26,27]. This topic merits further examination in future works as more data about shared notes become available.

Third, there is variation between these portals and physicians' experiences with them, with some participants being better versed in portal usage and others having no prior experience. This, however, reflects the diverse experiences of practitioners. The generalizability of these findings is limited due to half of the studies focusing on physicians' perceptions prior to portal use. Furthermore, while our eligibility criteria allowed for grouping of nurses, nurse practitioners, and physician assistants' perspectives with physicians' perspectives, this review did not address potential differences in perception. A review that captures the unique experiences of advanced practice providers with patient portals would be beneficial.

Fourth, the features offered among the portals across the studies differed. Due to the heterogeneity of portal functions, only the more common features were emphasized in this discussion. A future review that focuses on a specific feature of the inpatient portal would be helpful in capturing more nuanced opinions about inpatient portals. Lastly, most of the studies included in this review originated in the United States, which may not be directly translatable to other countries.

Conclusions

Overall, physicians and other health care providers acknowledge the many benefits and challenges of inpatient portals. In practice, they believed the portals improved communication and patients benefited from features such as viewing medications and scheduled appointments. However, the challenges that come with security, integration of portal use into workflow, sharing clinical notes, and allowing patient access to laboratory results pose potential barriers to portal adoption among physicians without prior portal experience. Training in use and portal-specific patient communications and expectation setting will be important to encouraging adoption among physicians. Recommendations by physicians should be considered during the design process to improve implementation and functions of the inpatient portal. In doing so, these platforms can be used more effectively to improve patient satisfaction and quality of care.

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Conflicts of Interest

None declared.

Multimedia Appendix 1
Search strategy per database.
[PNG File , 206 KB - ijmr_v11i2e39542_app1.png]

Multimedia Appendix 2

PRISMA (Preferred Reporting Items for Systematic reviews and Meta-Analyses) checklist.
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Abbreviations

HITECH: Health Information Technology for Economic and Clinical Health
PRISMA: Preferred Reporting Items for Systematic Review and Meta-Analysis
PROSPERO: International Prospective Register of Systematic Reviews
SPIDER: Sample, Phenomenon of Interest, Design, Evaluation, Research

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Review

The Impact of Heating, Ventilation, and Air-Conditioning Design Features on the Transmission of Viruses, Including SARS-CoV-2: Overview of Reviews

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Abstract

Background: The COVID-19 or SARS-CoV-2 outbreak was declared a pandemic by the World Health Organization in March 2020. Almost 2 years later (early February 2022), the World Health Organization reported over 383 million cases of the disease caused by the virus, with over 5.6 million deaths worldwide. Debate regarding the routes of transmission was substantial early in the pandemic; however, airborne transmission emerged as an important consideration. Infectious airborne agents can spread within the built environment through heating, ventilation, and air-conditioning (HVAC) systems. Multiple features of HVAC systems can influence transmission (eg, ventilation, filtration, UV radiation, and humidity). Understanding how HVAC features influence airborne transmission is critical to mitigate the spread of infectious agents.

Objective: Given the airborne transmission of SARS-CoV-2, an overview of reviews was conducted to understand what is already known from the scientific literature about how virus transmission may be affected by HVAC design features in the built environment.

Methods: Ovid MEDLINE and Compendex were searched from inception to January 2021. Two reviewers independently screened the titles, abstracts, and full text of potentially relevant reviews, using a priori inclusion criteria: systematic reviews examining the effects of HVAC design features on virus transmission. Two reviewers independently assessed the methodological quality using AMSTAR2.

Results: Searching identified 361 citations, of which 45 (12.5%) were potentially relevant and 7 (2%) were included. Reviews were published between 2007 and 2021 and included 47 virus studies. Two earlier reviews (2007 and 2016) of 21 studies found sufficient evidence that mechanical ventilation (airflow patterns and ventilation rates) plays a role in airborne transmission; however, both found insufficient evidence to quantify the minimum mechanical ventilation requirements. One review (2017) of 9 studies examining humidity and indoor air quality found that influenza virus survival was lowest between 40% and 80% relative humidity; the authors noted that ventilation rates were a confounding variable. Two reviews (2021) examined mitigation strategies for coronavirus transmission, finding that transmission decreased with increasing temperature and relative humidity. One review (2020) identified 14 studies examining coronavirus transmission in air-conditioning systems, finding that HVAC systems played a role in virus spread during previous coronavirus outbreaks. One review (2020) examined virus transmission interventions in public ground transportation, finding ventilation and filtration to be effective.

Conclusions: Seven reviews synthesizing 47 studies demonstrated a role for HVAC in mitigating airborne virus transmission. Ventilation, humidity, temperature, and filtration can play a role in the viability and transmission of viruses, including coronaviruses. Recommendations for minimum standards were not possible owing to few studies investigating a given HVAC parameter. This overview examining HVAC design features and their effects on the airborne transmission of viruses serves as a starting point for future systematic reviews and identifying priorities for primary research.

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KEYWORDS

COVID-19; public health; epidemiology; outbreak; pandemic; environment; literature review; virus transmission; ventilation; coronavirus

Introduction

Background

The COVID-19 or SARS-CoV-2 outbreak, first detected in Wuhan, China, was characterized as a pandemic by the World Health Organization (WHO) in March 2020 [1]. Almost 2 years later (early February 2022), the WHO reported over 383 million cases of the disease (COVID-19) caused by the virus (SARS-CoV-2), with over 5.6 million deaths worldwide [2]. Early in the pandemic, there were conflicting views and debate about the routes of transmission [3-6]. Several recent reviews of the scientific literature have identified evidence indicating airborne transmission, which could be particularly problematic in confined and crowded indoor spaces [7-9]. Public health recommendations acknowledge airborne transmission as important and advise to maximize ventilation; ensure proper maintenance and functioning of heating, ventilation, and air-conditioning (HVAC) systems; and increase the use of fresh air where possible [10].

Airborne transmission occurs as a result of bioaerosols (biological particles suspended in air) staying aloft longer because of their small size and, therefore, traveling further because of air currents [3]. Several possible mechanisms of airborne coronavirus transmission exist, including 1) bioaerosol generation by infectious persons through coughing, sneezing, breathing, and talking, which remain airborne for a period of hours to days; 2) short- to long-range transport through HVAC systems and subsequent inhalation of bioaerosols by other people; and 3) airborne transport of bioaerosols to surfaces (or the contamination of surfaces by physical contact), followed by resuspension, inhalation, or contact with surfaces [11,12].

Prior Work

Previous research demonstrated that infectious airborne bioaerosols spread to other spaces via HVAC systems [12,13]. Multiple features within HVAC systems may influence transmission, including ventilation (eg, ventilation rate, air changes per hour, airflow pattern, and pressurization), filtration (eg, minimum efficiency reporting value rating, filter age, and extent of use), UV radiation (eg, UV power and UV dose), and humidity [12]. Understanding the influences of HVAC systems on airborne transmission in the built environment is critical for building scientists to develop effective engineering control strategies to protect the occupant's health and well-being and affect timely public health policies. Previous systematic reviews provided a starting point for understanding what is already known from the scientific literature about HVAC systems and the airborne transmission of viruses. A comprehensive synthesis of previous systematic reviews can help identify knowledge gaps, helping to guide and prioritize future primary research. Therefore, we conducted an overview of reviews to identify and synthesize previous systematic reviews on this topic.

Methods

Standards recommended by the international Cochrane organization for the conduct of an overview of reviews [14] were followed. The research question guiding this work was as follows: what is the current synthesized evidence about the effects of HVAC design features on virus transmission?

Search Strategy

A research librarian (GMT) conducted searches in Ovid MEDLINE and Compendex from inception to June 2020, using concepts related to viruses, transmission, and HVAC. The search was updated in January 2021. The search strategies are presented in Multimedia Appendix 1. The unfiltered search strategies were peer reviewed by 2 librarians (TL and AH), and the filter for systematic reviews in Ovid MEDLINE was provided by a third librarian (LD). The unfiltered search strategies were part of a larger systematic review project that was registered [15], and its protocol is publicly available [16]. The reference lists of the included reviews were screened to identify any other relevant reviews. Conference abstracts and preprints retrieved through the searches were screened to determine whether a full peer-reviewed manuscript was published. The references were managed in EndNote; duplicate records were removed before screening.

Study Selection

Two reviewers (GMT and LH) independently screened the titles and abstracts of all the citations retrieved from the electronic searches and other sources. Studies were classified as yes, no, or maybe. The first stage of screening was completed in Covidence. We retrieved the full text of all the studies classified as yes or maybe. The same reviewers independently applied the inclusion and exclusion criteria (Multimedia Appendix 2 [16]) to each full-text document and classified the studies as included or excluded. Discrepancies were resolved through discussion between the 2 reviewers. The reasons for excluding studies at the full-text stage were documented.

Inclusion and Exclusion Criteria

The inclusion and exclusion criteria are detailed in Multimedia Appendix 2. We planned to include systematic reviews published in English that searched for and included primary research studies examining the effects of HVAC design features on the transmission of viruses. The HVAC features of interest were mechanical ventilation (ventilation rate, air change, air exchange, and airflow), filtration (air filtration, filter type, minimum efficiency reporting value rating, filter age and use, pressure drop, holding capacity, replacement, and change frequency), UV germicidal irradiation (power, dose, uniformity of dose, flow rate, bioaerosol inactivation efficiency, and location), and humidity or relative humidity (RH). Inclusion was staged in 2 ways. Our primary interest was viruses, and we

excluded those reviews that were not specific to virus. We were initially interested in systematic reviews defined by the international Cochrane organization as reviews that use a predefined, systematic approach and follow standard approaches to search the literature, select studies for inclusion, assess the methodological quality of the included studies, and extract, synthesize, and analyze data from the included studies. As we found few systematic reviews meeting these criteria, we included review articles that satisfied specific requirements for methodological approach and objective. For methodological approach requirements, the authors had to search ≥2 databases, describe inclusion and exclusion criteria, and describe a process for study selection. For objective requirements, the objective of the review had to be related to one of the HVAC design features, namely ventilation, filtration, UV radiation, or humidity.

Quality Assessment

The methodological quality of the included reviews was assessed using AMSTAR2 [17]. AMSTAR2 is a valid and reliable tool containing 16 items about the methodological conduct of a systematic review [18]. Two authors (GMT and LH) independently assessed the included reviews. Discrepancies were resolved through discussion.

Data Extraction

The following information was extracted from each review: citation information (eg, authors, year of publication, and country of corresponding author), objectives, search strategy, inclusion and exclusion criteria, settings, population characteristics (as applicable), agent studied (eg, type of virus and bioaerosol), HVAC design features studied, number and characteristics of studies relevant to this overview's research question, results (as reported by the review authors), and review authors' conclusions relevant to this overview's research question. Our primary outcome was the quantitative measure of the association between HVAC design features and virus transmission; however, we extracted any results reported by the review authors that were relevant to our research question. One reviewer (LH) extracted data using a predefined form. A second reviewer (EK) verified the data. Discrepancies were resolved through discussion and by referring to the relevant publication.

Data Analysis

We anticipated that the included reviews would not have conducted meta-analyses. We planned to present the results in tabular and narrative forms. Tables were created describing the reviews, their results (including any quantitative data of the associations between HVAC features and virus transmission or proxy outcomes) and conclusions, and their methodological quality. A narrative summary of the findings of each review has been provided. We only summarize review findings that were relevant to our research question; for example, if the review included studies of ventilation, humidity, etc, in the outdoor and indoor environments, we only report on studies specific to the indoor (built) environment.

Results

Included Reviews

The search retrieved 361 citations, of which 45 (12.5%) were considered potentially relevant and 7 (2%) met the inclusion criteria (Figure 1). Tables 1 and 2 provide summaries of the included reviews. The reviews varied somewhat in their objectives (eg, investigate mechanical ventilation, ventilation rates, airflow patterns, effects of humidity, or stability of bioaerosols containing coronaviruses), agents (eg, coronaviruses or influenza viruses), and settings (eg, built environment, health care settings, or public ground transportation). The reviews were published between 2007 and 2021 (median year 2020) and included a total of 47 unique virus studies published between 1961 and 2020 (median year 2005) that were relevant to our research question (median 4 studies per review including shared references; Table 3; Multimedia Appendix 3 [13,19-71]). The reasons for excluding studies at the full-text stage were documented (Multimedia Appendix 4 [7-9,11,12,24,72-103]).

Figure 1. Flow of studies through the selection process.

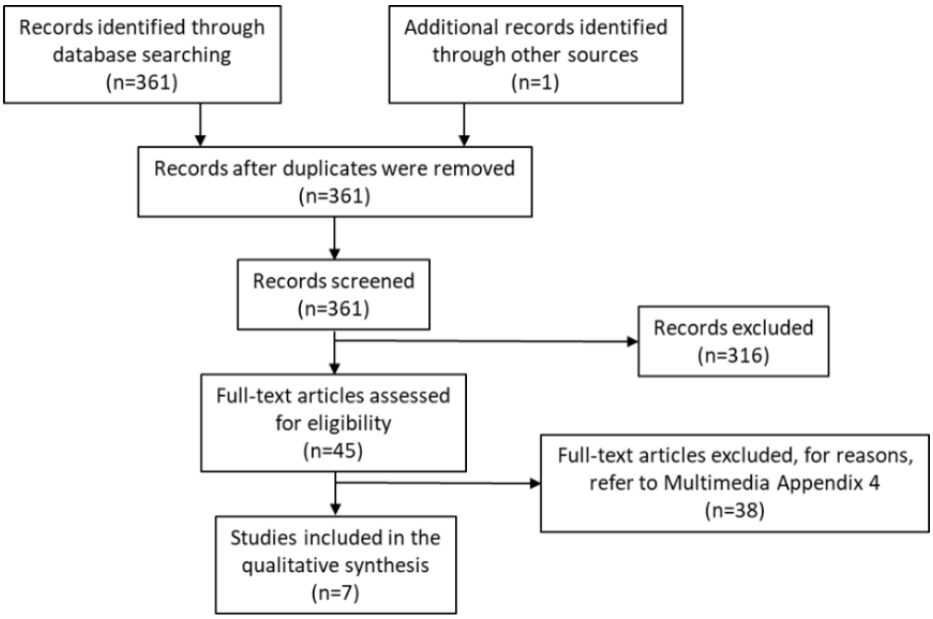


Table 1. Summary of the characteristics of relevant reviews.

Author, year, country, agent, and setting	Purpose or objectives	Search: databases and years	Inclusion criteria	Exclusion criteria	Study designs
• Author and year: Li et al [13], 2007 • Country: China • Agent: airborne infectious diseases • Setting: multiple built environments	• "1) Is there sufficient evidence to support that the ventilation rate and/or the airflow pattern are contributing cause(s) for the spread of airborne infectious diseases? 2) If so, is there good evidence/ data to support the specification and quantification of minimum ventilation requirements to minimize the transmission of airborne infectious diseases in different settings (nosocomial or otherwise)?"	MEDLINE, ISI[a] Web of Knowledge, and ScienceDirect (1960 to March 2005); reviewed the references of retrieved articles	• "Relevance of the article to the two key research questions" • "Research techniques employed must have been scientifically robust, repeatable and reliable" • "Original articles in English"	• Conference papers and abstracts • "Descriptive articles without an explicit detailed analytic component" • Work before 1960	Epidemiological studies (+/− detailed ventilation studies), case-control, cohort, intervention, questionnaire, animal, mathematical modeling
• Author and year: Luongo et al [19], 2016 • Country: United States • Agent: infectious agents • Setting: buildings	• To review epidemiological studies examining the association between ventilation (at least one HVAC[b] parameter) and airborne transmission of infectious agents in buildings • "To assess the quality and quantity of available data and to identify research needs"	Science Direct, Web of Knowledge, MEDLINE or PubMed, Engineering Village, and Google Scholar (search dates not reported)	• "Specifically used an epidemiologic study design and that described or measured some HVAC parameter within the context of the hypothesized associations"	• Modeling studies	"Epidemiologic studies investigating the association of at least one HVAC-related parameter with an infectious disease-related outcome in buildings (almost all studies reported ventilation rates or CO_2)"
• Author and year: Derby et al [20], 2017 • Country: United States • Agent: multiple infectious agents • Setting: laboratory and multiple built environments	• "To conduct a broad survey of post-1985 literature regarding the effects of low humidity on comfort, health, and IEQ [indoor environmental quality]" • "To identify existing knowledge and knowledge gaps, as well as confounding variables"	Engineering Index (Compendex), Web of Science, and Google Scholar; citation search of key papers in Scopus and Google Scholar (search dates not reported); citation checking of relevant review papers	• Controlled studies that focus on healthy, human participants in residences and workplaces with at least one data point where the relative humidity is 40% and provide new data and report temperature	• Publication after 1985 (unless papers present unique data not previously reviewed) • Review papers not analyzed in depth	Experimental studies (laboratory testing studies), transmission studies with animal models, modeling studies, and epidemiological studies
• Author and year: Chirico et al [21], 2020 • Country: Italy (corresponding author) • Agent: SARS-CoV-1[c], MERS-CoV[d], or SARS-CoV-2 • Setting: indoor environments	• "To evaluate the COVID-19 risk associated with the presence of air-conditioning systems"	PubMed or MEDLINE, PubMed Central, Google Scholar, and medRxiv (July 11, 2020); cross-referencing	• Original studies (observational and experimental) of humans in indoor environments, exposed to air-conditioning systems, with respiratory infection outbreaks caused by SARS-CoV-1, MERS-CoV, or SARS-CoV-2 • Studies in English • Studies with no time limit	• Narrative reviews, opinions, and commentaries • Experimental studies on airborne transmission of coronaviruses not associated with outbreaks	Observational and experimental studies (including modeling and CFD[e] simulation studies)

Author, year, country, agent, and setting	Purpose or objectives	Search: databases and years	Inclusion criteria	Exclusion criteria	Study designs
• Author and year: Zhen et al [23], 2020 • Country: South Africa (corresponding author) • Agent: viruses such as influenza, SARS-CoV, or MERS-CoV • Setting: public ground transportation	• "To assess the abilities of different interventions to decrease the incidence of droplet-based infections among people using public ground transport"	MEDLINE (PubMed), CENTRAL (Cochrane Library), Web of Science (Clarivate Analytics); reference lists of relevant reviews; WHO[f]'s database "Global Research on Coronavirus Disease (COVID-19)"	• Interventions (eg, PPE[g]) and relationship to infections from viruses (eg, influenza, SARS-CoV or MERS-CoV) in "humans using public transportation (taxis, buses, trains and subways)" • Studies published between 2000 and 2020 in English	• "Participants/context of the intervention were healthcare workers in healthcare facilities"	Systematic reviews, clinical trials, comparative observational studies, and modeling studies (owing to limited relevant research, the authors discuss international and national guidance documents)
• Author and year: da Silva et al [25], 2021 • Country: Portugal • Agent: SARS-CoV, MERS-CoV, and SARS-CoV-2 • Setting: indoor and outdoor environments	• To discuss "the viability/stability of aerosols containing SARS-CoV and MERS-CoV viruses...to provide information on potential mitigation strategies for SARS-CoV-2 airborne transmission"	PubMed or MEDLINE, Web of Science, and Scopus; references of studies were screened	• Studies published since 2002 (the emergence of SARS-CoV) • The virus studied was SARS- CoV, MERS-CoV, or SARS-CoV-2 • Viability of the virus sampled from air was assessed • Studies with no language limits	• N/A[h]	Real-world sampling and laboratory studies
• Author and year: Noorimotlagh et al [29], 2021 • Country: Iran • Agent: HCoVs[i] • Setting: laboratory experimental setups	• "To collect all available studies concerning inactivation methods, environmental survival, and control and prevention strategies"	Scopus, ISI Web Science, Google Scholar, PubMed (MEDLINE), WHO, and American Centers for Disease Control and Prevention; 1990-2020	• Original studies • Studies published in English • Studies available electronically (online) • Studies that focus on disinfections, environmental survival, and control and prevention strategies of HCoVs	• Review articles • Book review • Guidelines • Book chapters • Duplicate articles • Short communications • Conference documents • Oral presentation • Comments	Original research (study designs were not described, and mostly experimental laboratory-based studies appear)

[a]ISI: Institute for Scientific Information.

[b]HVAC: heating, ventilation, and air-conditioning.

[c]SARS-CoV-1: severe acute respiratory syndrome coronavirus 1.

[d]MERS-CoV: Middle East respiratory syndrome coronavirus.

[e]CFD: computational fluid dynamics.

[f]WHO: World Health Organization.

[g]PPE: personal protective equipment.

[h]N/A: not applicable.

[i]HCoV: human coronavirus.

Table 2. Summary of the results and conclusions from relevant reviews.

Author and year	Results	Conclusions
Li et al [13], 2007	• Based on multidisciplinary consensus panel: "of the 40 studies, 18 were considered as nonconclusive or not meeting evidentiary threshold to support a direct contributory role of ventilation rate/airflow pattern to the airborne spread of infectious agents, 12 were partly conclusive or met threshold somewhat, 10 were deemed clearly conclusive supporting a direct contribution."	• "There is insufficient data to specify and quantify the minimum ventilation requirements in hospitals, schools, offices, homes and isolation rooms in relation to spread of infectious diseases via the airborne route." • "There is strong and sufficient evidence to demonstrate the association between ventilation, air movements in buildings and the transmission/spread of infectious diseases such as measles, tuberculosis, chicken pox, influenza, smallpox and SARS."
Luongo et al [19], 2016	• Of 13 studies (1988-2013), 11 were observational and 2 were intervention studies. • Building-related factors (eg, ventilation rates) were associated with increased measures of illness in 11 studies. • One study showed no association and one was inconclusive.	• "Studies to date show an association between increased infectious illness and decreased ventilation rate, however, there are insufficient data to quantify how mechanical ventilation may affect the airborne transmission of infectious agents." • "The weight of the data implies that HVAC system factors in buildings have a role in APT; however, more studies need to be completed, with the eventual goal of a meta-analysis to integrate results."
Derby et al [20], 2017	• Approximately 70 articles were included overall. • Nine papers examined the effects of humidity on viability or the transmission of airborne viruses. • Four studies showed decreased virus viability at midrange (~50%) RH[a]. • Five studies showed "a canonical dip between 40 and 80% RH." • Three studies suggested greater transmission at lower humidity (eg, 20%-35% vs 50% RH). • One study showed the importance of ventilation rates in removing airborne viruses, especially in smaller droplets.	• Influenza virus survival dips between 40% and 80% RH. • "Lower humidity increased virus survival for influenza." • Survival declines with increased length of exposure. • "Across many low humidity studies, ventilation rates and exposure times were noted as confounding variables."
Chirico et al [21], 2020	• A total of 14 studies of outbreaks associated with air-conditioning systems, all in Far East (Asian countries), were included. • In total, 6 of 7 studies on SARS-CoV-1[b] indirectly proved the role of HVAC. • One study of MERS[c] showed the contamination of HVAC[d]. • In total, 4 of 6 studies on SARS-CoV-2 diffusion of virus through HVAC was suspected or supported by computer simulation.	• There is evidence of HVAC systems facilitating the spread of coronaviruses in previous outbreaks in Asian (Far East) countries. • Evidence for SARS-CoV-2 is limited and does not provide sufficient evidence that SARS-CoV-2 can be transmitted by HVAC systems. Generalization of results to other regions is limited because of the technological differences in HVAC systems.
Zhen et al [23], 2020	• A total of 4 studies were included. • One systematic review showed that the use of public transportation increased the risk of influenza transmission. • One case-control study did not show increased risk of influenza diagnosis with the use of public transport. • Two modeling studies showed that airborne infection on trains can be reduced with facemasks, adequate ventilation, and filtration in cases where nonrecirculated air is not possible.	• "Filtering air being circulated within the bus can reduce airborne transmission of influenza between passengers, and improving ventilation on a train can decrease the risk of influenza infection." • Public transport increases the risk of transmission of influenza. • Risk increases with trip duration and proximity to an infected individual. • Modeling studies suggest that adequate ventilation could reduce transmission risk.
da Silva et al [25], 2021	• A total of 11 studies were included: 8 studies on air sampling and 3 laboratory-based experimental studies. • One MERS-CoV study showed decreased stability at 70% RH compared with 40% RH at 20 °C. • One MERS-CoV study found high robustness and strong capability to survive (63.5% of viruses remaining infectious 60 minutes after aerosolization) at 25 °C and 79% RH. • One SARS-CoV-2 study showed an aerosol survival time of 3 hours.	• "Temperatures ranging from 20 °C to 25 °C and relative humidity ranging from 40% to 50% were reported to have a protective effect on viral viability for airborne SARS-CoV and MERS-CoV." • "Higher temperatures and high relative humidity can have an effect on SARS-CoV-2 viability in the environment as reported in previous studies" (conclusions relate to both indoor and outdoor environments).

Author and year	Results	Conclusions
Noorimotlagh et al [29], 2021	• A total of 42 studies (20 of inactivation and disinfection methods, 12 of environmental survival, and 10 of prevention and control strategies) were included. • One study of Phi6 showed highest virus survival at RH >85% and RH <60% with significant decrease at RH 60%-85%. • At a fixed RH of 75%, infectivity decreased 2 orders of magnitude between 19 and 25 °C. • One study where aerosolized MERS-CoV data were reported in da Silva et al [25]. • One study of MERS-CoV found its robustness and strong capability to survive at 25 °C and 79% RH. • One study showed an aerosol survival time for SARS-CoV-2 of 3 h at 40% RH and 21 to23 °C and that the stability of SARS-CoV-2 similar to SARS-CoV-1.	• "Temperature and relative humidity are important factors in the survival of SARS-CoV-2." • "Disease transmission via droplets is inhibited by increasing both temperature and RH in buildings." • SARS-CoV-2 can survive in aerosols for approximately 3 hours. • "Proper ventilation of the buildings in time of aerosol generating" is recommended (however, studies of ventilation were not reviewed).

[a]RH: relative humidity.

[b]SARS-COV-1: severe acute respiratory syndrome coronavirus 1.

[c]MERS: Middle East respiratory syndrome.

[d]HVAC: heating, ventilation, and air-conditioning.

Li et al [13] examined the role of ventilation (specifically, ventilation rates and airflow patterns) in the airborne transmission of infectious agents in indoor settings. The authors included 40 English-language studies overall, with 16 (40%) specific to viruses reported between 1962 and 2005 (median year 1985/1996). Of the 16 studies, 3 (19%) included multiple papers (Table 3), which increased the total count to 21. Of these 21 studies, 16 (76%) studies were epidemiological, 4 (19%) involved other observational designs, and 1 (5%) was experimental. Of the 21 studies, 3 (14%) studies had limited and 4 (19%) had no investigation of ventilation rates or airflow. Studies involved a variety of settings: hospitals, hospital wards, or health clinics (9/21, 43%); aircrafts (3/21, 14%); nursing homes (3/21, 14%); schools (2/21, 10%); high-rise apartments (2/21, 10%); an office (1/21, 5%); and an animal cage (1/21, 5%). The viral agents included severe acute respiratory syndrome coronavirus 1 (SARS-CoV-1; 7/21, 33%), influenza (5/21, 24%), measles (4/21, 19%), chicken pox (2/21, 10%), rhinovirus (1/21, 5%), common cold (1/21, 5%), and smallpox (1/21, 5%). Overall quality was assessed as good for 12 (57%) studies, average for 5 (24%) studies, and unsatisfactory for 4 (19%) studies. The researchers convened a panel of experts in medicine, public health, and engineering. They used a modified Delphi approach with a final consensus meeting to rate the "evidentiary threshold" to support their hypothesis, that is, the direct contribution of ventilation to airborne transmission. Among the virus studies, 8 (38%) were rated as conclusive, 8 (38%) were partly conclusive, and 5 (19%) were nonconclusive. Among the 8 conclusive studies, 2 (25%) examined ventilation rates and showed higher rates of infection for influenza with lower ventilation rates and 6 (75%) demonstrated an association between airflow patterns and the transmission of measles (pediatric office suite), chicken pox (hospital), smallpox (hospital), and SARS-CoV-1 (hospital). In all the studies, the bioaerosols traveled a "considerable distance," which the reviewers noted, "seemed to be related to building design" [13] (eg, placement of heating radiator, room pressure, and functional status of return air outlet). None of the virus studies provided data to support "specification and quantification of the minimum ventilation requirements" [13].

Luongo et al [19] examined evidence from epidemiological studies for the association of mechanical ventilation (at least one HVAC parameter) with the airborne transmission of infectious agents in buildings. Although the authors included 13 English-language studies, 3 (23%) were specific to viruses; all the studies were observational and were reported between 1996 and 2011 (median year 2004). One of the studies had 2 papers, which increased the total count to 4 (Table 3). All 4 virus studies were also included in Li et al [13]. The settings included nursing homes (2/4, 50%), an office building (1/4, 25%), and a hospital (1/4, 25%). The viruses represented in the studies included influenza (2/4, 50%), SARS-CoV-1 (1/4, 25%), and rhinovirus (1/4, 25%). The review authors did not assess methodological quality but provided a narrative commentary on the strengths and limitations of each study. Of the 4 studies, 2 (50%) found an association between virus incidence rates, self-reported incidence rates, and the risk of exposure with HVAC design features. In a retrospective cohort study of a SARS-CoV-1 outbreak in a hospital, the authors measured ventilation rates and found that "proximity to index patient associated with transmission" [19]. The authors of the second study blindly adjusted outdoor air supply dampers in 3 office buildings and found a significant positive association between average CO_2 concentration greater than 100 ppm above background and the frequency of rhinovirus detection in air filters. The third study found a lower incidence of influenza in newer nursing homes that had 100% outside air delivery (compared with older homes with 30%-70% recirculated air) and filtered room supply (compared with no filtration) during 1 season; however, data collected over 5 subsequent years, reported in the fourth study, found no clear association. None of the studies quantified the minimum ventilation requirements.

Table 3. Relevant studies from the included reviews that are pertinent to the overview's research question.

	Li et al [13], 2007	Luongo et al [19], 2016	Derby et al [20], 2017	Chirico et al [21], 2020	Zhen et al [23], 2020	da Silva et al [25], 2021	Noorimotlagh et al [29], 2021	Topics
Akers et al [39], 1966			✓					Humidity
Bloch et al [40], 1985	✓							Ventilation (airflow)
Browne et al [24], 2016					✓			Ventilation (ventilation rate)
Castilla et al [41], 2013					✓			Virus survival or detection
Chen et al [42], 2011				✓				Ventilation (airflow)
de la Noue et al [43], 2014			✓					Humidity
Drinka et al [34], 1996[a,b]	✓	✓						Ventilation (airflow) and filtration
Drinka et al [44], 2002[a]	✓							Ventilation (airflow)
Drinka et al [35], 2004[a,b]	✓	✓						Ventilation (ventilation rate)
Furuya [45], 2007					✓			Ventilation (ventilation rate)
Gustafson et al [46], 1982	✓							Ventilation (airflow)
Harper [47], 1961			✓					Humidity
Hemmes et al [48], 1962			✓					Humidity
Kim et al [22], 2016				✓		✓		Ventilation (airflow and ventilation rate)
Le et al [49], 2004	✓							Ventilation (airflow)
Leclair et al [50], 1980	✓							Ventilation
Lee et al [51], 2003				✓				Virus survival or detection
Li et al [32], 2005[c]	✓			✓				Ventilation (airflow and ventilation rate)
Li et al [38], 2005	✓			✓				Ventilation (airflow)
Li et al [52], 2020				✓				Ventilation (ventilation rate)
Lowen et al [53], 2007			✓					Humidity
Lowen and Steel [54], 2014			✓					Humidity
Lu et al [55], 2020				✓				Ventilation (ventilation rate)
Mizumoto and Chowell [56], 2020				✓				Ventilation (airflow)
Moser et al [57], 1979	✓							Ventilation (ventilation rate)
Myatt et al [36], 2004	✓	✓						Ventilation (ventilation rates)
Noti et al [58], 2013			✓					Humidity
Olsen et al [59], 2003	✓							Ventilation (ventilation rate)
Prussin et al [30], 2018							✓	Humidity
Pyankov et al [27], 2018						✓	✓	Humidity

	Li et al [13], 2007	Luongo et al [19], 2016	Derby et al [20], 2017	Chirico et al [21], 2020	Zhen et al [23], 2020	da Silva et al [25], 2021	Noorimotlagh et al [29], 2021	Topics
Qian et al [60], 2020				✓				Ventilation (ventilation rates)
Remington et al [61], 1985	✓							Ventilation (ventilation rate)
Riley [62], 1978[d]	✓							Ventilation (airflow)
Riley [63], 1979[d]	✓							Ventilation (airflow)
Schulman and Kilbourne [64], 1962	✓							Humidity
van Doremalen et al [26], 2013						✓	✓	Humidity
van Doremalen et al [28], 2020						✓	✓	Virus survival or detection
Wehrle et al [65], 1970	✓							Humidity
Wong et al [31], 2004[c]	✓	✓		✓				Ventilation (airflow) and humidity
Xu et al [66], 2020				✓				Ventilation
Yang and Marr [67], 2011			✓					Humidity
Yang et al [68], 2012			✓					Humidity
Yu et al [37], 2004	✓			✓				Ventilation (airflow)
Yu et al [33], 2005[c]	✓			✓				Ventilation (airflow)
Zhang et al [69], 2013				✓				Ventilation (airflow)
Zhu et al [70], 2012					✓			Ventilation (airflow)
Zitter et al [71], 2002	✓							Ventilation (airflow)
Total number of studies relevant to this overview per included review	21	4	9	14	4	4	4	N/A[e]

[a]Li et al [13] evaluated Drinka et al [34], Drinka et al [44], and Drinka et al [35] as one.

[b]Luongo et al [19] evaluated Drinka et al [34] and Drinka et al [35] as one.

[c]Li et al [13] evaluated Li et al [32], Wong et al [31], and Yu et al [33] as one.

[d]Li et al [13] evaluated Riley et al [62] and Riley et al [63] as one.

[e]N/A: not applicable.

Derby et al [20] conducted a literature review to assess the effects of low humidity (≤40% RH) on comfort, health, and indoor environmental quality. Although the review included approximately 70 papers, 9 (13%) papers examined the effects of humidity on the viability or transmission of airborne viruses. Of these 9 studies, 7 (78%) were experimental (involving laboratory testing), 1 (11%) was a reanalysis of the data from one of the experimental studies, and 1 (11%) study involved modeling. Most studies focused on influenza, with 1 study each examining Columbia SK viruses, murine norovirus, and multiple viruses (influenza, vaccinia, Venezuelan equine encephalomyelitis, and poliomyelitis). Most studies examined a wide range of RH, from approximately 5% to 25% RH at the lower range to 75% to 100% RH at the upper range. The absolute humidity was approximately ≤25 g/m^3 in all 9 studies except 1 (11%) (which ranged from 25 to 125 g/m^3). The review authors did not assess the methodological quality of the included studies. In terms of virus viability, 4 studies (44%) showed a reduction in midrange RH (ie, approximately 50% RH). The review authors further noted that 5 studies (56%) showed that "virus survival exhibited a canonical dip between 40 and 80% RH" [20] and that in almost all the cases, the decline in survival was correlated with increased length of exposure. In total, 3 studies (33%) examined influenza transmission. One study showed reduced influenza transmission among guinea pigs at 50% RH versus 20% to 35% RH; however, the same pattern was not found when the researchers analyzed the data based on absolute humidity. A second study examined transmission via coughing using manikins and found 5 times more infectious virus at 7% to 23% RH than at >43% RH. A modeling study of influenza virus transmission via coughing showed that the infectious virus concentration was 2.4 times more at 10% RH than at 90% RH after 10 minutes, and the ratio increased over

time. They also demonstrated that the effect of humidity is related to the particle size: the settling of larger particles and inactivation of smaller particles (<5 μm) with greater humidity. They concluded that the inactivation resulting from high RH coupled with ventilation was important to remove smaller particles.

Chirico et al [21] conducted a rapid review (streamlined systematic review methods) to examine the potential role of air-conditioning (HVAC) systems in "outbreaks of coronaviruses (SARS-CoV-1, MERS-CoV, SARS-CoV-2) in indoor environments" [21]. The authors identified 14 studies published between 2003 and 2020 (n=11, 79% peer-reviewed studies and n=3, 21.4% preprints all concerning SARS-CoV-2); the studies investigated outbreaks in Hong Kong (n=7, 50%), South Korea (n=1, 7%), Japan (n=3, 21%), and China (n=3, 21%). Of 14 studies, 7 studies (50%) examined 2 outbreaks associated with SARS-CoV-1: 5 (71%) studies examined outbreaks (different areas or groups of individuals) within the same hospital, and 2 (29%) studies investigated an outbreak in the same private high-rise housing estate. Of the 7 SARS-CoV-1 studies from Chirico et al [21], 5 (71%) are shared references with Li et al [13] (Table 3). The review authors indicated that 6 of 7 SARS-CoV-1 (86%) studies indirectly demonstrated a role for the HVAC system (through epidemiological data, spatiotemporal patterns of infection, or modeling). Of 14 studies, 1 (7%) study investigated an outbreak of Middle East respiratory syndrome coronavirus (MERS-CoV) in a hospital setting and demonstrated the contamination of the HVAC system through environmental sampling [22]. Of 14 studies, 6 (43%) studies investigated outbreaks of SARS-CoV-2: 1 (17%) study examined 318 outbreaks in 120 cities in China, including community and workplace settings; 3 (50%) studies examined an outbreak on a ship in Japan; and 2 (33%) studies examined the same outbreak in a restaurant. A total of 3 (50%) observational studies suspected a role for the HVAC system, 2 (23%) studies (both of ship outbreak) did not find evidence of a role for HVAC based on the spatiotemporal distribution of cases, and 1 (17%) study (of restaurant outbreak) supported a role for HVAC by computer simulation. The review authors indicated that they were not able to appropriately evaluate the quality of the included studies. The review authors concluded that there is sufficient evidence from SARS-CoV-1 and MERS-CoV studies demonstrating a role for HVAC in the airborne transmission of the viruses; however, there was not sufficient evidence that HVAC systems play an important role in the case of SARS-CoV-2. Although there is a lack of evidence for SARS-CoV-2, there was no evidence of no role.

Zhen et al [23] conducted a rapid review of "the role of public ground transport in COVID-19 transmission" and "interventions that may reduce transmission" [23]. The authors searched for studies published since 2000 and identified 4 relevant studies, published between 2007 and 2016, namely 1 (25%) systematic review, 1 (25%) case-control study, and 2 (50%) modeling studies. The systematic review by Browne et al [24] identified 41 studies examining the risk of transmission of Influenza A (H1N1/09) (n=29, 71% studies), SARS-CoV (n=5, 12% studies), both influenza and SARS-CoV (n=2, 5% studies), MERS-CoV (n=2, 5% studies), or unspecified viruses (n=3, 7% studies) related to sea (n=6, 15% studies), ground (n=6, 15% studies), or air (n=29, 71% studies) transport. Zhen et al [23] summarized results from 4 quantitative studies included in Browne et al [24] and concluded that the "use of public transport increased the risk of influenza transmission" [23]. Zhen et al [23] identified a multicenter case-control study that showed a lower probability of Influenza A (H1N1/09) diagnosis with public transport use (metro, bus, tram, or local train) and no association with diagnosis and the use of trains, airplanes, or taxis. The case-control study was assessed as having a moderate risk of bias by Zhen et al [23]; the risk of bias was not reported for the other 3 studies (75%). Zhen et al [23] also identified 2 modeling studies: one estimated the reproduction number for influenza infection in a train, and the other tested simulations to predict influenza infection probability for 4 bus ventilation systems. The first modeling study showed that masks could decrease the reproduction number, resulting in a lower risk of disease transmission, with high-efficiency particulate air masks being more effective than surgical masks. Furthermore, doubling the ventilation rate reduced the risk, similar to the use of high-efficiency particulate air masks, and was considered more feasible and cost-effective. The second modeling study showed that influenza transmission risk can be reduced when the infected passenger is positioned closer to the exhaust opening and with high-efficiency filtration in the case where nonrecirculated air cannot be provided. Given the limited number of research studies, Zhen et al [23] also identified and discussed national and international guidance documents, for example, those published by WHO [104-110]. Although general recommendations have been made to reduce risk (eg, minimizing the use of public transport, environmental controls, respiratory etiquette, hand hygiene, and mask use), there is no indication of the empirical evidence specific to these measures, in particular mechanical ventilation.

da Silva et al [25] conducted a systematic review to discuss "the viability/stability of aerosols containing SARS-CoV and MERS-CoV viruses" with an intent "to provide information on potential mitigation strategies for SARS-CoV-2 airborne transmission" [25]. The review authors identified 11 studies. Of these 11 studies, 8 (73%) studies examined the viability of coronaviruses in air samples, but the review authors did not describe the relationship with HVAC features, including 1 (13%) MERS-CoV study [22], which was described earlier by Chirico et al [21]. The remaining 3 (27%) studies were laboratory-based experimental studies of coronaviruses. In one MERS-CoV study, the virus was aerosolized at 20 °C with 40% or 70% RH, showing decreased stability at 70% RH compared with 40% RH [26]. The other MERS-CoV study examined virus inactivation under 2 conditions [27]: common office environment (25 °C and 79% RH) and Middle Eastern region climate (38 °C and 24% RH). In the simulated office environment, "the virus demonstrated high robustness and strong capability to survive with about 63.5% of viruses remaining infectious 60 min after aerosolisation. Virus decay was much stronger for hot and dry air scenario with only 4.7% survival over 60 min procedure" [25]. One of the studies showed an aerosol survival time of 3 hours for SARS-CoV-2 [28]. The review authors did not assess the methodological quality of the included studies; however, they commented on some limitations.

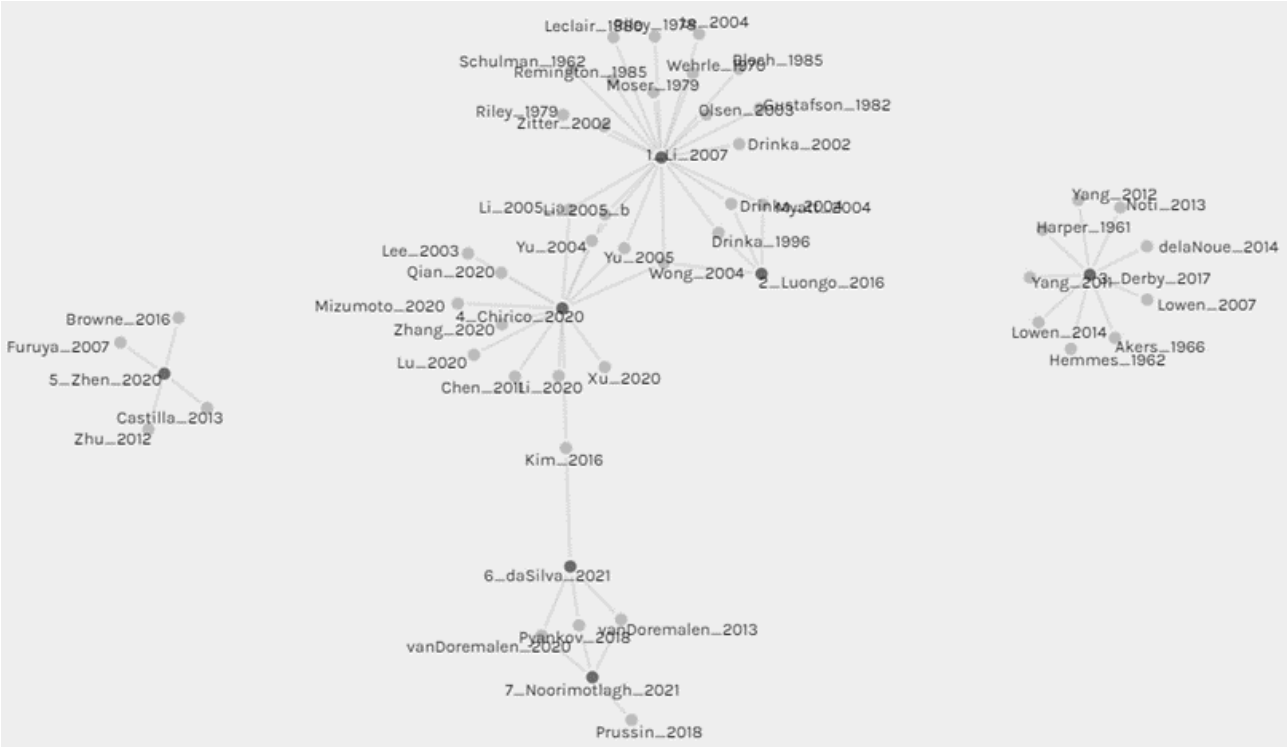
The review authors concluded that "higher temperatures and high relative humidity can have an effect on SARS-CoV-2 viability in the environment as reported in previous studies to this date" [25]. However, their conclusions were based on studies of both indoor and outdoor environments.

Noorimotlagh et al [29] performed a systematic review of SARS-CoV-2 literature "to collect all available studies concerning inactivation methods, environmental survival, and control and prevention strategies" [29]. Although 42 studies were identified, 4 provided information on temperature and humidity in the built environment, investigating MERS-CoV (n=2, 50%), SARS-CoV-1 and SARS-CoV-2 (n=1, 25%), and Phi6 (n=1, 25%), which is a bacteriophage used as a surrogate for viruses. All of them were laboratory-based experimental studies. The review authors did not assess or comment on the methodological quality of the included studies. The aerosolized MERS-CoV data from van Doremalen et al [26] were reported by da Silva et al [25] although not extracted by Noorimotlagh et al [29]. A MERS-CoV study found that the virus had robustness and strong capability to survive at 25 °C and 79% RH [27]; this was a shared reference with da Silva et al [25]. Although da Silva et al [25] reported the SARS-CoV-2 survival time from van Doremalen et al [28], Noorimotlagh et al [29] further clarified that the aerosol survival time of 3 hours for SARS-CoV-2 was at 40% RH and 21–23 °C and that the stability of SARS-CoV-2 was similar to that of SARS-CoV-1 [28]. The Phi6 study showed the highest virus survival at >85% RH and <60% RH with a significant decrease between 60% and 85% RH [30]. At a fixed humidity of 75% RH, infectivity decreased by 2 orders of magnitude between 19 and 25 °C [30]. The review authors concluded that "temperature and relative humidity are important factors in the survival of SARS-CoV-2" [29] and that "disease transmission via droplets is inhibited by increasing both temperature and RH in buildings" [29]. A review recommendation was "proper ventilation of the buildings in time of aerosol generating" [29]; however, studies of ventilation were not reviewed.

Network of Included Reviews

The network of the 7 included reviews and their 47 references relevant to this overview was created using Palladio (Figure 2). Overall, 12 references were shared among the 7 included reviews. However, the network clearly demonstrates that Derby et al [20] and Zhen et al [23] shared no references with the 5 other reviews. In actuality, the 12 references were shared between 5 reviews (Figure 2). da Silva et al [25] and Noorimotlagh et al [29] shared 3 references regarding experimental studies of MERS-CoV and SARS-CoV-2 [26-28] (Table 3). In addition, da Silva et al [110] shared 1 reference on MERS-CoV isolation wards [22] with Chirico et al [21]. Three reviews, Li et al [13], Luongo et al [19], and Chirico et al [21], shared a reference on SARS-CoV-1 in hospital wards [31]. Li et al [13] and Chirico et al [21] shared other related references on SARS-CoV-1 in hospital wards [32,33]. Similarly, Li et al [13] and Luongo et al [19] shared studies on influenza in nursing homes [34,35] and rhinovirus in offices [36]. Li et al [13] and Chirico et al [21] shared 2 other references regarding SARS-CoV-1 in high-rise apartment complexes [37,38]. Not only were the 12 references shared only between 5 reviews, 8 of these references were shared with 1 2007 review by Li et al [13], and the remaining 4 references were shared with 1 2021 review by da Silva et al [25] (Figure 2). Although 35 of the 47 references were not shared, the 12 shared references were captured by the earliest review (2007; [13]) and one of the latest reviews (2021; [25]).

Figure 2. Network representing relevant references (gray circles) from the 7 included reviews (black circles): 1_Li_2007; 2_Luongo_2016; 3_Derby_2017; 4_Chirico_2020; 5_Zhen_2020, 6_daSilva_2021; 7_Noorimotlagh_2021. Shared References are as follows: 1_Li_2007, 2_Luongo_2016, and 4_Chirico_2020 share Wong_2004; 1_Li_2007 and 2_Luongo_2016 share Drinka_1996, Drinka 2004, and Myatt 2004; 1_Li_2007 and 4_Chirico_2020 share Li_2005_a, Li_2005_b, Yu_2004, and Yu_2005; 4_Chirico_2020 and 6_daSilva_2021 share Kim_2016; 6_daSilva_2021 and 7_Noorimotlagh_2021 share vanDoremalen_2013, Pyankov_2018, and vanDoremalen_2020.



Quality Assessment

Table 4 provides the assessments of the methodological quality of the reviews based on AMSTAR2. In total, 3 (43%) papers described themselves as systematic reviews, 2 (29%) were rapid reviews, 1 (14%) was a broad literature survey, and 1 (14%) was described simply as a review. The majority provided detailed research questions, explained study designs considered for inclusion, used a comprehensive search strategy, described the included studies, discussed the heterogeneity of results, and reported potential conflicts of interest. None or few reviews provided an a priori protocol, performed study selection and data extraction in duplicate, provided a list of excluded studies, conducted risk of bias assessments of individual studies, or reported on the sources of funding for the included studies. None of the reviews conducted a meta-analysis; all of them provided a narrative synthesis of the results and observations across the included studies. A previous review [19] spoke about the need for more well-designed studies (including representative sampling and clear and consistent measurement methods and reporting of data) with the goal of using meta-analysis to integrate the results.

Table 4. Methodological quality of the relevant reviews based on AMSTAR2.

AMSTAR2 question	Li et al [13], 2007	Luongo et al [19], 2016	Derby et al [20], 2017	Chirico et al [21], 2020	Zhen et al [23], 2020	da Silva et al [25], 2021	Noorimotlagh et al [29], 2021
1. Did the research questions and inclusion criteria for the review include the components of PICO?	Yes	Yes	Yes	Yes	Yes	Yes	Yes
2. Did the report of the review contain an explicit statement that the review methods were established prior to the conduct of the review and did the report justify any significant deviations from the protocol?	No	No	No	No	No	No	No
3. Did the review authors explain their selection of the study designs for inclusion in the review?	Yes	Yes	Yes	Yes	Yes	No	No
4. Did the review authors use a comprehensive literature search strategy?	Yes	Partial Yes	Partial Yes	Yes	Yes	Yes	Partial Yes
5. Did the review authors perform study selection in duplicate?	Yes	No	No	No	No	Yes	Yes
6. Did the review authors perform data extraction in duplicate?	No	No	No	No	No	No	No
7. Did the review authors provide a list of excluded studies and justify the exclusions?	No	No	No	No	No	No	No
8. Did the review authors describe the included studies in adequate detail?	Yes	Yes	Partial Yes	Yes	Yes	Yes	Yes
9. Did the review authors use a satisfactory technique for assessing the risk of bias (RoB) in individual studies that were included in the review?	No	No	No	No	Partial Yes	No	No
10. Did the review authors report on the sources of funding for the studies included in the review?	No	No	No	No	No	No	No
11. If meta-analysis was performed did the review authors use appropriate methods for statistical combination of results?	No meta-analysis conducted	No meta-analysis conducted	No meta-analysis conducted	No meta-analysis conducted	No meta-analysis conducted	No meta-analysis conducted	No meta-analysis conducted
12. If meta-analysis was performed, did the review authors assess the potential impact of RoB in individual studies on the results of the meta-analysis or other evidence synthesis?	No meta-analysis conducted	No meta-analysis conducted	No meta-analysis conducted	No meta-analysis conducted	No meta-analysis conducted	No meta-analysis conducted	No meta-analysis conducted
13. Did the review authors account for RoB in individual studies when interpreting/discussing the results of the review?	Yes	Yes	No	No	Yes	Yes	No
14. Did the review authors provide a satisfactory explanation for, and discussion of, any heterogeneity observed in the results of the review?	Yes	Yes	Yes	Yes	Yes	Yes	No
15. If they performed quantitative synthesis did the review authors carry out an adequate investigation of publication bias (small study bias) and discuss its likely impact on the results of the review?	No meta-analysis conducted	No meta-analysis conducted	No meta-analysis conducted	No meta-analysis conducted	No meta-analysis conducted	No meta-analysis conducted	No meta-analysis conducted
16. Did the review authors report any potential sources of conflict of interest, including any funding they received for conducting the review?	Yes	Yes	Yes	Yes	Yes	Yes	Yes

Discussion

Principal Findings

This comprehensive overview of reviews provides a map of the existing synthesized evidence on the role of HVAC in airborne virus transmission. The earliest review by Li et al [13] published in 2007 found evidence of an association between ventilation rates and airflow patterns in buildings and the transmission of viral diseases. Li et al [13] found no studies that provided minimum ventilation requirements to prevent the spread of viral diseases; however, they found 1 study showing that tuberculin conversion was significantly associated with ventilation rates of <2 air changes per hour in general patient rooms [111]. Published in 2007 shortly after the 2003 SARS-CoV-1 epidemic, Li et al [13] called for a “multidisciplinary research culture” to study outbreaks, as well as smaller-scale transmission occurrences, for filling the gap with respect to quantifying minimum ventilation standards in both clinical and nonclinical

settings. A subsequent review by Luongo et al [19] published almost 10 years later, in 2016, included a subset of 4 of the virus studies identified by Li et al [13], with similar conclusions about the possible association between ventilation features (low outdoor air supply and imbalance in supply and exhaust airflow rates) and airborne virus transmission. Luongo et al [19] also pointed out the lack of data to quantify how mechanical ventilation may affect airborne transmission and the need for more well-designed multidisciplinary epidemiological studies. More recently, in response to the current COVID-19 pandemic, Chirico et al [21] examined HVAC systems and their role in the airborne transmission of coronaviruses; they concluded that there was sufficient evidence demonstrating an association for SARS-CoV-1 and MERS-CoV, whereas there was a lack of evidence for SARS-CoV-2. Derby et al [20] specifically examined the role of humidity in relation to indoor air quality; the evidence they identified was specific to influenza and showed that virus survival was lowest between 40% and 80% RH and that survival time decreased with the length of exposure to humidity. One of the studies from Noorimotlagh et al [29] indicated that aerosolized SARS-CoV-2 can survive for 3 hours at 40% RH and 21 to 23 °C [28]. In another recent review published in 2021, da Silva et al [25] examined mitigation strategies and found 2 studies demonstrating that coronavirus transmission decreased with increasing both temperature and RH in buildings. A recent review (2020) by Zhen et al [23] examined interventions to reduce virus transmission in public ground transportation; 2 modeling studies showed ventilation and filtration to be effective.

Comparison With Prior Work

Although there is an extensive body of literature examining HVAC and its role in airborne virus transmission, there is a lack of empirical evidence to quantify the minimum standards for HVAC design features in the built environment. Previous reviews have discussed this gap, stressed the need for methodologically rigorous epidemiological studies involving multiple disciplines (eg, engineering, medicine, epidemiology, and public health), and discussed considerations for future research, including the specificity of the virus, its construction and envelope composition, the infectious dose, and the size of the particle containing the virus. The review authors have called for standardizing experimental conditions, measurements, terminologies, and reporting as well as simulating real-world conditions [19,20,25]. An important consideration in designing rigorous studies is controlling for confounding factors. HVAC systems operate in a complex environment; for example, Derby et al [20] noted several confounding variables to be considered when interpreting their findings on humidity and temperature including "variation in air exchange rate, length of organism exposure, variation in the biological structure and routes of entry, variation of pathogen survival on different fomites, and variances in human host response" [20]. They further noted that the number and complexity of the variables to consider "greatly increases the test matrices required" [20] to build a comprehensive evidence base. Studies have also demonstrated the importance of the positioning of the infected person relative to HVAC features and other occupants, mobility patterns and activities (eg, type and intensity of respiratory activity) of the occupants, time spent within a space, occupancy, and occupant density. Despite the specification of airflow parameters, the flow of air in occupied spaces is almost always turbulent (vs laminar) such that particles "are constantly mixing and moving in varied ways across a space," making assessments and predictions challenging [112]. Finally, research results need to be interpreted in light of the technological differences in the HVAC systems around the world [21]. Engineers have developed sophisticated methods (through modeling, computational fluid dynamics, etc) that allow for the isolation of features and control for confounding variables. However, these studies rely on many assumptions that may not hold in real-world settings or are specific to an assumed building design or configuration. In addition, these studies may isolate 1 component in the chain of transmission, which does not necessarily equate to the actual disease (eg, the detection of viral particles vs infectivity vs disease outcomes) [19,20,25]. The results from modeling studies need to be considered alongside epidemiological studies. Previous reviews have highlighted many challenges with studying outbreaks: Li et al [13] mentioned that the "most inherent limitation in almost all existing investigations is due to the rapid disappearance of airborne evidence of infection, once the infectious period is over" [13]. They proposed as a solution "contemporaneous air-sampling and environmental measurements" [13] in locations during a patient's illness, which could be extended to locations of high use or occupancy during a pandemic or seasonal epidemics.

Strengths and Limitations

The strengths of this study include its comprehensiveness and the use of methods to avoid bias, such as the prespecification of inclusion and exclusion criteria and involvement of at least two reviewers at all stages. The main limitation stems from the limits of the included reviews. We initially intended to include only systematic reviews that met internationally recognized definitions and methodological expectations. However, we relaxed our criteria given that many reviews did not meet this standard. Although most reviews prespecified their research question and conducted a comprehensive search, few conducted study selection and data extraction in duplicate as recommended to avoid bias, and very few assessed the methodological quality or risk of bias of the included studies, which is key to determining the validity and certainty of the available evidence. We also did not find reviews of all HVAC design features; for example, none of the included reviews examined UV germicidal irradiation (although a recent narrative review has been published in the context of COVID-19 [72]), and only a small number of studies across the reviews examined filtration.

Implications

The findings of this overview have several implications for public health measures to mitigate the spread of viral transmission in buildings. First, ventilation rates and airflow patterns have been shown to be associated with virus transmission. Second, humidity and temperature are associated with virus survival. Third, filtration can be effective in removing pathogens if the filter rating is commensurate with the size of the particles of interest [19]. The reviews have also mentioned

the importance of regular maintenance of HVAC systems and features to ensure optimal functioning. Across the reviews, there was a clearly stated need for more methodologically rigorous interdisciplinary research with a specific focus on quantifying the minimum specifications for HVAC features. Although one of the reviews did not find sufficient evidence of association between HVAC and airborne transmission specific to SARS-CoV-2, the authors did advise (based on evidence for MERS-CoV and SARS-CoV-1) that attention be given to the design and management of HVAC systems as a precautionary measure until further evidence indicates otherwise [21].

Conclusions

Airborne transmission is now recognized as a route of transmission for different viruses, including coronaviruses, specifically SARS-CoV-2, which has been the source of immense global impacts in terms of morbidity, mortality, and the peripheral effects of pandemic restrictions. HVAC systems and their specific features have the potential to mitigate transmission in built environments: there is evidence that ventilation rates, airflow patterns, humidity, temperature, and filtration can influence virus transmission. Enhancing HVAC systems in built environments (including schools, office buildings, commercial spaces, recreation centers, and transport vehicles) could have important implications for the current pandemic as well as seasonal epidemics and other diseases and impacts that are associated with general indoor air quality. These measures will be of utmost relevance to countries that experience cooler climates and where people spend an inordinate amount of time (80%-90%) indoors. Moreover, mitigation strategies that do not rely on human behavior and result in other (eg, social) consequences will be more sustainable [21]. This overview synthesized 7 previous reviews that included 47 studies examining HVAC design features and their effects on the airborne transmission of viruses, serving as a starting point for future systematic reviews and identifying priorities for primary research.

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Conflicts of Interest

None declared.

Multimedia Appendix 1
Search strategies for Ovid MEDLINE and Compendex.
[PDF File (Adobe PDF File), 563 KB - ijmr_v11i2e37232_app1.pdf]

Multimedia Appendix 2
Inclusion and exclusion criteria for the overview of reviews [16].
[PDF File (Adobe PDF File), 544 KB - ijmr_v11i2e37232_app2.pdf]

Multimedia Appendix 3
Relevant studies from the included reviews that are pertinent to the overview's research question (with full citations).
[PDF File (Adobe PDF File), 703 KB - ijmr_v11i2e37232_app3.pdf]

Multimedia Appendix 4
Publications excluded at full-text screening with reasons.
[PDF File (Adobe PDF File), 584 KB - ijmr_v11i2e37232_app4.pdf]

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Abbreviations

HVAC: heating, ventilation, and air-conditioning
MERS-CoV: Middle East respiratory syndrome coronavirus
RH: relative humidity
SARS-CoV-1: severe acute respiratory syndrome coronavirus 1
WHO: World Health Organization

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Original Paper

Veterans Affairs Health Care Provider Perceptions of Virtual Reality: Brief Exploratory Survey

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Abstract

Background: Virtual reality (VR), a simulated experience that can be similar to or completely different from the real world, has become increasingly useful within the psychiatric and medical fields. This VR technology has been applied in medical school trainings, exposure therapy for individuals with posttraumatic stress disorder (PTSD), and reminiscence therapy associated with mood disorders for older adults. Perceptions of VR through the lens of the health care provider require further exploration. VR has grown in popularity; however, this modality continues to be underused in most Veterans Affairs (VA) hospitals.

Objective: A web-based survey was used to explore health care provider perceptions of immersive VR availability and use for older adults and identify potential barriers for immersive VR use in older adults with cognitive impairment.

Methods: An 8-item web-based survey was developed to obtain health care provider feedback. This survey was disseminated throughout a single Veterans Integrated Services Network (VISN). The VR survey was developed via the Survey Monkey platform and distributed through the secure VA email network. Providers were asked to voluntarily participate in the brief, anonymous survey and offer their perceptions of immersive VR use within their patient population. Survey data were reviewed and interpreted using descriptive statistics.

Results: A total of 49 respondents completed the survey over a 15-day period. Of them, 36 respondents (73%) had heard of a VR device, though the majority (n=44, 90%) had never used or prescribed a VR device. Respondents identified several potential barriers to immersive VR use in older adults with cognitive impairment (eg, hearing difficulties, perceptions of technology, cognitive concerns, access to resources, and visual impairment). Despite the barriers identified, providers (n=48, 98%) still reported that they would feel comfortable prescribing immersive VR as an intervention for their patient population.

Conclusions: Survey findings revealed that health care providers within this VISN for VAs have heard of VR, although they may not have actively engaged in its use. Most of the providers reported that they would prescribe the use of an immersive VR intervention for their older adult patients. This key point highlights the desire to implement VR strategies for patient use by their providers. If underlying barriers can be addressed and relatively resolved, this technological intervention has the potential to create substantial breakthroughs in clinical care.

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KEYWORDS

virtual reality; older adults; provider perception

Introduction

Nonpharmacological interventions in health care are an alternative approach to pharmacological therapies and are recommended as a first-line treatment prior to introducing medications. This is especially important for older adults due to the increased risk for adverse outcomes. One nonpharmacological intervention with increasing recognition and application among health care providers involves the use of virtual reality (VR) devices. For the purposes of this survey, health care providers include any licensed independent provider or clinician who provides health care to older adults (eg, physicians, nurses, and psychologists). These VR devices use technology to create a simulated environment. VR is a computer-generated simulation in which one can interact with the surrounding environment by using various devices such as computers, smartphones, or head-mounted devices that can be immersive or nonimmersive [1]. In this survey, immersive VR was described to participants and used as the type of VR experience. VR has been shown to be a viable option for older adults [2]. Its design allows for a more immersive experience by reducing external distractions [3]. It is rapidly expanding as an intervention for many diagnoses and clinical presentations. In mental health, VR abilities provide its users with a virtual exposure (vs in vivo) to stimuli, making it an ideal intervention for addressing posttraumatic stress disorder (PTSD) [4]. VR has been used to treat mental health diagnoses of anxiety [5], eating disorders [6], obesity [7], sexual dysfunctions [8], phobias [9], and PTSD [10,11].

The medical education field has also used VR to educate providers on various medical conditions [12,13], have a cost-effective way to teach students in medical school programs [14], and training them in team building exercises [15]. Provider perception is key to implementing appropriate interventions and referral options for their patients. Limited research exists in the area of health care providers prescribing VR use for their patients. The hesitancy of psychotherapists to prescribe VR devices has been explored in research [16]; however, hesitancy from other health care providers has yet to receive as much attention.

Ways to seamlessly integrate the use of technology in older adults has been a topic of interest since the late 1980s [17]. More recently, VR use has been studied in cognitively impaired older adult population for neuropsychiatric testing [18,19], cognitive rehabilitation [20], and reducing neuropsychiatric symptoms associated with dementia [21]. Researchers have worked to find innovative ways to reduce neuropsychiatric symptoms in those diagnosed with dementia. An additional way VR has been used in older adults is through exploring its use in reducing symptoms of apathy [22]. In studies such as these, VR was used by engaging the individual in experiences that involved music, art, cognitive stimulation, and reminiscence therapy [23]. Other uses have included memory enhancement training in those with a previous diagnosis of dementia [24]. Additionally, the use of VR could reduce medication burden in the medical field for varying mental health conditions. Increasing nonpharmacological techniques for older adults has the potential to aid the individuals themselves and their families and reduce the national financial burden of caring for these individuals. In order to connect these individuals to nonpharmacological approaches, such as VR, it is important to understand how their treating providers view VR and explore possible barriers for providers prescribing its use to their older adult population.

Although there is strong evidence to support the use of VR in older adults, it is important to understand if health care providers support the use of immersive VR in their patient populations. This survey was developed as preparatory to a funded research study to examine the use of immersive VR in older veterans with cognitive impairment. The aim was to use a web-based survey to explore health care provider perceptions of immersive VR availability and use in older adults as well as to identify potential barriers for VR use in older adults with cognitive impairment. Through analysis of the responses, possible obstacles or stigma were identified to better understand current perceptions and advise future directions for immersive VR use with older adults.

Methods

Participants

All health care providers from a single Veterans Affairs (VA) Veterans Integrated Services Network (VISN) were invited to participate in a web-based, anonymous, closed survey. Health care providers were selected from one VA VISN that included 8 VA medical centers to better understand views from this specific population. The Veterans Affairs Health Administration is divided into 18 VISNs (or regional systems) across the nation. These regional divisions are meant to increase access to care and resources for veterans throughout the United States.

Survey Design

The survey, included in Multimedia Appendix 1, was developed by an experienced nurse researcher with vast knowledge of education and evaluation and an experienced psychology researcher working on immersive VR research. Participants were allowed to take the survey only once, based on the computer IP address. Author expertise in this area includes prior experience with implementing VR in a clinical setting and as part of a national research study. Through combined experiences, the authors were aware of a portion of the potential obstacles and benefits related to provider buy-in with immersive VR devices. A more focused look into this area is needed to aid in further exploration of the field. The web-based survey was developed on the Survey Monkey platform and emailed out to the health care providers within one VA VISN for voluntary feedback. A brief explanation of immersive VR and the purpose of the survey were included in the email with the link to the survey. The estimated time of survey completion was also included. The 8-item survey was made available for approximately two weeks for participants to complete. No incentives were offered to participants for completing the survey.

Ethical Considerations

The Institutional Review Board of the Central Arkansas Veterans Health Care System deemed the survey as nonresearch

and preparatory to research activity and therefore exempted it from ethics review.

Statistical Analysis

Descriptive statistics were used to analyze, summarize, and present the survey data findings. Frequency distribution was used to depict the frequency or count of different outcomes in the sample. The frequency distribution was presented in a table format to summarize the health care disciplines and potential VR barriers in older adults with cognitive impairment. Each entry in the table was accompanied by the count or frequency along with associated percentages.

Results

A total of 49 participants completed the survey. Table 1 displays disciplines for the participants of the project. Each participant who self-identified as a physician was asked to specify their discipline. Of the physicians who completed the survey, their disciplines were identified as follows: 5 psychiatry, 1 geriatrician, 2 family medicine, 1 ophthalmology, 1 primary care or internal medicine, and 1 behavioral health. Of note, one participant who identified as an administrator noted being a physician of family medicine. This participant was not included in the overall physician count. Of 49 participants, 36 (73%) reported that they had heard of VR devices. A substantially smaller portion (n=5, 10%) reported previously using the device or prescribing the device for a patient. Of the individuals who reported previously using or prescribing the VR device, 12 (25%) reported that either themselves or their patients did not enjoy the experience. When asked if providers believed that immersive VR devices could be used with older adults, 46 (94%) reported yes. A distinction was made between using immersive VR with older adults with cognitive impairment and those without it. When asked if immersive VR could possibly be used with older adults with cognitive impairment, most providers (n=42, 86%) still reported yes. Overall, an overwhelming majority of providers (n=48, 98%) reported that they would refer their patients to a program that uses immersive VR devices. Respondents were given an option to check certain barriers that they felt may be present for older adults when using immersive VR devices or write in barriers that were not included on the preestablished barrier list. Table 2 depicts the breakdown of barriers identified by the respondents. From the participants who marked “other” for identified barriers, the following were reported as possible barriers to immersive VR use: mental health issues (eg, PTSD), connectivity issues in rural areas, resistance to device going over their head (especially in older adults with dementia), apathy, resistance to new technology, and unwillingness to make changes.

Table 1. Percentage of health care providers by discipline (N=49).

Provider disciplines	Values, n (%)
Social worker	14 (29)
Nursing	10 (21)
Physician	10 (20)
Psychologist	6 (12)
Administration	3 (6)
Chaplain	2 (4)
Physical therapist	1 (2)
Recreation therapist	1 (2)
Neuropsychologist	1 (2)
Research health specialist	1 (2)

Table 2. Perceived barriers to virtual reality use by health care providers (N=12).

Barriers	Values, n (%)
Cognitive issues	36 (74)
Perceptions of technology	36 (74)
Hearing loss	35 (71)
Vision problems	33 (67)
Access to resources	28 (57)
Frailty	10 (20)
Mood issues	8 (16)
Other	5 (10)

Discussion

Principal Results

Our data yielded results highlighting that health care providers agreed that VR devices can be used with older adults, and furthermore, with older adults who have cognitive impairment. This information matches previous data in studies where older adults engaged in VR-based research [1,23,24]. Although providers highlighted barriers to immersive VR use in this population, the majority of health care providers would refer their patients to a program where immersive VR devices are used. Key barriers included physical, social, emotional, and cognitive obstacles that providers believed could hinder VR use in older adults with cognitive impairment.

Interpretation of Results

Results of this project are consistent with literature in the field addressing provider acceptance of VR use for patients. Additionally, social barriers identified by providers regarding the use of VR devices in practice have been reported [25]. A limited number of studies have explored physical factors (eg, frailty, vision impairments, or mobility issues) displayed by patients that providers believe can inhibit the use of VR devices. These physical factors have been identified as barriers for other social groups, although they have been highlighted more frequently with older adults. The two significant barriers identified in the above-mentioned study by providers were cognitive issues displayed by the patient and patient's perceptions of technology. Even though cognitive impairment can serve as a hinderance for engagement in some VR activities, VR has also acted as an assessment tool for diagnosing mild cognitive impairment [26]. Researchers have found that VR applications can be used toward improvement of cognitive impairment [27,28]. Few studies have thoroughly evaluated the perception of technology as viewed by older adults with cognitive impairment.

Comparison to Prior Work

Chung et al [29] conducted a similar type of work, where perceptions of VR were explored with clinicians and service managers. Their study included barriers not only from the clinician's view but also from the patient's and the organization's view. Three broad themes emerged from the analysis of the survey barrier data (clinical factors, organizational factors, and professional factors). Overall, participants of the project agreed that VR could be used to break down barriers of care. Additionally, participants noted that VR could prove to be a beneficial mental health intervention for those who may have found traditional psychotherapy methods to be ineffective [30]. Two main barriers for implementation of VR use addressed in their work include concerns for proper safety or ethics and concerns for resourcing (eg, staff, costs, or space). An additional study found that providers find VR to be a valuable tool and would continue to use it in their own practice [27].

Limitations

One major limitation of our study is the small sample size reported; the project yielded results from 49 respondents. Second, we included only 8 items for the total survey. It is possible that additional information was unable to be analyzed due to the low item number. The third limitation includes the restriction of sending the survey to only one VA VISN and only VA health care providers. Some health care providers may have other roles in different care settings, though they would have required a VA affiliation to have access to this project survey.

Future Work

Future areas of consideration include understanding the perception of health care providers toward using VR or referring patients to engage in immersive VR-based interventions. Similarly, research can explore perceptions of technological use, specifically immersive and nonimmersive VR use, in older adults with cognitive impairment. Identifying additional barriers for both forms of VR use and brainstorming possible solutions to these barriers are also required in the future.

Conclusions

Immersive VR continues to emerge as a viable option for a myriad of clinical presentations and medical education purposes. Various uses of this technology are being identified and researched. Although systemic, professional, and individual barriers have been highlighted, the field continues to address these obstacles with the hopes of improving the overall VR experience.

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Data Availability

The deidentified data sets generated and analyzed for this study are available from the corresponding author upon reasonable request.

Conflicts of Interest

None declared.

Multimedia Appendix 1
Veterans Affairs health care providers perceptions of virtual reality survey.
[DOCX File , 16 KB - ijmr_v11i2e38490_app1.docx]

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Abbreviations

PTSD: posttraumatic stress disorder
VA: Veterans Affairs
VISN: Veterans Integrated Services Network
VR: virtual reality

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Original Paper

The Association Between Telehealth Utilization and Policy Responses on COVID-19 in Japan: Interrupted Time-Series Analysis

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Abstract

Background: Telehealth using telephones or online communication is being promoted as a policy initiative in several countries. However, there is a lack of research on telehealth utilization in a country such as Japan that offers free access to medical care and regulates telehealth provision—particularly with respect to COVID-19.

Objective: The present study aimed to clarify telehealth utilization, the characteristics of patients and medical institutions using telehealth, and the changes to telehealth in Japan in order to support the formulation of policy strategies for telehealth provision.

Methods: Using a medical administrative claim database of the National Health Insurance and Advanced Elderly Medical Service System in Mie Prefecture, we investigated patients who used telehealth from January 2017 to September 2021. We examined telehealth utilization with respect to both patients and medical institutions, and we determined their characteristics. Using April 2020 as the reference time point for COVID-19, we conducted an interrupted time-series analysis (ITSA) to assess changes in the monthly proportion of telehealth users to beneficiaries.

Results: The number of telehealth users before the reference time point was 13,618, and after the reference time point, it was 28,853. Several diseases and conditions were associated with an increase in telehealth utilization. Telehealth consultations were mostly conducted by telephone and for prescriptions. The ITSA results showed a sharp increase in the proportion of telehealth use to beneficiaries after the reference time point (rate ratio 2.97; 95% CI 2.14-2.31). However, no apparent change in the trend of increasing or decreasing telehealth use was evident after the reference time point (rate ratio 1.00; 95% CI 1.00-1.01).

Conclusions: We observed a sharp increase in telehealth utilization after April 2020, but no change in the trend of telehealth use was evident. We identified changes in the characteristics of patients and providers using telehealth.

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KEYWORDS

telehealth; COVID-19; health services research; interrupted time series

Introduction

A patient's access to health care services is a major factor affecting health care outcomes. Telehealth is the provision of health care services to patients from providers at different locations using telephone or video consultations. By improving patients' geographic access or saving on travel costs and time, telehealth reportedly enhances efficacy in increasing continuity of care and medication adherence [1,2]. With its strong contribution to follow-up, telehealth can be widely applied from

acute diseases to chronic conditions [3]. Thanks to its administrative benefits, the merits of adopting telehealth have been reported from the viewpoints of both patients and providers: reducing the use of resources in health care facilities, improving access to care, and—notably—minimizing the risk of direct infection transmission [4].

The advantages of telehealth have been reported. However, its effectiveness and availability in real-world settings need verification: External environmental changes and stakeholder decisions (eg, adaption of medical institutions and patient behavior) can affect the utilization of telehealth services [5]. As a key discussion related to effectiveness, some countries (or payers) have limited the coverage of telehealth services to patients living in rural areas [6]. From the standpoint of considering these differences in delivery systems by insurer, additional research would be needed to evaluate how evidence on telemedicine applies in a health care delivery system to which patients have free access, as in Japan. As a preliminary step, an assessment of the prevalence of telehealth is important information not only to support in test evidence but also to evaluate its relevance to policy.

The Japanese government's conservative strategy for telehealth, in conjunction with its various policy responses to COVID-19, have faced a watershed in the years after 2020. With some exceptions, telehealth in Japan has been applied only as a complement to routine care for the sake of ensuring diagnostic accuracy [7]. Similarly, over the past 2 decades, using telehealth for initial consultations has been limited in Japan. In recent years, the Japanese government has promoted telehealth as part of a national growth strategy for information and communication technology; however, regulations have prevented its widespread use [8]. Since early 2020, COVID-19 and associated policy responses have promoted the wider application of telehealth. Many countries and insurers have expanded telehealth services to facilitate patient access to medical services or prescriptions under partial quarantine (eg, school closures and government-imposed social distancing restrictions) [9-12]. Similarly in Japan, regulations on the application of telehealth have been relaxed amid measures such as declaring a state of emergency, closing schools, and triaging for outpatient visits. To increase the number of medical institutions providing telehealth and maintain the delivery of medical care to self-isolating patients, Japan temporarily lifted restrictions on telehealth for initial consultations [13]. The Japanese government has developed these measures to promote telemedicine as temporal measures but made them permanent starting in April 2022. However, the system has been designed to reimburse medical institutions more for face-to-face consultations than for telehealth, which raises concerns about their widespread use. Thus, it is necessary to examine how those measures enacted during the pandemic have affected health care provision in Japan.

Despite the importance of discussions about the future provision of telehealth, there is a lack of data on telehealth use in Japan since COVID-19. In the present study, using the Japanese health care claims database, we examined the following: (1) whether telehealth utilization has increased since COVID-19 and the associated institutional response, (2) whether trends in telehealth use after COVID-19 have increased or decreased, and (3) whether characteristics of telehealth users and providers have changed before and since COVID-19. In order to support the formulation of policy strategies for telehealth provision, we also discuss the future of telehealth provision in Japan, which is regarded as a highly accessible environment for health care with no restrictions on patient access to visit medical facilities of their own choosing.

Methods

Data Source

In this retrospective cohort study, we analyzed data from the administrative database of health insurance claims in Mie Prefecture, Japan. Health insurance is mandatory for residents in Japan. The database stores information related to the National Health Insurance and Advanced Elderly Medical Service System; those covered are self-employed individuals as well as retirees and their dependents aged 75 years or above. These insured under that scheme amounted to 37.8% of the total Japanese population in 2020 [14]. The claims data include diagnoses, use of medical care (face-to-face or telehealth), prescriptions, and expenditures related to medical procedures.

The diagnosis information is recorded using the International Classification of Diseases 10th Revision (ICD-10) codes and Japanese diagnosis codes, with flags indicating the diagnosis. With links to insurance information, the database includes patients' sex, date of birth, and place of residence.

We conducted this study in Mie Prefecture. The prefecture is located toward the center of Japan; it had a population of 1.77 million (22nd highest among the 47 prefectures) and an aging rate of 29.4% (18th highest) [15]. Figure 1 shows the geographic and demographic details for Mie Prefecture in 2020; Table 1 presents information about the medical facilities.

Figure 1. Geographic and demographic details of Mie Prefecture in 2020.

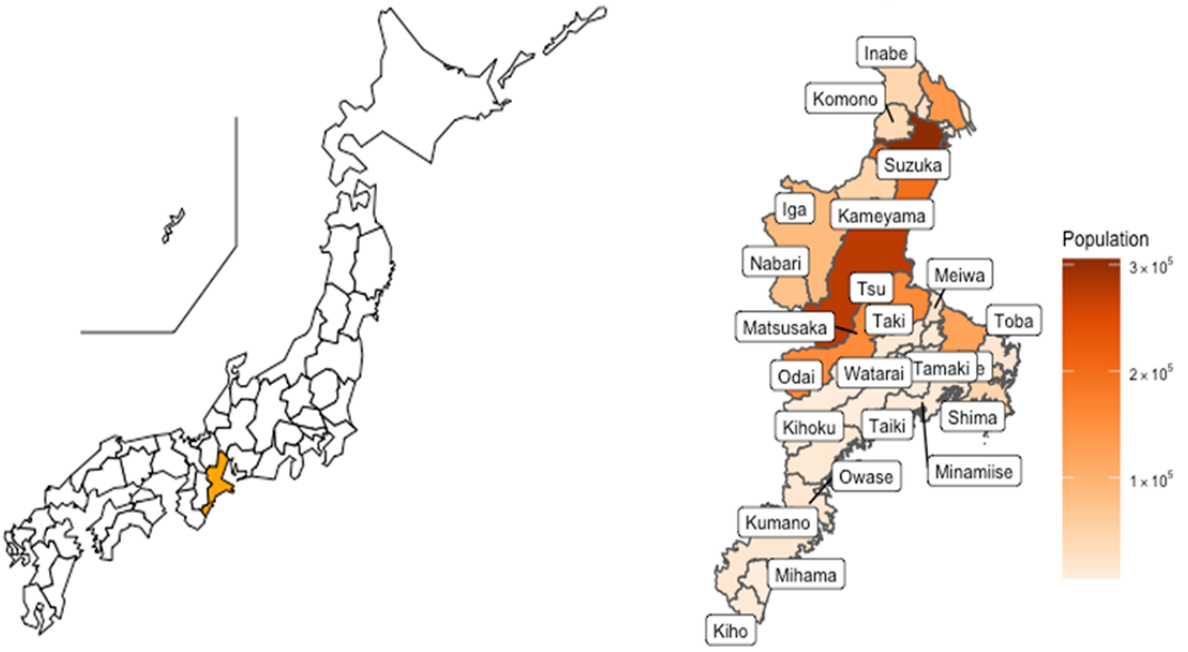

Table 1. Comparison of the population and medical facilities between Mie Prefecture and all of Japan in 2020.

Item	Mie Prefecture	Japan
Population, n	1,770,254	126,146,099
Population aged 65 years and over, n	522,073	35,335,805
Aging rate, %	29.4	28.4
Clinics per 100,000 population, n	45.81	44.81
Hospitals per 100,000 population, n	5.31	6.49
Physicians per 100,000 population, n	225.45	250.83

Participants

The term “telehealth” is polysemous and defined differently in different contexts. In this study, we categorized telehealth services as follows: online (using videoconferencing systems or devices), telephone, and monitoring (using a monitoring device such as a cardiac pacemaker and continuous positive airway pressure). We identified individuals who used any telehealth service at least once from January 2017 to September 2021. We determined the role of telehealth for each patient, such as for prescriptions and home care for COVID-19. Furthermore, we obtained data about sex, age when the patient used the service, and diagnoses. To calculate the monthly proportion of people using telehealth services, we identified the number of patients who received face-to-face consultations (visits to clinics or hospitals). The diagnoses were categorized by diseases according to ICD-10. We followed previous studies regarding the selection of diseases of interest for telehealth, mapping the targeted diseases, and ICD-10 classification [16,17]. We summarized the following: sex, age, type and frequency of telehealth services used, medical expenses recorded with the same claims as used with telehealth, and disease or condition when patients used telehealth. We determined the characteristics of medical institutions that provided telehealth at least once with respect to clinics or hospitals, number of beds, and location (within or outside Mie Prefecture) using a unique number code applied to medical institutions.

We compared the characteristics of telehealth users for a year before and after April 2020 as the reference time point, which was the first declaration of the state of emergency in Japan [18]. We also identified patients who used telehealth for initial consultations following the Japanese government announcement on April 10, 2020, that patients could do so.

Ethics Approval

The data set included in the study was provided by the regional public health care insurers in Mie prefecture with the approval of the personal information protection commission in charge of each of the local government areas and by contract with the local governments and the insurers.

Outcome

The outcome was a change in the monthly proportion of telehealth users to beneficiaries. We evaluated the outcomes by stratifying patients into 2 age groups: 65 years old and older

and younger than 65 years. To evaluate the impact of each disease, we applied stratification based on diseases and conditions. The secondary outcome was the change in the monthly proportion of telehealth users to beneficiaries.

Statistical Analysis

We compared continuous variables for the 2 groups using the Wilcoxon rank sum test. Categorical data (such as sex) were compared using the chi-square test with Yates correction.

To determine the outcomes, we undertook an interrupted time-series analysis (ITSA) [19,20] to evaluate the association between the reference time point and the outcomes from January 2017 to April 2021. Also referred to as segmented time-series regression, ITSA is applied to statistically measure changes in various levels and trends in a postintervention period compared with a pre-intervention period [21]. Owing to the frequency of telehealth use, we used ITSA in the present study with a log-linear model as the link function and assumed a Poisson error structure with adjusted seasonality, which could also be called a segmented time-series Poisson regression:

Y_t represents the monthly number of telehealth users to beneficiaries at time point t; $beneficiaries_t$ signifies the number of monthly beneficiaries. We set it to calculate the proportion of telehealth users to beneficiaries as a log-offset term. T_t represents the time since January 2017; T_0 is a dummy variable signifying t at the reference time point, the 40th month in this study. X_t is a dummy variable indicating the time after the reference time point: After April 1, 2020, it was 1; before, it was 0. β_0 signifies the level of Y_t at t=0. β_1 represents the pretrend; β_2 is the outcome change immediately after the outbreak of COVID-19 in Japan and the policy responses to it; β_3 is the change in the trend compared with before the reference time point. $harmonic_t$ was set as the Fourier term to adjust for seasonality [19].

To remove the effect of an immediate increase at the reference point, we excluded 1 month's observations before and after that point [22]. For subgroup analysis, the same Poisson regression was applied to the groups under 65 years old and 65 years old and older. For the sensitivity analysis, we changed the bandwidth for the removal for the overall telehealth user population from 0 months to 2 months; we did so to assess robustness and goodness of fit for each model based on the Akaike information criterion (AIC).

We performed all statistical analyses using R version 4.1.0 (R Foundation for Statistical Computing, Vienna, Austria). All statistical tests were 2-sided; we set the significance level at 5%, and we used 95% CIs for interval estimations of the outcomes.

Results

The characteristics of patients who used telehealth services appear in Table 2. The number of users before the reference time point was 13,618; after that time point, the number increased to 28,853 (111.87% growth). At any time, there were more female patients. We observed increases in the following for using telehealth services: frequency of annual use per patient (average from 1.41 to 2.26), proportion of users for initial consultation (from 0.2% to 2.2%), and medical expenses (median from 12,550 yen to 15,020 yen).

Regarding the mean values for telehealth, over 90% (12,905/13,618, 94.8% before April 2020; 26,331/28,853, 91.3% after April 2020) of patients received a consultation by telephone. There was an increase in the use of monitoring equipment after the reference time point (from 707/13,618, 2.5% to 2511/28,853, 8.8%). Online consultation was rarely used: Only 0.8% (11/28,853) of the sample used it after the reference time point. For over 90% (12,943/13,618, 95.0% before April 2020; 26,494/28,853, 91.8% after April 2020) of cases, telehealth was used for prescriptions.

The characteristics of medical facilities where telehealth services provided appear in Table 3. The number of medical facilities that provided telehealth before the reference time point was 1007; after that time point, the number increased to 1392 (38.2% growth). Regarding the type of facility, the number of hospitals increased; regarding location, the ratio of services provided to patients within the same prefecture to those provided to out-of-prefecture patients reversed, and the number of services provided to out-of-prefecture patients increased.

Figure 2 presents the density distribution of the frequency of monthly telehealth use and face-to-face visits. Telehealth use showed an increase after the time reference point compared with before; face-to-face care evidenced a decrease.

Figure 3 presents the monthly frequency of telehealth use during the study period. The dashed lines in that figure indicate the ITSA estimation results of a Poisson regression model, adjusted trend as seasonality. We observed an immediate increase in the proportion of telehealth users to beneficiaries after the Japanese government first declared a state of emergency for COVID-19.

We evaluated the immediate increase after the reference time point and the change in the trend of telehealth use using the rate ratio (RR) through the ITSA (Table 4). The RR for overall telehealth use during COVID-19 (April 2020 to September 2021) compared with pre-COVID-19 (January 2017 to March 2020) was 3.23 (95% CI 3.14-3.31). Thereafter, the frequency of telehealth use during COVID-19 was substantially unchanged (change in trend 1.00; 95% CI 1.00-1.01). In the subgroup of users aged over 65 years, the RR for the immediate change was 3.25 (95% CI 3.15-3.34), and the change in the trend was 1.00 (95% CI 1.00-1.00). Similarly, in the subgroup of users aged under 65 years, the immediate change was 2.48 (95% CI 2.35-2.62), and the change in the trend was 1.00 (95% CI 1.00 to 1.01). As shown in Multimedia Appendix 1, no autocorrelation and association with the number of COVID-19 confirmed patients was found for the number of patients who used telemedicine over time.

The results of our sensitivity analysis appear in Table 5. In all cases, the RR and its CI consistently exceeded 1. Without removal adjustment, the AIC was highest at 8390.9; the AIC

was lowest in models with the removal bandwidth at 1 month before and after the time reference point (base model).

Table 2. Characteristics of patients who used telehealth at least once for consultations before and after April 2020.

Characteristics	Before April 2020	After April 2020	*P* value
Unique patient IDs with confirmed telehealth use, n	13,618	28,853	_[a]
Age (years), mean (SD)	73.38 (17.58)	72.26 (18.30)	<.001
Female, n (%)	8569 (62.9)	17,629 (61.1)	<.001
Frequency of telehealth use per user, mean (SD)	1.41 (1.12)	2.26 (2.49)	<.001
Users who used telehealth for initial consult, n (%)	76 (0.2)	622 (2.2)	<.001
Medical expense at the same claims (yen[b]), median (IQR)	12,550 (4450-27,842.5)	15,020 (5940-35,720)	<.001
Type and role of telehealth services, n (%)			
Online	6 (0.4)	11 (0.8)	.29
Monitoring	707 (2.5)	2511 (8.8)	<.001
Telephone	12,905 (94.8)	26,331 (91.3)	<.001
Prescription	12,943 (95.0)	26,494 (91.8)	<.001
Home care for COVID-19[c]	–	213 (0.7)	–
Disease or condition, n (%)			
Anemia	298 (1.8)	502 (1.7)	.20
Arthritis	264 (1.6)	438 (1.5)	.16
Cancer	69 (0.4)	147 (0.5)	.38
Cerebrovascular disease	133 (0.8)	207 (0.7)	.13
Asthma	193 (1.2)	274 (0.9)	.005
Chronic kidney disease	49 (0.3)	98 (0.3)	.73
Coronary heart disease	237 (1.5)	487 (1.6)	.21
Dementia	127 (0.8)	323 (1.1)	.003
Diabetes	386 (2.4)	720 (2.4)	.96
Hyperlipidemia	412 (2.6)	940 (3.1)	<.001
Cardiovascular disease	1471 (9.1)	3162 (10.6)	<.001
Hypertension	377 (2.3)	781 (2.6)	.08
Hyperuricemia	126 (0.8)	252 (0.8)	.52
Spine disorder	533 (3.3)	810 (2.7)	<.001
Digestive system disorder	1791 (11.1)	3488 (11.7)	.08
Mental disease	277 (1.7)	1031 (3.4)	<.001

[a]Not applicable.

[b]US $1 = 118.48 yen on April 1, 2020.

[c]Number of claims based on incentives granted by the Japanese government for telehealth to COVID-19 patients receiving home or overnight care (August 16, 2021); includes both initial consultations and follow-up.

Table 3. Characteristics of medical facilities where telehealth services were used at least once before and after April 2020.

Characteristics	Before April 2020	After April 2020	*P* value
Medical institutions with unique IDs confirmed to have provided telehealth, n	1007	1392	_[a]
Type of facility[b], n (%)			
Clinic	891 (88.5)	1173 (84.3)	.004
Hospital	116 (11.5)	219 (15.7)	
Number of beds, n (%)			
<20	891 (88.5)	1173 (84.3)	.10
20-100	36 (17.9)	61 (19.1)	
100-200	33 (16.4)	67 (21.0)	
200-300	17 (8.5)	33 (10.3)	
300-400	10 (5.0)	14 (4.4)	
400-500	10 (5.0)	16 (5.0)	
>500	10 (5.0)	28 (8.8)	
Clinics without beds, n (%)	806 (80.0)	1073 (77.1)	.09
Location, n (%)			
In the prefecture	552 (54.8)	626 (45.0)	<.001
Out of the prefecture	455 (45.2)	766 (55.0)	

[a]Not applicable.

[b]The Japanese Medical Care Act defines medical institutions with over 20 beds as hospitals and those with fewer than 20 beds as clinics.

Figure 2. Density plot and boxplot of monthly numbers of (A) telehealth and (B) face-to-face consultations before and after April 2020.

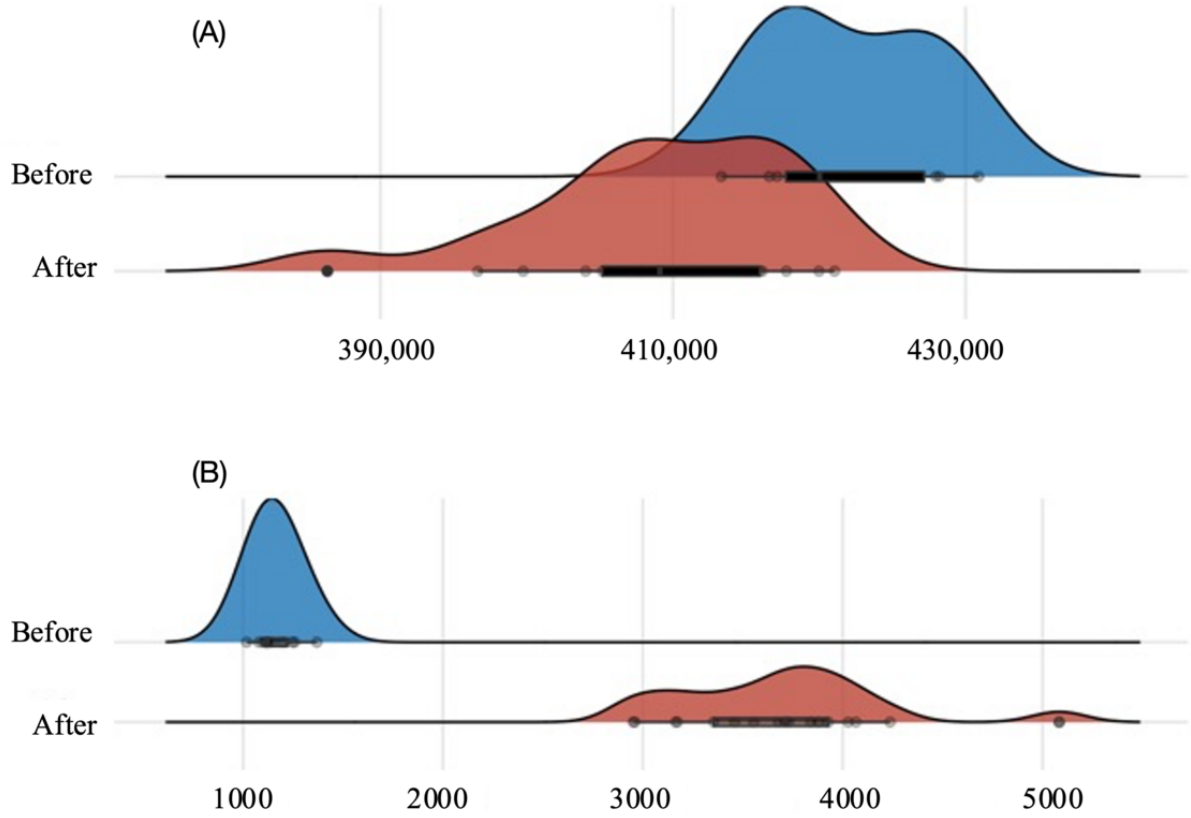

Figure 3. Monthly frequency of telehealth used (scatter plot) by (A) everyone, (B) those aged at least 65 years, and (C) those aged less than 65 years, with Poisson regression adjusted seasonality (dashed lines).

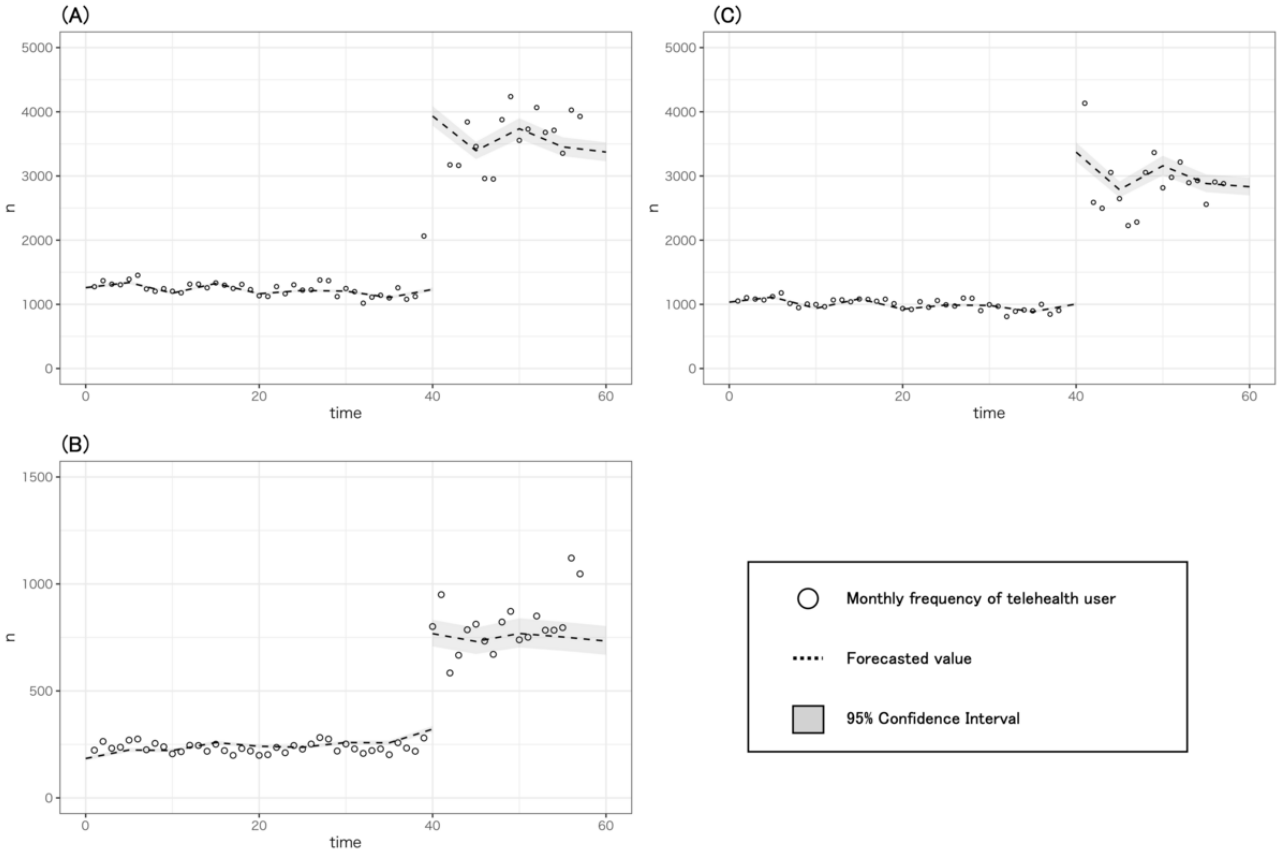

Table 4. Results of the interrupted time-series analysis (ITSA) for the immediate change and changes in the trend.

Subsample	RR[a] (immediate change at reference time point)	95% CI	*P* value	Change in trend	95% CI	*P* value
Telehealth users overall	2.97	2.14-2.31	<.001	1.00	1.00-1.01	<.001
≥65 years old	2.98	2.89-3.07	<.001	1.01	1.00-1.00	<.001
<65 years old	2.93	2.76-3.12	<.001	1.03	1.02-1.03	<.001

[a]RR: rate ratio.

Table 5. Comparison of model estimates with the sensitivity analysis.

Sensitivity case	RR[a]	95% CI	Change in trend	95% CI	AIC[b]
No removal	2.27	2.22-2.32	0.99	0.99-0.99	8390.9
Removal bandwidth = 1 (base model)	2.97	2.14-3.31	1.00	1.00-1.01	1122.3
Removal bandwidth = 2	2.94	2.86-3.02	1.01	1.01-1.02	1106.4
Removal bandwidth = 3	2.98	2.88-3.09	1.01	1.01-1.01	968.5

[a]RR: rate ratio.

[b]AIC: Akaike information criterion.

Discussion

Principal Findings

Table 1 presents the basic information about patients who used telehealth. During the observation period, 13,618 patients (33.71 per 1000 beneficiaries, 18.62 per 1000 outpatients) used telehealth before April 2020, and 28,853 (71.42 per 1000 beneficiaries, 39.46 per 1000 outpatients) did so after that time. An immediate increase after the reference time point was also significantly evident with ITSA (RR 2.97; 95% CI 2.14-2.31). However, no change in the trend was observed (change in trend 1.00; 95% CI 1.00-1.01). Among the patients who used telehealth, there was a higher proportion of women than men. After the reference point, there were increases in the frequency of telehealth use per patient, the number of telehealth users for

initial consultations, and medical expenses. Regarding diseases and conditions associated with telehealth use, we observed an increase in hyperlipidemia, cardiovascular disease, hyperuricemia, and mental disease. Most telehealth services were provided by clinics, but we identified an increase in the number of hospitals using telehealth. We observed an increase in the proportion of telehealth utilization in medical institutions outside Mie Prefecture compared with inside the prefecture.

Recent studies have reported an increase in telehealth use with COVID-19 [17,23]. However, no reports have examined how telehealth utilization has changed in a country such as Japan, where patients have free access to medical care and facilities are abundant but where the government has imposed restrictions on telehealth. With ITSA, this study confirmed the immediate increase in telehealth use after April 2020. However, no following change in the trend was evident with either model. This is not consistent with results from a previous study in the United Kingdom, where universal health coverage is provided through the National Health Service, similar to Japan [24]. When focusing on the Japanese policy strategy for telehealth from the point of view of providers, until at least 2022, telehealth has not spread widely in Japan because face-to-face consultations are more profitable for medical institutions than telehealth. Therefore, to expand the use of telehealth, not only deregulation but also a review of the incentive system are considered necessary. In addition, since deregulation of telehealth was a temporary measure until April 2022, medical institutions' use of telemedicine may have been inhibited. This should also be researched, by extending the observation period.

We should state that our database did not include all patients; employee-insured patients, for example, were excluded. Our database mainly covered the population who were older than 65 years, which allowed us to capture the impact of telehealth utilization on this group. Nevertheless, we obtained consistent results when the ITSA was conducted with a subgroup analysis—with patients divided into those aged under 65 years and those aged 65 years and older. Whether similar results can be obtained for the entire population younger than 65 years of age is a matter for additional analysis.

We found that telehealth use was mostly by telephone and for prescriptions. Such utilization has the potential to serve as an alternative to conventional consultations, but additional verification of patient safety is required. We observed that online consultation was rarely used by public insurance services. In the Japanese health care system, telehealth is mainly limited to follow-up purposes, and it is likely that telephone consultation was chosen because many cases had little need for face-to-face consultation. Since online consultation is a relatively new system in Japan, having been issued in 2018, it is necessary to continue to investigate its prevalence. In addition, the Japanese government's deregulation of telehealth in April 2020, which was announced as a temporary measure, may have slowed the increase in the number of medical institutions intending to adopt telehealth or caused them to defer decisions about it.

With respect to telehealth use, we observed changes in patient characteristics and in disease composition as well as increased medical costs after the time reference point. Our results suggest that the Japanese government should not only examine the spread of telehealth in terms of the increased number of cases but also focus on changes in the characteristics of patients who use telehealth. If drug treatment becomes the main treatment strategy, medical resource allocation should be considered in conjunction with pharmacy allocation. The complementary role of telehealth should also be evaluated: It is difficult to provide only telehealth when physical treatment, such as nutritional guidance and rehabilitation, is involved.

Japanese patients are not generally treated by primary care physicians or general practitioners; not all patients have specific physicians they consult on a regular basis. Given that more patients are using telehealth for initial consultations, it is necessary to promote a communication infrastructure that offers the following: vetting of eligible patients, clarification of criteria for the type of treatment (changing to face-to-face consultations), and collection of the required information. With regard to the type of medical institutions providing telehealth, the number of hospitals has increased; thus, the government needs to design a system that takes into account changes in providers. The increasing use of medical institutions outside the patient's prefecture of residence suggests that access to telehealth is affected by factors other than geography.

Limitations

One strength of the present study was identifying the use of telehealth and how it changed after COVID-19 in part of Japan, which has free access to medical care and abundant medical facilities. However, several limitations of this study deserve mention. First, this was an observational study limited to Mie Prefecture. Therefore, caution should be exercised regarding the applicability of our results to the general population; our results should be verified for Japan as a whole. Second, this study did not cover all insured individuals, which may have led to selection bias. In particular, it should be noted that our results strongly reflected the trends among older adults; there was a lack of information on telehealth use among people enrolled in employee insurance (ie, the population of working age). Third, several studies have reported better outcomes in improving treatment adherence and preventing serious events with telehealth use [25-27]. Longer observation periods than in the present study would be needed to determine the incidence of events that could serve as medical outcomes; thus, this is a matter for future study. Finally, we observed changes in patient and health care provider characteristics and trends only as a temporary state. However, it is possible that circumstances after COVID-19 will continue to change dynamically. Therefore, further data collection and analysis over a longer period are needed.

Conclusions

The observations of this study from January 2017 to September 2021 indicate that telehealth use temporarily increased after COVID-19; however, the diffusion trend remained unchanged. The attributes of patients who used telehealth and the medical institutions that provided it underwent change: Decision makers for related policies need to design their systems in light of this environment.

Acknowledgments

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Data Availability

The data set can be utilized for limited use, and its sharing with third parties is not allowed but, if needed, will be shared on request with the permission of the regional insurers in Mie, Japan.

Conflicts of Interest

None declared.

Multimedia Appendix 1
Supplemental material.
[DOCX File , 111 KB - ijmr_v11i2e39181_app1.docx]

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Abbreviations

AIC: Akaike information criterion
ICD-10: International Classification of Diseases 10th Revision
ITSA: interrupted time-series analysis
RR: rate ratio

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Original Paper

An Assessment of the Potential Benefits of Video Consultation in the Emergency Department: Mixed Methods Study

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Abstract

Background: District general hospital emergency departments may refer patients to a tertiary center depending on the information available to a generalist clinician in discussion with a specialist team. If there is uncertainty, the lowest-risk strategy is often to transfer the patient. Video consultation allowing the specialist team to see and talk to the patient and local clinician while still in the emergency department could improve decision-making for patient transfer.

Objective: The aim of this study is to assess the potential benefit of real-time video consultation between remote specialists and emergency department patients and clinicians across all specialties.

Methods: Detailed patient data were collected prospectively for 6 months (between January 16, 2012, and July 15, 2012) on all patients presenting to a district general hospital emergency department who required input from a specialist team at the nearest tertiary care center. These patients were discussed retrospectively with the specialist teams to determine whether videoconferencing could have benefited their management. The logistics for the use of videoconferencing were explored.

Results: A total of 18,799 patients were seen in the emergency department during the study period. Among the 18,799 patients, 413 referrals (2.2%) were made to the tertiary center specialist teams. A review of the patients transferred indicated that 193 (46.7%) of the 413 patients who were referred might have benefited from video consultation (193/18,799, 1% of all patients). If the specialist team could be accessed via videoconferencing only while a senior member was available in the hospital (8:00 AM-10:00 PM), then a maximum of 5 patients per week across all specialties would use the equipment. If 24-hour specialist access was available, this would increase to 7 patients per week.

Conclusions: In regions where there is direct transportation of patients by ambulance to specialist centers and there is a regional picture archiving and communication system in place, video consultation between emergency department patients and specialists has limited potential to improve patient management.

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KEYWORDS

emergency medicine; telemedicine; health service research; eHealth; emergency; video consultation; remote; specialist; video conferencing; videoconferencing; video conference; telehealth; benefit; patient management

Introduction

Tertiary-level specialist input may be needed for patients in a district general hospital (DGH) emergency department (ED) to help with diagnosis or provide complex care beyond the capability of the DGH. Communication is usually done by telephone and decisions are based on reported history, examination, and preliminary investigations, often performed by a junior trainee. The specialist has few options for obtaining further reliable information at this stage and there is pressure to make a quick decision. The safest option is usually a patient transfer to the tertiary center, but that interrupts the continuous care of the patient, removes them from full resuscitation facilities during transfer, and isolates them from family and friends. The inappropriate transfer of patients also wastes resources in the tertiary center and ambulance service. There are other patients for whom the need for early specialist input may go unrecognized and, as a result, they would experience poor outcomes.

These difficulties in interhospital communication and patient transfer may be helped by the use of real-time videoconferencing (telemedicine) between the patient and local clinician at one end and the specialist clinician at the other. This allows the specialist to see the patient, ask focused questions relating to their condition, and observe specific aspects of the examination performed by the on-site clinician. This may confirm the need for transfer but allow it to be timed more appropriately, perhaps 1 day later, when the patient can be admitted directly to the specialist ward and treated on a planned elective list. Alternatively, it may lead to continued care in the secondary care hospital with advice from tertiary care. If specialist input can be accessed easily in the ED, then any patients for whom there is uncertainty in the decision to transfer could be assessed in this way with the aim of optimizing management.

Telemedicine, via videoconferencing, has been used to facilitate referrals between primary and secondary care, usually for the diagnosis and management of nonurgent conditions [1,2]. It has also allowed major EDs to provide support to smaller units in remote settlements and minor injury units [3-7]. Tertiary-level specialties have set up their own telemedicine services, particularly in cardiology and stroke medicine. The cardiology systems initially used the transmission of prehospital electrocardiograms performed by paramedics to enable early treatment with intravenous thrombolysis for myocardial infarction before arrival at the hospital [8]. This same system can now be used to divert an ambulance to a tertiary-level center to enable quicker percutaneous coronary revascularization and better outcomes [9-11]. Specialist stroke services have developed links with secondary care for early audiovisual patient assessment, with an aim of starting intravenous thrombolysis on-site within the 3-hour “therapeutic window” after a stroke [12-15]. These studies have shown that the audiovisual assessment of acute stroke compares well with conventional consultation [15]. Other areas where telemedicine has helped emergency care include plastic surgery [16,17], ophthalmology [18-20], and ear, nose, and throat (ENT) [21,22].

Single-specialty telemedicine links to a DGH may have a limited life expectancy if treatment protocol changes. It becomes redundant, for example, when patients who have had a stroke are transported directly from their homes to a tertiary center for intraarterial thrombolysis. Treatments change with time across all specialties and telemedicine is merely a tool to facilitate change. It will have an expanding role in some areas but a limited role in others. Within a DGH ED, therefore, telemedicine facilities are likely to be more useful if used flexibly across a range of conditions to communicate with specialist care clinicians. They would no longer be subject to the vagaries of a single specialty but could evolve with the development of techniques for aiding distant diagnosis, such as real-time ultrasound examination [23] and with new treatments which might be supported in a DGH.

The Horton General Hospital (HGH) ED transfers approximately 800 patients per year to specialties in Oxford. The Interhospital Telemedicine Study was designed to collect data on HGH ED patients requiring specialist input in the 6 months before and 6 months after the introduction of video consultation to assess the impact of the intervention. The analysis of the data from the first 6 months indicated that the impact would be minimal, and it was decided that the study should be terminated early. The results of the study are presented here.

Methods

Hospitals Involved in the Study

The HGH is a 277-bed DGH in Banbury, United Kingdom, serving the population of North Oxfordshire, South Warwickshire, and South Northamptonshire. It provides the following services: general medicine and surgery, cardiology (noninterventional), obstetrics and gynecology, and orthopedics; the HGH also has outpatient clinics but no full-time coverage for ophthalmology, plastic surgery, urology, and vascular surgery. It has a 2-bed intensive care unit. It is part of the Oxford University Hospital (OUH) Trust.

The Oxford services of the OUH are based in the John Radcliffe Hospital (JRH) and Churchill Hospital, 3 miles apart and 26 miles from Banbury. Most emergency provision is on the John Radcliffe site. The Oxford services provide tertiary-care services to the northern part of the South Central Regional Health Authority.

The Oxford and Banbury hospitals share a common picture archiving and communication system (PACS) so that radiological images from HGH can be readily viewed by Oxford clinicians. Local ambulance protocols are in place to take patients experiencing myocardial infarction or stroke directly from their homes to the OUH to ensure appropriate early intervention.

Participants

All patients for whom specialist advice from the JRH was sought after assessment in the HGH ED, excluding those who had a clear diagnosis which required rapid transfer to the JRH, such as a ruptured abdominal aortic aneurysm, were included in this study.

Ethics Approval

Ethics approval for the project was sought from the Oxfordshire Research Ethics Committee. The Research Ethics Committee advised us that the project was undertaking a service review rather than research and therefore permission was not required.

Data Collected

A research manager and research nurse reviewed the notes of all patients about whom the JRH-based specialist team was contacted within 36 hours of the consultation between the HGH ED and the JRH-based specialist team. The research manager and research nurse collected the following data (see Multimedia Appendix 1 for the full data set):

- Age, sex, major comorbidities
- Date and time of the initial HGH ED assessment and transfer (if any) to JRH
- Next step in the patient pathway from the ED

Background data were collected over the same 6 months on the total number of patients seen in the HGH ED and the total number admitted to the HGH from the ED

Data Analysis

Data were collected on the total number of presentations to the HGH ED, and admissions to the HGH and transfers to the JRH were collated under specialty headings with subgroups according to the nature of patient presentation within those groups.

Focus Group Discussion

During and after the 6-month data collection period, discussions were held with the specialist teams who received the majority of referrals. These meetings included senior and junior medical staff and senior nurses and involved a review of the data collected on patients referred to each specialty to determine the reasoning and basis for the decision to transfer a patient or not. The meetings also aimed to determine the ways in which video consultation could have provided the potential benefit of teleconsultation.

The data on admissions to HGH were discussed with the HGH consultants most involved with this activity to determine if they perceived any potential advantage of teleconsultation in the ED before admission.

Discussions were also held with HGH ED staff and direct observations were made of activity in the department to understand the logistics of using teleconsultation.

Results

Patient Transfers

Between January 16, 2012, and July 15, 2012 (27 weeks), 18,799 patients were seen in the HGH ED. Of these 18,799 patients, 413 (2.2 %) were transferred to the JRH in Oxford and 3659 (19.5 %) were admitted directly to the HGH (Table 1 and Table 2).

Data on the specialties to which HGH admissions from the ED had occurred were analyzed for the first 3 months of this period. A total of 1539 patients were admitted to all specialties, with most being admitted to general medicine, general pediatrics, gerontology, and cardiology (Table 2).

Table 1. Data on transfers among patients from the Horton General Hospital emergency department to the John Radcliffe Hospital in Oxford, United Kingdom.

Specialty	Patients (n=413), n
Plastic surgery	98
Ophthalmology	88
Ear, nose, and throat	75
Pediatrics	39
Oral and maxillofacial surgery	32
Neurology	19
Vascular surgery	15
Urology	13
Stroke medicine	10
Cardiac medicine	9
Trauma	7
Renal medicine	2
Colorectal surgery	1
Gynecology	1
Miscellaneous	4

Table 2. The most common types of admission from the Horton General Hospital emergency department.

Specialty	Patients (n=1539), n (%)
General medicine	373 (24.2)
General pediatrics	213 (13.8)
Gerontology	162 (10.5)
Cardiology	142 (9.2)
Chest medicine	123 (8)
Others	526 (34.2)

Focus Group Discussions

Specialty Groups

Plastic Surgery and Oral and Maxillofacial Surgery

Most transfers to these specialties were related to facial or hand fractures. There are protocols indicating which patients should be transferred, and most decisions were based on radiology images, which are accessed easily from both the HGH and Oxford.

Most facial lacerations were sutured at the HGH and there are guidelines on transfer. There appears to be no advantage to transmitting an image or holding a videoconference with the patient, except in the case of pediatric patients, for whom having an image would allow the surgical closure to be planned without disturbing the dressings beforehand. However, digital photographs can be taken and stored on Photoweb (Photoweb SAS) within the Trust in this situation. Occasionally images of intraoral lacerations might have assisted management decisions but generating high-quality images would be extremely difficult.

Ophthalmology

Most patients seen in the HGH ED had trauma to the front of the eye. There is a slit lamp available on-site and 3 ophthalmology clinics at the HGH during the week. Most patients were treated on-site and followed up with within 48 hours in-clinic if necessary. The few cases which needed transfer were discussed on the phone and the clinical opinion was that neither a direct detailed history from the patient (via a videoconference) nor video or still images would help in management decisions.

Ear, Nose, and Throat

Most transfers to ENT occurred because of persistent epistaxis. There appeared to be no advantage to videoconferencing or having further images sent from the HGH in these circumstances. Occasionally, patients presented with compromised airways at the HGH ED. These cases are best managed by the trained senior ED staff immediately available on-site and did not need immediate support from ENT specialists in Oxford, although some patients were transferred for subsequent care. Again, there seems to be no advantage to videoconferencing in these circumstances.

Pediatrics

Transfers to pediatric specialists occurred for a wide variety of problems, usually because the child required sedation and intubation. Videoconferencing provided no obvious advantage in these cases.

HGH Services

We also discussed with the HGH stroke physicians and cardiologists whether the management of patients they admitted to the HGH could be improved by videoconferencing from the ED. There are clear ambulance protocols for stroke and chest pain, which lead to most patients with a short history of stroke or myocardial infarction being transported directly to Oxford for emergency intervention. There are clear protocols for managing patients who are seen in the HGH ED. Very occasionally, there will be an unusual presentation of stroke, but this can usually be managed with phone advice from the JRH. There did not appear to be a role for videoconferencing here.

HGH ED Staff

Concerns were raised over the nature of the hardware required for video consultation. The initial plan had been to use a trolley-mounted videoconferencing unit (Poly, Poly Inc) that could be moved to the patient's trolley in the ED to provide the clinician at the JRH with a high-resolution image of the patient via a controllable unit with a mounted camera. It became clear from observation and discussion that moving such a large unit into a confined cubicle area would take time and effort and would be inconvenient for staff. It could only be justified if there was a clear and immediate benefit to patient management. We therefore looked at alternative technology for providing videoconferencing and considered tablets and smartphones. Unfortunately, using a small and easily portable device to improve the accessibility of videoconferencing also means that the device could be easily removed from the department, and there were concerns over equipment retention and the expenses of regular replacement

There were also concerns about developing familiarity with the teleconsultation system and making it a part of normal practice.

Logistical Problems

The communication of clinical information must be secure and confidential. There is broadband communication between the HGH and Oxford-based hospitals, which can be used for videoconferencing. At present, we do not have the ability to extend this to clinicians outside the hospital (ie, at home). If we implemented videoconferencing with a specialist team in JRH, where the senior team members return to their homes at night, it is only likely to be effective (ie, involve a senior, experienced

member of the team) during the day (possibly from 8:00 AM-10:00 PM).

We analyzed all 413 transfers to the JRH over 6 months. Only 46.7% (193/413) of transferred patients had a condition where videoconferencing or photography might have helped their management. Of the 413 transferred patients, 136 were seen between 8:00 AM and 10:00 PM and could potentially have benefited from videoconferencing. This is equivalent to only 5 patients per week across the range of specialties cited previously. If a video specialist link was available 24 hours per day, then 7 patients per week might have benefited from it. There are approximately 12 middle-grade physicians employed in the HGH ED between 8:00 AM and 10:00 PM each week; therefore, over the course of 6 months, each physician would see 13 patients (1 every other week) for whom videoconferencing or imaging might support specialist advice from the JRH. It seems unlikely that these physicians would consider using videoconferencing with so few cases per physician. The specialist team at the JRH could ask for videoconferencing but, again, it would be used only occasionally by each individual within the specialist team. Unless an intervention is used regularly by the individuals involved, with some tangible benefit to its use, it seems unlikely that it would be used at all.

Discussion

Principal Findings

This study has shown that in a well-run DGH ED with regular links to a tertiary center, the common presentations which require specialist advice can be managed with the use of protocols regarding patient transfer, supplemented by radiological image transmission (PACS) and image management. This study has also shown that, contrary to expectation, a specialist history and/or real-time patient imaging is rarely critical in deciding on management. Redesigning patient pathways from home, so that ambulances go directly to a major center for certain categories of patients has also had a major impact on delivering patients to the appropriate location for assessment and treatment.

Comparison With Prior Work

The data indicate that potential opportunities to use telemedicine for referral are few in a DGH (up to 7 per week), and at such low levels, it is unlikely that the required skills would be maintained or that use would persist. This matches findings from other studies; one review found relatively few EDs (146 out of 4507 respondents) in the United States were using telemedicine for the transfer of patients [24]. Other reviews indicate that the majority of reports on the use of telemedicine for transfer in emergency medicine are from pilot projects that report favorably on user experience during the project, but there is no assessment of the potential for use [25]. Further reviews of the use of telemedicine in EDs conclude that video consultation has significant potential but there is still a lack of evidence supporting improved patient outcomes [26] and feasibility [27].

However, we have been unable to find any reports providing an audit of the potential for the use of telemedicine in making referrals from a DGH ED to a tertiary care center for the comparison of results.

Future Directions

Changes in patient management in the future may create opportunities for the use of videoconferencing between patients in the ED and specialist teams, but systems need to be developed that combine ease of access with security measures to retain equipment. The cost-effectiveness of any such intervention would rapidly decline if tablets or phones had to be frequently replaced. Such systems should also seek to improve specialist access to videoconferencing through the flexible use of different devices (eg, smartphone, tablet, desktop PC, or laptop) in different sites (operating room, office, home) to allow 24-hour service provision and the engagement of clinicians.

Limitations

The study has the limitation that it was conducted in a single DGH in England and was therefore influenced by local policies for emergency admission (eg, patients known to have experienced a stroke are taken directly to a specialist stroke center), and the distance between the hospitals was relatively small. However, experiences will vary in areas with different local policies for referral and different influences of geography on location and distance between hospitals.

Conclusions

We have collected detailed information on the patients transferred from a DGH ED to a specialist center and admitted locally over a 6-month period. We have used that data to explore the potential for the use of videoconferencing with the specialists and local clinicians involved. Additionally, we have shown that the use of videoconferencing between patients and specialists in regions where there is a policy of direct transportation of patients by ambulance to specialist centers as well as a regional PACS has limited potential when used for the common presentations in a DGH ED. Further research is required to determine the potential for use in other locales.

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Conflicts of Interest

None declared.

Multimedia Appendix 1
Data collected on each patient for whom specialist advice was sought.
[DOC File , 34 KB - ijmr_v11i2e36081_app1.doc]

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Abbreviations

DGH: district general hospital
ED: emergency department
ENT: ear, nose, and throat
HGH: Horton General Hospital
JRH: John Radcliffe Hospital
NIHR: National Institute for Health and Care Research
OUH: Oxford University Hospital
PACS: picture archiving and communication system

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Original Paper

Barriers and Facilitators Influencing Real-time and Digital-Based Reporting of Adverse Drug Reactions by Community Pharmacists: Qualitative Study Using the Task-Technology Fit Framework

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Abstract

Background: Medication use can result in adverse drug reactions (ADRs) that cause increased morbidity and health care consumption for patients and could potentially be fatal. Timely reporting of ADRs to regulators may contribute to patient safety by facilitating information gathering on drug safety data. Currently, little is known about how community pharmacists (CPs) monitor, handle, and report ADRs in Australia.

Objective: This study aimed to identify perceived barriers to and facilitators of ADR reporting by CPs in Australia and suggest digital interventions.

Methods: A qualitative study with individual interviews was conducted with CPs working across Victoria, Australia, between April 2022 and May 2022. A semistructured interview guide was used to identify perceived barriers to and facilitators of ADR reporting among CPs. The data were analyzed using thematic analysis. We constructed themes from the CP-reported barriers and facilitators. The themes were subsequently aligned with the Task-Technology Fit framework.

Results: A total of 12 CPs were interviewed. Identified barriers were lack of knowledge of both the ADR reporting process and ADR reporting systems, time constraints, lack of financial incentives, lack of organizational support for ADR reporting, inadequate IT systems, and preference to refer consumers to physicians. The proposed facilitators of ADR reporting included enhancing CPs knowledge and awareness of ADRs, financial incentives for ADR reporting, workflow-integrated ADR reporting technology systems, feedback provision to CPs on the reported ADRs, and promoting consumer ADR reporting.

Conclusions: Barriers to and facilitators of ADR reporting spanned both the task and technology aspects of the Task-Technology Fit model. Addressing the identified barriers to ADR reporting and providing workplace technologies that support ADR reporting may improve ADR reporting by CPs. Further investigations to observe ADR handling and reporting within community pharmacies can enhance patient safety by increasing ADR reporting by CPs.

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KEYWORDS

pharmacovigilance; adverse drug reaction; pharmacist; Task-Technology Fit; digital health

Introduction

Background

Pharmacovigilance (PV) is defined by the World Health Organization as the "science and activities relating to the detection, assessment, understanding, and prevention of adverse events or any other drug-related problem." The collection and reporting of safety data commence from the initial stages of drug development, throughout the clinical trials, and continue once a medicine is registered and marketed around the world, that is, postmarketing surveillance [1,2]. Medication use can result in adverse drug reactions (ADRs) that cause increased morbidity and health care consumption for patients and could potentially be fatal. In Australia, approximately 7.2% to 11% of hospital admissions are ADR related [3]. Globally, studies have reported ADR-related hospital admissions ranging from 3.6% to 15.6% [4,5]. The health care costs of ADRs may be high owing to complexities associated with ADR treatment, with a reported mean length of hospital stay increasing from 8 to 20 days [6]. In Australia, the annual cost of medication-related problems was reported as Aus $1.4 billion (US $900,207) in the Pharmaceutical Society of Australia's medication safety report (2019) [7].

In 2017, the Therapeutic Goods Administration (TGA) of Australia received approximately 18,600 reports of adverse drug events [8]. Among the ADRs reported to the TGA, approximately 53.75% (n=9998) were from sponsors, that is, marketing authorization holders; 18.5% (n=3441) from state and territory health departments; 10.1% (n=1879) from hospitals and hospital pharmacists; 6.45% (n=1201) from consumers, that is, the public; 6.29% (n=1170) from community pharmacists (CPs); 3.11% (n=579) from general practitioners; and 1.93% (n=359) from other sources [8]. Increased participation of CPs in ADR reporting is important, as CPs are usually the first point of contact regarding medication-related issues and the most frequently visited health care professionals (HCPs) in Australia [9].

As of May 9, 2022, there were 5822 community pharmacies across Australia and, on average, a consumer is estimated to visit a community pharmacy approximately 18 times each year in metropolitan, rural, and remote locations [10,11]. In metropolitan cities, 97% of the consumers are within 2.5 km of a pharmacy and in regional or remote areas, 65% of the people are within 2.5 km of a pharmacy [10]. Annually, more than 462 million patients visit community pharmacies [11,12]. CPs are the most frequently accessed and visited of HCPs, with almost 218.3 million prescriptions dispensed through the Australian Pharmaceutical Benefits Scheme in 2021 [10]. As a general aspect of community pharmacy practice, CPs interact with and may counsel consumers about their medications, adverse effects, or other medicine-related issues that the consumer may have experienced [7,13].

In Australia, CPs are expected, as part of their training, to possess medication counseling skills and professional knowledge on topics including pathophysiology, therapeutics, disease prevention, management, and treatment within their scope of practice [13,14]. Patients or consumers can visit CPs without needing an appointment, offering professional health management services that can complement the services of other health professionals, for example, CPs triage consumers and refer them to other health professionals, as necessary. This may decrease the public's demand for services in congested emergency departments and medical clinics [14]. Such support is especially important during a health crisis such as the COVID-19 pandemic. Therefore, in Australia, CPs are ideally placed to provide a person-centered solution to support the public regarding their health concerns [7,14].

As noted by Li et al [9,15], there is very little literature on the perspectives of CPs on ADR reporting in Australia. The barriers to ADR reporting by CPs in Australia have not been extensively investigated, and to our knowledge, only 1 study concerning the perspectives and knowledge of reporting of ADR by Australian CPs has been identified [9,15]. In the study by Li et al [9], 43% (n=101) of the respondents agreed that a lack of time within their professional practice limited their reporting of ADRs, and 65% (n=150) agreed that remuneration would encourage them to report ADRs. The integration of autopopulation features within the dispensing software was identified as an efficient way to facilitate ADR reporting by CPs [9]. Such findings are also consistent with those of studies in other countries [16-18].

Leveraging Technology in ADR Reporting

The incorporation of technology into health care provisions is currently prevalent [19]. As an example, the COVID-19 pandemic–related lockdowns acted as a *catalyst* that accelerated digital health transformation through the introduction of telehealth and electronic prescribing [11]. To maximize the benefits of incorporating technology into the practice of health professionals (including CPs), the service provided by the technology should reasonably match the practice requirements of the clinician [11,20]. Therefore, it is also necessary to understand the factors that may affect an end user's workflow tasks and information requirements [20]. A 2020 systematic review of interventions to improve ADR reporting concluded that there was a lack of consideration of theoretical frameworks in the design of interventions [16]. Furthermore, there is also a lack of end-user input (ie, HCPs) in the design of ADR reporting systems, with only the needs of regulatory agencies taken into account [21].

Knowledge gaps exist regarding ADR reporting by CPs in Australia and the need for IT support within the ADR reporting domain. As such, research is needed to better understand the factors influencing ADR reporting within the CPs workflow and related digital intervention needs. This study aimed to identify the barriers to and facilitators of ADR reporting by CPs, which may inform the design and development of tailored technological interventions.

Methods

Overview

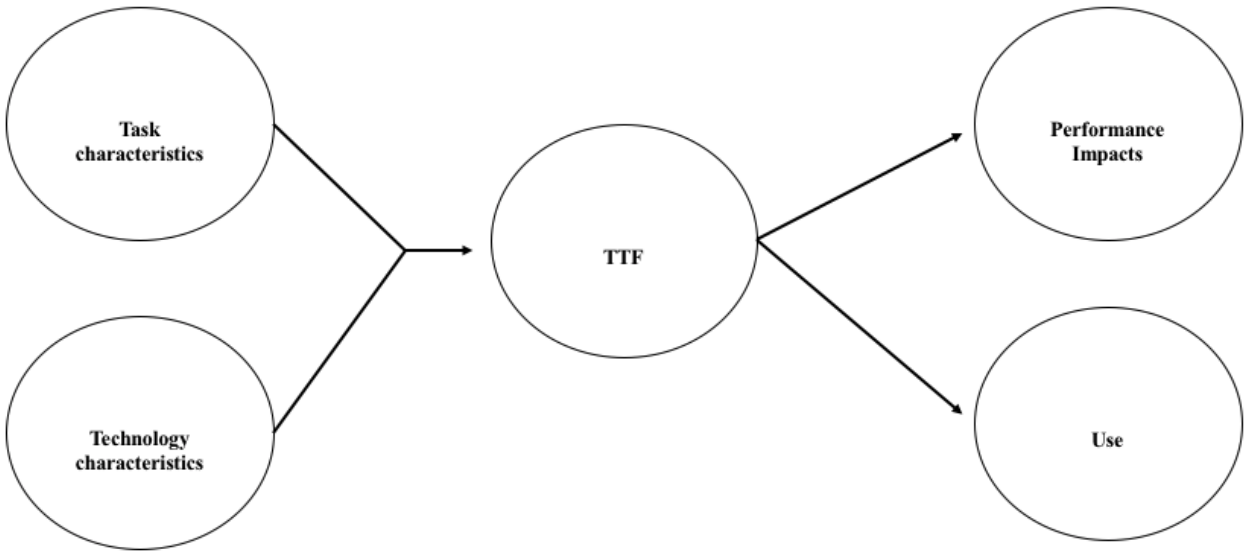
A qualitative study with semistructured interviews was conducted with CPs (N=12) working in community pharmacies across Victoria, Australia, between April 2022 and May 2022. To understand knowledge constructed through a pharmacist practice lens, the underlying epistemology stemmed from the social-constructivist paradigm. Purposive sampling was used to select eligible participants working in community pharmacies listed on the Pharmacy Guild of Australia and Health Direct website. Participants were invited by email to recommend other CPs for participation. Eligible participants were sampled according to the modified Monash (MM) category. The model measures rural remoteness and population size on a scale of MM1 to MM7, where MM1 is a major city and MM7 is very remote [22]. A qualitative study design was used to highlight the individual and system-related factors that influence ADR reporting among CPs. The classification of barriers and facilitators associated with ADR reporting was mapped to 2 target domains of a sociotechnical framework.

Other studies have discussed interventions to improve ADR reporting among health professionals in different countries [15,16]. However, it is important to note, the rationale for selecting these interventions may not have a theoretical base [16,23]. Therefore, it is necessary to understand the ADR reporting behavior of CPs using a well-defined theoretical approach [16]. Interventions are not uniform, that is, an intervention applied in one setting may not be appropriate for another health setting, and there is a need for stronger evidence that guides the selection of relevant and comprehensive interventions [24].

Theoretical Model

Researchers have used technology adoption models and diffusion theories to build a foundation for studies to understand innovation adoption and diffusion [25]. Technology has become a fundamental aspect of our society and is being embedded within every aspect of health care delivery, with a shift toward a digital health care ecosystem [11]. HCPs' behavior in reporting ADRs can be influenced by different factors, including individual characteristics and those that involve the external environment [26]. As such, the Task-Technology Fit (TTF) theory provides a theoretical lens and guidance for research (Figure 1) [26,27].

Figure 1. Task-Technology Fit (TTF) theory [27].



Task characteristics refer to the attributes of a task that can be executed using information communication technologies to satisfy work practice needs (eg, dispensing a prescription or ADR reporting). Tasks can vary in several dimensions, including task nonroutineness, task interdependence, and time criticality. The users' workflow and environment are also key considerations when assessing the "Fit" [27].

Technology characteristics refer to the tools used by individuals to carry out their tasks. Aspects of technology tools may influence technology use and user perceptions. The TTF model considers the importance of fitting the functionality and attributes of technology to the demands imposed by individual needs. These tools can either be hardware or software [28].

The TTF model has been applied in health care settings where businesses require technology solutions [29]. Because this research also sought to explore strategies to implement innovative technologies to facilitate ADR reporting, the TTF model offered guidance when developing the semistructured interview questions and categorizing identified themes [11].

Data Collection

All participants were asked the same semistructured questions, and appropriate probing questions were used when necessary to draw out information for the study from each respondent. They were also given the freedom to express additional views on topics discussed at the end of each interview session. Participants were informed about the purpose of the study, which was not to audit their practice but to understand their perceptions

of the problems of spontaneous ADR reporting and ways to improve the current system in place. The research team developed an interview guide during several rounds of discussions. The questions were categorized according to the TTF model to cover the relevant domains. A total of 2 pilot interviews with CPs were conducted to test the interview guide for comprehensibility and clarity. Participants provided feedback on the interview guide, and after minor adjustments, a final version was made. Each interview session lasted approximately 20 to 50 minutes and was conducted by the researcher at a place and time convenient for the pharmacist, mostly via a web-based video, using Microsoft Teams, or face to face in a private area within the premises where the pharmacist practiced. The interviews were audio recorded and transcribed verbatim, automatically, using the Otter.ai transcription service. The researcher then listened to the tapes and manually rechecked the transcripts line by line for accuracy and removed any identifying information. We continued to collect data until no new themes related to the research questions could be identified.

Ethics Approval

Before conducting the interviews, all participants provided informed written consent to participate in the study and were advised that the information provided, although deidentified, could be used for publication. Participants' demographic data were collected using a self-administered questionnaire attached to the consent form. All procedures were in accordance with Australia's National Statement on Ethical Conduct in Human Research (2018). This study was approved by the Swinburne University of Technology Human Research Ethics Committee (reference 20214304-6249).

Data Analysis

Thematic analysis began once the interviews were completed using NVivo (version 12; QSR International) software. Initially, open codes were generated inductively from participants' descriptions of their experiences in reporting ADRs and the barriers to or facilitators of reporting. Following the initial coding of the transcripts, preliminary themes that captured information relevant to the research questions were generated. This process involved identifying patterns within the data, including recurring ideas, perspectives, and descriptions that depicted each participant's context and perspective. The final analysis focused on the key themes constructed from the interviews and were subsequently mapped to the TTF model. Data concordance was verified by NW and RM, researchers with extensive experience in public and digital health research. Key themes were discussed with the research team that included JFT and RAY, clinicians with expertise in quality use of medicine and drug safety. The interviews concluded when no additional themes could be identified and mapped to our theoretical framework.

Results

Overview

After interviewing 12 participants, including 6 (50%) CPs from MM1 (metropolitan areas or major cities), 5 (42%) from MM2 (regional centers), and 1 (8%) from MM4 (medium rural town), interviews were concluded. No participants were interviewed from MM3 (large rural towns), MM5 (small rural towns), MM6 (remote communities), or MM7 (very remote communities) per the MM category described in Multimedia Appendix 1. The demographic characteristics of the participants are presented in Table 1.

Table 1. Demographic characteristics of the community pharmacists (N=12).

Demographics	Participants, n (%)[a]
Sex	
Male	7 (58)
Female	5 (42)
Pharmacist age (years)	
20-25	—[b]
26-35	10 (83)
36-45	2 (17)
46-55	—
56-65	—
66-75	—
Employment status	
Supporting pharmacist	2 (16)
Pharmacist in charge	5 (42)
Manager	5 (42)
Owner	—
Pharmacist experience in community pharmacy (years)	
<1	—
1-2	4 (33)
2-4	—
5-10	5 (42)
>10	3 (25)
Pharmacist education level	
Bachelor	1 (8)
Honors	4 (33)
Graduate certificate	1 (8)
Graduate diploma	1 (8)
Master	5 (42)
PhD	—
Pharmacy's average number of prescriptions per day	
0-50	1 (8)
51-150	3 (25)
151-250	2 (17)
251-350	3 (25)
351-450	1 (8)
451-550	—
>550	1 (8)
Not disclosed	1 (8)
Number of hours working in community pharmacy per week	
<10	2 (17)
11-20	—
21-30	—

Demographics	Participants, n (%)[a]
31-40	4 (33)
>40	6 (50)
Pharmacy's classification of rural rank[c]	
MM1[d]	6 (50)
MM2	5 (42)
MM3	—
MM4	1 (8)
MM5	—
MM6	—
MM7	—

[a]The sum of percentages may not be 100%, as the values were approximated to the nearest tenth.

[b]Not available.

[c]Refer Multimedia Appendix 1.

[d]MM: modified Monash.

All participants reported capabilities in identifying drug interactions or side effects during their daily practice; however, most were not accustomed to the conscious practice of PV, that is, ADR monitoring, handling, and reporting. Of the 12 participants, 2 (17%) had reported 1 ADR in the past 12 months, both relating to a COVID-19 vaccination, and 2 (17%) recalled completing at least one ADR report relating to medications over the past 5 to 10 years. Conversely, other participants (8/12, 66%) had never reported an ADR to a state or regulatory authority. Three major themes were identified in our results: (1) poor knowledge of PV, (2) low awareness of ADR reporting, and (3) work environment or resources influencing ADR reporting.

Overall, participants reported having little to no training in PV at the university or postuniversity level. All participants acknowledged that education could improve their awareness about ADRs and ADR reporting:

> *I don't think I learned about it in university and I've been working since second year i.e. in community pharmacy. None of the pharmacists I've seen ever makes a reporting of adverse reaction.* [CP3]

> *I really don't think any of the pharmacists think about it to be honest, because it's not something you're trained to do, and you're not incentivised to do it. It's not part of the workflow.* [CP10]

According to 17% (2/12) of reporting pharmacists with experience working outside the community pharmacy sector, lack of education and understanding of ADRs is a common factor:

> *In terms of looking at the undergraduate and registration year, I don't think it teaches much, in particular, understanding the differences between side effects, adverse drug events, and adverse drug reactions.* [CP5]

> *I had no idea what that word meant. When I was working in the pharma industry, I had all these SOPs to read on pharmacovigilance and I'm like, "what is that?" I hope it's part of the syllabus now, because I think pharmacists should be at the forefront of pharmacovigilance.* [CP11]

Themes were divided into 2 broad categories, corresponding to the components of the TTF model. Perceived barriers to and facilitators of ADR reporting affected tasks and technology. These themes are discussed and illustrated using quotes (Textbox 1).

Textbox 1. Barriers and facilitators perceived by participants categorized into the Task-Technology Fit model.

Factors affecting the task

- Barriers
  - Lack of support (lack of time)
  - Lack of financial incentive (low adverse drug reaction [ADR] priority)
  - Referring consumer to corresponding physicians or hospital takes priority
- Facilitator
  - Enhanced knowledge or awareness of pharmacovigilance and ADR reporting
  - Environmental restructuring (financial incentive for ADR reporting and workplace support)
  - Empower consumer reporting

Factors affecting technology use

- Barriers
  - Low awareness or lacking knowledge of reporting systems
  - Inadequate IT systems
  - Fragmented reporting systems
- Facilitator
  - Centralized or streamlined reporting systems
  - User-friendly reporting systems (integrated within the clinician workflow; autopopulation features; efficient reporting forms; artificial intelligence)
  - ADR reporting mobile apps
  - Consumer follow-up and clinician feedback

Barriers

Participants were asked about factors that negatively affected their willingness to report ADRs. All participants said they did not report the ADRs that they encountered in practice owing to either a lack of time or financial incentive, where workload pressure and not knowing how to access the reporting forms were identified as key drivers in the "lack of time" for reporting.

Task

Lack of Support as a Driver of Time

The participants' professional organizations and lack of supporting staff were key barriers to reporting ADRs. This was related to the effort and time needed to complete an ADR during or after clinical interaction with customers:

> *If I did e.g. sick certificate and I know it's going to take 5 to 10 minutes and there are people constantly coming in and out dropping off scripts. When I come back to the scripts, what might have been a 10-minute wait before is now a half an hour wait. So, there are times when people [CPs] just send them away.* [CP2]

> *Unless you're doing it exactly at the time of the adverse event, it takes time. First of all you find time between your work to do it, then you have to recollect everything as accurately as you can, which also becomes more time consuming because you spend more time trying to remember what happened, because you can't do it at the time of the incident.* [CP3]

Lack of Financial Incentive as a Driver of ADR Nonreporting

Most participants expressed a lack of incentives in the form of financial rewards, stating that prescriptions are what brings money to the pharmacy:

> *So rightly or wrongly, the pharmacists focus is on getting to the next prescription or satisfying the customers.* [CP4]

> *I feel like there should be some kind of incentive like last year, with the 6th CPA [community pharmacy policy agreement] agreement.* [CP10]

Referring Patients to Corresponding Physicians

When discussing how the participants handled ADRs or adverse events in their daily practice, most participants considered ensuring safety as the initial priority and then notified their physician or referred them to the hospital as the default:

> *If there's an adverse reaction, you'd call the doctor to explain what's happened and do everything to see that the patient is fine. I was never encouraged or ever prompted to, "hey, this is a risk and that you*

> *need to report it" So yeah, there's probably a huge underreporting.* [CP12]
>
> *Well, if a customer comes in and says "something [medication] is giving me this side effect." Then, I'll go through each medication and see what potentially could be causing it, then contact the prescriber and maybe switch over to a different one.* [CP9]

Technology

Lack of Knowledge of Reporting Systems

The participants were asked about their familiarity with the PV and ADR reporting systems, and most stated that they would normally use Google search. This included both the reporting and nonreporting CPs:

> *When I say confusing, let's say, I want to report something online. I need to Google it, find out what organization it is and under what platform.* [CP6]
>
> *I know how to report vaccines' adverse reaction, but regarding medications, not really. If someone came in with an ADR, then I'll have to Google and that would take a chunk i.e. [time] out of my day and I don't want to report it to the wrong place.* [CP3]

Low Awareness of the Guild ADR Recording Module

The participants were asked if they had used the GuildCare professional service programs before. This was followed up with their familiarity with the built-in ADR recording module, that is, the first ADR reporting feature enabling CPs to report directly to the TGA in Australia. All participants recalled using the platform at some point within the practice to carry out professional services; however, none were aware of the ADR reporting feature:

> *I use GuildCare a little bit for HMRs [Home Medication Review] and medchecks i.e. [pharmacist medication reviews services] and no, this is the first I've ever heard of it. Well in my experience, I would say the first barrier is awareness, I've practiced for 13 years and I have never even known it existed.* [CP7]
>
> *Now we only use it for project-stop i.e. [national pseudoephedrine drug surveillance system] or Covid-19 RAT tests [rapid antigen test].So no, because I also worked for a year in New South Wales, there they also used GuildCare, I only did medchecks but I didn't know about the adverse reaction was part of it.* [CP1]

Inadequate IT Systems

Participants emphasized the need for an adequate and user-friendly IT system that facilitates ADR reporting. For instance, functional fields that are easy and quick to access during a consultation. Participants also valued a single national system that facilitated information exchange with other relevant HCPs in primary or secondary care:

> *It takes like a long time, you have to create like different 10 accounts, then link them and just to answer five questions or some questionnaires won't allow me to specifically say, what the adverse reaction is. If I have to choose between five options and it's none of the five, then I'm going to have to choose the closest thing and just it doesn't feel right.* [CP3]
>
> *I know this sounds bad, it's a lot of paperwork, like I said with COVID-19, we do a lot of reporting as a company which is fantastic. But the fact that sometimes when you have to go on a website, find the link, download the link, fill it out, submit it to this authority, then you have to go to another authority, which is on a completely different website, and then you get an email back which you have to follow up. It's not very streamlined, and I'm not going to lie, It's hard work.* [CP9]

Facilitators

CPs were asked what would facilitate the ADR reporting process; the interviewees highlighted the importance of feedback from authorized agencies, the inclusion of topics related to ADR reporting in the pharmacy curriculum, improvements in the training programs, continuing professional development, financial incentives, and integrating innovative information systems within their workflow.

Task

Enhanced Knowledge and Awareness of ADRs

Participants recalled briefly learning about PV during university, and were not aware of any professional training modules or education campaigns:

> *Probably more awareness on it, make it part of the actual pharmacy school and part of the Intern Training Programs so it becomes a routine thing. If they wanted to start to bring it up right now you have to run basically an awareness campaign so it's something that you do remember.* [CP2]
>
> *Yeah, awareness and education, modules, maybe push the managers go through it with the team on how to report and show them the system.* [CP7]

Environmental Restructuring (Financial Incentive for ADR Reporting)

All participants agreed that if ADR reporting could be incentivized, that could encourage more reporting:

> *You know, this sounds really bad. But I'm sure if there were incentives for people would do it.* [CP9]
>
> *I said the boss's aim is you can't just stand there and do something that's not going to bring in the money whilst people take their business elsewhere. So even if it was just a tokenistic amount of money to recognize that it takes time to fill in these forms, would be an enabler.* [CP4]

Empower Consumers Reporting

Encouraging consumers to become more active in ADR reporting was highly regarded by the participants. Furthermore, this was also regarded as a positive way to reduce workload pressure:

> *If the consumers know this as well or if there's a way to give them a pamphlet and say, "just report it, it's important that you do it, it helps in the future." So maybe if there's a system like that, it might be taking the pressure off us but still able to get the information across.* [CP5]

> *I think patients can be empowered more to report then they don't have to go to the healthcare professional. So, education and messaging to patients to take a bit of ownership on their medications, their adverse events and reporting it to either the TGA or to the company.* [CP11]

Technology

Centralized or Streamlined Reporting Platform

The participants reported having a single and streamlined reporting system would encourage more ADR reporting:

> *I think just having a one stop shop.* [CP1]

> *One system for pharmacists to report.* [CP5]

User-friendly Reporting Systems (Integrated IT Systems Within the Clinical Workflow)

Having multiple reporting platforms and login passwords was considered a barrier by all participants. Integrating ADR reporting within their workflow was highly regarded.

> *If it was incorporated into the software. Like if we use Fred and you could just type it in there and then somehow feed its way through to TGA that'd be good.* [CP7]

> *If they want quick reporting, it should be built into the dispense program. If you bring the patients profile you click the drug that had a bad reaction and report the adverse drug reaction, then it pulls the information from the dispense software.* [CP10]

User-friendly Reporting Systems (Autopopulation Features Within the Dispensing Software)

Participants mentioned that future ADR reporting platforms should not only be integrated within the dispensing software, but the system design should be clinician focused:

> *It would be easy if you could just go through a patient's history and say, click on it and that would pre-populate with patients details from the dispensing software so you've automatically got the patient initials, details of the other medicines that they are taking, which may or may not be relevant, but the software could automatically do that.* [CP8]

> *I work with one i.e. [CP] that's a bit on the older side, and technology for her is not a strong point. If you're getting them to go between different programs, then for them to type in information when they're not quick at typing. That is [reporting] should be as easy as possible and I can't think of anything easier than it being built-in into the dispense system, so just right click the drug and then go and report adverse reaction.* [CP2]

User-friendly Reporting Systems (Efficient Reporting Forms)

Participants who had previously reported ADRs suggested having clear and succinct reporting forms, capturing the most pertinent information would facilitate ADR reporting:

> *Something that saves time and makes reporting more efficient than having to type out paragraphs and essays of what you're trying to report.* [CP9]

> *SafeVac was actually really easy to sign in. I can't remember if I had to create an account, even if I did, it was surprisingly short. But I didn't feel like with SafeVac. I made a difference in any way because I just reported that he had a headache and then nausea, but I wanted to say that it was more prolonged, but it didn't allow me to say that, it was a multiple choice.* [CP3]

User-friendly Reporting Systems (Implementation of Artificial Intelligence to Detect ADRs Within Dispensing Systems)

Implementing reporting systems leveraging innovative technologies such AI was seen as an effective strategy to facilitate ADR reporting and reduce workload:

> *I think if there is something that we could do within the dispensing software that can expand to not just dispensing, if there's AI built into it, to detect any notes or clinical interventions that have ADRs in it and can pick up alerts.* [CP3]

> *Say your dispensing software. Fred dispense prompts you to fill out what allergy or reaction that happened, when it happened, pulls all the patient demographics info. If it then had a little thing, do you want to submit this to the TGA? and your able to go yep, bang, and then it would map and link all of the structured data and then send it off. That's good.* [CP5]

Implementing ADR Reporting Mobile Apps

Participants suggested mobile apps could facilitate ADR reporting by allowing CPs to report through their point of care digital tablets (Ipads) or integrating ADR reporting into existing systems (My Health Records app):

> *Even an app that people can report on their phones, sometimes in a pharmacy setting or their lunch break.* [CP11]

> *Maybe like an app or something, you can do it and pre-populates your information, like your name, that sort of stuff.* [CP9]

Consumer Follow-up and Clinician Feedback

Participants who previously reported an ADR suggested feedback from regulatory agencies could provide positive reinforcement and facilitate ADR reporting:

> *I think some feedback would be good because sometimes you got questions, right? Is this actually happening across Australia or globally?* [CP11]

> *Maybe now that this information is housed somewhere centrally [after ADR reporting], they can even contact you like after three months, six months or twelve months to see how your adverse drug reaction was.* [CP7]

Discussion

Principal Findings

The knowledge and perspectives of CPs in Australia regarding ADRs and ADR reporting practices have been quantitatively described by Li et al [9]. However, in this study, we conducted a qualitative analysis. To our knowledge, this is the first qualitative study in Australia that explores the perceptions of CPs regarding PV by using a theoretical framework that maps out the barriers to and enablers of ADR reporting and recommends digital intervention strategies.

In summary, this study demonstrated that lack of knowledge is a key driver of low awareness of PV or reporting systems, while workplace factors and lack of facilitating resources are key drivers of the lack of time to report by CPs in Australia. Developing multifaceted digital reporting systems within the pharmacist's workflow can facilitate ADR reporting. A multifaceted digital reporting tool may use autopopulation features as well as an integrated ADR reporting and feedback system within the pharmacist dispensing interface.

Lack of Knowledge as Driver of Low Awareness

The interview findings revealed a lack of awareness among the participants concerning ADR reporting systems and reporting of ADRs to Australian regulators, with all participants stating "Google" as their primary starting point. Furthermore, all CP participants (N=12) were unaware of the built-in adverse event recording module or feature of the GuildCare system, despite having used the system to conduct various clinical tasks; for example, distributing COVID-19 rapid antigen tests and recording immunizations, dose administration aids, or home medicine reviews. What is important to note is that the GuildCare ADR reporting feature has been available to CPs since 2014. A small number of CPs, that is, 33% (4/12), had previously reported an ADR directly to a regulatory authority. Among the 4 CPs, 2 (50%) had made an ADR report following immunization (ie, COVID-19 vaccines), and the other 2 (50%) CPs reported ADRs associated with medications. In Australia, it is important to note that vaccination providers, including CPs, are required to report vaccines administered to the Australian Immunisation Register, and jurisdictional legislation to report serious adverse events following immunization (AEFI) to local public health authorities may also apply [30,31]. By contrast, reporting ADRs associated with medicines (ie, excluding vaccines) is voluntary [11]. Therefore, jurisdictional legislation on vaccine reporting may have influenced the 2 CPs who reported ADRs after immunization. This possibility raises the potential for mandatory policy for ADR reporting as an intervention strategy that can be used in further research. In their submission to the 2015 TGA review of Australian Medicines and Medical Devices regulations, the Consumers Health Forum also argued for mandatory requirements for physicians and pharmacists to report ADRs [9].

A major theme identified within the data was the "reported" lack of sufficient education and training at a foundational level. Most respondents suggested increasing training and awareness to facilitate ADR reporting. All 12 participants recalled having little to no education on ADR reporting during the pharmacy curriculum and postgraduate internships, highlighting a key area for further exploration. Another theme was within the CPs workflow, where respondents suggested that their primary response to an ADR was to first ensure patient safety and then notify the prescriber. This was considered a satisfactory clinical workflow by all the respondents, and there was no mention of further activity such as reporting to the TGA. Nevertheless, to participate in PV, one must understand what PV is. The respondents subjectively used the terms "reporting drug allergies," "incident reporting," or "reporting drug interactions" within the context of ADR reporting, suggesting a lack of consensus on what constitutes ADRs. A lack of consensus on what constitutes an ADR among CPs suggests that considerations need to be given to include or provide more training on PV and ADR reporting such as within pharmacy curricula, prelicensure training, and continuing professional education workshops. This is consistent with previous studies showing that CPs have limited knowledge of PV, which may affect their ability to report ADRs in clinical practice [9,32].

Work Environment or Resources as Drivers of Lack of Time

All CPs reported a lack of time as a major barrier to ADR reporting. Our findings are consistent with those from a previous quantitative survey, which suggested that nonreporting pharmacists were more likely to report lack of time as a barrier ($P<.001$) [9].

However, our qualitative analysis of the interviews allowed us to probe further into the theme of "lack of time" as a barrier to ADR reporting by discerning what CPs generally mean when they say, "lack of time to report." According to our data, we were able to contextualize CPs' reported "lack of time" as either a constraint to stop performing regular duties or perform an ADR reporting process, that is, from the consumer or patient contact to ADR report submission. The second context referred to the time to "completing a reporting form"; for example, the TGA or SafeVac web-based reporting webforms. Therefore, is "lack of time" simply a barrier to ADR reporting? Or, are there barriers limiting the time to report ADRs? Within the first context, "lack of time" is a dependent variable, influenced by external factors, such as the work environment and lack of support staff, while in the second context, it refers to the cumbersome reporting forms.

This brings us to the second point, regarding the lack of time to report. From our data, 33% (4/12) CPs had previously completed an ADR report, expressing frustrations around the "multitude of reports required to complete a single ADR reporting event, that is, the large amount of paperwork or administrative work involved" or the "number and types of questions asked, including the lack of appropriate response options available on the web-based reporting forms." Nevertheless, all the participants in our study expressed challenges within their work environment as barriers, limiting

their time to report. Many highlighted that there is not enough time to undertake their basic roles as a pharmacist and provide ADR reporting. If there were financial incentives, then this may support pharmacists by perhaps "buying" time for them to undertake this task in a busy pharmacy. However, while workplace resources were a challenge that could affect CPs' capacity to report, the CPs who had previously reported an ADR (ie, 4/12, 33%) further stressed the need for succinct, centralized, and more user-friendly digital reporting forms. CPs who had previously reported an ADR associated their "lack of time to report" with a frustrating and inefficient ADR reporting form, affecting their time to complete the form.

These findings are consistent with a 2018 cross-sectional quantitative survey, in which CPs who had reported ADRs to the TGA did not perceive time as a barrier. The study noted that the underlying perspectives of individual pharmacists affected how they allocated time to perform ADR reporting as part of their professional practice [9]. Therefore, our findings suggest that clarity and a distinct understanding of what is meant by the phrase "lack of time to report" may be useful in designing more targeted intervention strategies. The first context relates to the organizational or workplace structures that may affect their time, and the second context relates to operational IT infrastructures that may affect time to complete ADR reports.

Technology as a Facilitator of ADR Reporting

All CPs voiced the need to develop and integrate reporting systems using autopopulation features within pharmacy dispensing software, with a feedback loop. To our knowledge, 2 PV systems currently exist in Australian community pharmacies. In June 2014, a pharmacy software vendor GuildLink created GuildCare, an adverse events recording module linked to community pharmacy dispensing software and integrated directly into the TGA ADR web service [9]. Although integrating reporting systems into pharmacists dispensing software presents opportunities, it is important to note that not all community pharmacies in Australia make use of the same dispensing software or professional service program. Therefore, it is crucial for regulators or software vendors to develop uniform reporting or surveillance systems that can be integrated with available pharmacy dispensing programs [33].

One such systems integration was recently implemented for vaccine surveillance in Western Australia, in response to the COVID-19 pandemic; the vaccine safety surveillance system (SmartVax) was linked and integrated to a cloud-based community pharmacy software system (MedAdvisor) to measure AEFI reports [30]. MedAdvisor is a professional service data management system used by CPs that automatically reports immunizations administered directly to the Australian Immunization Register. SmartVax is a participant-centered active vaccine safety surveillance system that integrates with national surveillance networks in Australia [30]. Drug safety surveillance systems may be active or passive [34]. Passive surveillance systems provide opportunities for health care personnel to confidentially and voluntarily report ADRs, and active surveillance systematically monitors particular patient encounters to seek detailed information about adverse events that occur [30,34].

Therefore, implementing an automated active surveillance system that can link directly to all pharmacy medication systems may offer a simple and rapidly scalable option for drug safety surveillance with little impact on the pharmacist's workload. These interventions may be further supported by the use of artificial intelligence that identifies possible ADRs and prompts the pharmacist when recording clinical data or dispensing medications. Furthermore, the use of mobile phone apps to facilitate ADR reporting was highly regarded by CPs. Comments on the use of mobile apps involved the ability to empower consumers to make their own reports. This may involve developing PV infrastructures within "My Health Record," which is a personal electronic health record available to all Australians and integrating this directly to the TGA may also provide transparency to the major stakeholders within the digital health ecosystem. Mobile tools for active surveillance of AEFI via SMS text messaging have already been implemented in Australia [35]. Furthermore, apps for passive surveillance also exist in Europe and Canada and can provide the necessary benchmarks [36,37].

Key Contributions and Recommendations

Besides addressing barriers to ADR reporting in Australia and suggesting interventional strategies to improve ADR reporting, the qualitative nature of this study provides context to the themes identified, such as "lack of time to report." We theorize that it is not the end users (CPs) who need behavior change through more enticements or enforcement, but rather that the work practices and technologies that support their work need review or further investigations and altered where suitable.

On the basis of the findings of this study, our team posits 5 recommendations that may improve the rate of ADR underreporting by CPs in Australia. First, considerations need to be given to including more PV and ADR reporting into the pharmacy curricula at universities and licensure training and development of continuing education workshops to increase awareness and knowledge of ADR reporting. Second, work practices need to be revised to support the ADR reporting workflow, which may be supported by policies and procedures from organizations, such as the Pharmacy Guild of Australia or the Pharmaceutical Society of Australia. Third, to ensure the uptake and utility for clinical care, dispensing systems must act as a mechanism to document work and, with the use of autopopulation features, easily share information between the pharmacy and regulatory authorities; the addition of feedback loops may serve as positive reinforcement. Fourth, the use of artificial intelligence or integrating active ADR surveillance systems into existing medication management systems may be used to provide ADR alerts and warnings. Furthermore, surveillance systems can also be linked to the established national surveillance networks in Australia. Finally, consumers should be empowered to report ADRs via mobile phone apps. The development of these systems should consider all stakeholders within the health care ecosystem, ensuring transparency of information [38]. With the diffusion of new electronic prescription systems such as the Active Script List, considerations could be made to include ADR reporting within the system architecture. The use of existing systems, such as

Australia's national My Health Records, may also present an opportunity [39,40].

Strength and Limitations

The strength of this study is its qualitative approach. This format allowed contextual insight into the participants' responses, such as the commonly mentioned phrase "lack of time to report" and their perceived barriers and facilitators. We were also able to sample participants from different community pharmacy settings across rural and metropolitan areas. Barriers and facilitators emerged within the different domains of the TTF model and could offer insights into designing suitable improvements to optimize the quantity and quality of ADR reports. Implementing active and passive surveillance systems, as well as improving reporting systems, could enhance the exchange of safety data, prevent ADR-associated hospital admissions, and reduce health care expenditures. This could also be an essential step in making the data readily accessible for patient registries, research, or PV activities.

However, this study has some limitations that may affect the generalizability of our findings. The findings may be limited, as the sample was confined to a small number of participants working in Victoria, Australia. The CPs were selected by purposive sampling, which could have resulted in selection bias. All participants were from the geographic state of Victoria, and their responses may have been shaped by the organizational context for reporting ADRs within the jurisdiction. We also acknowledge that participants in this study self-selected to participate and may provide an element of responder bias, as more motivated individuals or those with a personal interest in PV or medication safety may have opted to participate. Some CPs may feel guilty for not reporting ADRs and therefore may have altered their responses to provide "socially desirable" responses about their perspectives toward ADR reporting. Although the sample may be seen as a limitation, there were varied opinions and from many who did not regularly report ADRs, suggesting that the strength of socially desirable bias may not be too strong. This study also focused its inquiry using a theoretical model, which may have limited the exploration of other important factors.

Conclusions

This study highlights the individual and system-related barriers that influence ADR reporting among CPs practicing in Victoria, Australia. Classification of both barriers and facilitators using a theoretical framework could be effective in designing more tailored and suitable interventions targeting ADR underreporting. The results of the study demonstrated that lack of knowledge is a key driver of low awareness of PV or reporting systems among CPs, and work environment or resources are key drivers of the lack of time to report by CPs in Australia. Understanding the meaning and nature of "lack of time to report" may be useful to design more targeted intervention strategies, the first relating to the organizational workplace structure and the later, operational or IT infrastructure.

Future Research

This study identifies several barriers and proposes different facilitators to overcome them as the first step. This study may encourage further research to evaluate the effectiveness of proposed intervention strategies. Future observational fieldwork should be conducted to observe physicians and pharmacists within their work settings. This approach will allow us to gain an understanding of the clinical workflow, work environment, and how ADRs are diagnosed, documented, and reported and barriers to reporting. In addition, research can be conducted to investigate and compare the perspectives of hospital pharmacists and CPs toward ADR reporting. Consumers' perspectives and knowledge of ADRs could also provide insights into the barriers to and facilitators of consumer ADR presentations to CPs. It may be useful to explore policy changes including remuneration and mandatory reporting. Studies can be conducted with end users (CPs) and software vendors to discuss facilitators of ADR reporting including their involvement in the design of any future ADR reporting tools and their practical implementations.

As technology advances, risks and challenges may arise; therefore, further research may focus on developing standardized frameworks and guidelines that govern system integration and interoperability [41]. Finally, an ongoing evaluation of the effectiveness of existing and new ADR reporting technological systems may offer insights into the continual optimization of ADR reporting interventions.

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Conflicts of Interest

None declared.

Multimedia Appendix 1
Modified Monash category (2019).
[PNG File , 619 KB - ijmr_v11i2e40597_app1.png]

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Abbreviations

ADR: adverse drug reaction
AEFI: adverse events following immunization
CP: community pharmacist
HCP: health care professional
MM: modified Monash
PV: pharmacovigilance
TGA: Therapeutic Goods Administration
TTF: Task-Technology Fit

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Original Paper

A Computerized Pharmacy Decision Support System (PDSS) for Headache Management: Observational Pilot Study

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Abstract

Background: Headaches are common and often lead patients to seek advice from a pharmacist and consequently self-medicate for relief. Computerized pharmacy decision support systems (PDSSs) may be a valuable resource for health care professionals, particularly for community pharmacists when counseling patients with headache, to guide treatment with over-the-counter medications and recognize patients who require urgent or specialist care.

Objective: This observational pilot study aimed to evaluate a newly developed PDSS web app for the management of patients seeking advice from a pharmacy for headache. This study examined the use of the PDSS web app and if it had an impact on patient or pharmacy personnel counseling, pharmacy personnel perception, and patient perception.

Methods: The PDSS web app was developed according to Francophone des Sciences Pharmaceutiques Officinales (SFSPO) recommendations for headache management, and was made available to pharmacies in 2 regions of France: Hauts de France and New Aquitaine. Pharmacy personnel received 2 hours of training before using the PDSS web app. All people who visited the pharmacies for headache between June 29, 2020, and December 31, 2020, were offered an interview based on the PDSS web app and given information about the next steps in the management of headaches and advice on the proper use of their medication. Patients and pharmacy personnel reported satisfaction with the PDSS web app following consultations or during a follow-up period (January 18 to 25, 2021).

Results: Of the 44 pharmacies that received the PDSS web app, 38 pharmacies representing 179 pharmacy personnel used the PDSS web app, and 435 people visited these pharmacies for headache during the study period. Of these, 70.0% (305/435) asked for immediate over-the-counter analgesics for themselves and consulted with pharmacy personnel with the use of the PDSS web app. The majority of these patients were given advice and analgesics for self-medication (346/435, 79.5%); however, 17.0% (74/435) were given analgesics and referred to urgent medical services, and 3.5% (15/435) were given analgesics and referred to their general practitioner. All pharmacy personnel (n=45) were satisfied or very satisfied with the use of the PDSS web app, and a majority thought it improved the quality of their care (41/44, 93.2%). Most pharmacy personnel felt that the PDSS web app modified their approach to management of headache (29/45, 64.4%). Most patients were very satisfied with the PDSS web app during their consultation (96/119, 80.7%), and all felt mostly or completely reassured.

Conclusions: Use of the PDSS web app for the management of patients with headache improved the perceived quality of care for pharmacy personnel and patients. The PDSS web app was well accepted and effectively identified patients who required specialist medical management. Further studies should identify additional “red flags” for more effective screening and management

of patients via the PDSS web app. Larger studies can measure the impact of the PDSS web app on the lives of patients and how safe or appropriate pharmacy personnel recommendations are.

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KEYWORDS

headache; pharmacy; counselling; over-the-counter (OTC) medication; self-medication; decision support system; patient perception

Introduction

Self-medication with nonprescription or over-the-counter (OTC) medications represents a growing challenge to community pharmacies worldwide, especially in the context of pain management [1]. This is due to the risk of harm to the patient, which could occur following an incorrect self-diagnosis, inappropriate use of medication, side effects of the medications used, or interactions with concurrent medications [2]. Overuse of symptomatic medication can even lead to chronification of the condition, giving rise to chronic medication-overuse headaches from previously acute conditions [3]. Community pharmacies represent the ideal location for prevention of these risks [1].

The Global Burden of Disease study has ranked headache disorders as the second leading cause of years lived with disability worldwide [4], and pharmacists may be the first or only health care professionals to advise patients about self-medication [5]. Previous studies using simulated patient methodology have demonstrated the role of community pharmacists in self-medication. The studies suggest that pharmacists have a clear overview of medications taken by the patient, with pharmacists being easily accessible and ideally placed to identify inappropriate self-medication [6]. In the context of headache and migraine management, pharmacists may be considered crucial in their management, but only if they have a clear understanding of patient symptoms and are able to recommend an appropriate analgesic treatment or refer the patient for further care, either with the patients' general practitioner (GP) or a specialist [7].

Pharmacy decision support systems (PDSSs) are often paper-based and have value in this form; however, a computerized PDSS can be a valuable tool to aid patient-pharmacist counseling and guide the information gathered by the pharmacist. For example, in a study by Bertsche et al [8], the authors used a PDSS for the counseling of patients with allergic rhinitis and conjunctivitis requiring OTC medications in a method similar to that used in this study. The authors found that the PDSS efficiently guided the pharmacist through counseling and, without use of the PDSS, the questions most commonly missed were those that would have informed the need for a referral to other health care services [8]. Similar tools are being developed in other therapy areas; for example, a cross-platform web app in an initial pilot has been shown to enhance pharmacist care for lower back pain [9], and authors of migraine studies have suggested that digital tools, such as trackers, may aid medical communication and optimize management [10]. Advantages of a computerized PDSS in the form of a web app include that this is easily accessed by pharmacies worldwide, enables consistency across many pharmacies, and will create a data repository that can be used for further analysis. These digital health tools aid the pharmacy in patient management and have the potential to reach the many patients visiting pharmacies each day and support the changing role of community pharmacists. Community pharmacy practice has changed in recent years from being "product-oriented" to "service-oriented" across most European countries in light of changes in national and European legislation as well as pharmacist or pharmacy organizations; the focus on the patient in pharmaceutical care has increased, in part due to the introduction of pharmacy principles for appropriate medication use and preventative care [11]. Considering the influence of OTC medications on societal health, more pharmacists and pharmacy personnel are being provided opportunities to expand their contribution to facilitate patients' self-care [12]. This relieves the pressure on doctors who are receptive to pharmacists supporting patients with OTC diagnoses, and likewise, pharmacists are receptive to engaging more in a medical expert role [13]. The scope of clinical pharmacy practice across France alone is rapidly expanding in order to accommodate more public health issues and meet the challenges raised in areas affected by medical desertification—the inadequate access to health care for the population.

We are not aware of any specific algorithm-based computerized PDSSs for the management of headache disorders in the context of a primary care setting such as a community pharmacy. Therefore, this observational pilot study evaluates the use of a newly developed computerized PDSS platform (web app), based on previously published algorithms for the management of headache by pharmacists [14], to guide patient-pharmacy personnel counseling and referrals to appropriate medical services, dispensation of appropriate analgesic treatments, and identification of patients who require specialist care. The study aims to examine whether patient pathways, pharmacist satisfaction, and patient satisfaction are impacted by use of the PDSS web app.

Methods

Study Design

This was an observational pilot study designed to evaluate the impact of a PDSS web app on the management of headache by pharmacy personnel and the satisfaction of pharmacy personnel and patients. The PDSS web app was used for consultations between pharmacy personnel and patients in 2 regions of France: New Aquitaine (from June 29, 2020, to December 31, 2020) and Hauts de France (from September 1, 2020, to December 31, 2020). Pharmacists and patients reported their satisfaction with the PDSS web app during these times and during a follow-up period from January 18 to 25, 2021. The start date

of the study was delayed in Hauts de France due to the effects of the COVID-19 pandemic.

Ethical Considerations

This study was conducted in compliance with the provisions of Law no. 78-17 of January 6, 1978, relating to the processing of data, files, and freedoms, and those of the EU General Data Protection Regulation (GDPR) 2016/679 of May 25, 2018; security measures were put in place to protect personal data. Due to the observational nature of the study and according to the criteria defined by article L1123-7 of the French Public Health Code, it was not necessary to seek approval from an ethics board or the Comité de Protection des Personnes (committee for the protection of individuals).

Patient Population

There was no selection of patients; demographic data of all patients visiting a selected pharmacy for headache were collected. Patients requiring OTC analgesics for immediate pain relief were asked for consent to participate by pharmacy personnel before proceeding with their consultation using the PDSS web app. Patients were systematically informed of the approach to manage their headache and could refuse to participate.

Development of the PDSS Web App

The PDSS web app was developed in partnership with Sanofi, following a validation process for developing and testing apps based on the Good Automated Manufacturing Practice (GAMP 5) guidelines and the US Food and Drug Administration (Code of Federal Regulations 21 Part 11) and the European Union (EU Annex 11) regulations. An independent computerized system quality expert closely followed the validation process to ensure specification and testing activities were adequately covered and in accordance with the involved functional risks. The PDSS web app management algorithms are based on national French guidelines and have been previously published by the Société Francophone des Sciences Pharmaceutiques Officinales (SFSPO; French Scientific Pharmacist Society; Multimedia Appendices 1 and 2) [15]. Briefly, a multidisciplinary group including pharmacists, pharmacy students, patient associations, doctors, and members of the French Scientific Society for Pain (SFETD) contributed to the development of the SFSPO recommendations using the management algorithms [14] and the principles of design thinking, a working method that focuses on collective intelligence, human-centered research, and deep understanding for end user needs [16].

Development of the PDSS and digitalization to a computer web app was performed by a digital health provider (Observia). Development and testing of the PDSS web app followed good practice guidelines related to computerized systems; a plan test and independent computerized system quality expert test were carried out to identify scenarios and perform tests of nondeviation. Pharmacies tested the PDSS web app, and the final version was adopted after 3 steps of validation and quality assessment. A digital training program was developed for this study for the pharmacy personnel by *Le Monde Pharmaceutique* led by professors from the University of Bordeaux. The program was delivered over 2 hours of online training to include three topics: (1) the science of headache; (2) understanding the "red flags," recommendations, and the questions to ask the patients; and 3) how to use the PDSS web app.

Evaluation of the PDSS Web App

The study protocol and PDSS were validated by SFSPO and the regional presidents of the Regional Unions of Health Professionals (URPS); both are authorized by law to propose and conduct experiments and to implement health procedures at a national level if the results are conclusive. Pharmacists were solicited by the URPS presidents for the region, were informed, and volunteered to participate. URPS validated the pharmacies that volunteered. Personnel (including pharmacists, team members, and pharmacy assistants) at all selected pharmacies were trained to use the PDSS web app before using it for patient consultations to inform patients about the next steps in headache management (including hygiene and dietary practices, treatments, and their interactions and contraindications). A training certificate was sent to URPS following completion of the training, and only after receiving URPS approval was the pharmacy able to register on the PDSS web app. Participating pharmacies received financial compensation for the additional time spent during consultations via the regional health agency, representing the Ministry of Health (Agences Régionales de Santé [ARS]) in Hauts de France or via the URPS in New Aquitaine. Patients did not receive any incentives for participation.

Patient and pharmacy personnel perception of the PDSS web app were assessed via an online or paper satisfaction assessment questionnaire, which was developed by the SFSPO and validated by the URPS. Pharmacists were asked to complete the questionnaire after every 5 consultations, and all active pharmacies were contacted to answer the questionnaire over the phone during the follow-up period. Pharmacies were either asked to answer 9 questions (if they had previously completed any questionnaire) or 12 questions (if they had not previously answered any questionnaire). Patients were offered the option to complete the questionnaire after every consultation either on paper, or via QR code or website link.

Study End Points

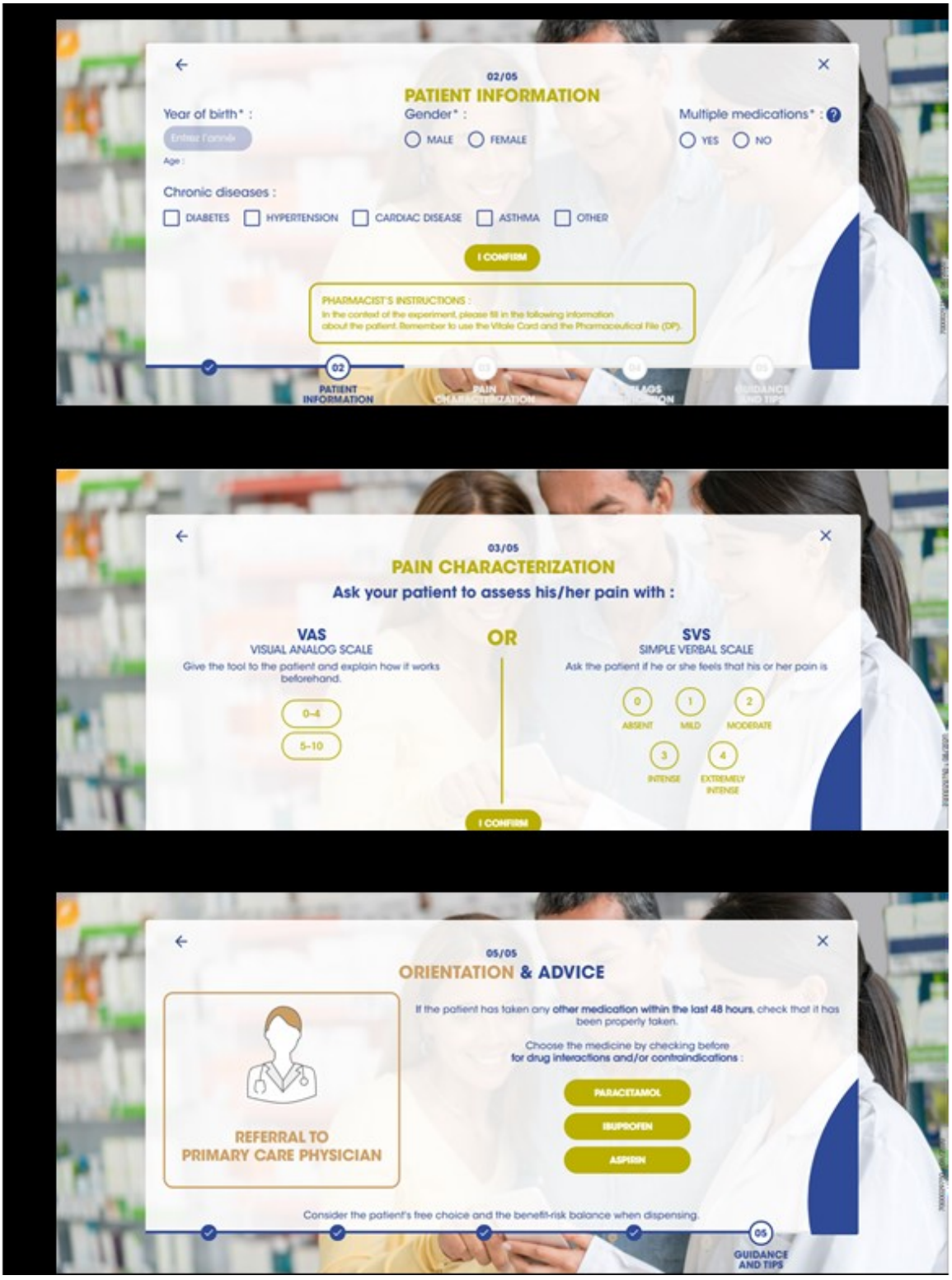
End points were reported by the patients and the pharmacy personnel. End points from the PDSS web app to guide the management of headache included concomitant medications, pain history, pain intensity, pain location, comorbidities, and drug contraindications. Pain intensity was reported by the patient either using a visual analog scale (VAS; 1 representing "no pain" to 10 representing "severe pain") or a simple verbal scale (SVS; 0 representing "absent," 1 representing "mild," 2 representing "moderate," 3 representing "intense," and 4 representing "extremely intense"). All patients and pharmacy personnel who used the PDSS web app were asked to complete a perception and satisfaction questionnaire on the usefulness of the PDSS.

Results

Development of the PDSS Web App

The PDSS web app was developed with up to 15 questions to be asked during patient-pharmacy personnel consultations and an estimated completion time of 4 minutes (Figure 1). Of the 435 consultations, the majority (n=346, 79.5%), were shorter than 4 minutes.

Figure 1. Screenshots of the pharmacy decision support system web app showing examples of information gathered during pharmacist-patient consultations: (a) patient characteristics, (b) patient-reported severity of pain, and (c) recommendations for referral to other medical services.

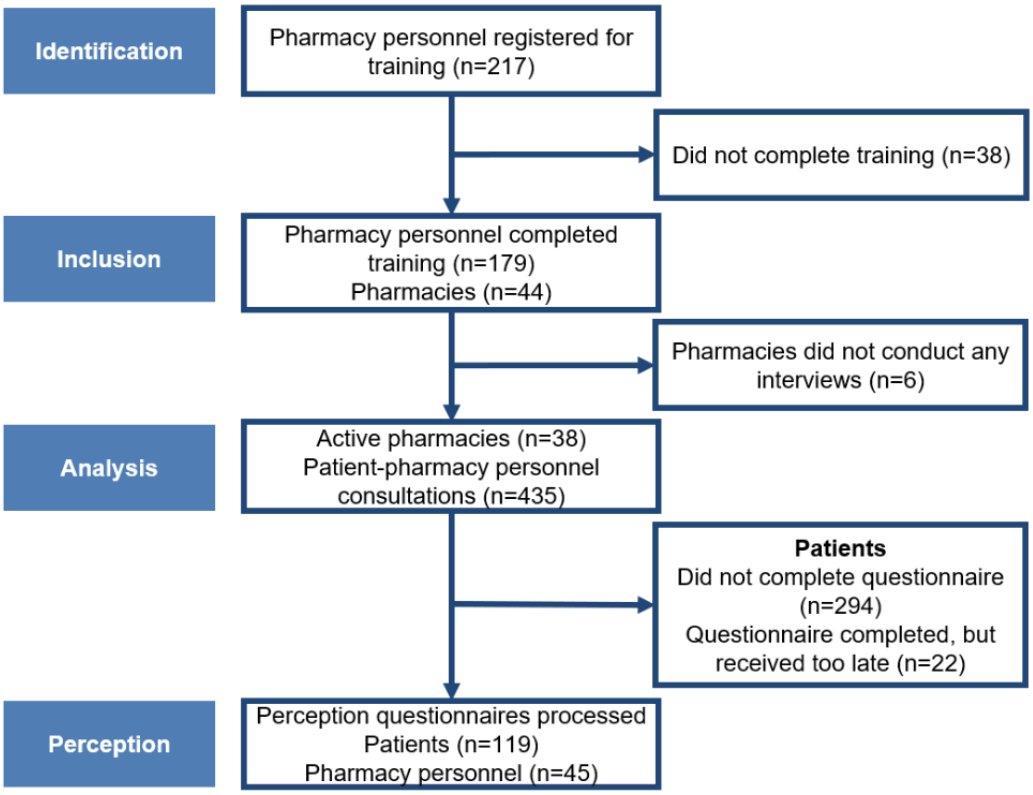


Patient Demographic and Pain Characteristics

A total of 69 pharmacies (Hauts de France n=46; New Aquitaine n=23) registered for the training, representing 217 pharmacy personnel (Figure 2). Of these, 44 pharmacies (Hauts de France n=32; New Aquitaine n=12), representing 179 pharmacy personnel, completed the training and were consequently selected to use the PDSS web app. Pharmacy personnel were generally satisfied (n=112, 62.5%) or very satisfied (n=56, 31.3%) with the training for the PDSS web app. At the end of the study period, 38 pharmacies (Hauts de France n=29; New Aquitaine n=9) had received visits from 435 patients or people acting on behalf of patients asking for relief from headache. Of the 435 people who visited the pharmacy, the majority were female (308, 70.1%) and under 50 years of age (mean age 43 years).

Out of the 435 people who visited the pharmacy for headache, 305 required immediate pain relief for their own self-medication, and 130 were acting on behalf of the patient. People visiting the pharmacy on the behalf of the patient were not asked questions with the PDSS web app beyond the first question; instead, they were given an information sheet for the patient and asked some questions to guide the recommendation (Multimedia Appendix 1): either an OTC analgesic to give to the patient or a recommendation for the patient to see their GP. Of the 435 people who visited the pharmacy for headache, 17.9% (78/435) were already prescribed >2 medications for other health issues (such as hypertension, diabetes, cardiovascular diseases, and asthma). Of the 305 patients in need of immediate pain relief for their own headache, 35.7% (109/305) of patients were already regularly taking analgesic treatment. As patients proceeded through the algorithm, they were asked questions dependent on their previous answer, resulting in a different number of respondents per question. Patients were taking other treatment for moderate pain (43/142, 30.3%) or for severe pain (34/74, 45.9%).

Figure 2. STROBE (Strengthening the Reporting of Observational studies in Epidemiology) flowchart.



Evaluation of the PDSS Web App

Of the 305 patients asking for immediate OTC analgesics, pain was mild in 60.3% (n=184) of patients, moderate in 24.3% (n=74) of patients, and severe in 15.7% (n=48) of patients. Some patients (n=44, 14.4%) had not previously experienced the same type of pain, and nearly half of the patients (n=148, 48.5%) described their pain as one that they had not experienced before or as one with an intensity of more than 5 on the VAS or more than 3 on the SVS (Figure 3).

Due to the algorithm, 157 patients were asked when the pain had started. The majority of patients' pain was recent and had started earlier than 4 days prior (142/157, 90.4%). Red flags (pain with sudden onset or with increasing intensity) were identified in 64 patients, leading to specific advice and either a referral to their GP or to urgent medical services (Table 1).

At the end of the consultation, with the help of the PDSS web app, patients would either receive a referral for urgent medical services or a recommendation to make an appointment with their GP, or the pharmacy personnel member would discuss and dispense an appropriate OTC analgesic (paracetamol, ibuprofen, or aspirin). Following all 435 consultations using the PDSS web app, 79.5% (n=346) of patients only required OTC analgesics and pharmacy advice, 17.0% (n=74) were referred to urgent medical services, and 3.5% (n=15) were referred to the care of their GP (Table 2). Across all 435 consultations, paracetamol

was the most common analgesic dispensed by a pharmacist (n=275, 63.2%), followed by ibuprofen (n=136, 31.3%), and aspirin (n=24, 5.5%). Among the patients who did not need a further referral, paracetamol was again the most common analgesic dispensed by a pharmacist (paracetamol: 178/346, 51.4%; ibuprofen: 139/346, 40.2%; aspirin: 28/346, 8.1%). However, among patients referred to urgent medical services, ibuprofen was more frequently prescribed (37/74, 50.0%) versus paracetamol (30/74, 40.5%) and aspirin (7/74, 9.5%).

Figure 3. Description of patients' pathways for the 148 patients with high pain intensity or unusual pain who did not need referral to emergency medical services. SVS: simple verbal scale; VAS: visual analog scale.

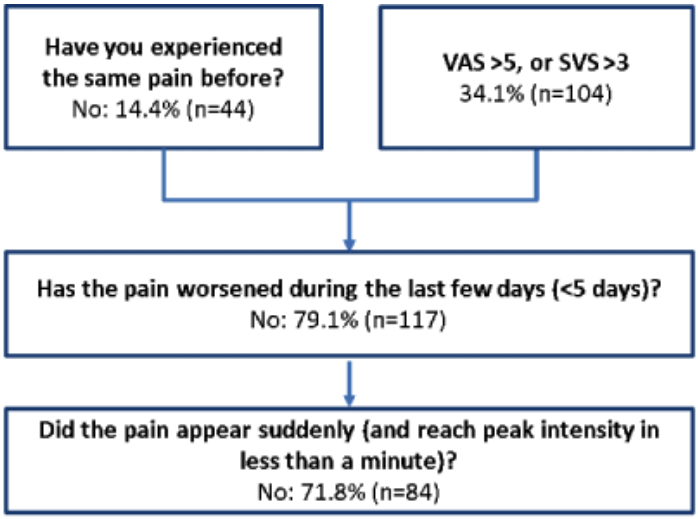


Table 1. Headache pain characteristics of patients in need of immediate pain relief at the pharmacy.

	Value, n/N (%)
Patients using >2 concomitant medications	78/435 (17.9)
Patients regularly taking analgesic medications	109/305 (35.7)
For moderate pain	43/142 (30.3)
For severe pain	34/74 (45.9)
Patient-reported assessment of pain	
Mild	157/261 (60.2)
Moderate	63/261 (24.1)
Severe	41/261 (15.7)
Patients with experience of the same pain	
Yes	261/305 (85.6)
No	44/305 (14.4)
Patients asked if pain lasting >4 days	
Yes	15/157 (9.6)
No	142/157 (90.4)
Patients with no prior experience of the same pain or pain with an intensity >5 (VAS[a])	148/305 (48.5)
Red flags identified	
Intensity of pain increased in past 5 days	31/148 (20.9)
Sudden onset of pain	33/117 (28.2)

[a]VAS: visual analog scale.

Table 2. Management outcomes of all people who entered the pharmacy for headache.

Type of support given	Patients, n (%) (N=435)
Pharmacist advice	346 (79.5)
Pharmacist advice + paracetamol	229 (52.6)
Pharmacist advice + ibuprofen	97 (22.3)
Pharmacist advice + aspirin	20 (4.6)
Referral to urgent medical services	74 (17.0)
Referral to urgent medical services + paracetamol	37 (8.5)
Referral to urgent medical services + ibuprofen	35 (8.0)
Referral to urgent medical services + aspirin	2 (0.5)
Referral to GP[a]	15 (3.5)
Referral to GP + paracetamol	9 (2.1)
Referral to GP + ibuprofen	4 (0.9)
Referral to GP + aspirin	2 (0.5)

[a]GP: general practitioner.

Pharmacist and Patient Perception of the PDSS Web App

Out of all 435 patient–pharmacy personnel consultations, 119 patient questionnaires and 45 pharmacy personnel questionnaires (9 questions: n=22 pharmacies, New Aquitaine=4, Hauts de France=18; 12 questions: n=16 pharmacies, New Aquitaine=5, Hauts de France=11) were completed to assess satisfaction with the PDSS web app. The use of the PDSS web app during the consultation was very well accepted, with high levels of satisfaction reported by both pharmacy personnel and patients. All 45 pharmacy personnel were satisfied or very satisfied with the PDSS web app (Table 3). The majority considered the PDSS web app helpful to their clinical practice (34/44, 77.3%) and to the patient (38/44, 86.4%). Patient-pharmacy personnel consultation with the PDSS web app modified the management of patients' headache by the pharmacy personnel in 64.4% of cases (29/45). Most of the 119 patients were very satisfied with the advice given by the pharmacy (n=96, 80.7%) and with the quality of information provided (n=92, 77.3%), and 100% of patients were mostly or completely reassured during the visit. Nearly all patients (n=115, 96.6%) declared they would follow the advice and recommendations given by the pharmacy (Table 4).

Table 3. Pharmacy personnel perception of the pharmacy decision support system web app.

Question asked	Response, n (%) (N=45)
How satisfied were you with the digital tool? (n=37)	
Not satisfied	0 (0)
Satisfied	26 (70.3)
Very satisfied	11 (29.7)
Do you think that use of this digital tool improved your quality of care? (n=44)	
Yes	41 (93.2)
No	3 (6.8)
Do you think the digital tool was helpful for your practice? (n=44)	
Very useful	6 (13.6)
Useful	34 (77.3)
Somewhat useful	4 (9.1)
Not useful	0 (0)
Do you think the digital tool was helpful for your patients? (n=44)	
Very useful	3 (6.8)
Useful	38 (86.4)
Somewhat useful	3 (6.8)
Not useful	0 (0)
Have you followed the recommendations of the digital tool? (n=44)	
Yes	43 (97.7)
No	1 (2.3)
Would you have managed the patient the same way had the digital tool been unavailable? (n=45)	
Yes	16 (35.6)
No	29 (64.4)

Table 4. Patient perception of the pharmacy decision support system web app.

Response by question asked	Response, n (%) (N=119)
Overall, how satisfied were you with the advice given by the pharmacist during your visit?	
Not satisfied	0 (0)
Satisfied	27 (22.7)
Very satisfied	92 (77.3)
Did you feel comfortable and reassured during your visit?	
Not at all reassured	0 (0)
Not really reassured	0 (0)
Mostly reassured	87 (73.1)
Completely reassured	32 (26.9)
Will you follow the advice given by your pharmacist?	
Yes	116 (97.5)
Partially	3 (2.5)
No	0 (0)

Discussion

Principal Findings

This pilot study demonstrated that use of a PDSS web app in community pharmacies for the management of mild, moderate, and severe headache disorders is a valuable tool, both to pharmacy personnel and patients. The PDSS web app effectively identified patients to be referred to urgent medical services or to their GP for further care. Pharmacists generally reported that the PDSS web app modified their management of the patient. The PDSS web app was generally well accepted and both pharmacy personnel and patients were satisfied with the tool.

Self-Medication With OTC Drugs

Pain is a highly prevalent symptom and is often associated with self-medication [17], with 48.2% of a community sample population using medication for pain relief [18]. According to the association of Nères (representing pharmaceutical companies which manufacture and sell self-medication products in France), sales of OTC pain medication for self-medication increased by 5.3% in 2021 versus 2020 [19]. Self-management of chronic pain conditions can provide marginal short-term and long-term benefits to the patient [20], but many patients express substantial concern over the need for pain medication and the potential for harmful effects [17]. Access to OTC medications has increased over the past decade due to switches in status from prescription only to OTC and the increased availability of OTC drugs (according to local regulations). In France in 2013, 500 million boxes of paracetamol were sold overall, and about 22,000 boxes were sold per pharmacy. Due to the risks of incorrect use and overdosing, the ANSM (Agence nationale de sécurité du médicament et des produits de santé; French National Drug and Health Products Safety Agency) requested pharmacists to have a greater role in the availability of OTC analgesics [19,21].

The Role of Pharmacists in OTC Management

Pharmacists and “pharmacist-led medication” are crucial for the improvement of pain management and the reduction in the misuse of OTC drugs. As pharmacists have a key role in patient care being positioned directly between the patient and the physician, the public needs full confidence in the role of the pharmacist. Studies have highlighted the future potential role of pharmacist-led intervention in countries such as Canada, where a cohort study of patients with chronic pain demonstrated a low level of patient satisfaction with pain treatment in a primary care setting. This study also highlighted the potential value of pharmacists’ role in patient education, discussion of barriers and attitudes toward pain and its treatment, and monitoring pain-related disability [22]. As members of medication management teams who are easily accessible to patients, pharmacists are necessary for identifying inaccurate self-diagnoses, educating patients, and providing referral support [5,23]. This could help to ease the burden on GPs and emergency services and help the patient to select the correct treatment and right care path. The feasibility of pharmacist-led intervention for chronic pain, through assessment and adjustment of prescriptions, has been demonstrated in a previous study, with the recommendations made by the pharmacist often being implemented by the GP [24]. Furthermore, in a review of 5 randomized clinical trials, a pharmacist-led medication review reduced pain intensity, improved physical function, and improved patient satisfaction in patients with chronic pain [25].

In order to help patients, it is crucial for pharmacists to communicate effectively and gain important insight into the needs of the patient to reach positive outcomes [26,27], for example, in the dispensation of the appropriate medication or the referral to further care where appropriate. Previous evidence has suggested that a suboptimal management of OTC medications in community pharmacies is due to a lack of information gathered from the patient [28]. This study has demonstrated that the PDSS web app facilitates communication with and management of patients in the pharmacy.

Providing the patient with accurate medical advice is also key to managing pain disorders such as headache. Medication overuse is a common issue in patients with headache disorders and can cause an existing acute headache to become chronic, which is referred to as a medication-overuse headache [3]. In a study of patients with acute headache recruited at pharmacies, only 14.5% had been advised to limit their intake of treatments [29]. In the context of migraine, few self-medicating patients or patients with migraine treated by GPs are considered to be in possession of the correct treatment [30]. The Global Burden of Disease study has shown that in 2019, migraine alone was the second leading cause of disability and the leading cause of disability among women under 50 years of age [31].

Tools have previously been developed to improve screening during patient-pharmacist consultations for OTC medications, for example, a self-administered questionnaire which was shown to be a valid and reliable tool for the screening of migraine headaches in a primary care setting [32]. The use of PDSSs has been demonstrated for other conditions, for example in allergic rhinitis and conjunctivitis [8], lower back pain [9], and migraine [10]; however, to our knowledge, the PDSS web app evaluated in this study is the first to be developed for pharmacist use.

Effect of the COVID-19 Pandemic

There was an effect of the COVID-19 pandemic on this study, with the start date in the Hauts de France region being delayed by 6 months, as pharmacies were not able to implement additional practices other than screening and vaccination for COVID-19. The study period was then extended to 4 months rather than 2 months as originally planned. In addition, a cross-sectional study of 431 people via questionnaire indicated that people became more reliant on pharmacies for medication during the COVID-19 pandemic [33].

Strengths and Limitations

The PDSS web app developed for this study focuses on headache only, thus reducing the scope of this study in the context of self-medication. However, due to the similarities in the counseling process for all OTC indications, the results are likely similar in other areas of self-medication. Our study supports the implementation of the PDSS web app across more pharmacies in France and across the globe; however, the lack of qualitative data to show how management of patients was altered and which aspects of the PDSS web app require improvement is a limitation of this study that should be

addressed in future trials. Furthermore, the anonymity of the PDSS web app does not allow a link between the patient data (eg, pain characteristics) and their satisfaction to be made. All patients preferred to fill in the paper form of the questionnaire, (ie, not the online version of the form), leading to possible bias regarding the homogeneity of patient type. Likewise, the uptake of the PDSS webapp will be voluntary for pharmacies, leading to possible bias toward pharmacies and personnel that are willing to adopt new technology as well as pharmacists specializing in pain management.

Future Directions

Self-medication is an important part of a patient's treatment plan and should be encouraged, as it gives patients control over their treatment. Recommendations from health care professionals, particularly pharmacists, therefore need to be carefully individualized to the patient to ensure safety. With this in mind, studies should be conducted to identify patient profiles, behaviors, and characteristics associated with responsible self-medication and, consequently, to develop multichannel digital tools to allow pharmacists and GPs to quickly assess the level of risk associated with patient self-medication. Computerized tools such as the PDSS evaluated in this study do not aim to replace health care professionals in decision-making during patient management but rather aim to meet the needs of the patient regarding safe self-medication. As such, future studies could benefit training programs for pharmacists and pharmacist-led medication and better emphasize and inform the "red flags" that indicate a patient is at risk of drug misuse or misdiagnosis. Such "red flags" should be screened for by the PDSS web app so that patients are diverted to appropriate further care, such as their general practitioner or urgent medical services. Larger studies should measure the impact of the PDSS web app on the lives of the patients and the safety of the pharmacist recommendations. Interventional trials should also examine the impact of the mandatory training prior to PDSS web app use on pharmacist satisfaction; the time dedicated to training or certain aspects of the training given (ie, the scientific background and "red flags" that pharmacists may already be aware of) may decrease the satisfaction with the PDSS web app. However, the algorithm itself might have helped to teach pharmacists and pharmacy personnel how to manage headache in real-world situations and more easily and efficiently during an epidemic such as that of COVID-19. This may in turn increase satisfaction with the PDSS web app although this should be examined in future trials. The COVID-19 epidemic has shown the crucial positioning of the pharmacist when a patient first seeks medical help. This type of PDSS web app can help pharmacy teams better take care of patients and manage them, particularly as algorithms are further digitalized.

Conclusions

Community pharmacies are valuable in the study and management of headaches. Proper patient-pharmacist counseling is crucial to inform next steps of treatment for headache. A newly developed PDSS web app effectively guided pharmacy personnel recommendations for self-medication with analgesics and identified patients who required referrals to specialist care. The PDSS web app was well accepted by patients and pharmacy personnel, and further studies are warranted to optimize such tools for OTC self-medication.

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Data Availability

The data sets generated during or analyzed during the current study are available from the corresponding author upon reasonable request.

Conflicts of Interest

SP has received consultation fees from Sanofi. DB and AC are employees of Sanofi and may hold shares or stock options in the company. APT, BC, GT, and FM have no conflicts of interest to declare.

Multimedia Appendix 1
Recommended management algorithm for use by pharmacy for patients with headache (initial consultation and for nonsevere pain).

[DOCX File , 290 KB - ijmr_v11i2e35880_app1.docx]

Multimedia Appendix 2
Recommended management algorithm for use by pharmacy for patients with severe headache or red flags.
[DOCX File , 187 KB - ijmr_v11i2e35880_app2.docx]

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Abbreviations

ANSM: Agence nationale de sécurité du médicament et des produits de santé
ARS: Agences Régionales de Santé
GAMP: Good Automated Manufacturing Practice
GDPR: EU General Data Protection Regulation
GP: general practitioner
OTC: over the counter
PDSS: pharmacy decision support system
SFETD: French Scientific Society for Pain
SFSPO: Société Francophone des Sciences Pharmaceutiques Officinales
SVS: simple verbal scale
URPS: Regional Unions of Health Professionals
VAS: visual analog scale

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Original Paper

The Use of Compression Stockings to Reduce Water Retention in the Legs During Gaming and Esports: Randomized Controlled Field Study

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Abstract

Background: With the increasing digitalization of daily life, internet-based entertainment such as gaming and streaming has advanced to one of the megatrends of the 21st century. Besides offering a multitude of controversially discussed opportunities for entertainment and social interaction, there is reasonable concern about health issues caused by the absence of physical activity among activities linked to gaming and streaming.

Objective: The aim of this study is to compare the water balance of recreational gamers with and those without compression stockings during a gaming event.

Methods: We measured body composition and water balance with 8-electrode bioelectrical impedance analysis among 46 recreational gamers with an average age of 27.1 (SD 6.5) years (5/46, 11% women and 41/46, 89% men) before and after 24 hours at a gaming event. Of the 46 gamers, 23 (50%) gamers wore compression stockings for the duration of the study.

Results: Our study shows that prolonged gaming and associated behaviors during a 24-hour time frame lead to an increase in total body water (+0.76 L; $P<.001$) and a decrease of phase angle in the lower extremities (−0.47°; $P<.001$) but not in the upper extremities (+0.09°; $P=.80$), when no compression is used. Gamers using compression socks did not show any significant negative effects on their body composition.

Conclusions: Prolonged gaming and streaming are serious risk factors for diseases associated with water retention in the legs, and these risks can be measured by bioelectrical impedance and reduced by wearing compression stockings. We conclude that these findings should be discussed and replicated in larger studies and that there is a considerably large market for compression stockings among gamers and live streamers.

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KEYWORDS

esport; streaming; gaming; water retention; fluid balance; compression stockings; bioelectrical impedance; mobile phone

Introduction

Background

A multitude of diseases caused by physical inactivity is well-documented [1-3]. It is also known that physical activity (PA) reduces the association of sitting time with mortality [4], and an active lifestyle during childhood reduces the risk for several diseases in adulthood [5]. Therefore, the World Health Organization promotes PA as part of a healthy lifestyle [6]. Among youth, recent epidemiological studies point to stagnation at insufficient amounts of PA [7-9], paralleled by a global increase in screen time [10], and reviews and meta-analyses proclaim a global *PA crisis* with only approximately 25% of youth reaching the PA guidelines by the World Health Organization [7,8]. Recent studies show that the absence of PA

and the factors associated with intensive media use are independent risk factors for a variety of different nonspecific (eg, overweight and metabolic syndrome) and specific [11-15] diseases.

Besides the aforementioned long-term consequences and risks of physical inactivity, negative short-term consequences from even a single event of prolonged physical inactivity have been confirmed by experimental studies [16]. One disease that is discussed to be aligned with single periods of continuous physical inactivity is thrombosis of the deep leg veins or venous thromboembolism (VTE) as initially described by Homans in 1954 [17]. This disease was specifically found after long air travels in the 1980s and therefore initially called the *economy class syndrome* [18,19]. In the 2000s, similar clinical scenarios were found among professions with prolonged sitting or standing time, which were described as the *seated immobility thromboembolism* (SIT) in various studies [20-24]. SIT is directly correlated to physical inactivity and is even worsened by other recently common risk factors such as obesity and low levels of general PA [25]. With the increasing relevance of screen media in occupational and recreational lifestyle, thrombosis caused by intensive use of computers and the internet was given the new name *e-thrombosis* in 2003 by Beasley et al [26] as they described a case report about a 32-year-old man, in whom immobility associated with sitting for long periods while using a computer caused life-threatening VTE [26]. As computers became increasingly popular in the recreational setting and as new professions involving prolonged gaming arose, the topic gained interest, and the authors stated that gaming may be the 21st century variant of seated immobility [27,28].

Although heavily described as a risk factor [25-36], only a few studies tried to identify the driving or causal factors that lead to VTE during recreational use of screen time, and to the best of our knowledge, studies describing SIT or e-thrombosis in the context of gaming-related live streaming do not exist.

In a pilot study in 2017, we could show that 1 day of intensive gaming results in a significant increase in the amount of water in the lower extremities, paralleled by a significant and meaningful decrease in local and total body phase angle (PhA) measured by bioelectrical impedance analysis (BIA) [37]. Therefore, we returned to the event for the following 2 years and conducted a randomized controlled field study to measure the bioelectrical impedance of a total of 50 (n=46 complete data sets) male and female gamers with and without compression stockings before and after 1 day at the event.

Objective

In this paper, we present the results of 46 gamers over 3 study years and discuss the effect of compression stockings on different parameters of body composition measured by BIA. The study is defined as a field study, and we did not control for the behavior of the gamers (eg, net amount of gaming, eating, or sleeping patterns). This study aims to clarify whether this population is at risk during their normal behavior and whether this risk can be measured by BIA and reduced by compression.

Our hypotheses were the following:

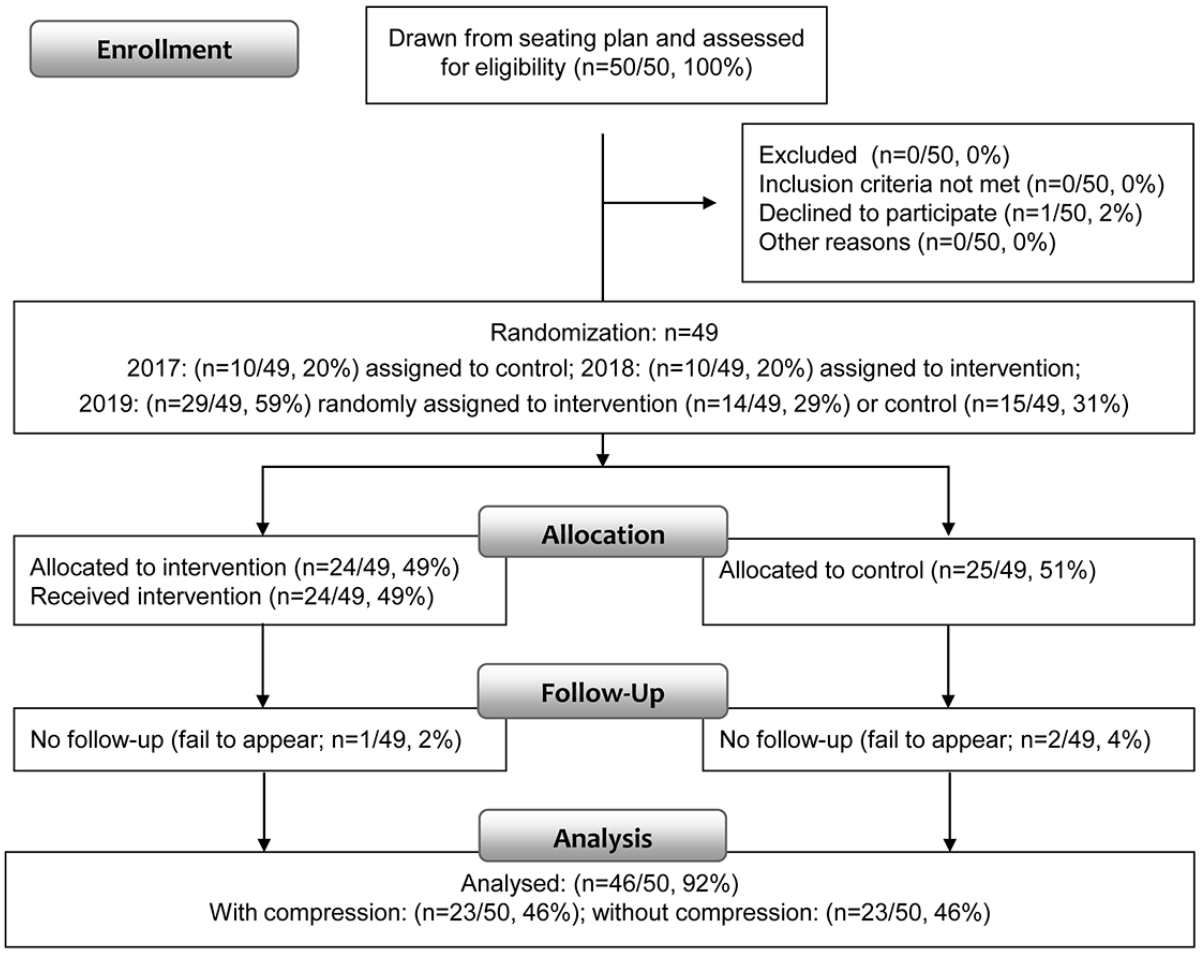
1. Prolonged gaming and associated behaviors cause an increase in total body water (TBW), which can be measured by BIA.
2. Prolonged gaming and associated behaviors cause an increase in body water as measured by a decrease in local bioelectrical tissue resistance (R) in the lower extremities but not the upper extremities.
3. Prolonged gaming and associated behaviors cause a decrease in the bioelectrical PhA in the lower extremities, which indicates an overall stronger pronounced increase in extracellular fluids compared with intracellular fluids.
4. Prolonged gaming and associated behaviors lead to an increase in extracellular body mass (ECM) but not in intracellular body mass (ICM).
5. The use of compression stockings can reduce the decrease in PhA and the increase in TBW.

Methods

Sample

The data were collected on gaming conventions in a rural area in Germany in May 2017, April 2018, and May 2019, hosted by a local computer club. The convention houses 400-430 participants annually and is one of the oldest gaming conventions in Germany, starting in the 1990s. Participants were recruited randomly using dice to select invitations from the 40×10 places large public seating plan. In 2017, a total of 20% (10/50) of the final participants were selected and received no compression. In 2018, a total of 20% (10/50) of participants were selected and all of them received compression. In 2019, a total of 60% (30/50) of participants were selected and alternately allocated to either the group with compression (15/30, 50%) or the group without compression (15/30, 50%). A total of 46 participants with a mean age of 27.2 (SD 6.9) years (5/46, 11% women and 41/46, 89% men) participated in both the pretest and posttest assessment and were included in the final sample (Figure 1). Participants without compression stockings are referred to as the control group (CG), whereas participants with compression stockings are referred to as the intervention group (IG). Participants agreed to participate in the study and received a US $23 cash incentive on completing the tests. Eligibility criteria included being a registered participant of the convention; that is, having a number on the seating plan; no current medication; and not being under the influence of legal drugs. All participants answered the questionnaires in the presence of a qualified interviewer on site. Participants were not informed about the research question or possible results of the study.

Figure 1. Recruitment process and design of the study.



Procedure

Overview

We used the same devices, questionnaires, and electrodes every year, and similar weather conditions occurred. The convention always started on Friday and ended on Sunday. The pretest assessment was hosted on Friday from 6 PM until midnight, and participants joined the posttest assessment after 24 hours, with a maximal deviation of 90 minutes.

Participants in the IG received a pair of VenoTrain cocoon (Bauerfeind) after measuring body height and calf circumference to ensure the accuracy of fit. They also received a pair of special gloves to wear the stockings easily and were advised to wear the stockings until they go to bed and wear them again immediately after awakening until the second measurement in the evening. During their stay at the event, participants were free to engage in any kind of activity they wanted. All participants brought their computers and played casually or in tournaments during the event. A participant reported having live-streamed his gaming during the event.

Anthropometry, Complaints, PA, and Media Use

Body weight was measured to the nearest 0.1 kg with a calibrated scale (seca) and standing height was measured to the nearest 0.5 cm using a stadiometer (seca), with the participant wearing light clothes and no shoes. BMI was calculated using the following formula:

$$\text{BMI}=\text{weight (kg)}/\text{height (m)}^2 \quad \textbf{(1)}$$

Participants were asked about the average time (minutes per day) on a normal week they spend with gaming on a smartphone, tablet, computer, or console; their total average daily screen time; active sports club membership (yes or no); and the days per week with at least 60 minutes of moderate to vigorous PA [38]. Recreational smartphone use was excluded from total sedentary screen time because it is not explicitly accompanied by sitting or physical inactivity.

We also tracked complaints regarding the lower extremities using a standardized numeric pain rating scale with seven 10-point items before the first BIA and immediately after the last BIA: “How do you sense your legs regarding the following symptoms: heavy legs, swollen legs, tingling, tension, pain, itching, or muscle aching? 1=no complaints to 10=very strong complaints.” This scale was provided directly by the manufacturer Bauerfeind and is not published.

BIA Procedure

BIA was conducted by trained investigators according to the European Society for Clinical Nutrition and Metabolism guidelines for BIA in clinical practice [39]. All participants

were nonpregnant and healthy, defined as the absence of a clinical condition that could influence fluid balance; for example, renal, endocrine, or myocardial disease, as ascertained by an interview. Fasting was not a precondition for study participation. An 8-electrode BIA measurement of R and bioelectric reactance (Xc) was taken at a fixed frequency of 50 kHz between the right wrist and ankle, as well as the left wrist and ankle (standard placement of surface electrodes) with a body impedance analyzer (BIA 2000-S; Data Input) while the participants were in a supine position on a nonconductive surface, with no contact with external metal objects. Before the examination, participants laid quietly in a supine position for a minimum of 3 minutes. R and Xc were measured at a 10-second interval until no changes in R and Xc between 2 measurements were observed, and the last measurement was noted.

BIA uses R to estimate TBW and to derive fat-free mass and fat mass. Besides R, BIA also provides information about the Xc, which is only caused by living cells with intact membranes [40]. From Xc, information about the amount of intracellular fluid can be derived, and this information was used to estimate the total body cell mass (BCM). In addition, the PhA as of 57.297×arctan (R/Xc) is reported. Fat-free mass, BCM, and fat mass were derived from formulas included in the NutriPlus software package by Data Input [41].

The supine, single frequency BIA using adhesive electrodes has a technical error of <0.5% [42] and a 24-hour retest reliability of r>0.82 with an intraclass correlation coefficient >0.96 [43]. With r=0.96, the validity of estimating BCM versus dual-energy x-ray absorptiometry is high [44].

Statistics

All statistical tests were conducted using SPSS (version 25; IBM Corp). Statistical significance was set to P<.05 and repeated measurement analyses of variance (rmANOVAs) were used to detect significant differences between the changes among the IG and CG as of time×group interactions. Besides F and P values, effect sizes are reported through partial eta^2 (p. η^2).

Ethical Considerations

The Karlsruhe Institute of Technology institutional review board (IRB) has declared that this study type does not warrant ethics application as per their guidelines [45]. All participants provided informed consent. According to the Declaration of Helsinki, no humans were harmed during this study [46].

Results

Sample Characteristics

The characteristics and anthropometrics of the participants in the IG and CG are shown in Table 1.

Both groups showed a comparable range of age except for 1 older participant in the CG. Mean weight gain during the event was +0.8 (SD 1.1) kg and translated into a 0.2-point increase in BMI. In addition to age and anthropometrics, we asked the participants about their engagement in sports and their average daily gaming and total sedentary screen time (Table 2).

Table 1. Sample characteristics (n=46).

Group	Values, n (%)	Age (years), mean (SD); range	Height (cm), mean (SD)	Weight (kg), mean (SD)		BMI, mean (SD)	
				0 hours	+24 hours	0 hours	+24 hours
IG[a]	23 (50)	25 (4.5); 18-34	178.6 (10.2)	82.8 (11.7)	83.4 (12)	26 (3.6)	26.2 (3.7)
CG[b]	23 (50)	29.1 (7.6); 20-57	178 (7.5)	82 (13.0)	83 (13.2)	25.9 (3.7)	26.2 (3.7)
All	46 (100)	27.1 (6.5); 18-57	178.3 (8.8)	82.4 (12.3)	83.2 (12.5)	26 (3.6)	26.2 (3.7)

[a]IG: intervention group (compression).

[b]CG: control group (no compression).

Table 2. Gaming, screen time, and physical activity (n=46).

Group	Values, n (%)	Gaming (hours/day), mean (SD)			Sedentary screen time[a] (hours/day), mean (SD)	Active sports club membership, n (%)	Physical activity[b] (days/week), mean (SD)
		Smartphone and tablet	Computer	Console			
IG[c]	23 (50)	0.5 (0.7)	2.5 (1.5)	0.07 (0.3)	5.9 (3.2)	7 (30)	2.6 (1.6)
CG[d]	23 (50)	0.6 (0.8)	1.4 (0.7)	0.03 (0.1)	7.6 (3.9)	7 (30)	3.1 (31.6)
All	46 (100)	0.5 (0.7)	1.9 (1.3)	0.05 (0.2)	6.7 (3.6)	14 (30)	2.9 (1.6)

[a]Total business and recreational screen time (recreational smartphone use excluded).

[b]Days per week with at least 60 minutes of moderate to vigorous physical activity on a normal week.

[c]IG: intervention group (compression).

[d]CG: control group (no compression).

Bioelectrical Impedance Analyses

Participants reported that they reach the PA guidelines for adults on 2.6 (IG) and 3.1 (CG) days of a normal week and 30% (7/23) of participants in both groups were active members of sports clubs. Total sedentary screen time was slightly higher in the CG, with an average of 6.7 (SD 3.6) hours per day for the total sample, including a total of approximately 2.5 hours of daily gaming. Table 3 shows the results of the pre-event and postevent whole-body BIA and the related time and time×group interactions.

R, Xc, and all the derived parameters remained stable in the IG (Table 3). Among the participants in the CG, R, Xc, and PhA significantly declined, whereas TBW significantly increased, and a 0.8-kg increase in ECM was close to statistical significance (P=.05). The rmANOVAs revealed significant time and group interactions among R, Xc, PhA, and TBW. Descriptive differences in the change of ECM between groups were on the edge of statistical significance ($F_{1,44}$=3.56; P=.06; p. η^2=0.075), with participants in the IG losing 0.2 (SD 1) kg and those in the CG gaining 0.8 (SD 2.1) kg during the event.

The segmental BIA analyses showed no significant effects for time or time×group interactions for the upper extremities (Table 4). For the lower extremities, significant effects of time and time×group interactions were found for all parameters. Participants without compression showed a mean decrease of −11.4 (SD 15.8) Ω for R and −3.1 (SD 2.8) Ω for Xc, resulting in a mean decrease of the PA by 0.47 (SD 0.28) units, whereas participants with compression showed a slight increase of R (mean +3.6, SD 10.7 Ω), Xc (mean +0.9, SD 2.1 Ω), and PA (mean +0.09, SD 0.37 units).

Table 3. Pregaming and postgaming assessment of the bioelectrical impedance analysis results (whole body).

Measure	IG[a], mean (SD)	CG[b], mean (SD)	ANOVA[c] (time)			ANOVA (time×group)		
			F test (*df*)	*P* value	p. η^2	*F* test (*df*)	*P* value	p. η^2
R[d] (Ω)			0.86 (1,44)	.36	0.019	5.26 (1,44)	.02	0.107
0 hours	515.6 (55.1)	491.2 (69.2)						
+24 hours	520 (55.4)	481 (73.1)[e]						
Xc[f] (Ω)			3.56 (1,44)	.06	0.075	13.63 (1,44)	<.001	0.237
0 hours	61.3 (6.3)	58.4 (7.4)						
+24 hours	62.3 (7)	55.3 (6.8)[e]						
PhA[g] (°)			8.72 (1,44)	<.001	0.165	20.12 (1,44)	<.001	0.314
0 hours	6.80 (0.43)	6.84 (0.84)						
+24 hours	6.85 (0.45)	6.60 (0.81)[e]						
TBW[h] (L)			4.2 (1,44)	.04	0.087	5.28 (1,44)	.02	0.107
0 hours	44.8 (6.5)	46.5 (6.4)						
+24 hours	44.8 (6.6)	47.2 (6.7)[e]						
ICM[i] (kg)			0.04 (1,44)	.94	0.001	0.23 (1,44)	.63	0.005
0 hours	34 (5)	35.4 (6)						
+24 hours	34.1 (4.9)	35.4 (6)						
ECM[j] (kg)			1.79 (1,44)	.19	0.039	3.56 (1,44)	.06	0.075
0 hours	27.3 (4.1)	28.3 (4.2)						
+24 hours	27.1 (4.4)	29.1 (4.3)						

[a]IG: intervention group (compression).

[b]CG: control group (no compression).

[c]ANOVA: analysis of variance.

[d]R: resistance.

[e]Within-group post hoc *t* test (2-tailed) for the effect of time significant (P<.05).

[f]Xc: reactance.

[g]PhA: phase angle.

[h]TBW: total body water.

[i]ICM: intracellular mass.

[j]ECM: extracellular mass.

Table 4. Pregaming and postgaming assessment of bioelectrical impedance analysis results for extremities.

Extremity and measure	IC[a], mean (SD)	CG[b], mean (SD)	ANOVA[c] (time)			ANOVA (time×group)		
			F test (*df*)	*P* value	p. η^2	*F* test (*df*)	*P* value	p. η^2
Upper								
R[d] (Ω)			1.41 (1,44)	.24	0.031	0.05 (1,44)	.82	0.001
0 hours	260.1 (27.6)	248.5 (45.4)						
+24 hours	262 (29.6)	251.1 (49.2)						
Xc[e] (Ω)			0.27 (1,44)	.60	0.006	0.43 (1,44)	.51	0.010
Pregaming	29.9 (3.2)	28.7 (2.9)						
+24 hours	29.9 (3.6)	29 (3.2)						
PhA[f] (°)			0.35 (1,44)	.56	0.008	0.85 (1,44)	.36	0.019
Pregaming	6.57 (0.48)	6.71 (0.89)						
+24 hours	6.51 (0.51)	6.72 (0.88)						
Lower								
R (Ω)			3.85 (1,44)	.05	0.080	14.37 (1,44)	<.001	0.246
Pregaming	234.6 (28.1)	224.5 (29.7)						
+24 hours	238.2 (25)	213 (28.4)[g]						
Xc (Ω)			9.35 (1,44)	.004	0.175	29.26 (1,44)	<.001	0.399
Pregaming	29 (3.5)	27.4 (4.8)						
+24 hours	29.9 (3.8)	24.2 (4.3)[g]						
PhA (°)			15.81 (1,44)	<.001	0.264	33.17 (1,44)	<.001	0.430
Pregaming	7.08 (0.55)	6.89 (0.85)						
+24 hours	7.16 (0.54)	6.41 (0.81)[g]						

[a]IG: intervention group (compression).

[b]CG: control group (no compression).

[c]ANOVA: analysis of variance.

[d]R: resistance.

[e]Xc: reactance.

[f]PhA: phase angle.

[g]Within-group post hoc *t* test (2-tailed) for the effect of time significant ($P<.05$).

Complaints

Participants' complaints concerning their lower extremities directly before the first and after the last BIA measurements are shown in Table 5.

Participants without compression complained significantly more about heavy legs ($F_{1,34}=4.25$; $P=.04$; p. $\eta^2=0.111$) and swollen legs ($F_{1,34}=5.17$; $P<.001$; p. $\eta^2=0.132$) compared with participants with compression. Participants with compression reported significantly more itching ($F_{1,22}=4.33$; $P=.04$; p. $\eta^2=0.113$).

Table 5. Complaints regarding the legs directly before and after the bioelectrical impedance analysis measurements.

Complaint	IG[a] (0 hours), mean (SD)	IG (+24 hours), mean difference	CG[b] (0 hours), mean (SD)	CG (+24 hours), mean difference	rmANOVA[c] (time×group)		
					F test (*df*)	*P* value[d]	p. η^2
Heavy legs	1.1 (1.3)	+0.13	0.4 (0.9)	+1.46	4.25 (1,34)	.04	0.111
Swollen legs	0.9 (1.1)	+0.08	0.1 (0.3)	+1.53	5.17 (1,34)	.03	0.132
Tingling	1.2 (1.6)	+0.08	0.4 (0.8)	+0.15	0.02 (1,34)	.87	0.001
Tension	1.2 (1.1)	+0.13	0.8 (1.2)	+0.23	0.02 (1,34)	.87	0.001
Pain	1.4 (1.6)	−0.21	1.5 (2.4)	−0.53	0.24 (1,34)	.62	0.007
Itching	0.7 (0.8)	+0.56	0.8 (1.5)	−0.38	4.33 (1,34)	.04	0.113
Muscle aching	1.8 (2.2)	−0.87	0.8 (1.5)	−0.76	0.39 (1,34)	.84	0.001

[a]IG: intervention group (compression).

[b]CG: control group (no compression).

[c]rmANOVA: repeated measurement analysis of variance.

Discussion

Principal Findings

Our study shows that extensive screen time use by gamers can cause short-term effects on water balance and its allocation among body compartments, which can be measured by BIA and prevented by compression stockings. We have summarized findings with regard to our initial hypotheses in the subsequent sections.

Prolonged Gaming and Associated Behaviors Cause a Significant Increase in TBW, Which Can Be Measured by BIA

We found a significant increase of 0.76 (1.20) L in TBW among the participants without compression. Of the 23 participants, 14 (61%) participants without compression showed increased TBW during the course of the study (mean +1.4, SD 1.1 L), whereas 2 (9%) participants showed no changes and 7 (30%) participants showed decreased TBW (mean −0.3, SD 0.2 L).

Prolonged Gaming and Associated Behaviors Cause a Significant Increase in Body Water as Measured by a Decrease in Local R Among the Lower Extremities but Not the Upper Extremities

As there are no published methods for directly quantifying the water in body segments measured by the BIA that we used and as those that exist for other BIA methods depend heavily on a multitude of assumptions such as the resistivity of the blood [47], we relied on the raw data of R to compare the extremities. Particularly within a time frame of 24 hours, one can directly conclude the changes of the extracellular water (ECW) content of a tissue by its changes in bioelectrical R. In our setting, we found no significant increase in R in the upper extremities of participants in both groups. However, in the lower extremities, participants without compression showed a mean decrease in R of −11.4 (SD 15.8) Ω, whereas the participants in the IG showed a slight increase of +3.6 (SD 10.7) Ω. This is consistent with data from a pilot study on leg fluid accumulation during sitting that found an exponential-into-linear increase in fluid volume in the legs of 14 participants over 150 minutes [48].

Prolonged Gaming and Associated Behaviors Cause a Decrease in Bioelectrical PhA in the Lower Extremities, Which Indicates an Overall Stronger Pronounced Increase in Extracellular Fluids Compared With Intracellular Fluids

Our data confirm hypothesis 3, with a significant interaction between time and group for the PhA of the lower extremities ($F_{1,44}$=33.17; *P*<.001; p. η^2=0.430) and the whole body ($F_{1,44}$=20.12; *P*<.001; p. η^2=0.314). The participants in the CG showed a decrease in their mean PhA by −0.23° (SD 0.23°) for the whole body and −0.47° (SD 0.28°) for the lower extremities, whereas the PhA of the participants in the IG remained relatively stable at +0.01° (SD 0.20°) for the whole body and +0.08° (SD 0.37°) for the lower extremities. Analyses of variance showed large effect sizes with 43% (lower extremities) and 31.4% (whole body) explained variance among the PhA change throughout compression. As PhA is a ratio between Xc and R, it increases with the ability of cells to function as an alternating current resistor, which in turn increases with the quantity of intracellular fluid, which is a predictor of cell nutrition and functioning [49] and ultimately motor performance [50]. This can be interpreted as a meaningful positive effect of compression stockings during gaming and associated behaviors.

Prolonged Gaming and Associated Behaviors Lead to an Increase in ECM but Not in ICM

We found no changes in ICM among both groups but found a marginal decline of 0.2 kg in ECM among the participants in the IG and a 0.8 kg increase of ECM among the participants in the CG. With *P*=.06, the time and group interaction for ECM was at the edge of statistical significance. Further studies are needed to confirm or reject the hypothesis that an increase in TBW after prolonged gaming is mainly owing to an increase in extracellular but not intracellular fluid mass.

The Use of Compression Stockings Can Reduce the Decrease in PhA and the Increase in TBW (PhA Group and TBW*Group Interactions)*

Descriptive statistics and significant time and group interactions with effect sizes of 31.4% and 43% explained variance for the whole body and the lower extremities found by rmANOVAs show that compression can level out the accumulation of water after 1 day of gaming and associated behaviors. On average, the participants in the IG showed increased PhA during the study, which indicates the effectiveness of compression stockings as a preventive action during prolonged gaming. A recent study showed that periods of 3 hours of constant sitting already cause a decrease in intracellular fluid volume and increase in extracellular fluid volume, as well as a decrease in oxygenation levels without, but not with, the use of compression stockings [51]. A recent study showed that fluid accumulation in the legs grows exponentially during the first 45 minutes of seated immobility and then follows a linear function [48]. Further experimental studies on the dose–response mechanism of compression and large-scale epidemiological studies on the risk for SIT or e-thrombosis with and without compression are needed.

We think that these findings are of high relevance for public health and the prevention of future diseases in recreational gaming and the esports community. This is not only because of the increasing relevance of gaming during the recreational time of all age groups [9,10] but also for the prevention of diseases in the rising population of gaming-related professionals. The fact that prolonged sitting or standing can impair vascular function is not new. Many cases have been described in workplace settings [20-24] and also among gamers [25,29,33,35,36]. Table 6 shows a brief overview of reported clinical cases caused by prolonged gaming or computer use. A closer description of most studies can be found elsewhere [52].

Table 6. Examples of case studies about diseases caused by prolonged screen time.

Study	Patient description, age (years); gender	Disease	Trigger
Beasley et al [26]	32; male	Severe bilateral PE[a]	12 hours/day computer use
Ng et al [29]	12; male	DVT[b]	4 hours/day gaming
Lee [30]	24; male	Fatal PE	80 hours continuous gaming
Chew [31]	16; male	Severe PE	3-4 hours continuous gaming
Kim et al [32]	36; male	Severe PE	12 hours continuous gaming
Elikowski et al [33]			
	19; male	DVT	12 hours continuous gaming
	30; male	DVT	12 hours continuous computer use
	19; female	DVT	14 hours continuous gaming and computer use
	23; female	DVT	16 hours continuous computer use
	50; male	DVT	12 hours continuous computer use
	68; male	DVT	16 hours continuous computer use
Chung et al [34]	30; female	CVST[c]	≥12 hours continuous computer use
Chang et al [35]	31; male	Severe DVT	8 hours/day for 4 days continuous gaming
Braithwaite et al [36]	42; male	Severe PE	48 hours continuous gaming
Doctor and Seth [28]			
	50; male	Severe DVT	12 hours continuous computer use
	18; female	Severe DVT	Continuous computer use
Braithwaite et al [27]	44; male	Severe PE	36 hours continuous gaming
Kohorst et al [25]			
	18; male	Bilateral PE	12 hours continuous gaming
	15; male	Severe DVT and PE	4-12 hours/day continuous gaming
	13; male	PE	Continuous gaming
	17; male	DVT and severe bilateral PE	Continuous gaming

[a]PE: pulmonary embolism.

[b]DVT: deep venous thrombosis.

[c]CVST: cerebral venous sinus thrombosis.

Case studies (Table 6) and experimental studies [16,51,53] show that a single session of physical inactivity can impair vascular function. However, in a workplace setting [53] or during recreational watching of television [55], the effects are small and cases are rare. A simple explanation for this may be the fact that if we are not forced to stay physically inactive, such as physicians in surgery or travelers on an airplane, our natural behavior is to stand up and interrupt prolonged physical inactivity before damage is done to our vascular functioning. To date, we do not know to what extent this applies to highly competitive gamers and streamers. Regarding the latter, data from the web-based platform *twitch.tv* shows that not only the net revenue but also the actual viewer counts rise with the duration of a stream and that most gaming streams produce long-duration content [56,57]. At the same time, interruptions or breaks during the stream lead to a massive decline in viewership, even if the streamer just goes to the toilet for more than a minute.

In summary, studies have shown that the use of compression stockings to prevent impairments in vascular function is effective [51,58,59] and can impact physiological [60] and even psychological [61] responses to prolonged sitting or standing among healthy individuals. Our study adds that compression stockings can effectively address this issue among gamers and that BIA may be a valid tool for tracking risk factors or symptoms of diseases such as a decrease in PhA or an increase in TBW. However, the specific handling such as the duration of wearing, the optimal force of compression (eg, 15-20 mm Hg vs 20-30 mm Hg), and most importantly, a design that matches the demands of recreational and professional gamers and live streamers with usability is yet to be found. Future studies should focus on these points and the dissemination of knowledge about vascular functioning among the growing population of gamers and gaming-related live streamers.

Strength and Limitations

As we used a field setting where we did not control for behaviors (eg, eating, drinking, breaks, and sleep), we cannot generalize the effects we found specifically to one behavior associated with gaming. An increase in TBW is ultimately mediated by water consumption and, besides being very unlikely, we cannot ignore that some participants dehydrated during the 24-hour time frame or lost water because of malnutrition; and therefore, water retention might have been underestimated in some participants. Thus, future studies should focus on underlying mechanisms, specific negative behaviors during gaming, and preventive behaviors beyond compression such as using comfortable sitting options or standardized breaks [62] and control for food and water consumption. Other factors such as stress [63] and excitement could be partly responsible for the gamers' behavior and physical responses. However, as we used a randomized controlled design, the positive effects of the compression stockings persisted.

We analyzed the data collected during 3 consecutive years at the gaming event. Post hoc analyses showed that the analysis of only the final year data (30/50, 60% of the participants) showed results comparable with the whole sample, and as we used the same procedure and devices each year, we decided to match the data sets for this study.

BIA is a noninvasive, portable, and economic method to track the quality and quantity of body composition. The 8-electrode multifrequency BIA is considered as the gold standard among portable devices for estimating body composition in healthy populations [64]. The technique has also proven to be a valid tool to assess TBW in different body segments [65] and to estimate intracellular water (ICW) and ECW [66]. A recent study of 27 male judo athletes reported that the raw bioelectrical impedance parameters such as R, Xc, and PhA are useful in tracking fluid shifts and cell hydrations in male athletes [67]. Multifrequency BIA or bioelectrical impedance spectroscopy has been used to diagnose certain diseases that alter fluid balance [68,69]; however, reviews state that relatively large limits of agreement in estimating ICW and ECW in individual measurements limit its validity as a diagnostic instrument in single cases [70]. Nevertheless, in accordance with the study by Silva et al [67], an increasing number of recent studies report the successful use of raw segmental BIA data to track fluid changes in small samples [71] or in persons with arm and leg lymphedema [72]. BIA has been used to analyze ECW in clinical settings [73] and its usability has been proven in the assessment of lymphedema risk and its therapeutic monitoring [74]. Nevertheless, fluid distributions in the body can vary relatively quickly for various reasons. Especially among highly physically active athletes, BIA tends to have only mediocre validity and reliability in specifically assessing ICW and ECW [75]. In 2019, we also collected data for 5 kHz and 100 kHz BIA measurements to determine intracellular and extracellular fluids according to common BIA recommendations. The analysis showed similar results compared with ICM and BCM as reported in Table 4. Recent research focuses on improving the quality of segmental BIA analyses and on the distinction between ICW and ECW with the ability to track them continuously in everyday life [76]. Future studies should use these new technologies to disprove, replicate, or extend our results.

Conclusions and Forecast

At present, an increasing number of recreational gamers professionalize themselves with competitive gaming or streaming, and for many others, the struggle for a professional career becomes their hobby. From a public health perspective, these new-formed professions and hobbies share a crucial issue: not sitting in front of the screen is ineffective in reaching your goals. This raises different questions about health issues associated with seated immobility. Different preventive measures such as designing and setting up ergonomically suitable computer workstations, using comfortable sitting positions, and avoiding long and uninterrupted physical inactivity have recently been discussed [62]. However, to the best of our knowledge, no study has described the population of live streamers and recreational or professional esports athletes as a potentially high-risk group for e-thrombosis and the possibility to effectively countermeasure this with compression stockings. We conclude from our data that the use of compression stockings during prolonged gaming and streaming lowers the risk for diseases caused by seated immobility, such as SIT, VTE, and deep venous thrombosis; however, future

studies are needed to provide tailored recommendations. Finally, as there is no specific textile or clothing related to professional gaming and streaming yet, effective compression stockings may advance to a multimillion-dollar industry that favors both public health *and* the merchandise industry.

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Conflicts of Interest

None declared.

Editorial Notice

This randomized study was not registered, explained by authors that this was an observational study. The editor granted an exception from ICMJE rules mandating prospective registration of randomized trials, because the risk of bias appears low and the study was considered formative. However, readers are advised to carefully assess the validity of any potential explicit or implicit claims related to primary outcomes or effectiveness, as retrospective registration does not prevent authors from changing their outcome measures retrospectively.

Multimedia Appendix 1
CONSORT-eHEALTH checklist (V 1.6.1).
[PDF File (Adobe PDF File), 28103 KB - ijmr_v11i2e25886_app1.pdf]

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Abbreviations

BCM: body cell mass
BIA: bioelectrical impedance analysis
CG: control group
CONSORT: Consolidated Standards of Reporting Trials
ECM: extracellular body mass
ECW: extracellular water
ICM: intracellular body mass
ICW: intracellular water
IG: intervention group
PA: physical activity

PhA: phase angle
rmANOVA: repeated measurement analysis of variance
SIT: seated immobility thromboembolism
TBW: total body water
VTE: venous thromboembolism

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Original Paper

Association of Continuously Measured Vital Signs With Respiratory Insufficiency in Hospitalized COVID-19 Patients: Retrospective Cohort Study

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Abstract

Background: Continuous monitoring of vital signs has the potential to assist in the recognition of deterioration of patients admitted to the general ward. However, methods to efficiently process and use continuously measured vital sign data remain unclear.

Objective: The aim of this study was to explore methods to summarize continuously measured vital sign data and evaluate their association with respiratory insufficiency in COVID-19 patients at the general ward.

Methods: In this retrospective cohort study, we included patients admitted to a designated COVID-19 cohort ward equipped with continuous vital sign monitoring. We collected continuously measured data of respiratory rate, heart rate, and oxygen saturation. For each patient, 7 metrics to summarize vital sign data were calculated: mean, slope, variance, occurrence of a threshold breach, number of episodes, total duration, and area above/under a threshold. These summary measures were calculated over timeframes of either 4 or 8 hours, with a pause between the last data point and the endpoint (the "lead") of 4, 2, 1, or 0 hours, and with 3 predefined thresholds per vital sign. The association between each of the summary measures and the occurrence of respiratory insufficiency was calculated using logistic regression analysis.

Results: Of the 429 patients that were monitored, 334 were included for analysis. Of these, 66 (19.8%) patients developed respiratory insufficiency. Summarized continuously measured vital sign data in timeframes close to the endpoint showed stronger associations than data measured further in the past (ie, lead 0 vs 1, 2, or 4 hours), and summarized estimates over 4 hours of data had stronger associations than estimates taken over 8 hours of data. The mean was consistently strongly associated with respiratory insufficiency for the three vital signs: in a 4-hour timeframe without a lead, the standardized odds ratio for heart rate, respiratory rate, and oxygen saturation was 2.59 (99% CI 1.74-4.04), 5.05 (99% CI 2.87-10.03), and 3.16 (99% CI 1.78-6.26), respectively. The strength of associations of summary measures varied per vital sign, timeframe, and lead.

Conclusions: The mean of a vital sign showed a relatively strong association with respiratory insufficiency for the majority of vital signs and timeframes. The type of vital sign, length of the timeframe, and length of the lead influenced the strength of associations. Highly associated summary measures and their combinations could be used in a clinical prediction score or algorithm for an automatic alarm system.

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KEYWORDS

continuous monitoring; vital sign monitoring; COVID-19; general ward; vital sign; monitoring; respiration; data; respiratory insufficiency; cohort study; respiratory rate; heart rate; oxygen; clinical

Introduction

Hypoxic respiratory failure is a common complication of COVID-19, caused by severe viral pneumonia or concomitant pulmonary embolism [1,2]. Respiratory deterioration can occur suddenly and sometimes without signs of dyspnea [3,4], which complicates detection. Tools to assess the vital instability of patients more frequently could help to detect respiratory deterioration in a timely manner. Currently, most hospitals use a form of early warning score as a "track-and-trigger" system at the general ward to aid health care professionals in the detection of deterioration [5]. Early warning scores can vary from scores with a few physiological parameters, such as the Modified Early Warning Score [6], to machine-learning algorithms including baseline patient characteristics and laboratory results [7]. However, these models use intermittent measurements to update their prediction, and are therefore limited by the frequency of spot-check measurements and laboratory tests.

An alternative strategy to improve the early detection of deterioration could be continuous monitoring including assessment of vital signs. Continuous monitoring can be beneficial in two ways. First, trends in vital signs over time have been shown to have higher predictive accuracy than isolated vital sign values when incorporated in prediction models [8,9]. With continuous monitoring, trends in vital signs are available at any point in time, and can therefore be used to make up-to-date predictions more frequently. Unfortunately, prediction models using continuously measured vital sign data at the general ward are not yet readily available for clinical use. A second benefit of continuous monitoring is that it enables health care professionals to access the real-time vital sign status of a patient remotely, and to use this information in clinical decision-making [10]. However, nurses and physicians at low-care wards are usually not used to, or trained in, evaluating continuous vital sign data [11]. Current practice is therefore mostly based on experience and expert opinion. Knowledge of "what to look for" in vital sign trends could aid nurses and physicians to interpret continuously measured data in a meaningful way.

In this study, we assessed several measures to summarize continuously measured vital sign data, and evaluated their association with respiratory insufficiency in COVID-19 patients admitted to the general ward. We aimed to find summary measures that could be clinically helpful to recognize respiratory deterioration early, which might further be useful to incorporate into an algorithm for automatic alarming.

Methods

Population and Setting

At the beginning of April 2020, a continuous wireless system for vital sign monitoring was introduced at the COVID-19 cohort ward of the tertiary hospital University Medical Center Utrecht, Utrecht, the Netherlands. This system recorded heart rate (HR) and respiratory rate (RR) using a validated wireless patch sensor [12] (Biosensor Voyage, Philips Electronics Netherlands BV), and peripheral oxygen saturation (SpO2) via a finger pulse oximeter (EarlyVue VS30, Philips Electronics Netherlands BV) every 30 seconds approximated over the past 30 seconds. Data were stored in the software program AnStat (CarePoint Nederland BV, Ede, the Netherlands). Pulse oximeters were delivered later than the wearable sensors (end of May 2020). We included patients from April 2020 until March 1, 2021. Patients were included if they were ≥18 years old, diagnosed with COVID-19, and continuously monitored during their admission at the study ward (either with the biosensor, pulse oximeter, or both). Patients with a pacemaker did not receive a sensor since RR measurements are unreliable in paced rhythms. All continuously measured data were available in real time for hospital staff, without a predefined protocol on how to use continuously measured data or how to detect respiratory insufficiency. The protocol in use for detecting deterioration in general was the National Early Warning Score (NEWS) 2 [13]. The updated Charlson Comorbidity Index was used to assess the baseline risk of 1-year mortality [14].

Ethical Considerations

The study was conducted according to the principles of the Declaration of Helsinki and the General Data Protection Regulation [15,16]. Ethical review was waived by the medical ethical committee Utrecht (MEC-20-365). Patients were offered the chance to opt out of retrospective data analyses during hospital registration and again at hospital discharge, according to the institutional protocol. The data were previously used in a study of circadian rhythm in continuously measured vital signs [17].

Primary Endpoint

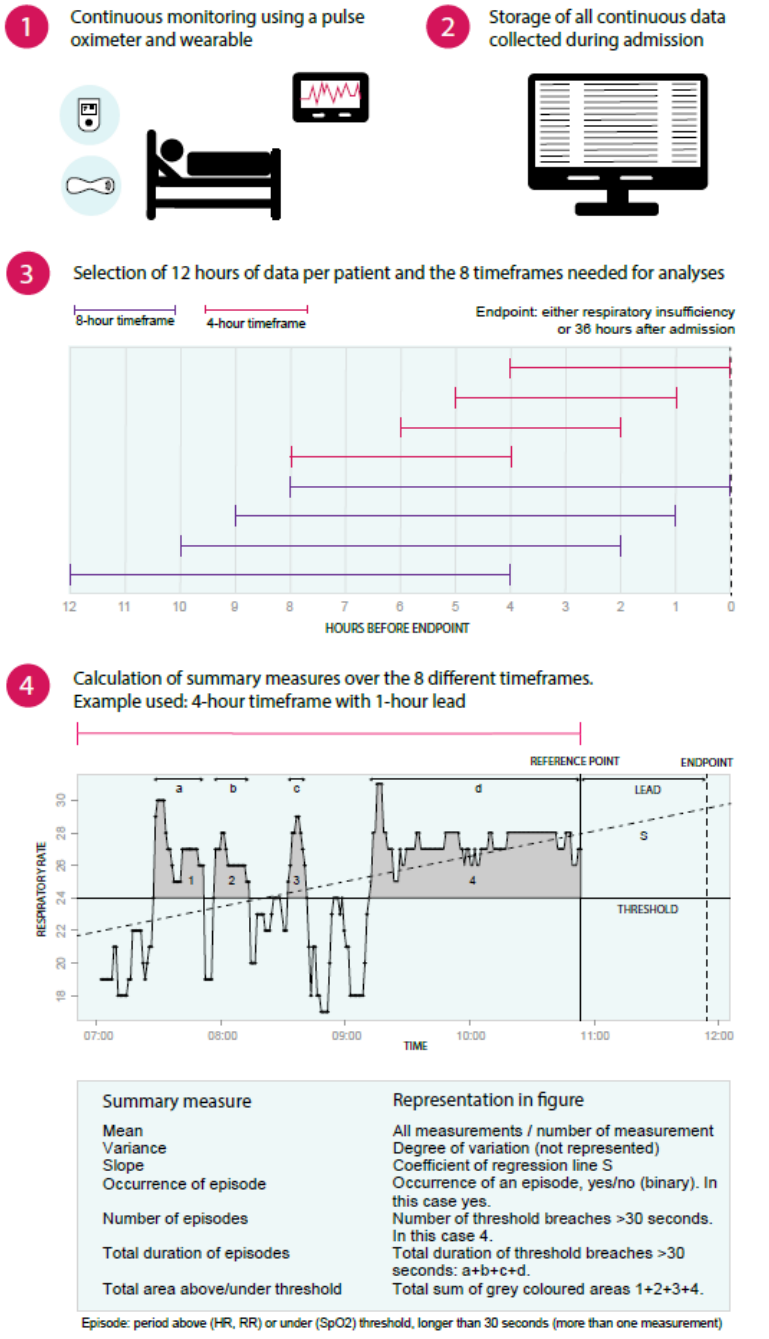
The primary endpoint was respiratory insufficiency, which we defined as the need for 15 L/min oxygen, high-flow nasal oxygen therapy, or mechanical ventilation, whichever came first. We did not deem intensive care unit (ICU) admission or death to be a suitable endpoint since a substantial portion of the population had treatment restrictions preventing them from receiving cardiac resuscitation, mechanical ventilation, and/or ICU admission. Moreover, high-flow nasal oxygen therapy was also given at the general ward, since ICU beds were not always available. The first documentation of the endpoint in the electronic patient record was used as the time point for respiratory insufficiency.

Data Selection

For each patient, we selected 12 hours of continuous vital sign data. For patients who became respiratory-insufficient, we selected the 12 hours of data prior to the onset of respiratory insufficiency. The distribution of the timing of reaching the endpoint in our cohort was approximately 40 hours after starting monitoring, with a right-skewed distribution (ie, several cases reached respiratory insufficiency before the 40-hour point). For patients who did not reach this endpoint, we selected the data from 24 hours up to 36 hours after admission (Figure 1). We chose this window since the majority of patients were connected to the monitoring system within 24 hours after admission. Moreover, the median time until respiratory insufficiency in our cohort was 40.6 hours (IQR 22.6-70.4) after starting monitoring with a right-skewed distribution. By selecting 24-36

hours after starting monitoring for the control group, the timing for the timeframes for both the endpoint and control group were fairly similar. Potential artefacts (RR<1/min or >80/min, HR <30/min or >280/min, SpO2<50%, and large abrupt changes in RR [>20 breaths/min] and HR [>25 beats/min] that lasted for less than 2 minutes) were removed. For each patient, we divided the selected data of 12 hours into 8 different timeframes of either 4 or 8 hours long (Figure 1). We chose these lengths because they clinically correlate with the length of a usual half and full shift of hospital professionals. In addition, we shifted timeframes either 0, 1, 2, or 4 hours from the end of the selected 12-hour data window (the "lead") (Figure 1). For example, with a lead of 4 hours, we assessed whether associations could already be observed 4 hours before the onset of respiratory insufficiency. To handle missing data, timeframes were only included if the first measurement of a timeframe was within 30 minutes of the start of the timeframe and the last measurement was within the last 30 minutes of the timeframe. We did this to avoid selection of timeframes that were actually smaller than assumed due to missing data (eg, if a timeframe of 8 hours only contains 5 hours of data, it is not actually an 8-hour timeframe but rather a 5-hour timeframe).

Figure 1. Data selection for continuous heart rate (HR), respiratory rate (RR), and oxygen saturation (SpO2).



Selection of Summary Measures

As the continuous monitoring of vital signs provides measurements twice every minute, we summarized the continuously measured data into "summary measures." Summary measures are either unrelated to a certain threshold (eg, the mean HR) or related to a threshold (eg, duration of HR>89/min). For all threshold-related variables, we chose three thresholds per vital sign. Thresholds for HR were based on the three upper thresholds for tachycardia of the NEWS2: >90/min, >110/min, and >130/min [13]. For tachypnea, we used the upper two levels of the NEWS2, >20/min and >24/min, and added a third level, >30/min, since the first upper threshold of the NEWS2 would be met by almost every COVID-19 patient. We used the lower two levels of SpO2, <94% and <92%, and added <90% for similar reasons. We chose not to include bradycardia or bradypnea since these were very uncommon as signs of respiratory insufficiency in our population. An episode was defined as more than one measurement (longer than 30 seconds) above or under a certain threshold. Initially, we defined 12 summary measures based on the literature and clinical reasoning [8,18] (Multimedia Appendix 1). Correlation plots of these summary measures showed high correlations between several measures. The summary measure "standard deviation" showed high correlation with "variance" and was therefore eliminated. "Mean duration," "maximum duration," and "total duration" above/under the threshold were highly correlated; therefore, we only included "total duration." A similar choice was made for area above/under the threshold. Ultimately, we selected seven summary measures for analysis: three summary measures unrelated to a threshold and four summary measures related to a threshold (Figure 1).

Statistical Analysis

Baseline characteristics are described for both cohorts. For every patient, all selected summary measures were calculated for the eight timeframes. To investigate the crude association between each of the summary measures and the development of respiratory insufficiency, univariable logistic regression was performed. Effect estimates are reported as odds ratios (ORs) with accompanying CIs. Since the mean and slope of SpO2 have a negative relationship with the endpoint (a decrease in oxygen saturation is associated with the endpoint instead of an increase), the inverse effect estimate is reported for these two summary measures of SpO2. As the selected summary measures had different units of measurement (eg, duration in minutes, area above the threshold in /min×duration or %×duration), we could not directly compare their associations with each other based on crude ORs. Therefore, we used standardized odds ratios (sORs) to compare the association of different summary measures with respiratory insufficiency on a similar magnitude. Standardized summary measures for each patient were calculated using the formula $Z=(x-\mu)/\sigma$, where Z is the newly computed standardized value, x is the summary measure for a particular patient, μ is the mean of the same summary measure for all patients in this timeframe, and σ is the standard deviation of all patients in the respective timeframe. With these standardized measures, the sORs were calculated. For example, an sOR of 2 for a certain summary measure means that if the standard deviation of this measure increases by one, the association with respiratory insufficiency increases by two.

To take multiple testing into account, we tested against a *P* value of .01 for all aforementioned analyses. Bonferroni adjustment was deemed too conservative since the chosen summary measures are highly dependent on each other. We used R software version 4.0.3 (R foundation for Statistical Computing, Vienna, Austria 2021) for all analyses.

Results

Cohort Characteristics

The description of the cohort is provided in Table 1. Of the 429 patients that were monitored, 334 were included for analysis (Figure 2), 66 (19.8%) of whom developed respiratory insufficiency. These patients more often had pulmonary embolism, ICU and medium-care unit admissions, treatment restrictions, and had higher mortality rates (Table 1). Two patients who did not experience respiratory insufficiency were shortly admitted to a high-care unit during monitoring: one patient required monitoring for severe hypokalemia, and the other patient suffered a stroke and was admitted for thrombolysis. All patients had available HR data. The sample of patients with RR data was smaller (n=288) since the sensor had to be calibrated to measure RR, which was not always executed immediately. Due to late delivery and noncompliance of patients with the pulse oximeter, SpO2 data were available for only 238 patients. At baseline, these samples differed slightly with respect to the number of patients that received dexamethasone and the number of patients that reached the endpoint (Multimedia Appendix 2). Overall, patients who developed respiratory insufficiency had a higher occurrence of threshold breaches, and spent more time above thresholds for HR and RR and under the thresholds for SpO2 in both the 4-hour and 8-hour timeframes (Multimedia Appendix 3). The mean number of measurements per hour was 79 for 4-hour timeframes and 74 for 8-hour timeframes. Of all timeframes used, 98.8% contained at least 120 measurements.

Table 1. Baseline characteristics and summary of available data.

Characteristic	All (N=334)	No respiratory insufficiency (n=268)	Respiratory insufficiency (n=66)
Age (years), median (IQR)	65 (55.3-73.8)	63 (55-72)	67 (60-75)
Male sex, n (%)	207 (62.0)	168 (62.7)	39 (59.1)
Charlson Comorbidity Index, median (IQR)	0 (0-1)	0 (0-1)	0 (0-2)
Dexamethasone during admission, n (%)	262 (78.4)	208 (77.6)	54 (81.8)
Diagnosed with pulmonary embolism, n (%)	24 (7.2)	14 (5.2)	10 (15.2)
Treatment restrictions[a], n (%)	91 (27.2)	62 (23.1)	29 (43.9)
Length of hospital stay, median (IQR)	7 (5-12)	6.5 (4.8-10)	13 (9-24)
ICU[b] or MCU[c] admission, n (%)[d]	57 (17.1)	30 (11.2)	27 (40.9)
Mortality, n (%)	23 (6.9)	2 (0.7)	21 (31.8)
Heart rate			
Patients with available data, n (%)	334 (100.0)	268 (100.0)	66 (100.0)
Duration per patient (hours), mean (SD)	11.7 (1.1)	11.8 (0.8)	11.4 (1.7)
Respiratory rate			
Patients with available data, n (%)	288 (86.2)	231 (86.2)	57 (86.4)
Duration per patient (hours), mean (SD)	11.6 (1.4)	11.7 (1.1)	11.1 (2.1)
Peripheral oxygen saturation			
Patients with available data, n (%)	238 (71.3)	184 (68.7)	54 (81.8)
Duration per patient (hours), mean (SD)	11.4 (1.4)	11.5 (1.1)	10.9 (2.1)

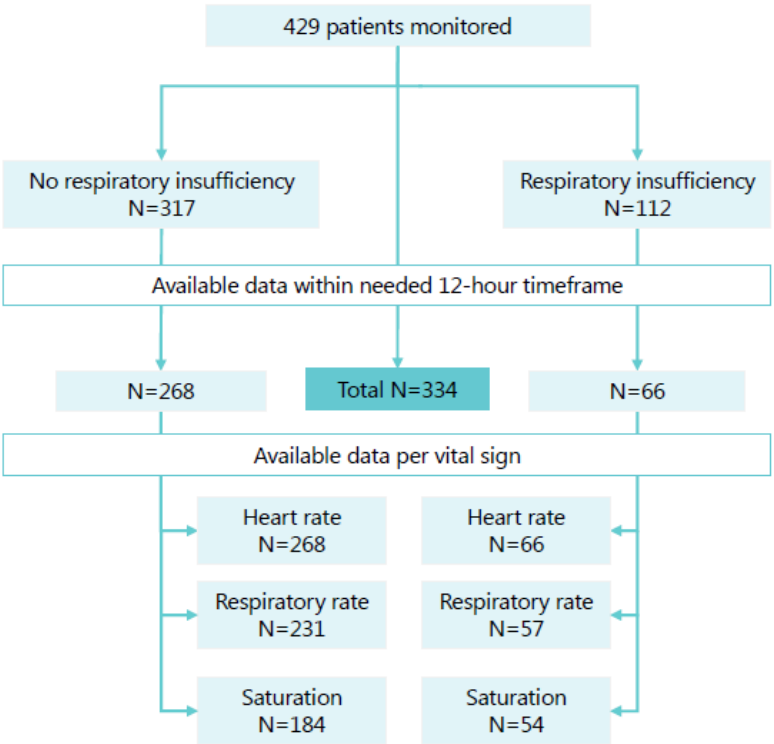
[a]Treatment restrictions: no resuscitation, no ventilation, and/or no ICU admission.

[b]ICU: intensive care unit.

[c]MCU: medium-care unit.

[d]If a patient was monitored after ICU admission and did not reach the endpoint while being monitored, they were included in the "no respiratory insufficiency" group.

Figure 2. Flowchart of patient inclusion based on data availability.



Association of Summary Measures with Respiratory Insufficiency

Since the highest crude ORs were observed in the 4-hour timeframe without a lead, we have outlined the results of the analysis for this timeframe in Table 2 and Table 3 for measures without and with a threshold, respectively. The summary measure with the highest crude OR was the occurrence of RR>24/min (Table 3). For many summary measures of RR and SpO2, CIs were extremely wide, in particular in summary measures that were threshold-dependent and for which the threshold was breached by the majority of the patients in an outcome group. For example, a threshold breach for SpO2 of <90% occurred in all but one case of patients who experienced respiratory insufficiency, leading to a 99% CI of 1.64-915.0. This phenomenon was also seen in other timeframes. When comparing the standardized ORs in the 4-hour timeframe without a lead, we found stronger associations for RR and SpO2 than for HR. The mean showed a strong association for all three vital signs, with an sOR of 2.59 (99% CI 1.74-4.04) for HR, 5.05 (99% CI 2.87-10.03) for RR, and 3.16 (99% CI 1.78-6.26) for SpO2.

Table 2. Results of univariable, nonstandardized, analyses for 4-hour timeframes without a lead for measures with no threshold.

Parameter	Mean[a]		Slope[b]		Variance[c]	
	OR[d] (99% CI)	*P* value	OR (99% CI)	*P* value	OR (99% CI)	*P* value
Heart rate	1.06 (1.03-1.08)	<.001	1.02 (0.99-1.00)	.64	1.00 (0.99-1.00)	.99
Respiratory rate	1.44 (1.27-1.67	<.001	1.30 (0.88-1.93)	.09	1.09 (1.01-1.17)	.003
Oxygen saturation	1.61 (1.27-2.04)	<.001	1.79 (0.90-3.70)	.03	1.21 (1.09-1.38)	<.001

[a]Calculated as /min for heart rate and respiratory rate and as % for oxygen saturation.

[b]Calculated as /min/hour for heart rate and respiratory rate and as %/hour for oxygen saturation.

[c]Calculated as /min^2 for heart rate and respiratory rate and as %^{2} for oxygen saturation.

[d]OR: odds ratio.

Table 3. Results of univariable, nonstandardized, analyses for 4-hour timeframes without a lead for measures with a threshold.

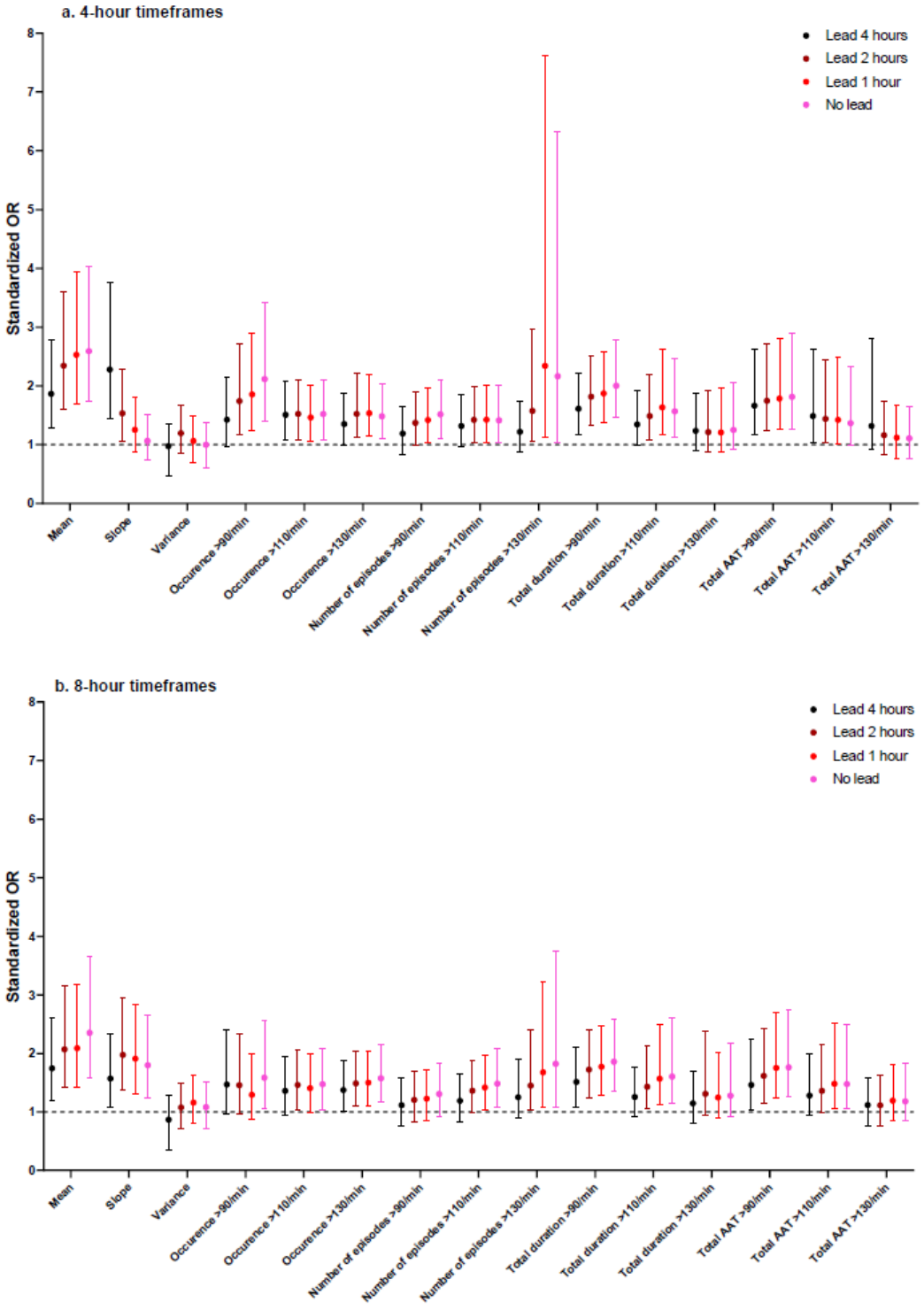
Threshold	Occurrence		Number of episodes		Total duration (min)		Total area above threshold (/10 min)	
	OR[a] (99% CI)	*P* value	OR (99% CI)	*P* value	OR (99% CI)	*P* value	OR (99% CI)	*P* value
Heart rate (/min)								
>90	4.50 (1.95-11.8)	<.001	1.12 (1.03-1.23)	<.001	1.01 (1.01-1.01)	<.001	1.00 (1.00-1.01)	<.001
>110	2.79 (1.24-6.18)	<.001	1.16 (1.02-1.35)	.005	1.01 (1.00-1.03)	.002	1.00 (1.00-1.01)	.04
>130	6.09 (1.56-25.5)	<.001	1.98 (1.04-5.01)	.03	1.01 (1.00-1.04)	.08	1.00 (0.99-1.02)	.37
Respiratory rate (/min)								
>20	7.35 (1.03-531.0)	.05	0.89 (0.77-1.01)	.03	1.02 (1.01-1.03)	<.001	1.04 (1.02-1.05)	<.001
>24	13.8 (3.68-103.4)	<.001	1.21 (1.09-1.35)	<.001	1.02 (1.01-1.03)	<.001	1.05 (1.03-1.08)	<.001
>29	8.53 (3.63-21.2)	<.001	1.59 (1.32-1.98)	<.001	1.02 (1.01-1.04)	<.001	1.07 (1.03-1.13)	<.001
Oxygen saturation (%)								
<94	12.6 (4.11-47.7)	<.001	1.30 (1.11-1.56)	<.001	1.05 (1.02-1.09)	<.001	0.80 (0.67-0.91)	<.001
<92	12.3 (3.07-94.5)	<.001	1.30 (1.15-1.49)	<.001	1.03 (1.02-1.05)	<.001	0.88 (0.82-0.94)	<.001
<90	11.9 (1.64-915.0)	.02	1.09 (1.01-1.19)	.006	1.02 (1.01-1.03)	<.001	0.93 (0.90-0.96)	<.001

[a]OR: odds ratio.

Summary Measures for HR

The highest sORs were observed for mean HR in the 4-hour timeframe without a lead (2.59, 99% CI 1.75-4.04) (Figure 3). Only three summary measures were significantly associated with respiratory insufficiency in all timeframes: the mean, total duration >90/min, and total area above the threshold>110/min. In general, associations were stronger for summary measures in 4-hour timeframes compared with 8-hour timeframes. A notable exception was the slope, for which the associations were low or insignificant in three 4-hour timeframes, but relatively strong in the 8-hour timeframes. Differences in sORs between leads were small for most summary measures.

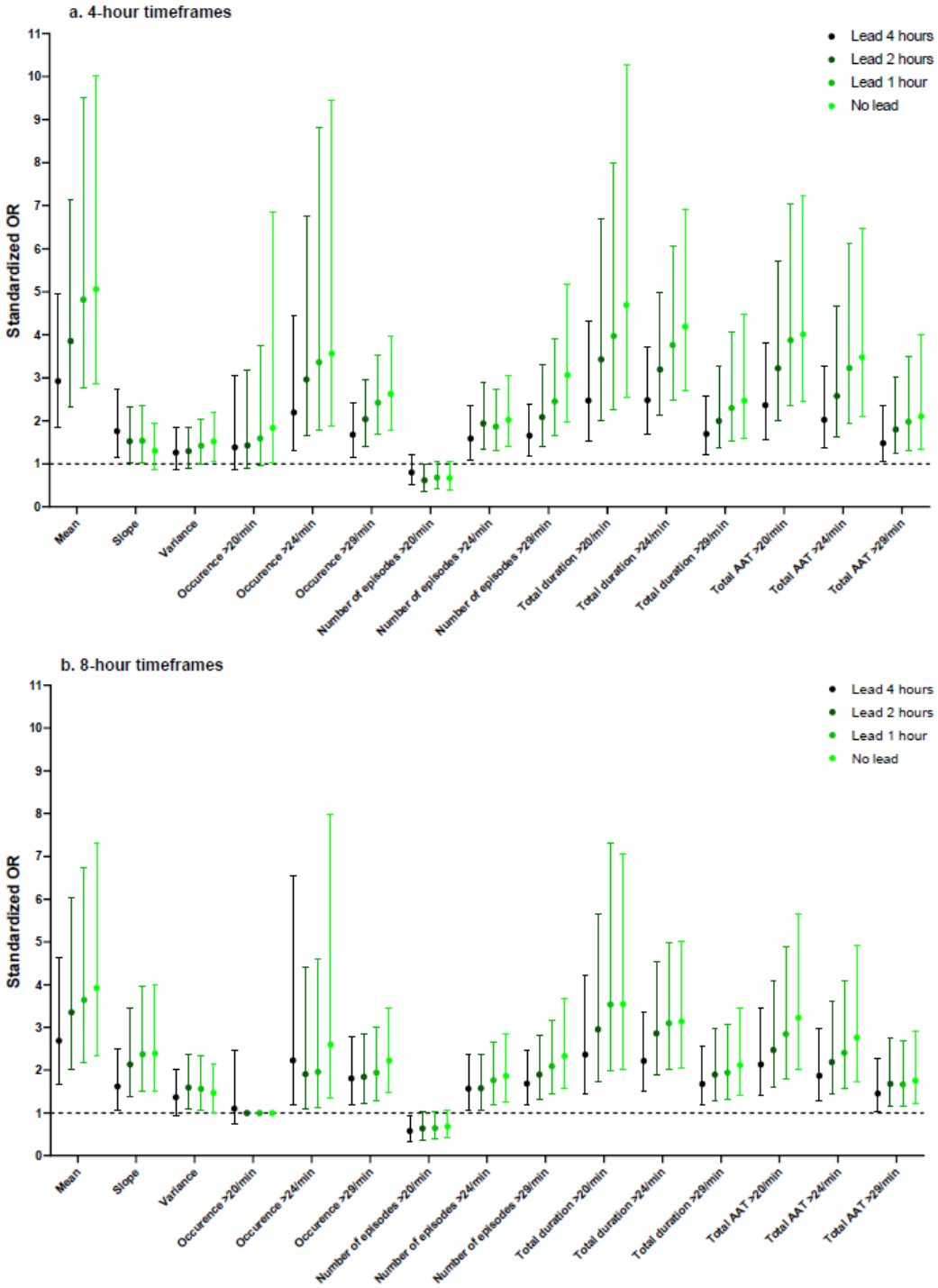
Figure 3. Standardized odds ratios (ORs) for heart rate. AAT: area above threshold.



Summary Measures for RR

The highest sORs were observed for mean RR (sOR 5.05, 99% CI 2.87-10.03) and the total duration of RR>20/min (sOR 4.69, 99% CI 2.55-10.29) in the 4-hour timeframe without a lead (Figure 4). For most threshold-dependent summary measures, the strength tended to decline when the lead increased, but still reached significance. Summary measures calculated over 4-hour timeframes had stronger associations than those calculated over 8-hour timeframes. Remarkably, the number of episodes >20/min was negatively associated with respiratory insufficiency, likely because to have multiple episodes above 20/min, a patient would also need periods of time with an RR under 20/min, which was not exhibited by the patients showing the most deterioration.

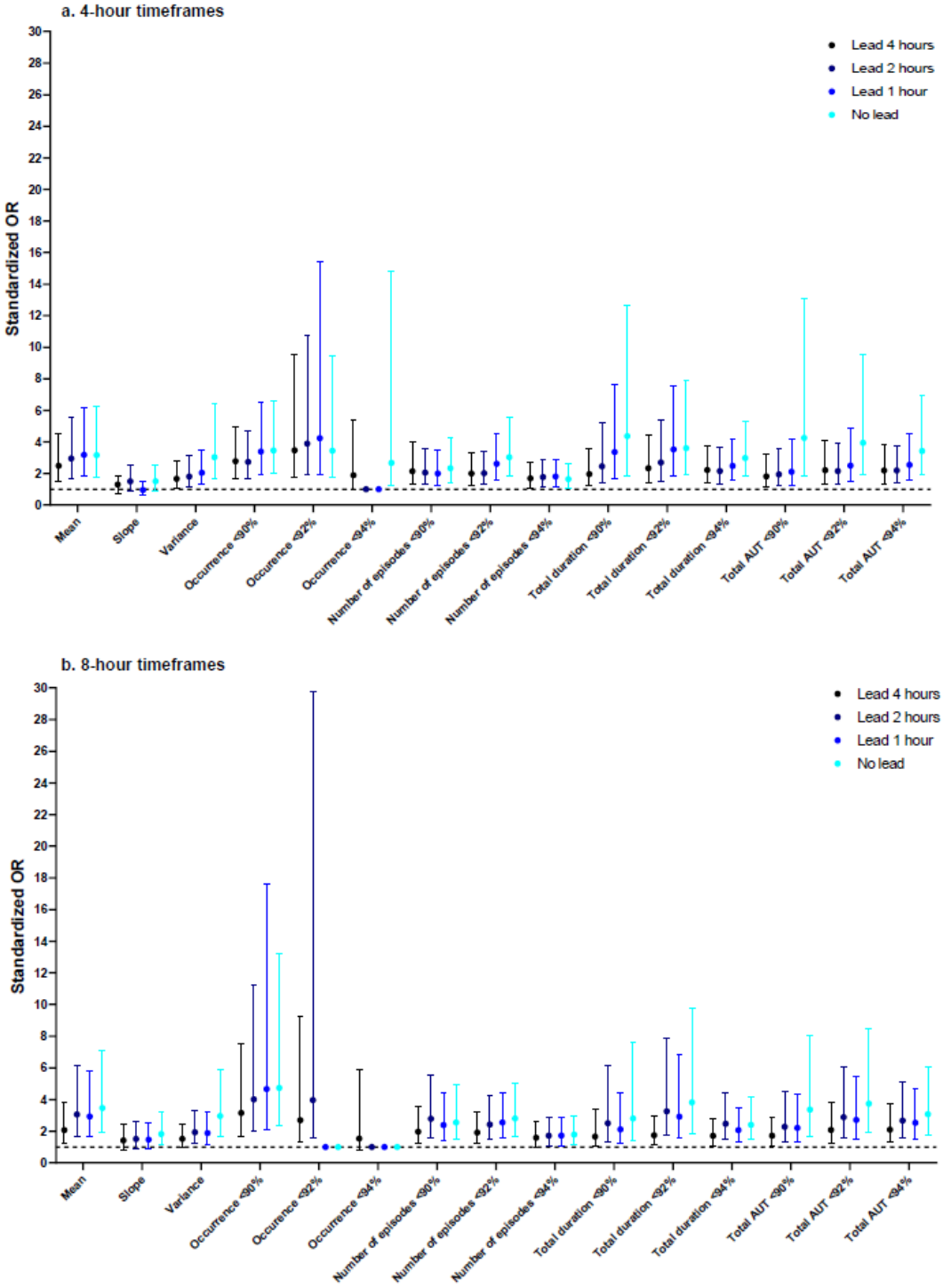
Figure 4. Standardized odds ratios (ORs) for respiratory rate. AAT: area above threshold.



Summary Measures for Oxygen Saturation

For SpO2, CIs were generally wider due to the smaller sample size. The strongest association was found in the 8-hour timeframe without a lead, for occurrence of SpO2<90% (sOR 4.74, 99% CI 2.36-13.23) (Figure 5). SpO2 was the only vital sign for which associations were generally slightly stronger in 8-hour timeframes. For many summary measures, the association with respiratory insufficiency was evidently stronger in the timeframes without a lead, especially for variance, total duration, and total area under the threshold. The mean showed a weaker association than some threshold-related summary measures such as occurrence of SpO2<94% in 4-hour timeframes. Nonetheless, the mean was significantly associated with respiratory insufficiency in all timeframes.

Figure 5. Standardized odds ratios (ORs) for oxygen saturation. AUT: area under threshold.



Discussion

Principal Findings

In this study, we aimed to explore which summary measures for continuously measured HR, RR, and SpO2 data could be helpful in recognizing imminent respiratory insufficiency in COVID-19 patients at the general ward. We found that summary measures over timeframes of continuously measured data close to the endpoint of respiratory insufficiency showed stronger associations than timeframes further removed, and that 4-hour timeframes performed better than 8-hour timeframes. The summary measure "mean" was consistently strongly associated with respiratory insufficiency for all vital parameters. The strength of associations of summary measures depended on the vital sign, timeframe, and lead.

Comparison With Prior Work

RR has repeatedly been marked as the best discriminator to identify patients at risk for deterioration [19,20]. In our study, we confirmed that RR showed stronger associations with respiratory insufficiency than HR. SpO2 was also strongly associated with respiratory insufficiency, which can partly be explained by the population (COVID-19 patients) and the endpoint (respiratory failure). In a previous study on trends in vital signs of hospitalized patients, Churpek et al [8] used several summary measures for trend analysis of intermittent data to predict clinical deterioration. They found that the slope, mean, and standard deviation were better predictors than the current value for HR and RR, and the mean performed well for SpO2. In our study, we confirmed a strong association of the mean of all three vital parameters with respiratory insufficiency. However, the slope and standard deviation were less informative. This might be caused by differences between intermittently and continuously measured vital signs. Due to the high density of measurements, continuously monitored vital sign data show more variance than intermittent data in our experience, and are more subject to peaks and troughs depending on a patient's activity level. Akel et al [9] also found that the (intermittently measured) maximum RR and HR were important predictors. We did not use the maximum value, since we expected the maximum value to rely highly on both activity level and outliers (eg, due to coughing or talking), and would therefore not be clinically useful. A recent study did use summary measures for continuously measured vital signs (mean, standard deviation, range, and mean absolute deviation) over 3-hour timeframes [21]. The authors created a machine-learned model of these summary measures along with other data features, and managed to predict complications in postoperative patients with a lead of 12 hours. Unfortunately, this method does not allow for comparison of the value of these different summary measures. In our study, we only used leads up to 4 hours to limit the number of computations. We found that shorter leads led to stronger associations. This might be an obvious finding, as vital instability is often a gradual process of decline, most pronounced at the end when a patient becomes respiratory-insufficient [22]. However, this finding nuances earlier failure-to-rescue statements and illustrates that the information content is less dense 12 hours prior to the event [23,24]. In current clinical practice (and at our study ward) the NEWS2 is often used to detect deterioration [13]. Our thresholds were based on this score. In the NEWS2, more severe threshold breaches receive more points, and thus correspond with a higher risk of poor outcome. From this context, we would have expected summary measures of more severe thresholds to have a stronger association with respiratory insufficiency. Interestingly, this was not the case.

Methodological Decisions and Limitations

In this exploratory study, we made several methodological decisions that affected the results. First, we chose a cross-sectional method to determine the association of summary models with respiratory insufficiency, by comparing patients who reached the endpoint with those who did not. A longitudinal assessment of risk for respiratory insufficiency (eg, using a dynamic prediction model) might be an approach that is more in line with clinical practice. In a dynamic prediction model, previously recorded data of a patient can be included to update the estimated patient's risk of developing the outcome of interest at consecutive time points. However, the sample sizes of existing continuous monitoring studies are relatively small and the populations are heterogeneous, which may complicate the development of robust prediction models [10]. Larger studies and open sharing of continuous data might speed up the process of developing and validating such longitudinal dynamic models. A second methodological key decision was to only select summary measures, timeframes, and models that could easily be understood by health care professionals. Hereby, we limit the "black box" effect of complex models, for which the exact computational procedure is opaque [25]. These models might have better predictive accuracy, but are unintelligible for clinical professionals, which makes clinicians reluctant to use and rely on them [25]. For this explorative study, we aimed to increase the understanding of the association between continuous vital signs and deterioration, and therefore we chose a transparent methodology. However, machine-learning models have proven to be more accurate than current practice in several fields of medicine [26]. In predicting deterioration, some studies have shown that machine-learning models outperform "simple" regression models [9,27,28]. In a recent study, a machine-learning model was developed that uses several summary measures of vital signs to predict the deterioration of high-risk patients [21]. Explorative studies such as the present study could provide insight into which summary measures to include into such a machine-learning model [21]. A final addition to a model with continuous monitoring data could be nonvital sign parameters such as the amount of administered oxygen. The combination of administered oxygen with RR and SpO2 has previously shown to accurately predict respiratory insufficiency in COVID-19 patients [29]. Regardless of the type of prediction model or algorithm that is constructed using continuously measured vital sign data, any model should be well calibrated and be externally validated before implementation in clinical practice [30].

Strengths and Limitations

Beside the above-mentioned methodological considerations, this study has several limitations. We relied on a small convenience sample size, which resulted in limited accuracy, and we were unable to validate our findings in a larger data set. A significant portion of the initial sample had to be excluded owing to lack of continuous monitoring data within the needed 12-hour timeframe for multiple reasons such as loss of connection with the patch, nurses that were not able to or forgot to connect a patient to the system, or patients who reached the endpoint before or within a short time after getting the patch. The exact reasons for these periods of missing data are hard to reconstruct retrospectively. Additionally, there were differences in the number of patients with available data for each vital sign. Patients who were relatively less ill wore the pulse oximeter less often, because they found it annoying, they were mobilizing beyond the reach of the monitor, or the nurse agreed it was no longer necessary to monitor SpO2. The smaller sample size with a relatively high percentage of patients reaching the endpoint might have strengthened the association between SpO2

and respiratory insufficiency. For control patients, we included the 24-36 hours of data following admission to the ward. This was a pragmatic decision, but the choice of timeframes early in the admission period could have influenced the results. Nevertheless, respiratory insufficiency also mostly occurred early in the admission, and therefore the timing of the selected data of the control group and the respiratory insufficiency group was fairly similar. Conclusions can only be drawn for COVID-19 patients. For other patient populations, alternative vital signs and summary measures might be more informative [31]. Since the continuous monitoring system was not implemented alongside standard intermittent monitoring, we could not compare the performance of summary measures with care as usual. All continuous data were visible to the nurses and physicians during the study. The vital sign aberrations they spotted during monitoring will have influenced their decision to start treatment, thus influencing the endpoint. However, staff was limited in the options for additional treatment, and thereby also limited in their influence to avoid the endpoint. Moreover, we do believe the decision to start 15 L/min oxygen therapy, high-flow oxygen therapy, or mechanical ventilation was not solely based on the continuous data but was rather mostly based on the overall clinical condition of the patient. Due to the retrospective nature of the study, we relied on documentation in the electronic patient record to determine the time point of respiratory insufficiency. A prospective design might result in a more accurate estimation of the timing of onset.

Considerations for Future Research

Summary measures of vital signs that show a strong association with the occurrence of respiratory insufficiency could be helpful in several ways. First, they might be used in a clinical score for direct use by nurses and physicians. For intermittently measured vital signs, the early warning score created both a framework to measure vital stability and a language for nurses to communicate instability to a physician [32]. Nurses are empowered by these aspects of the early warning score. Furthermore, they can use the early warning score to easily package and summarize information about a patient, which helps physicians to prioritize care [32]. For continuous data, no such language or score currently exists to communicate observations of continuously measured vital signs. Summary measures could be used to create such as score. For example, the most strongly associated summary measures could be used to create an easy-to-use prognostic score, or could directly aid nurses in physicians to interpret, summarize, and articulate continuous monitoring data of COVID-19 patients.

Second, summary measures may be useful to be incorporated in an automatic alarm system, especially under circumstances where the nurse-to-patient ratio is low. For example, during a night shift, an alarm system with high predictive accuracy that could detect deteriorating patients that otherwise might have been missed would be valuable [33]. However, clinical scores might not be suitable for automatic alarming. Early warning scores have previously been applied as an alarm system by using the means of continuously monitored vital signs over a short period (eg, 5 minutes) as input values [34,35]. The downside of this strategy is that some thresholds of commonly used early warning scores, such as RR>20/min or HR>90/min in the NEWS2, are easily breached, especially in active patients. In our study, the mean RR for patients who did not experience respiratory insufficiency was 20.5/min; thus, half of all measurements would score a point on the NEWS2. In a recent study, both patients who did and did not experience deterioration met the criteria for a high early warning score if continuous monitoring of vital signs was used [35]. This high number of threshold breaches could, if followed up with an alarm, lead to alarm fatigue [36]. To develop an adequate alarm system, a new predictive model for continuous monitoring data might be more helpful, in which summary measures could be used as input values instead of single threshold breaches. Since such an alarm system can operate in the background and does not have to be used by hospital professionals directly, it would allow for more complexity than the clinical score that is used on the ward. The previously mentioned study by Kristinsson et al [21] is a promising example.

Conclusions

We explored several possible ways to summarize continuous vital sign data of COVID-19 patients on the general ward. The mean showed a relatively strong association with respiratory insufficiency for HR, RR, and SpO2. Overall, shorter timeframes with smaller leads showed stronger associations. Highly associated summary measures and their combinations could be used in a clinical prediction score or algorithm for an automatic alarm system.

Data Availability

The data sets analyzed during this study are stored in the data repository DataverseNL [37]. Metadata are publicly available. The data themselves are not publicly available due to their privacy-sensitive nature, but can be requested via DataverseNL.

Conflicts of Interest

None declared.

Multimedia Appendix 1
Considered and selected summary measures.
[DOCX File , 16 KB - ijmr_v11i2e40289_app1.docx]

Multimedia Appendix 2

Baseline characteristics of patients stratified by availability of vital sign data.
[DOCX File , 18 KB - ijmr_v11i2e40289_app2.docx]

Multimedia Appendix 3
Mean summary measures for 4-hour and 8-hour timeframes.
[DOCX File , 30 KB - ijmr_v11i2e40289_app3.docx]

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Abbreviations

HR: heart rate
ICU: intensive care unit
NEWS: National Early Warning Score
OR: odds ratio

RR: respiratory rate
sOR: standardized odds ratio
SpO2: peripheral oxygen saturation

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Original Paper

Influence of COVID-19 Protocols on the Efficiency of Trauma Theater: Retrospective Observational Study

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Abstract

Background: The COVID-19 pandemic has influenced health care delivery significantly. Numerous studies have highlighted that trauma theater efficiency has decreased during the COVID-19 pandemic; however, there is limited information as to exactly which stage of the patient theater journey is causing this decreased efficiency and whether efficiency can be improved. In the trauma theater of Warrington Hospital, United Kingdom, we have attempted to maintain trauma theater efficiency despite the requirement for increased infection control.

Objective: The aim of this study was to evaluate the effects of additional COVID-19 infection control protocols on trauma theater efficiency in our center, considering the length of time taken for specific theater events, and to find out whether our interventions were successful in maintaining theater efficiency.

Methods: We compared the efficiency of the trauma theater in a busy unit in December 2019 (pre–COVID-19) and December 2020 (with COVID-19 protocols in place). We collected time logs for different theater events for each patient in December of both years and compared the data.

Results: There was no significant difference in the average number of cases performed per session between the COVID-19 and pre–COVID-19 time periods (P=.17). Theater start time was significantly earlier during the COVID-19 period (P<.001). There was no significant difference between the two periods in transport time, check-in time, preprocedure time, anesthetic time, and the time between cases (P>.05). A significant difference was observed in the check-out time between the two groups in the two time periods, with checking out taking longer during the COVID-19 period (P<.001).

Conclusions: Our results show that our theater start times were earlier during the COVID-19 pandemic, and the overall theater efficiency was maintained despite the additional COVID-19 infection control protocols that were in place. These findings suggest that well-planned infection control protocols do not need to impede trauma theater efficiency in certain settings.

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KEYWORDS

operation theatre; COVID-19; utilization; efficiency; pandemic; health care; trauma management; infection control; health care delivery; trauma theater

Introduction

There is no doubt the incidence of all acute traumas decreased during the COVID-19 lockdowns. One study demonstrated a decrease of 22.4% in the overall incidence of trauma [1], but the incidence of falls and hip trauma in particular increased compared to the pre–COVID-19 period [2-4]. In December 2020, COVID-19 restrictions were in place across the United Kingdom. In the trauma theater of Warrington Hospital, the infection control protocols were in place from the onset of the pandemic and had become refined. Infection control protocols had a major impact on how surgeries were performed. The patient was brought into the operating room (OR) directly from the ward with no stops in between.

Several studies reported an increase in patient turnaround times with a decrease in theater utilization times, resulting in an overall decrease in theater efficiency during the COVID-19 pandemic due to the additional infection control protocols [5-7].

The aim of this study was to evaluate the effects of additional COVID-19 infection control protocols on trauma theater efficiency in Warrington Hospital, considering the length of time taken for specific theater events, and to find out whether our interventions were successful in maintaining theater efficiency.

Methods

Procedure

This study was performed in a busy district general hospital. Because all traumas with an Injury Severity Score >15 goes to a major trauma center in the United Kingdom, the district general hospitals usually handle closed fractures, mostly fragility fractures, including neck of femur or fractures in adults and children that are isolated injuries. We retrospectively analyzed all patients undergoing an operation in the trauma theater of Warrington Hospital, in Warrington, United Kingdom, during December 2019 and December 2020 (ie, when COVID-19 infection control protocols were in place). In our hospital, for all patients, their theater journey events time was recorded live into ORMIS software (version [7.55]; iPath Software). The time log events that were relevant to our study and recorded were “patient sent for,” “patient at reception,” “patient in AR,” “administration of anesthesia start time,” “anesthesia administration complete,” “patient shifts into OR,” “procedure start,” “procedure end,” and “out of OR.”

The above data for all patients having trauma surgery during December 2019 and December 2020 were collected retrospectively and compared. All patients undergoing an operation in the trauma theater were included.

The differences between the two groups with regard to patient flow or pathway are detailed in Table 1. The key difference in patient flow was that the AR and the recovery room were not used during December 2020. During the COVID-19 pandemic period (December 2020), we used an “isolated corridor” for shifting patients from the ward to the theater, where the porters had to clear the whole path of the patient transport to avoid cross-infections. We had to inform the ward and the porters in advance. In the ward, the patient was prepared and kept ready to be shifted; porters arranged the isolated corridor for the transfer. A 15-minute telephone warning was given to the ward.

The patient was brought into the OR directly from the ward with no stops in between. The patients were checked at the entrance of the OR, they were then taken into the OR where the anesthesia was administered, surgery was performed, and the patient was recovered. Prior to COVID-19, the patients were transferred from the ward to the theater complex, the safety checks were performed at the theater reception, patients were then transferred into the AR, where the anesthesia was administered; patients were then taken to the OR, where the surgery was performed; following surgery, the patients were transferred into the recovery room for extubating and recovery from anesthesia.

During the COVID-19 pandemic period (December 2020), personal protective equipment was used by all staff entering the OR. All cases were considered COVID-19 suspect, as we aimed to take every trauma case to theater as early as possible, and there was not enough time for positive results to show up in a good number of patients [8,9]. We chose the month of December 2020 for data analysis as COVID-19 infection protocols had been in place for several months, allowing staff to become sufficiently familiar with them, comparable to the familiarity they had with the pre–COVID-19 protocols a year prior. Further, we chose December because it has a higher volume of trauma operating, with previous studies showing a higher proportion of admitted patients requiring surgery during winter in the United Kingdom [10]. There is added winter pressure on the hospitals in December, and the second COVID-19 lockdown restrictions were in place during December 2020; this made the month ideal for comparison with pre–COVID-19 times.

The calculated time durations for preprocedure time, check-out time, and transport time are detailed in Table 2. The ORMIS software allows for the recording of different events with timed entries. When the theater staff call the ward to send for the patient, “patient sent for” is recorded; and when the patient arrives at the common theater complex, “in suite” time is recorded—this has been termed as the “transport time” in our paper. A member of the theater staff then goes through a checklist with the patient and takes a formal handover from the nurse accompanying the patient. The checklist includes patient identification, confirmation of consent, patient belongings, dentures, nil by mouth status, etc. This is then followed by the patient being shifted into the AR and “in anesthesia room” time is recorded. A World Health Organization (WHO) Surgical Safety Checklist sign-in is done next, followed by preparation and administration of anesthesia. When the anesthetist begins the process, “anesthetist start time” is recorded, followed by “anesthesia ready,” when the patient is anesthetized and ready to be shifted to the OR. Once in the OR, “in OR” time is recorded, the patient is positioned on the operating table, preprocedure imaging is done if needed, and the surgeons scrub. The “procedure start” time is recorded when the WHO time-out is done. The time interval from “in anesthesia room” to “procedure start” defines the “preprocedure time” in our study. “Procedure end time” is recorded when the surgical wound is

dressed. This is closely followed by the WHO sign-out phase and shifting of the patient out of the OR when the "out of OR" time is recorded in ORMIS. The time interval between "procedure end" to "out of OR" constitutes the check-out time. In addition, check-in time (ie, "patient at reception" to "patient in AR") and anesthetic time were also calculated. The time between cases was calculated as the time duration between "out of OR" of the previous case to "in AR" of the next case. The time between cases was not measurable for the last case of the day.

The standard theater functioning time was calculated from 8 AM to 5 PM (for 2 sessions). If the list overran the 2 sessions, then we considered it as a 3-session list in both groups. The statistical analysis was done using IBM-SPSS software (Version [1.0.0.1406]; IBM Corp). The independent *t* test (2-tailed) was applied to test statistical significance between means of unrelated groups. This was preceded by Levene Test for equality of variances. The *t* test was modified if equal variances were not assumed to use unpooled variances and correction of degrees of freedom.

Table 1. Comparison of theater events recorded in pre–COVID-19 and during COVID-19 time periods.

Theater events	Time period	
	December 2019 (pre–COVID-19)	December 2020 (during the COVID-19 pandemic)
At theater reception	• Ward nurse gives a handover to theater practitioner • Safety checklist done by theater practitioner	• Theater reception area was not used • The handover and checklist were done outside the operating room entrance
In anesthetic room	• Signing in • Preparation of anesthesia • Anesthesia given, including spinal, nerve blocks, arterial access, venous access, and catheterization	• Not used (as thoroughfare only)
In operating room	• Safety check • Patient positioning • Pre-op imaging • Procedure • Shifting out of operating room	• Signing in • Preparation of anesthesia • Anesthesia given, including spinal, nerve blocks, arterial access, venous access, and catheterization • Safety check • Patient positioning • Pre-op imaging • Procedure • Shifting out of operating room • Extubation • Wait for 15 minutes after • Aerosol generating procedure • Recovery from anesthesia and transfer to the ward • Cleaning of theater
In recovery room	• Extubation • Recovery of patient	• Not used

Table 2. Calculated time durations and their correlation to the time logs in the ORMIS software (version [7.55]; iPath Software) and patient location in 2019 and 2020.

Time duration calculated and the log entry in ORMIS software	Location of patient	
	December 2019	December 2020
Transport time[a]		
"Patient sent for" and "patient at reception"	Patient transported from the ward to the theater reception	Patient transported from the ward to the OR[b] door
Preprocedure time[c]		
"In anesthesia room"	Patient in AR[d] (preparation for anesthesia begins after safety check)	In AR (only used as a thoroughfare)
"Anesthetist start time" (anesthetist begins procedure)	In AR	In OR
"Anesthetist end time" (patient is anesthetized and ready)	In AR	In OR
"In OR" (patient shifted to the OR)	In OR	In OR
"Procedure start"	In OR	In OR
Check-out time[e]		
"Procedure end"	In OR	In OR
"Out of OR"	Exiting OR	Exiting OR

[a]From when the patient is sent for to when the patient is at the reception or theater front door.

[b]OR: operating room.

[c]From when the patient is in the anesthetic room to the procedure start.

[d]AR: anesthetic room.

[e]From the procedure end to out of the operating room.

Ethical Considerations

Ethics approval and consent to participate were not required for this study, as the data were collected for quality improvement and as part of an audit.

Results

A total of 76 patients underwent an operation in our trauma theater in December 2019, and a total of 68 patients in December 2020. In December 2019, the 76 cases were operated in 68 sessions, at an average of 1.11 cases per session, while in December 2020, the 68 cases were operated in 66 sessions, the average being 1.03 cases per session (P=.17, t test). The average time when the first case entered the OR in December 2019 was 10:39 AM, and in December 2020, it was 9:36 AM (P<.001, t test). The average time of the last case out of the OR in December 2019 was 4 PM and in December 2020 was 5 PM (P=.09, t test).

There was no significant difference between the two groups in the time log calculation of the transport time, check-in time, preprocedure time, anesthetic time, and the time between cases. However, a significant difference was observed in the check-out time between the two groups (Table 3).

Table 3. Comparison of the length of time for various theater events between pre–COVID-19 and during COVID-19 time periods.

Theater event time duration	Length of time (min:s)		P values (t test)
	December 2019	December 2020	
Transport time	20:51	19:56	.74
Check-in time	07:56	08:56	.63
Preprocedure time	45:12	46:36	.63
Anesthetic time	20:09	23:44	.10
Check-out time	10:21	20:51	<.001
Time between cases	46:30	46:48	.41

Discussion

Overview

The principal findings of our study showed that there was no statistical difference in the transport time, check-in time, preprocedure time, anesthetic time, and time between cases of the two groups, even though infection control protocols were changed during December 2020.

Our study found that there was no significant difference between the COVID-19 and pre–COVID-19 periods with regard to theater efficiency, unlike several other studies [5-7]. We observed a similar number of operations being performed per theater session across both groups, with the only significant difference between groups occurring in the "procedure start" time and the length of time for check-out after a procedure.

Comparison With Prior Work

We observed a decrease in the number of cases operated during the pandemic period, which is similar to the observations made by Andreata et al [11], who found a decrease in the number of surgeries done during the COVID-19 lockdown compared to a similar time period before the pandemic.

In our study, the timing of starting the first case significantly improved during December 2020. This is in contrast to the findings by Khadabadi et al [7], who found that their start time was significantly higher during the COVID-19 pandemic, and 94.2% of their lists began late in 2020. The start time of the first case is one of the main measures of theater efficiency [12,13]. Delay in starting the first case could cause delays in the whole list as a downstream effect [14]. In pre–COVID-19 times, the trauma list was populated at 8 AM every day, followed by patient assessment by the surgical and anesthetic team and a huddle in the theater. There was a single anesthetist allocated to the trauma theater, who would assess the cases listed for the theater and then attend the huddle. During December 2020 (ie, COVID-19 pandemic), the trauma list was populated at 8 AM every day. There was an extra anesthetist available, as elective operating was suspended. The anesthetist assessed the first patient and was available in the theater for the huddle, while the second anesthetist continued to assess the remaining patients on the list. The ward rounds were also shorter for the surgical team due to fewer admissions. We believe these changes contributed significantly to the earlier start times in December 2020.

Transport of patients from ward to theater was found to be a cause of significant decrease in theater productivity in a few studies [15,16]. We observed no statistically significant difference in the transport times between the two groups. For shifting of patients, we used an "isolated corridor," where the porters had to clear the whole path of patient transport to avoid cross-infections; a 15-minute telephone warning to the porters and the ward helped to keep the patient and corridor ready. This is similar to a study by Ang et al [17] that has shown that the availability of dedicated porters in the theater can improve transport times.

Delay in sending for the patient was also a significant factor causing decreased theater efficiency in a study by Ang et al [17]; however, due to the "isolated corridor" policy, we had to inform the porters earlier, so they were ready in time to shift the patient; a 15-minute telephone warning was also given to the ward, so that the patient was ready when the porters arrived.

Several studies have found a significant increase in their theater turnaround times (ie, time between cases) during the COVID-19 pandemic [5-7]. In our trauma theater, the patient was intubated and extubated in the OR itself, giving a window of 15 minutes after any aerosol generating procedure, with minimal necessary staffing in the room during that time; the doors were not to be opened in accordance with infection control protocols. The OR and AR underwent a "deep clean" and surfaces were wiped with the viricidal wipes after every case. The trolleys and other instruments that were not necessary were shifted to another room apart from the OR. Despite these additional steps, we observed no statistically significant difference in our time between cases in the two groups. As elective procedures were paused, the staff from elective surgery theaters were used at the trauma theater. This made additional staff available outside the OR to do the cleaning. There was also one extra operating department practitioner in the theater who helped in the arrangement of the trolleys and doing pre-op checks as soon as the next patient arrived, while the current patient was recovered.

Although the requirement to wear personal protective equipment within the AR or OR can add to the turnaround time and has been found to decrease theater efficiency [18], the staff within our hospital made sure the time for donning and doffing did not delay any proceedings. Preparedness, a dedicated cleaning team, and sending for the next patient as soon as cleaning began, in addition to the improvement in transport arrangements helped to maintain our time between cases. Daniel Fletcher et al [19] have observed that the theater time between cases (ie, turnaround time) can be improved by the introduction of a 15-minute warning to the preoperative rooms, performing the check-in process in the preoperative rooms rather than in the theater, sending for the patient prior to the completion of theater cleaning and finally, a 5-minute warning given to the theater cleaning staff. They have shown a 45% reduction in mean turnaround times with these measures [19].

Our study found no difference in the average anesthetic time and pre-procedure time, similar to the study by Mercer et al [5]. Regional anesthesia techniques and anesthesia delivered by senior doctors (ie, consultants and senior registrars) were thought to decrease anesthetic time [5]. Our observations were similar, with largely the consultants themselves performing the procedures, and trainees redistributed to care for COVID-19 patients in the wards. Preparedness of the team and a preference for regional anesthesia, thus avoiding the 15-minute aerosol generating procedure downtime, also helped to reduce the anesthetic time.

We observed a significant difference in check-out times, as the patient spent more time in the OR during the COVID-19 period. This was due to the patient recovering in the OR and subsequently being transferred to the ward directly from the OR.

The overall theater efficiency of our study is different compared to other studies, which have shown a significant decrease in

theater efficiency [5-7,9] at varying time events during the patient journey.

Strengths and Limitations

Our study has certain strengths. It presents the systematic analysis of a patient journey through theater, examining every step and the causes of delays. We have discussed in detail how these delays were overcome without compromising on infection control. We believe our study would help in effective theater management and in turn, reducing the waiting lists.

The study has certain limitations, including the small sample size and clubbing of weekdays and weekends together in data analysis. Nevertheless, the strength of this study lies in the calculation of all time durations involved in the patient journey, which we have not encountered in such detail in any other study during the pandemic. We have not considered the comorbidities of the patients, which might indirectly and insignificantly affect the preprocedure times.

Future Directions

Further research is needed to calculate the costs of the above-mentioned interventions and how they apply to an elective surgery setting, so that the waiting lists can be reduced by efficient theater management. This study could be used as a template to further investigate theater efficiency in elective surgery theaters. It could also serve as a baseline for a quality improvement project that could apply these interventions and measure the effect of each. The study could also be a helpful guide in making theaters cost-effective.

Conclusions

Early theater start time, organized patient transport, a 15-minutes prewarning to the ward and the porters, checking patients at the theater entrance, availability of senior anesthetists, preference to use regional anesthesia, and the presence of additional staff can help maintain theater efficiency even with infection control protocols in place during the COVID-19 pandemic. Effective theater management will also have implications for the waiting lists.

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Data Availability

Data are available upon reasonable request, through contacting the corresponding author via email.

Authors' Contributions

MF conceptualized the study, collected data, and wrote the manuscript. MM collected and analyzed the data, and wrote the manuscript. MSC analyzed the data, wrote the manuscript, and proofread it. ZN analyzed the data, designed the study, and helped in editing the manuscript. PC coordinated the writing, proofreading, and editing the paper; he also wrote parts of the manuscript. RMM wrote parts of the manuscript and helped in editing. All authors read and approved the final manuscript.

Conflicts of Interest

None declared.

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Abbreviations

AR: anesthetic room
OR: operating room
WHO: World Health Organization

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Review

Use of Bacopa monnieri in the Treatment of Dementia Due to Alzheimer Disease: Systematic Review of Randomized Controlled Trials

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Abstract

Background: *Bacopa monnieri*, a herb that has been used for many centuries in India, has shown neuroprotective effects in animal and in vitro studies; human studies on patients with Alzheimer disease have been inconclusive.

Objective: The primary objective of this review was to determine the clinical efficacy and safety of *B. monnieri* in persons with mild, moderate, or severe dementia, or mild cognitive impairment, due to Alzheimer disease.

Methods: We searched PubMed, Embase, Cochrane Library, clinical trial registries (World Health Organization, Australia-New Zealand, United States, and South Africa), the metaRegister of Controlled Trials, and CINAHL. We intended to include all randomized and quasi-randomized controlled trials that compared *B. monnieri*, its extract or active ingredients (at any dosage), with a placebo or a cholinesterase inhibitor among adults with dementia due to Alzheimer disease and in those with mild cognitive impairment due to Alzheimer disease.

Results: Our comprehensive search yielded 5 eligible studies. A total of 3 studies used *B. monnieri* in combination with herbal extracts while the remaining 2 used *B. monnieri* extracts only. Two studies compared *B. monnieri* with donepezil while the others used a placebo as the control. There was considerable variation in the *B. monnieri* dose used (ranging between 125 mg to 500 mg twice daily) and heterogeneity in treatment duration, follow-up, and outcomes. The major outcomes were Mini-Mental State Examination scores reported in 3 trials, Cognitive subscale scores of the Alzheimer's Disease Assessment Scale in 1 study, and a battery of cognitive tests in 2 studies. Using the Cochrane risk-of-bias tool, overall, we judged all 5 studies to be at high risk of bias. While all studies reported a statistically significant difference between *B. monnieri* and the comparator in at least one outcome, we rated the overall quality of evidence for the Alzheimer's Disease Assessment Scale-Cognitive Subscale, Postgraduate Institute Memory Scale, Mini-Mental State Examination, and Wechsler Memory Scale to be very low due to downgrading by 2 levels for high risk of bias and 1 more level for impreciseness due to small sample sizes and wide CIs.

Conclusions: There was no difference between *B. monnieri* and the placebo or donepezil in the treatment of Alzheimer disease based on very low certainty evidence. No major safety issues were reported in the included trials. Future randomized controlled trials should aim to recruit more participants and report clinically meaningful outcomes.

Trial Registration: PROSPERO CRD42020169421; https://www.crd.york.ac.uk/prospero/display_record.php?RecordID=169421

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KEYWORDS

Bacopa monnieri; Brahmi; Ayurveda; Ayurvedic; alternative medicine; traditional medicine; complementary medicine; herb; dementia; systematic review; Alzheimer's disease; Alzheimer disease; mild cognitive impairment; cognition; neuroprotection; memory; cognition; cognitive; treatment; therapy; clinical outcome; memory scale; neurology; neurodegenerative disease; randomized controlled trial; RCT

Introduction

Background

Alzheimer disease is the most common cause of dementia worldwide [1]. It is estimated that, in persons aged 65 years and above, mild cognitive impairment is present in up to 20% and dementia or major cognitive impairment is present in approximately 1% to 25% [2]. The number of people with dementia is likely to reach 44 million worldwide by 2030 [3]. The current major treatment for Alzheimer disease is drug therapy with an acetylcholinesterase inhibitor, such as donepezil [1]. These types of drugs have been found to be effective in treating dementia of all severities; however, they have no proven disease-modifying effect and, therefore, do not improve long-term outcomes [3]. In addition, their effect on patients with mild cognitive impairment due to Alzheimer disease (MCI-AD) is unproven. Furthermore, their use has been associated with adverse events such as nausea, vomiting, diarrhea, muscle spasms, insomnia, abnormal dreams, headaches, peripheral edema, weight loss, syncope, fatigue, asthenia, and tremors [4].

The search for other effective and safe treatments has led to an interest in herbs and extracts that have anecdotally been used to prevent and treat memory loss. Among many such herbs, *Bacopa monnieri* (also known as Brahmi, bacopa, or water hyssop) has attracted much attention [5-7]. This herb has been mentioned and extensively used for many centuries in Ayurveda (traditional Indian system of complementary medicine) for improving cognitive ability and preventing memory loss [8,9].

Several in vitro and animal studies have shown a neuroprotective effect of this plant and its extracts [6,10-12]. However, the use of this herb in humans has yielded conflicting results, and its role in treating patients with established Alzheimer disease is not clear. In addition, most studies [13-15] have been performed on healthy adults. Many studies (eg, [16]) from the Ayurveda stream have been anecdotal, and many others (eg, [17]) have methodologically weak designs. Systematic reviews [13,18-20] on *B. monnieri* have included studies on healthy individuals and have not included studies conducted in the last 5 years.

How the Treatment Might Work

The major active substances in *B. monnieri* with potential effects on cognition and memory are bacoside-A, bacoside-B, alkaloids, and flavonoids [5]. The therapeutic effects of bacosides demonstrated in preclinical and in vitro studies include enhancement of neurotransmission, potentiation of synaptic activity, and repair of damaged neurons by upregulating neuronal synthesis and kinase activity [6]. Holcomb et al [10] found a reduction in amyloid levels using *B. monnieri* extract in mice models. Cognitive enhancement and neuroprotective effects have been found in Alzheimer disease animal models [21-24]. Studies have found that amnesia induced by diazepam in mice could be reversed using *B. monnieri* [25] and that L-arginine N(omega)-nitro-L-arginine–induced anterograde and retrograde amnesia could be reversed using *B. monnieri* [26]. Recently, changes in metabolites in plasma, urine, and feces in healthy individuals after consuming *B. monnieri* essence for 12 weeks were found using liquid chromatography mass spectrometry and that aminoacyl-transfer RNA, aromatic amino acids, and branched-chain amino acid biosynthetic pathways were mainly related to the metabolites identified in all 3 types of samples [27]. Aromatic amino acids, particularly phenylalanine, are metabolites found to decrease in level in the plasma of healthy community-dwelling participants aged 70 years and older who later progressed to amnestic mild cognitive impairment or Alzheimer disease compared to normal controls [28].

Considering the potential of *B. monnieri* as a neuroprotective agent and the gap in the existing literature connecting *B. monnieri* and dementia, we aimed to perform a systematic review to determine whether it has beneficial effects on cognitive impairment due to Alzheimer disease and identify gaps in the literature.

Review Question and Objectives

We aimed to address the following question: What are the effects (benefits and harms) of *B. monnieri* on individuals with dementia due to Alzheimer disease?

Our objectives were to (1) determine the clinical efficacy and safety of *B. monnieri* in persons with mild, moderate, or severe dementia due to Alzheimer disease or with MCI-AD; and (2) compare the efficacy and safety of different doses of *B. monnieri*.

Methods

Search Strategy

A comprehensive search strategy (Multimedia Appendix 1) was employed to identify all relevant studies. We did not place any restrictions on language or publication status (published and in press) during the search. PubMed, Embase, Cochrane Library, clinical trial registries (World Health Organization, Australia-New Zealand, United States, and South Africa), the metaRegister of Controlled Trials, and CINAHL were searched from inception to January 2021. We also searched for studies in the reference lists of all studies included in the pool of retrieved papers. Where possible, we contacted authors to obtain the full text of the papers. The study has been reported according to the PRISMA (Preferred Reporting Items for Systematic Reviews and Meta-Analyses) guidelines, and the protocol is available on the International Prospective Register of Systematic Reviews (CRD42020169421).

Study Selection

We included randomized and quasi-randomized controlled trials that compared *B. monnieri*, its extract or active ingredients (at any dosage), with a placebo or a cholinesterase inhibitor among adults with dementia due to Alzheimer disease and MCI-AD. Cohort studies, case-control studies, case reports, systematic reviews, policy papers, letters to the editor, correspondence, and nonhuman studies were excluded. We also excluded trials that were confounded by treatment or a control group receiving another active treatment that has not been factored into the randomization. Furthermore, studies must report one or more of the following outcomes to be eligible for inclusion: cognitive function (determined by the change from baseline in the Alzheimer's Disease Assessment Scale-Cognitive Subscale (ADAS-Cog), Mini-Mental State Examination, Postgraduate Institute Memory Scale, or any culturally adapted or validated tools to assess cognition), activities of daily living using scores such as the Alzheimer Disease Cooperative Study, clinician-rated global impression tests, behavioral symptoms, and safety as measured by incidence of adverse effects, dependency, or death.

Data Extraction and Quality Assessment

Following the search, 2 authors (VVY and AB) screened titles, abstracts, and full-text papers independently and extracted data from each paper using standardized data extraction forms. Discrepancies were resolved by consensus between the 2 authors or by a third author (AA). Data on study characteristics, participant characteristics (age, gender, healthy adults, patients with Alzheimer disease), study setting, use of *B. monnieri* (formulation, dose), placebo, any active comparator, and outcomes of interest were extracted. Two authors (AB and BM) used the Cochrane risk-of-bias tool for randomized controlled trials [29] to determine the risk of bias for all eligible papers, and a third author (AA) independently assessed the papers that were found to be eligible to be included in this systematic review in terms of the level of concern (ie, low, some, or high). We did not group studies comparing *B. monnieri* with the placebo and those comparing *B. monnieri* with cholinesterase inhibitors since no meaningful comparisons were possible due to the heterogeneity of outcomes. Since none of the outcomes of interest was reported for all studies, we did not pool them during analysis.

Data Analysis

We used ReviewManager (version 5.4; The Cochrane Collaboration) for data analysis. Wherever possible, an intention-to-treat analysis was planned. Due to explicit clinical and methodological heterogeneity between available studies, we performed no statistical tests for heterogeneity. The data available from eligible studies precluded a meta-analysis, and we performed an interpretative synthesis of data from individual studies. The GRADE (Grading of Recommendations Assessment, Development and Evaluation) framework was used to summarize the certainty of evidence [30,31]. We did not attempt to ascertain publication bias since there were only a few eligible studies.

Results

Overview

Overall, 164 studies were identified by the search. The abstracts of all studies were screened, and 5 [32-36] were found to be eligible (Figure 1 and Multimedia Appendices 2 and 3).

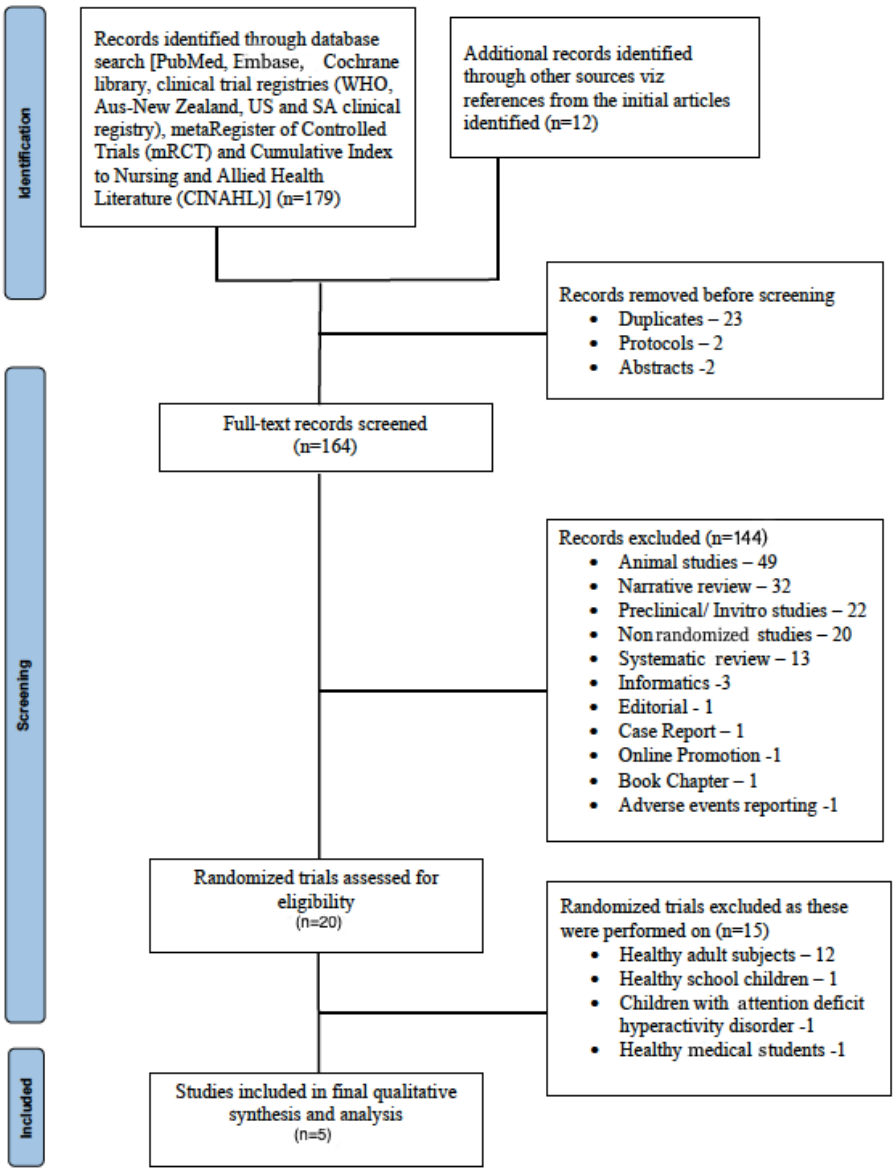
The primary objective of the study conducted by Prabhakar et al [32] was to determine if *B. monnieri* improved the memory of patients with Alzheimer disease and MCI-AD compared with donepezil [32]. The diagnosis of Alzheimer disease and MCI-AD was aided by magnetic resonance imaging of the brain, fluorodeoxyglucose-positron emission tomography of the brain, and cerebrospinal fluid biomarkers (beta amyloid and total tau). *B. monnieri* was administered once daily at a dose of 300 mg, while 10 mg of donepezil was given once daily for 12 months. Although a sample size of 48 patients (24 in each arm) was planned, only 34 patients (17 in each arm) could be recruited after 45 months, due to which the study was terminated. The primary outcome was the difference in change of the ADAS-Cog score and Postgraduate Institute Memory Scale score from baseline after 12 months of treatment between the 2 treatment groups. However, patients were followed up for changes in scores at 3, 6, and 9 months of treatment. Change from baseline of neuropsychological tests such as the verbal fluency-controlled oral word test and animal names test, quality of life-Alzheimer disease, activities of daily living inventory, adherence to treatment, and adverse events were secondary outcomes. The authors reported attempts to follow up on all patients with whom contact was lost during the study period, and an intention-to-treat analysis was used. Missing data were handled by multiple imputations due to loss of follow-up. A total of 4 and 9 patients were lost to follow-up in the donepezil and *B. monnieri* arms, respectively, at the end of 12 months. There were differences in baseline characteristics (more patients with Alzheimer disease in the donepezil arm and more patients with MCI-AD in the *B. monnieri* arm), which were adjusted for during analyses.

Cicero et al [33] compared the effect of a combination of agents (*B. monnieri*, L-theanine, *Crocus sativus*, copper, folate, vitamin B complex, and vitamin D) over 2 months and those of a placebo in improving cognitive functions in older adult patients. They included 30 participants with Mini-Mental State Examination scores between 20 and 27 or self-perceived cognitive impairment (whether the impairment was dementia or mild cognitive impairment was not reported). The primary outcome was change in Mini-Mental State Examination score from baseline at 2 months. The Perceived Stress Questionnaire and Self-Rating Depression Scale scores were other outcomes.

Sadhu et al [34] investigated the efficacy of a polyherbal test formulation composed of extracts of *B. monnieri*, *Hippophae rhamnoides*, and *Dioscorea bulbifera* (total dose of 500 mg) on cognitive functions [34]. The test formulation was compared with a placebo in healthy adults without dementia and the test formulation was compared with donepezil (10 mg twice a day) in older adult patients (aged 60-75 years) with Alzheimer disease (n=123; deterioration of memory in at least 3 of the following: poor orientation, poor judgment and problem-solving, difficulty in community affairs, inability to function independently at

home, or difficulties in personal care) for 12 months. Subsequently, the participants underwent a clinical screening using the Dementia Rating Scale-2 before being randomized to test formulation or donepezil. The primary outcome was cognitive function assessed by a composite of mental status (Mini-Mental State Examination), verbal memory, complex psychomotor tests, and attention or executive functions at 12 months.

Figure 1. PRISMA (Preferred Reporting Items for Systematic Reviews and Meta-Analyses) flowchart showing the identification, screening, and inclusion of trials for this systematic review. WHO: World Health Organization, US: United States, SA: South Africa.



Raghav et al [35] studied the efficacy of *B. monnieri* extracts in patients with age-associated memory impairment and no evidence of dementia or psychiatric illness [37]. Participants were adults older than 55 years of age with memory loss in daily activities and a logical subset score <6 on the Wechsler Memory Scale. Patients with a Mini-Mental State Examination score >24 were excluded. Eligible patients (N=40; *B. monnieri* group: n=20; placebo group: n=20) were randomized to receive 125 mg of *B. monnieri* extract or a placebo twice a day for 12 weeks followed by the placebo for both groups for another 4 weeks. The outcomes were the Mini-Mental State Examination and the Wechsler Memory Scale (subsets Logical Memory, Visual Reproduction, and Paired Associated Learning).

Barbhaiya et al [36] studied the effects of Bacomind(an enriched phytochemical combination containing 450 mg of standardized *B. monnieri* extract) on 65 individuals aged 50 to 75 years with self-reported memory impairment (Mini-Mental State Examination score >24) for at least 1 year. The study duration was 24 weeks (drug administered for 12 weeks, then no drugs for 12 weeks). Neuropsychological assessment was performed at baseline, week 12, and week 24. Outcomes were analyzed for attention, memory, and speed of information processing. Three patients were lost to follow-up for the second visit, and 15 patients were removed as outliers. The final analysis was completed for 44 patients (Bacomind: n=23; placebo: n=21). Further, 3 patients were lost to follow-up during the study.

Risk of Bias

Random Sequence Generation and Allocation

We judged all 5 studies to be at low risk of bias in terms of random sequence generation (Multimedia Appendix 4).

For allocation concealment, a judgment of low risk of bias was made for all studies except Raghav et al [35], which was considered as having some concerns. Barbhaiya et al [36] provided the drug and the placebo in coded bottles. Prabhakar et al [32], Cicero et al [33], and Sadhu et al [34] described the concealment of allocation in sufficient detail, while in the study by Raghav et al [35], the actual method of allocation concealment was unclear.

Deviations From the Intended Interventions

All 5 studies reported that they were double-blinded. Prabhakar et al [32] and Barbhaiya et al [36] described the use of identical-looking capsules as a placebo, while Cicero et al [33] described how the blinding of interventions was ensured throughout the study. Raghav et al [35] did not describe how blinding was performed or ensured till the end of the study. Sadhu et al [34] provided no details on the blinding process and how it was maintained throughout the study. Prabhakar et al [32] and Barbhaiya et al [36] used coded medicines in strips or bottles, respectively. None of the trials reported any deviations from intended interventions due to trial context.

Prabhakar et al [32] had envisaged an original sample size of 48; however, they could only recruit 34 patients (17 in each group). Finally, at the end of the study, only 13 remained in the donepezil group and 8 remained in the *B. monnieri* group (24% and 53% loss to follow-up, respectively). Although they described using intention-to-treat analysis, the loss to follow-up was considered sufficiently significant to be judged as a high risk of bias.

There was no loss to follow-up in the study by Cicero et al [33], and we considered it to be at low risk of bias. Sadhu et al [34] reported that out of 123 patients who took part in the study, 104 completed the study (15% lost to follow-up). However, there was no mention of how missing data were handled or if an intention-to-treat analysis was used. Hence, this study was also considered to have some concerns regarding the risk of bias. Raghav et al [35] reported that 5 out of 40 participants dropped out of the study. They used a per-protocol analysis and did not report how missing data were handled or the use of intention-to-treat analysis. We judged it to be at high risk of bias. Barbhaiya et al [36] reported a 32% loss to follow-up (21 out of 65 patients), out of which 15 patients were removed as outliers. Neither a definition for outliers nor an explanation for the patients' removal was given. Barbhaiya et al [36] used a per-protocol analysis and did not mention how missing data were handled. Hence, we judged this study to be at high risk of bias in this domain.

Missing Outcome Data

In this domain, we judged Cicero et al [33] to have a low risk of bias while all other studies were at high risk of bias considering that outcome data were not available for nearly all participants in these studies and that this missing data could have potentially biased the results.

Measurement of Outcome

Prabhakar et al [32] and Sadhu et al [34] were considered to have a low risk of bias for this domain. Cicero et al [33], Raghav et al [35], and Barbhaiya et al [36] were judged as having a high risk of bias considering that no information was available on the blinding of outcome assessors that could have potentially biased results.

Selection of the Reported Results

All 5 studies reported outcomes stated in their methods or protocol. However, only Prabhakar et al [32] reported the primary outcome of interest (ADAS-Cog). Overall, we judged all studies to be at low risk of bias for this domain.

Other Potential Sources of Bias

Prabhakar et al [32] had amended their protocol regarding the timing of primary outcome assessment. In their initial protocol, the primary outcomes were supposed to be assessed at 3, 6, 9, and 12 months. In their amendment, they had fixed the timeline at 12 months alone for the primary outcome. The primary outcome assessment at 12 months was delayed for many patients.

Sadhu et al [34] included healthy participants and patients with Alzheimer disease in the study; however, the healthy participants had low baseline Mini-Mental State Examination scores (group A, healthy older adult participants receiving a placebo: mean 17.48, SD 3.72; group B, healthy older adult participants receiving the test formulation: mean 16.93, SD 3.71) and cannot be considered healthy. Scores for the patients with Alzheimer disease were very low (group C, patients with senile dementia of the Alzheimer's type [SDAT] given donepezil 10 mg twice daily: mean 7.019, SD 1.316; group D, SDAT patients given the test formulation twice daily: mean 6.014, SD 1.212). The test formulation contained extracts of *B. monnieri* (whole plant), *Hippophae rhamnoides* (leaves and fruits), and *Dioscorea bulbifera* (bulbils). At baseline, among the healthy participants, 9 had psychotic features and 25 had depression. In the Alzheimer disease group, 68 had depression and 67 had psychotic features. Neuroimaging was not mentioned. In addition, there was a discrepancy in the reported outcomes: The text states that there was no significant improvement in immediate word recall, attention span, Functional Activity Questionnaire score, or depression scores at 12 months; however, in the tables, all these subsets of cognitive evaluation mentioned having statistically significant improvement. In the study by Raghav et al [35], the study duration was 3 months, and in that short period, there was a significant improvement with regards to the subsets Logical Memory, Mental Control, Digit Forward, and Paired Associate Learning, even in the placebo group.

Prabhakar et al [32] had registered their trial protocol in Clinical Trials Registry - India retrospectively. None of the other trials were registered. The diagnostic certainty of Alzheimer disease was high only in Prabhakar et al [32].

Overall Bias

All 5 studies were deemed to have a high risk of bias.

Effects of Intervention

None of the studies described the effects of *B. monnieri* in patients with different classes of disease severity (mild, moderate, severe Alzheimer disease and MCI-AD). Effects of different dosages of *B. monnieri* were not tested in any eligible studies. Hence, the primary and secondary objectives of the review remain unanswered.

Cognitive Functions

Only Prabhakar et al [32] reported effects on cognition using ADAS-Cog and Postgraduate Institute Memory Scale. Prabhakar et al [32], Sadhu et al [34], and Cicero et al [33] reported changes in Mini-Mental Status Examination; although Raghav et al [35] mentioned that Mini-Mental State Examination was performed at baseline in all participants, we could not extract data about the change in scores. Barbhaiya et al [36] used Mini-Mental State Examination only for screening.

Prabhakar et al [32] performed an intention-to-treat analysis; after adjustment for confounders, no difference in the rate of change in the ADAS-Cog score was noted between the *B. monnieri* arm and donepezil arm at any of the prespecified time points (3, 6, 9, and 12 months) from baseline. At 12 months, the mean ADAS-Cog score was 2.27 (SD 5.65) in the donepezil arm and 0.51 (SD 5.65) in the *B. monnieri* arm (mean difference –1.76; *P*=.39). There was a significant difference in the change in overall Postgraduate Institute Memory Scale score between the 2 arms at 12 months (donepezil: mean 0.46; SD 10.96; *B. monnieri*: mean 7.94, SD 10.96); mean difference –8.40; *P*=.04]. The donepezil arm had reduced progression of symptoms (measured by ADAS-Cog scores) in individuals with MCI-AD or mild-to-moderate AD, compared to those in the *B. monnieri* arm. However, analysis of individual components of the Postgraduate Institute Memory Scale revealed no differences.

Changes in Mini-Mental State Examination scores from baseline were reported by Sadhu et al [34], Cicero et al [33], and Prabhakar et al [32]. At 3 months, a significant difference in the mean change from baseline was noted between the donepezil arm (mean 0.72, SD 3.13) and the *B. monnieri* arm (mean –2.02, SD 3.13) by Prabhakar et al [32] (mean difference 2.74; *P*=.02); however, there were no differences between the arms at any further time points (6, 9, and 12 months). Sadhu et al [34] also found no difference between the donepezil arm (mean 7.882, SD 1.956) and the *B. monnieri* formulation arm (mean 7.914, SD 2.106) at 12 months in terms of change in Mini-Mental State Examination scores from baseline (*P*=.9375).

Cicero et al [33] found significant improvements in the Mini-Mental State Examination score and the Perceived Stress Questionnaire index in the *B. monnieri* formulation arm compared to the placebo. Both were reported as mean scores before and after treatment.

Raghav et al [35] used the Wechsler Memory Scale to report outcomes. They reported scores of individual subsets of the scale at baseline, 4, 8, 12, and 16 weeks as means and standard deviations. The total memory score of the *B. monnieri* arm showed a significant difference from the placebo arm in terms of change from baseline at 4, 8, and 12 weeks but not at 16 weeks. Raghav et al [35] also reported that 55% of participants in the *B. monnieri* arm showed more than 20% improvement in memory parameters compared with 44.4% of participants in the placebo arm (*P*<.01).

Barbhaiya et al [36] used various tests for attention (digit span, digit cancellation, serial subtraction), memory (Rey Auditory Verbal Learning Test, Wechsler Memory Scale-1, paired associates, and visual retention), speed of information processing (digital symbols). There was a significant improvement in the digit span backward task (*P*=.008) and digit cancellation time test (*P*<.001) between baseline and week 12. A significant improvement in list learning delayed recall (*P*=.014), paired associates dissimilar delayed recall (*P*=.047), and visual retention test (*P*=.035) were also reported.

Functional Outcomes

Different tools were used in the studies to determine functional outcomes. Prabhakar et al [32] found no significant difference in the change in activities of daily living scores such as Alzheimer Disease Cooperative Study activities of daily living at any time during follow-up between the donepezil and *B. monnieri* arms. Similarly, no changes were noted in quality of life measured using Quality of Life Patient and Informant questionnaires. Sadhu et al [34] used the Functional Activity Questionnaire and reported a significant difference in change at 12 months between the donepezil arm (mean 9.801, SD 1.458) and the *B. monnieri* formulation arm (mean 11.873, SD 2.751; *P*<.001). Raghav et al [35] did not report any functional or quality of life–related outcomes. Cicero et al [33] reported significant improvement in Self-Rating Depression Scale scores in the *B. monnieri* formulation arm. Barbhaiya et al [36] did not report any functional outcomes.

Safety

Prabhakar et al [32] reported no significant differences in the number of patients who experienced one or more adverse events. No major adverse events were reported either. There were 3 deaths (2 in donepezil arm and one in *B. monnieri* arm) reported due to myocardial infarction. Raghav et al [35] reported diarrhea in 1 patient and headache in 2 patients in the placebo arm. One participant of the *B. monnieri* arm was reported to have experienced rashes. Sadhu et al [34] reported nausea, constipation, and drowsiness; however, no data on the number of participants with these events were reported. In the study conducted by Cicero et al [33], 1 participant was reported to have an aftertaste following ingestion of the *B. monnieri* formulation. Barbhaiya et al [36] did not report any adverse events.

Quality of the Evidence

We used the GRADE (Grading of Recommendations Assessment, Development and Evaluation) approach to assess the certainty of the evidence in the included studies, using the criteria outlined in the Cochrane Handbook [37]. The certainty of the evidence for the reported outcomes was very low. We assessed the quality of evidence for 4 major clinically relevant outcomes (ADAS-Cog, Postgraduate Institute Memory Scale, Mini-Mental State Examination, and Wechsler Memory Scale). We judged that all 5 included studies had a high risk of bias, downgrading the evidence by 2 levels. We downgraded one

level for impreciseness due to the small sample size and wide CI. Hence, the overall certainty of evidence was very low.

Discussion

Principal Results

There was no high-quality evidence for the benefits of *B. monnieri* compared with a placebo or donepezil for cognitive function, functional outcomes, or adverse events. All 5 studies were heterogeneous with respect to doses of *B. monnieri*, *B. monnieri* as part of a polyherbal combination, use of a placebo or donepezil as the control group, duration of treatment (2 months to 12 months), cognitive tests to assess primary outcomes, and the diagnostic criteria for Alzheimer disease and mild cognitive impairment.

Lack of Neuroimaging for the Diagnosis

Prabhakar et al [32] was able to demonstrate a statistically better outcome in the donepezil group compared to the *B. monnieri* group, even though there was no difference at 3, 6, and 9 months. Any statistical significance in this study was limited by a small sample size (34 patients) due to poor recruitment (the trial was stopped prematurely because of this issue).

Raghav et al [35], Sadhu et al [34], and Cicero et al [33] were able to demonstrate improvements in one or more facets of cognition using *B. monnieri* compared to the placebo or donepezil. All 3 studies had small sample sizes. Furthermore, duration of treatment and follow-up were also short. Since Sadhu et al [34] and Cicero et al [33] used a polyherbal preparation and combined nutraceuticals (with *B. monnieri* as one component), improvements noted cannot be attributed to *B. monnieri* alone. These 2 studies [33,34] did not use brain imaging; hence, the accuracy of Alzheimer disease diagnosis cannot be ascertained.

Although Barbhaiya et al [36] reported significant improvements in several tests of cognition, removal of 15 participants after randomization as outliers without giving any reasonable explanation and the absence of 33% of participants from the final analysis are major issues.

Comparison With Other Studies or Reviews

A previous meta-analysis [13] that evaluated the efficacy of *B. monnieri* for cognitive performance included studies with both healthy participants and individuals with memory impairment (518 participants from 9 studies); however, there were only 2 trials with cognitively impaired patients [35,36]. Similar to our observation, Barbhaiya et al [36] described an overall dropout of around 33%. However, there is no mention of the exclusion of 15 participants as outliers. A meta-analysis performed on data from 437 participants showed a shortened duration taken to complete the Trail B test (–17.9 ms, 95% CI –24.6 to –11.2; $P<.001$) and decreased choice reaction time (10.6 ms, 95% CI –12.1 to –9.2; $P<.001$). However, the Trail B test results were based on a single study with 46 healthy volunteers while the decreased choice reaction time was based on a subgroup analysis of 2 studies on healthy volunteers (46 and 62 participants) using 300 mg of *B. monnieri*. Hence, it cannot be truly considered as pooled estimates of efficacy in those with dementia. We did not perform a meta-analysis since the heterogeneity of data from the studies on people with dementia precluded meaningful pooling.

Another systematic review [18] on the effectiveness of *B. monnieri* as a nootropic, neuroprotective, or antidepressant supplement included studies involving healthy volunteers and those with dementia and depression. Three studies evaluated *B. monnieri* in Alzheimer disease or mild cognitive impairment [33,34,38], of which Goswami et al [38] was a nonrandomized study. A meta-analysis was not performed in this review.

In a systematic review by Cicero et al [19], the meta-analysis by Kongkeaw et al [13] was cited, and no new studies were included apart from those included by Kongkeaw and colleagues. Brioschi Guevara et al [20] had included 2 studies (Raghav et al [35] and Barbhaiya et al [36]) in their systematic review and described these studies as follows: “two old small studies on *B. monnieri* in individuals with memory complaints suggest a potential effect on some aspect of memory function or on attention tests that still need to be confirmed.” No data or study characteristics were mentioned in the review.

Though previous systematic reviews [13,19] had included most of the studies that this review also found eligible, they had not specifically addressed the question of the efficacy of *B. monnieri* in persons with Alzheimer disease. Inclusion of healthy volunteer studies and nonrandomized studies in these reviews makes it difficult to draw conclusions about similarities, and although significant improvements in specific tests had been noted in pooled analyses, they were mostly based on data from subgroups or single studies.

Strengths

We have thoroughly searched for and analyzed all the available evidence critically. Only 5 eligible trials were identified due to the use of stringent inclusion criteria. Due to severe heterogeneity in the included studies in terms of criteria for diagnosis, cognitive tests used, *B. monnieri* formulations (including polyherbal), duration of treatment, and lack of confidence in the diagnosis of dementia in the included patients, we did not conduct a meta-analysis.

Limitations

First, the use of very stringent inclusion criteria led to few eligible trials. However, this also means that the review question has been addressed specifically without any dilution of intent. Second, 1 author (VVY) was involved in a trial included in this review (ie, Prabhakar et al [32]). This potential source of bias was addressed because author VVY did not participate in the risk-of-bias assessment of trials (performed independently by authors AB and BM). Third, as with any systematic review, it is possible that some studies might have been missed. We ensured the inclusion of all potential studies by searching multiple databases. Moreover, independent screening of search output by 2 authors ensured that bias was minimized in assessing eligibility. We followed the guidance provided in the Cochrane Handbook to minimize potential biases in the review process [34]. Fourth, because only 5 trials were included in this review, we could not use funnel plots to assess the risk of publication bias.

Future Directions

As discussed above, this review found that there was no high-quality evidence for the benefits of *B. monnieri* compared with a placebo or donepezil for cognitive function, functional outcomes, or adverse events. All 5 studies had heterogeneity with respect to the *B. monnieri* dosage used in the trials, *B. monnieri* used as part of a polyherbal combination, use of a placebo or donepezil as the control group, duration of treatment (2 months to 12 months), cognitive tests used to assess primary outcomes, and diagnostic criteria used for Alzheimer disease and mild cognitive impairment. These hindered the generation of high-quality evidence for the use of *B. monnieri* in Alzheimer disease and MCI-AD. Based on these results, we opine the following design changes for future trials of *B. monnieri* in patients with Alzheimer disease.

Is B. monnieri Studied as a Disease-Modifying Drug or Only as a Symptomatic Treatment?

If the drug is tested as a disease-modifying treatment, then a placebo-controlled trial should be performed with stratification for the use of symptomatic medications (such as cholinesterase inhibitors) undertaken at randomization. If the drug has only a symptomatic effect, then it can either be tested against a placebo or with a cholinesterase inhibitor that is the standard of care for symptomatic management in many countries.

Drug Dosage

There is wide variation in the dosage of *B. monnieri* used in clinical trials. In the review by Kongkeaw et al [13], the most commonly used dosage was 300 mg twice daily. Our review also included studies where different doses of *B. monnieri* were used. The most commonly used dosage was again 300 mg twice daily. The analysis revealed no difference between *B. monnieri* and a placebo or donepezil in the treatment of Alzheimer disease or mild cognitive impairment. Both 300 mg and 450 mg of *B. monnieri* have been reported to be safe in a phase 1 study [39]. Hence, future trials of *B. monnieri* may consider using the higher dose (ie, 450 mg, twice daily) for efficacy. Since many studies use polyherbal preparations (eg, [40]), it is difficult to ascertain the role of each constituent.

Diagnosis of Dementia

The inclusion criteria for participants should be clearly defined, and internationally accepted criteria for dementia should be used. The International Working Group criteria and the National Institute on Aging –Alzheimer's Association criteria describe 3 stages in the Alzheimer disease continuum (preclinical Alzheimer disease, prodromal Alzheimer disease or MCI-AD, and Alzheimer disease dementia) [41].

Duration of Treatment

The trial duration depends on the intervention strategy (primary prevention vs secondary prevention), target population (preclinical Alzheimer disease and prodromal or MCI-AD vs established Alzheimer disease dementia), efficacy endpoints (cognition, functional, or global endpoints; behavioral; and psychiatric symptoms of dementia), and mechanism of intervention (symptomatic treatment vs disease-modifying treatment). Prevention trials require a minimum duration of 3 years. In patients with mild to moderate and prodromal Alzheimer disease or MCI-AD, a minimum duration of 18 months has been assumed to be sufficient [42]; longer durations might be necessary depending on the timing of the intervention and trial design (eg, delayed start or time to event approach). For symptomatic treatment of behavioral and psychiatric symptoms of dementia in established dementia, a duration of 8 to 12 weeks is recommended [42].

Effect Size Estimates and Sample Size

Since in most of the included trials, the diagnosis of Alzheimer disease itself was not conclusive and different outcome measures were used, it is difficult to estimate the required sample size for a future study. We would suggest that internationally accepted and harmonized clinical outcome measures such as the ADAS-Cog should be used in a future trial, with 2 caveats. First, the cross-cultural validity of the tool being used needs to be considered, and second, the possibility of a ceiling effect in prodromal (pre–mild cognitive impairment and mild cognitive impairment stages) Alzheimer disease should also be taken into account [43]. For the latter issue, studies are now using tools that are sensitive to detect changes in cognitively less impaired individuals and can capture the earliest clinically meaningful changes over a respectable time duration of the trial [44]. Emphasis is on the creation and validation of cognitive composite scores (eg, a composite score including delayed word list recall, logical memory, category fluency, tests of processing speed, tests of performance IQ) as primary efficacy measures in Alzheimer disease prevention trials to detect subtle cognitive changes between treatment and placebo groups [45]. There are several studies [46,47] on power calculations of clinical trials on Alzheimer disease.

Here, we consider the Alzheimer Disease Neuroimaging Database and its power calculations for sample size estimation [46,48]. The effect size can be estimated as a percentage of the anticipated mean rate of decline under the placebo or standard-of-care scenario. The sample size required to detect a 25% reduction in the annual rate of change for the ADAS-Cog in mild cognitive impairment (80% power and 2-sided α=.05), with an annual rate of change of 2.5 points is 1183 for a 1-year trial; however, if the estimate is for a 25% reduction of a 1.0-point rate of change per year, the sample size would be 2175. A similar calculation for patients with Alzheimer disease will yield a sample size from 312 to 624 per arm for a 1-year trial, assuming a 25% reduction of 3.8 to 4.3 points per year. Only Prabhakar et al [32] used the ADAS-Cog as their primary outcome, but data are not available separately for patients with mild cognitive impairment and Alzheimer disease; the annual rate of change of the score for the donepezil arm was 2.2 points. Hence, it is reasonable to assume annual rates of decline of 2.5 and 3.8 points in the placebo arm for mild cognitive impairment and Alzheimer disease, respectively; the required sample size for a 25% reduction in score in the *B. monnieri* treatment arms would be 1183 and 500 for mild cognitive impairment and Alzheimer disease, respectively, for a 1-year trial. The sample size can be reduced if a surrogate outcome like hippocampal atrophy is used. Using similar calculations as above, the sample size for mild cognitive impairment will be around 200 to 300 per arm for a 1-year trial if the assumed annual rate of

hippocampal atrophy is 2% to 3%. In Alzheimer disease, the sample size will be much less if we consider a 50% slowing of overall hippocampal atrophy; then the sample size can be reduced to less than 100 participants.

Outcome Measures

Primary outcomes for Alzheimer disease trials should include cognitive and functional endpoints or a single cognition-function composite endpoint, and the tools selected to capture these outcomes should have cultural validity and international harmony. Prodromal Alzheimer disease assessment requires newer, sensitive measures, such as tests of metacognition, social cognition, and prospective memory [43], rather than traditional neuropsychological tests. The detection of functional impairment in the early stages will also require instruments that are sensitive to subtle functional changes such as tests for financial capacity, performance-based skill assessments, and computerized assessments based on virtual reality and video technology [43]. Other options are time to onset of dementia or the proportion of patients who develop Alzheimer disease dementia; however, Alzheimer disease prevention trials that use time to event as an outcome require extended observation periods to accurately assess disease progression [49].

Conclusions

The evidence obtained from the present systematic review is of very low certainty. The evidence from 5 trials suggests that there is no difference between *B. monnieri* and a placebo or donepezil in the treatment of Alzheimer disease or mild cognitive impairment. No major safety issues were reported in the trials included in this review.

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Authors' Contributions

VV conceived the study. AB and VV took responsibility for the integrity of the data and the accuracy of the analyses. AB and VV conducted the literature search, performed the quality assessment of the selected studies, and extracted data. AB, VV, AA, BM, and AG interpreted the results and drafted the manuscript. AB, VV, and RK were responsible for data analysis. MVP critically revised the manuscript and helped with scientific discussion.

Conflicts of Interest

None declared.

Multimedia Appendix 1
Search strategy.
[DOCX File , 13 KB - ijmr_v11i2e38542_app1.docx]

Multimedia Appendix 2
Detailed baseline characteristics of the included studies.
[DOCX File , 27 KB - ijmr_v11i2e38542_app2.docx]

Multimedia Appendix 3
Quality of evidence, outcomes, and adverse events.
[DOCX File , 32 KB - ijmr_v11i2e38542_app3.docx]

Multimedia Appendix 4
Risk-of-bias assessment.
[PNG File , 491 KB - ijmr_v11i2e38542_app4.png]

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Abbreviations

ADAS-Cog: Alzheimer's Disease Assessment Scale-Cognitive Subscale
GRADE: Grading of Recommendations Assessment, Development, and Evaluation
MCI-AD: mild cognitive impairment due to Alzheimer disease
PRISMA: Preferred Reporting Items for Systematic Reviews and Meta-Analyses
SDAT: senile dementia of the Alzheimer's type

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Original Paper

Ranolazine Versus Allopurinol for Eligible Symptomatic Patients With a History of Angioplasty: Comparative Efficacy Study

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Abstract

Background: Recurrent angina, which is defined as a return of chest pain or chest discomfort, occurs in many patients undergoing coronary interventions.

Objective: This study aims to compare the antianginal efficacy of ranolazine versus allopurinol for eligible symptomatic patients with a history of angioplasty.

Methods: A total of 62 eligible symptomatic patients with a history of angioplasty were randomly allocated into two groups. For group A, 300 mg of allopurinol was administered twice daily, while for group B, 1000 mg of ranolazine daily was prescribed for a duration of 4 weeks. An initial screening visit was done for all participants where patients' medical history was recorded and a physical examination was given; electrocardiography, blood pressure, and heart rate measurements were done as well. The patients were also given a blood and exercise test. At the end of the medication period, participants were revisited, and the tests were done again. All the required data were collected via a researcher-made form, and data analysis was conducted using SPSS. The study was approved by a formal ethics committee.

Results: The mean age of participants in the two groups (A and B) was 57.36 (SD 8.36) and 60.27 (SD 9.17) years, respectively. Among the 62 patients, 34 (59%) were men, while 28 (41%) were women. Creatinine, fasting blood sugar, C-reactive protein, N-terminal prohormone of brain natriuretic protein, uric acid, white blood cell, and hemoglobin levels of participants were not significantly different between groups (P>.05). Both allopurinol and ranolazine increased the total exercise time and decreased the ST depression of the patients. Additionally, they both improved the chest pain severity and Duke Treadmill Score of patients. At the same time, ranolazine had a statistically greater effect on ST depression reduction (mean 2.64, SD 0.74 vs mean 1.57, SD 0.49), while allopurinol showed better efficacy in reducing chest pain severity (mean 1.86, SD 0.37 vs mean 0.59, SD 0.21) and the Duke Treadmill Score (mean –14.77, SD 3.65 vs mean –6.88, SD 1.93).

Conclusions: Based on the results, the antianginal efficacy of allopurinol and ranolazine was approved but with different effects on ST depression, chest pain severity, and the Duke Treadmill Score. Therefore, the precise differences in their effects need to be explored further.

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KEYWORDS

ranolazine; allopurinol; recurrent angina; exercise tolerance

Introduction

Cardiovascular diseases are considered as the most common cause of death and disability in most countries. For the health systems, prevention and treatment of diseases are among the main priorities [1]. Treatments of coronary artery diseases include medication and intravascular interventions in addition to controlling risk factors. Intravascular interventions include coronary artery bypass graft surgery and percutaneous

vasodilation [2]. Coronary angioplasty, as one of the most influential advances in the treatment of patients with coronary heart disease, can substantially reduce the need for vascular transplant surgery. However, restenosis of the coronary arteries after angioplasty is one of the most important concerns of cardiologists. In various studies, the rate of restenosis of arteries 6 months after angioplasty has been reported in about half of the cases [3]. To solve this problem, interventional cardiologists have introduced intracoronary stents, which is also an important breakthrough in the treatment of heart diseases. Numerous studies have shown that the rate of restenosis after stent implantation is significantly lower than balloon angioplasty in the first 6 months after the intervention [3-6]. Unfortunately, the introduction of this method has not completely solved the problem of coronary artery restenosis after the intervention. Existing studies show that restenosis and experiencing recurrent angina occur in a significant proportion of patients receiving cardiovascular stents [2,7-10]. Numerous factors such as older age, more stents, diabetes, and the use of aspirin and beta-blockers increase the chances of recurrence [11].

Recurrent angina is defined as the recurrence of chest pain or chest discomfort in patients undergoing coronary intervention. Due to the possible complications of artery restenosis after stenting, timely diagnosis and treatment plays an important role in patients' survival and quality of life (QOL) [12]. Although so far no specific diagnostic algorithm has been developed for these cases, electrocardiography, an exercise test, a stress-level detection test, or invasive coronary assessment may be required. However, some diagnostic methods such as invasive coronary angiography or noninvasive scanning are not routinely available due to the potential complications of invasive interventions as well as the high cost. Therefore, specialists often use exercise tests and clinical signs to diagnose restenosis [3,13]. To treat this complication, various options such as balloon angioplasty, restenting, rotational atherectomy, directional atherectomy, excimer laser angioplasty, intracoronary radiation therapy, or pharmacological methods are suggested. In cases where vascularization is not required, treatment approaches with a variety of available medications are used. Today, various medications including ranolazine and allopurinol are available for this purpose, and their efficacy has also been studied in numerous papers [3,6,10]. For instance, Chaitman et al [10] examined the effect of ranolazine in combination with amlodipine or diltiazem on exercise tolerance and angina recurrence in patients with chronic angina. Noman et al [9] investigated the effect of high-dose allopurinol on exercise tolerance in patients with chronic angina using a randomized controlled trial with a placebo. Chaturvedi et al [14] in a follow-up open labeled trial examined the efficacy and tolerability of ivabradine and ranolazine in patients with chronic stable angina pectoris. Al-Zahrani et al [15] studied the possible antianginal effect of allopurinol in a vasopressin-induced ischemic model in rats through an experimental study. Rousseau et al [16] have also compared the efficacy of ranolazine versus atenolol for chronic angina pectoris.

Despite this, and even though drug treatments in some studies have been compared, it is still not clear which medication regimen has the most favorable result. Therefore, suggesting appropriate drug treatment for patients with stable angina after stenting intervention requires further studies [6]. This study aimed to compare the efficacy of ranolazine versus allopurinol for eligible symptomatic patients with a history of angioplasty. To the best of our knowledge, there are some studies on the efficacy of ranolazine or allopurinol separately. Additionally, other studies have compared the efficacy of one of these with another drug, but the efficacy of ranolazine has not been compared with allopurinol in any previous study. Indeed, allopurinol has been reported as an inexpensive, well-tolerated, and safe option that should be studied further. As Noman et al [9] mention, the precise place of allopurinol in the management of angina pectoris needs to be explored further, but this drug might be especially appealing for use in low-income countries where coronary artery disease is rapidly increasing and where access to expensive drugs or invasive treatments is often restricted [9]. Therefore, comparison of these drugs' efficacy provides new insights for the clinicians. This was the main novelty of this study.

Methods

Setting

A clinical trial was conducted at Imam Khomeini Hospital, Tehran, Iran.

Participants

The study population included patients with a history of stenting but who still had the coronary clinical symptoms after the intervention and needed medical treatment.

Inclusion and Exclusion Criteria

Inclusion criteria are defined as follows: having a positive exercise tolerance test or limited capacity in the treadmill test based on the modified Bruce protocol (patients who had a total exercise time between 3 and 9 minutes); at least 6 months have passed since stenting; and having a history of chronic, recurrent, and stable angina after stent implantation. The exclusion criteria considered factors that prevented the correct interpretation of the electrocardiogram, grade 3 or 4 heart failure, intravascular reintervention in the last 6 months, the inability to perform exercise test due to leg and back problems, a history of acute myocardial infarction, a history of acute vascular syndrome, left ventricular rejection fraction less than 45, estimated glomerular rate less than 45 mm per minute, creatinine concentration greater than 180 mmol/ml, significant heart valve disease, atrial arrhythmia, electrocardiogram abnormalities that interfere with ST segment interpretation, and using the study drugs (allopurinol or ranolazine). Additionally, patients who had a total exercise time of less than 3 minutes, those who did not want to continue participation, and those who needed invasive cardiovascular intervention during the study were excluded.

Randomization and Blinding

All the participants were randomly divided into two groups: allopurinol and ranolazine. Randomization was done by random number generation in 12 blocks using SPSS Version 22 (IBM Corp) software.

For blinding, all visits, exercise tests, and clinical investigations of participants were performed under the supervision of a research team member who was unaware of the treatment allocation. The preparation of numbered medicine containers (allopurinol or ranolazine) was also done by a member of the research team who was not aware of the drug allocation and the results of the patients' tests. Random numbers and drug assignments were also created by a staff member of the hospital who was not a member of the research team. Additionally, other members of the research team and patients had no access to the assignment sequence.

Sample Size

For the sample size calculation, we anticipated a detectable 30-second difference of total exercise test tolerance time between the 2 groups based on the pilot analysis of 12 patients and the reports of previous studies [9,10]. The required sample size was then calculated as 58 (29 samples for each group) using a test power of 90% and an allocation ratio of 1. Finally, 62 patients were included for further analysis.

Procedure

A total of 62 patients participated in the study. First, the objective of the study was explained for the patients and an informed written consent was obtained. An initial screening visit was done for all the participants. In this visit, patients' medical history was recorded; a physical examination was carried out; and electrocardiography, blood pressure, and heart rate measurements were done. Additionally, a blood test including creatinine, fasting blood sugar, C-reactive protein, N-terminal prohormone of brain natriuretic protein, uric acid, white blood cell, and hemoglobin was carried out on the patients. In addition, an exercise test was performed by all patients. Patients who had a positive exercise test or a limited capacity treadmill test based on the modified Bruce protocol were eligible to participate in the study [17]. We included those patients who had the total exercise time between 3 to 9 minutes. For the allopurinol group, 300 mg twice daily was administered, and for the ranolazine group, 1000 mg daily was administered for 4 weeks. During the study, patients were allowed to take their underlying medications without modification. At the end of the medication period, participants were revisited. In this visit, patients' medical history was recorded; a physical examination was carried out; and electrocardiography, blood pressure, and heart rate measurements were done. Additionally, a blood test was carried out for the participants. In addition, for all patients, an exercise test was performed at peak times (4 hours after medication). Drug reactions were followed for all the patients, but no adverse reaction was documented.

Analysis

All the required data was collected via a researcher-made form. It should be noted that conducting the research did not incur any additional financial costs for patients. The collected data was analyzed using SPSS statistical software. Descriptive statistics (frequency, percentage, mean, and SD) and independent sample *t* test were used for analysis.

Ethics Approval

All participants provided an informed written consent to participate in the study and were assured that their information would be kept confidential. All study procedures were conducted in accordance with the ethical standards of the Declaration of Helsinki. The study was approved by the ethics committee affiliated with the Tehran University of Medical Sciences (IR.TUMS.IKHC.REC.1399.315).

Results

A total of 62 patients in 2 groups, allopurinol (group A) and ranolazine (group B), participated in the study. Figure 1 shows the study procedure.

As Figure 1 illustrates, a total of 107 patients were assessed for eligibility, from which 62 patients were allocated to the study groups randomly. The baseline characteristics of participants are presented in Table 1. All the participants were using aspirin, statin, P2Y12 inhibitor, beta-blocker, nitrates, and calcium blocker, which were continued during the course of the study.

As Table 1 indicates, most of the participants had hypertension or hypercholesterolemia. Additionally, the majority had one stent. The blood test results of participants are presented in Table 2.

As shown in Table 2, the blood test parameters of the 2 groups had no statistical differences. Tables 3 and 4 show the results of the exercise test for the 2 groups and the comparison of the outcomes between them.

Table 3 shows that allopurinol and ranolazine both significantly improved the total exercise time of patients, ST depression, chest pain severity, and Duke Treadmill Score from baseline. Therefore, the efficacy of studied drugs as an antianginal drug was approved.

Table 4 reports the comparison analysis of the studied drugs' effects on the outcomes. As seen, allopurinol and ranolazine both increased the total exercise time with no statistical difference. However, ranolazine showed better efficacy in improving ST depression and the Duke Treadmill Score, while allopurinol showed higher efficacy in decreasing chest pain severity.

Figure 1. The study procedure.

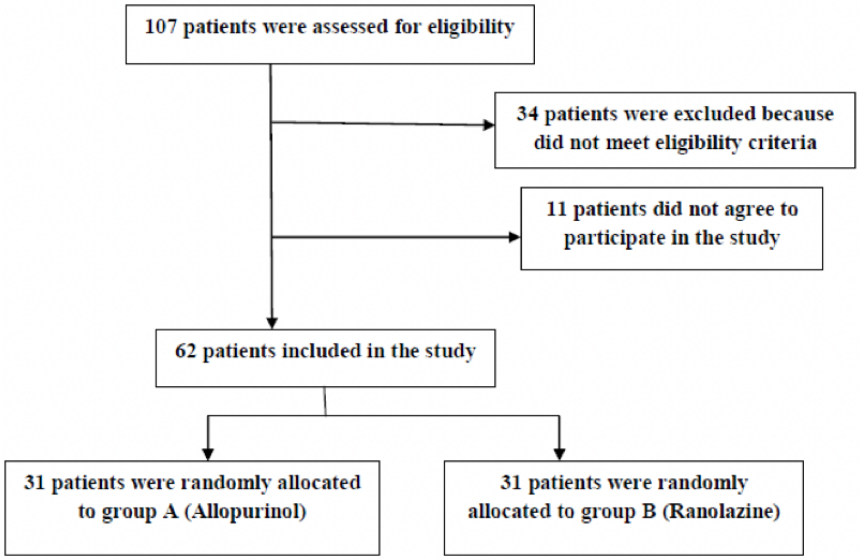

Table 1. Baseline characteristics of participants.

	Allopurinol (n=31)	Ranolazine (n=31)
Age (years), mean (SD)	57.36 (8.36)	60.27 (9.17)
Gender, n (%)		
Male	17 (55)	20 (65)
Female	14 (45)	11 (35)
Medical history, n (%)		
Hypertension	20 (65)	18 (58)
Diabetes mellitus	11 (35)	8 (26)
Hypercholesterolemia	19 (61)	23 (74)
Number of vessels with coronary artery disease		
1	8 (26)	11 (35)
2	8 (26)	6 (19)
3	0 (0)	0 (0)
Multiple	15 (49)	14 (45)
Number of stents		
1	14 (45)	18 (58)
2	11 (35)	8 (26)
3	6 (19)	5 (16)
>3	0 (0)	0 (0)
Smoking, n (%)		
Yes	6 (19)	9 (29)
No	27 (82)	22 (71)

Table 2. The blood test results of two groups.

Test	Allopurinol, mean (SD)	Ranolazine, mean (SD)	*P* value
Creatinine (μmol/L)	0.89 (0.23)	1.01 (0.17)	.16
FBS[a] (mg/dl)	103.00 (34.25)	87.36 (18.50)	.20
CRP[b] (mg/l)	1.54 (0.93)	1.18 (0.60)	.29
NT-pro BNP[c] (pg/ml)	98.10 (23.76)	102.30 (33.35)	.75
Uric acid (mg/dl)	2.99 (0.68)	3.30 (0.84)	.36
WBC[d] ($\times 10^9$ per L)	6.16 (1.35)	5.58 (1.12)	.29
HB[e] (g/dl)	12.66 (1.09)	13.02 (1.00)	.43

[a]FBS: fasting blood sugar.

[b]CRP: C-reactive protein.

[c]Nt-pro BNP: N-terminal prohormone of brain natriuretic protein.

[d]WBC: white blood cell.

[e]HB: hemoglobin.

Table 3. The results of the exercise test for the 2 groups.

Variable	Allopurinol, mean (SD)		*P* value	Ranolazine, mean (SD)		*P* value
	Baseline	After		Baseline	After	
Total exercise time (s)	263 (74)	342 (89)	*.03* [a]	371 (97)	454 (102)	*.02*
ST depression	2.43 (0.92)	1.72 (0.87)	*.04*	2.64 (0.74)	1.57 (0.49)	*.02*
Chest pain severity	1.86 (0.37)	0.59 (0.21)	*.03*	2.11 (0.43)	1.70 (0.46)	*.01*
Duke Treadmill Score	–14.77 (3.65)	–6.88 (1.93)	*.02*	–16.87 (3.89)	–6.72 (2.26)	*.01*

[a]Italics indicate significance at the $P<.05$ level.

Table 4. Comparison of the changes of studied outcomes between 2 groups.

Variable	Allopurinol[a], mean (SD)	Ranolazine[a], mean (SD)	*P* value
Total exercise time (s)	79 (37)	83 (39)	.18
ST depression	0.71 (0.25)	1.07 (0.28)	*.03* [b]
Chest pain severity	1.27 (0.29)	0.41 (0.14)	*.02*
Duke Treadmill Score	7.89 (1.76)	10.15 (2.94)	*.01*

[a]Changes of the outcomes after the course of treatment.

[b]Italics indicate significance at the $P<.05$ level.

Discussion

Principal Findings

This study aimed to compare the efficacy of ranolazine and allopurinol for eligible symptomatic patients with a history of angioplasty. Based on the findings, ranolazine and allopurinol showed appropriate antianginal efficacy. Both the medications increased total exercise time with no statistical difference. However, ranolazine affected ST depression and the Duke Treadmill Score more than allopurinol, while allopurinol showed a better efficacy in decreasing chest pain severity. Therefore, this study approved the efficacy of both drugs as an antianginal drug like the previous studies. It is recommended to study the different effects on the outcome measures in future studies.

Comparison to Prior Works

Our study approved the antianginal efficacy of both studied drugs but with some differences. Other studies have confirmed the efficiency of these treatments, but the available studies have reported different results in this area.

Noman et al [9] in a randomized placebo-controlled trial investigated the effect of high-dose allopurinol on exercise in patients with chronic stable angina. The results of this study showed that allopurinol is a useful, inexpensive, well-tolerated, and safe anti-ischemic drug for patients with angina. In this study, administration of allopurinol 600 mg per day was reported to be associated with a 43-second median increase in exercise time to ST-segment depression, a 58-second median increase in total exercise time, and a 38-second median increase in time to chest pain.

Alexander et al [13] in a clinical trial investigated the effects of ranolazine on angina and QOL after percutaneous coronary intervention (PCI) with incomplete revascularization. This study concludes that adding ranolazine in the angiographically identified population has no incremental benefit in angina or QOL measures. Stone et al [18] in the Efficacy of Ranolazine in Chronic Angina (ERICA) trial investigated the antianginal efficacy of ranolazine when added to the treatment with amlodipine in stable coronary patients. They have concluded that ranolazine significantly reduces the frequency of angina compared with the placebo while being well tolerated. Another study, the Type 2 Diabetes Evaluation of Ranolazine in Subjects with Chronic Stable Angina (TERISA) trials have reported a similar result for ranolazine administration in patients with type 2 diabetes mellitus, coronary artery disease, and chronic stable angina who remain symptomatic despite treatment with up to 2 antianginal agents [19]. Wilson et al [20] in a randomized, double-blind, placebo-controlled Metabolic Efficiency With Ranolazine for Less Ischemia in Non–ST-Segment Elevation Acute Coronary Syndromes (MERLIN-TIMI) 36 Trial have evaluated the efficacy and safety of ranolazine in a larger and diverse group of patients, and reported that ranolazine is effective in reducing angina and has favorable safety for patients with angina. Gutierrez et al [21] in another study from the MERLIN-TIMI 36 Trial have studied the effects of ranolazine in patients with chronic angina and showed that, in patients with chronic angina, ranolazine reduces recurrent ischemic events, regardless of whether patients did or did not receive PCI within 30 days of a non–ST-segment for acute coronary syndromes. Sendón et al [22], also in a Combination Assessment of Ranolazine in Stable Angina (CARISA) randomized trial of 258 patients, reported that ranolazine is effective for the symptomatic treatment of patients with stable angina on background therapy with maximally tolerated doses of first-line antianginal therapies.

Chaitman et al [10], in a randomized controlled trial with a placebo, investigated the effects of ranolazine with atenolol, amlodipine, or diltiazem on exercise tolerance and angina frequency in patients with severe chronic angina. The results showed that twice-daily doses of ranolazine increases exercise capacity and provides additional antianginal relief to symptomatic patients with severe chronic angina who are taking standard doses of atenolol, amlodipine, or diltiazem over 1 year to 2 years of therapy. Chaitman et al [5] in a double-blind randomized clinical trial evaluated the anti-ischemic effects and long-term survival during ranolazine monotherapy in patients with chronic severe angina. They concluded that ranolazine is well-tolerated and improves exercise performance without any significant adverse effect. Timmis et al [23] studied the effects of ranolazine on exercise tolerance and hemoglobin A_{1c} in patients with chronic angina and diabetes. They concluded that ranolazine makes similar improvements in exercise parameters, nitroglycerin use, and angina frequency in patients who are diabetic and nondiabetic.

Strengths and Limitations

Our study had some limitations alongside its strengths and applications. First, our sample size was small; although we used the results of previous studies to calculate the needed sample size, the study could be conducted with larger samples. The main cause of this limitation was the sampling restrictions caused by the COVID-19 pandemic. Second, screening of HLA B*5801 was not done for patients prior to initiating allopurinol due to the limited availability and cost concerns for the patients. However, we followed the drug reactions of all our patients.

Conclusion

In conclusion, based on our results, allopurinol and ranolazine are the useful, well-tolerated, and safe antianginal options for eligible symptomatic patients with a history of angioplasty. However, they showed different effects on some of studied outcomes. Therefore, the precise differences in their effects need to be further explored.

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Data Availability

The data that support the findings of this study are available on request from SB. The data are not publicly available due to privacy/ethical restrictions.

Conflicts of Interest

None declared.

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Abbreviations

CARISA: Combination Assessment of Ranolazine in Stable Angina
ERICA: Efficacy of Ranolazine in Chronic Angina
MERLIN-TIMI: Metabolic Efficiency With Ranolazine for Less Ischemia in Non–ST-Segment Elevation Acute Coronary Syndromes
PCI: percutaneous coronary intervention
QOL: quality of life
TERISA: Type 2 Diabetes Evaluation of Ranolazine in Subjects with Chronic Stable Angina

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Original Paper

Intervention in the Timeliness of Two Electrocardiography Types for Patients in the Emergency Department With Chest Pain: Randomized Controlled Trial

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Abstract

Background: In the emergency department (ED), the result obtained using the 12-lead electrocardiography (ECG) is the basis for diagnosing and treating patients with chest pain. It was found that performing ECG at the appropriate time could improve treatment outcomes. Hence, a wearable ECG device with a timer can ensure that the findings are continuously recorded.

Objective: We aimed to compare the time accuracy of a single-patch 12-lead ECG (SP-ECG) with that of conventional ECG (C-ECG). We hypothesized that SP-ECG would result in better time accuracy.

Methods: Adult patients who visited the emergency room with chest pain but were not in shock were randomly assigned to one of the following 2 groups: the SP-ECG group or the C-ECG group. The final analysis included 33 (92%) of the 36 patients recruited. The primary outcome was the comparison of the time taken by the 2 groups to record the ECG. The average ages of the participants in the SP-ECG and C-ECG groups were 63.7 (SD 18.4) and 58.1 (SD 12.4) years, respectively.

Results: With a power of 0.95 and effect sizes of 0.05 and 1.36, the minimum number of samples was calculated. The minimum sample size for each SP-ECG and C-ECG group is 15.36 participants, assuming a 20% dropout rate. As a result, 36 patients with chest pain participated, and 33 of them were analyzed. The timeliness of SP-ECG and C-ECG for the first follow-up ECG was 87.5% and 47.0%, respectively (P=.74). It was 75.0% and 35.2% at the second follow-up, respectively (P=.71).

Conclusions: Continuous ECG monitoring with minimal interference from other examinations is feasible and essential in complex ED situations. However, the precision of SP-ECG has not yet been proved. Nevertheless, the application of SP-ECG is expected to improve overcrowding and human resource shortages in EDs, though more research is needed.

Trial Registration: ClinicalTrials.gov NCT04114760; https://clinicaltrials.gov/ct2/show/NCT04114760

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KEYWORDS

imaging; electrocardiography; wireless technology; emergency department; emergency; angina; ECG; EKG; cardiology; chest; pain; electrocardiogram; randomized; randomization; heart; cardiac; diagnose; diagnosis; accuracy

Introduction

Twelve-lead electrocardiography (ECG) is an essential diagnostic tool in the emergency department (ED) for patients with chest pain [1]. The most important step to be taken for a patient who complains of chest pain is to identify the location of the pain. ECG should be performed to determine if the pain is caused by a cardiovascular disease [2]. According to the guideline of the Journal of European Heart, ECG was performed as the first step for evaluation and treatment when patients with chest pain visited the ED [3]. Currently, ED in South Korea is following the American Heart Association's recommendation to take an initial ECG within 10 minutes of the patient's visit with chest pain [4]. This is to determine whether it is chest pain caused by coronary artery disease and to improve the patient's clinical results through quick treatment if necessary. This is because rapid diagnosis of ST elevation myocardial infraction, or acute myocardial infarction, requires immediate treatment, and treatment among coronary artery diseases leads to a decrease in the patient's prognosis or mortality [5]. From 8.5% to 40% of patients with acute myocardial infarction have symptoms; however, the rise of the ST segment, which determines whether to perform an immediate procedure, is not visible on the ECG, and then the rise of the ST segment occurs over time [6].

Therefore, continuous ECG monitoring after the initial ECG is important [7]. If ECG is not performed on time, this may affect the clinical outcome of the patient. Timely ECG is associated with improved clinical outcomes in patients with serious cardiovascular diseases. Electrocardiographic findings during acute myocardial infarction can vary substantially depending on the type, stage, and extent of infarction and timing of the ECG acquisition [8-10]. Therefore, a delayed ECG in the ED, which can be due to overcrowding or shortages in human resources, can result in poor patient outcomes [11-13].

Complex and unstable circumstances in the ED are challenging for current monitoring systems. Patients often move from one location to another for various tests and procedures. In addition, the long physical lines and multiple large patches of current ECG devices are not suitable for long-term use and are time-consuming. Hence, a single-patch wireless 12-lead ECG (SP-ECG) with a timer can be beneficial in cases of predecided follow-up ECG. A single patch would enable patients to move outside the bed and could be used in complex emergency room situations requiring many tests. However, to the best of our knowledge, no studies have been conducted on such devices in ED settings. Thus, this study aimed to evaluate the effect of SP-ECG with a timer on the timeliness of follow-up ECG in the clinical setting for patients with chest pain.

Methods

Study Design

This was a prospective randomized controlled study conducted in the ED of an academic tertiary hospital. Participants who visited ED with chest pain were randomly assigned into the 2 groups of conventional ECG (C-ECG) and single-patch 12-lead ECG (SP-ECG). The main comparison variable was the timeliness of the recording time for the 2 ECG types. The study protocol was registered at ClinicalTrials.gov (NCT04114760). To clarify the methods, we followed CONSORT (Consolidated Standards of Reporting Trials) checklist (Multimedia Appendix 1) [14].

Study Setting

This study was conducted in the ED of an academic tertiary hospital in Seoul with approximately 2000 inpatient beds and around 2,000,000 annual outpatient visits. The average number of ED admissions is 78,000 per year. The first study participants were enrolled on July 30, 2020, while the last study participants were enrolled on October 8, 2020. The study was conducted for approximately 70 days.

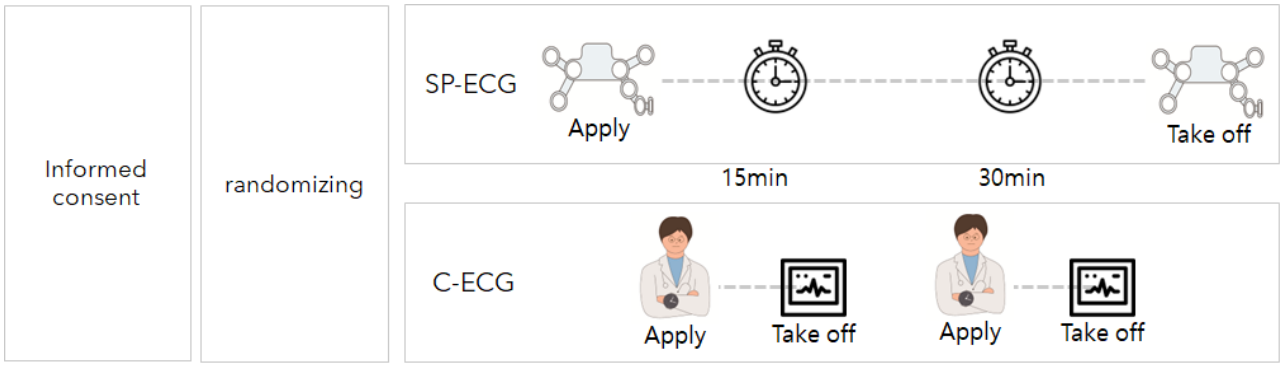
Recruitment

Patients who visited the hospital's ED with chest pain as the chief complaint were considered for inclusion in the study. The inclusion criteria were as follows: visits to the ED with chest pain or chest discomfort as the chief complaint, age more than 19 years, the ability to stay in the emergency room during the study, and provision of consent to participate in the study. The exclusion criteria were as follows: refusal to provide consent to participate, active "Do Not Resuscitate" order, shock or cardiac arrest status, Patients with Korean Triage and Acuity Scale score 2 to 5, and ST-segment elevation myocardial infarction observed in the first ECG test.

Study Protocol

All patients with a chief complaint of chest pain were examined using an ECG immediately after visiting the ED and were randomly divided into the SP-ECG and C-ECG groups after the confirmation of the absence of ST-segment elevation myocardial infarction and shock [15]. Both groups were required to undergo ECG measurements twice every 15 minutes from the baseline [16]. The criterion for the SP-ECG group was the time set on the device, whereas that for the control group was the order time of the physician after the patient was assigned a bed (Figure 1).

Figure 1. Study protocol. C-ECG: conventional electrocardiography (ECG); SP-ECG: single-patch 12-lead ECG.



Device and System

The devices used in the study were a page writer TC70 (existing device) and Healthrian SP-ECG. Healthrian SP-ECG was used as an intervention device and was approved by the Korean Ministry of Food and Drug Administration as a Holter ECG monitor (Figure 2).

Figure 2 shows the design configuration, where the main socket and the single-patch–type electrode are located. It consists of a main body and single-patch–type electrode. The dimensions of the main body were 46 × 35.6 × 16 millimeters with a weight of 30 grams. The patch measured 241.19 × 375.5 millimeters and weighed 35 grams. The main body was assembled in the socket of the patch. To perform the 12-lead ECG examination, the tablet and main body were wirelessly connected via Bluetooth for continuous monitoring.

Figure 3 shows the system architecture of SP-ECG. The main board of the device is based on a context-m4 digital signal-processing board. The analog front end consists of an ECG amplifier and an analog-digital converter to obtain a signal [17]. The ECG results were generated in a portable document format and were transmitted in real time to the researcher's dashboard via Long-Term Evolution networks when the tablet's "upload" button was clicked. The tablet used in this study was a Samsung Galaxy Tab S3 (SM-T825), which was connected to an LTE network. The dashboard used in this study was the Samsung Galaxy book (SM-W627NZFKOO), which could also be used on a PC. In addition, it used an LTE network. The differences between C-ECG and SP-ECG are significant. C-ECG has 10 separate electrodes, each connected to the patient by a physical long line. In SP-ECG, a single patch–type ECG is used to measure an ECG wirelessly. A signal is picked up and sent from a socket inside the single patch–type ECG.

Figure 2. Design configuration. 1. Main socket: socket of the patch for performing 12-lead electrocardiography. 2. Single-patch–type electrode. LA: left arm; RA: right arm; RL: right leg; V1-V4: voltage1-voltage.

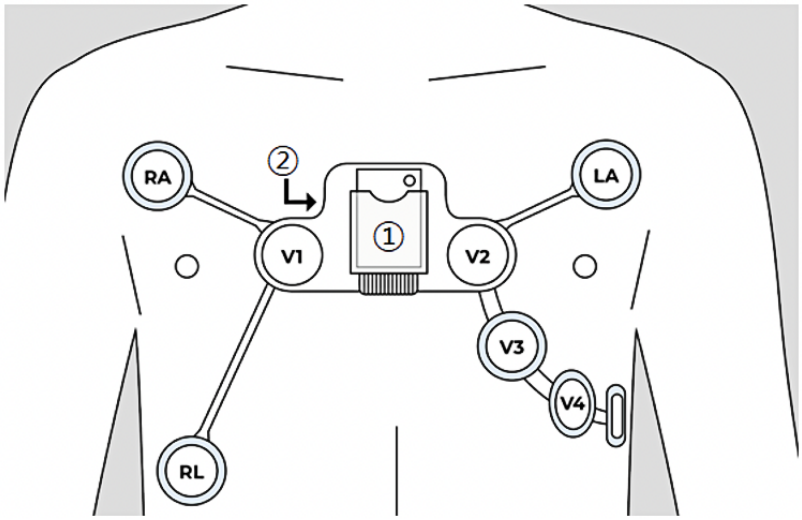
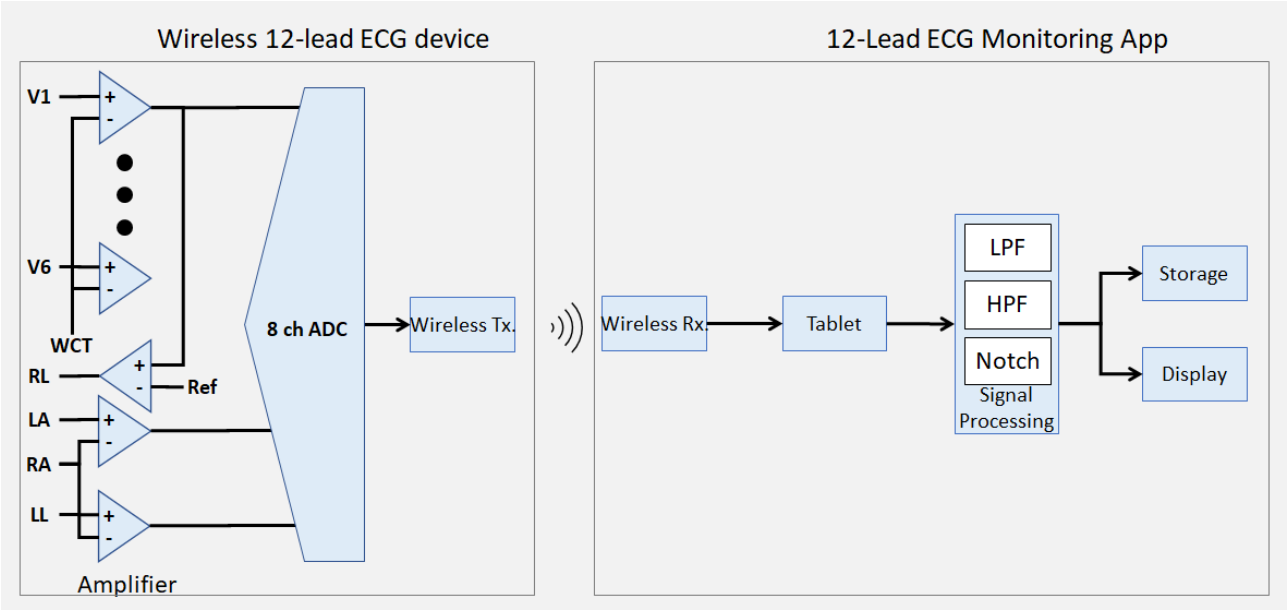


Figure 3. System architecture of the single-patch 12-lead electrocardiography (ECG). 8 ch DC: converts an amplified analog signal into a digital signal;amplifier: amplifies analog voltage obtained from the electrodes; digital signal processing: computes received digital signals as ECG signals through digital operations; display: converts output processed ECG data into a visualization graph; HPF (high-pass filter): eliminates low-frequency noise; LA: left arm; LL: left leg; LPF (low-pass filter): eliminates high-frequency noise; notch (notch filter): eliminates noise at a certain frequency, eliminates 60-Hz noise used for commercial power sources; RA: right arm; RL: right leg; storage: stores processed ECG data; V1-V4: voltage1-voltage4; WCT: Wilson's Central Terminal.



Measurement

The primary outcome in this study was the timeliness of the ECG measurements. The study protocol required subjects in both groups to be subjected to an ECG twice at 15-minute intervals. Participants in the C-ECG group underwent manual measurements by medical personnel at a specified time using the same 12-lead ECG. In the SP-ECG group, each ECG was automatically generated at a specified time using a pre-attached device. The SP-ECG device was attached to the participants at study initiation (time 0) and was removed after 1 hour.

Follow-up ECG was considered timely when it was taken within 3 minutes of the prespecified time. For example, if an ECG was recorded 14 minutes after the initial ECG, it was considered timely. Covariates, such as age, sex, Korean Triage and Acuity Scale score, heart rate, body temperature, respiratory rate, and blood pressure, were recorded based on the subjects' initial triage information at the ED.

Statistical Analysis

All data were stored in a Microsoft Excel spreadsheet. *P* values compared to baseline characteristics and time differences were calculated by comparing the means using the chi-square test. We compared the time differences between the 2 groups by comparing the means and standard deviations. Statistical significance was set at $P<.05$.

Sample Size

The *P* values in relation to the baseline characteristics and time differences were calculated by comparing the means via the chi-square test, 2-sample 2-tailed *t* tests, and statistical tests. The minimum number of samples for verification of the experimental hypothesis was calculated with a power of 0.95 and effect sizes of 0.05 and 1.36.

Based on previous pilot studies, 15 was calculated as the minimum sample size for each test and control group. Assuming a dropout rate of 20%, the total number of participants was 36.

Ethics Approval

The protocol of this study was reviewed and approved by Samsung Hospital's Institutional Review Board (IRB #2019-01-046-008).

Results

A total of 36 participants were enrolled in this study. The median ages in the SP-ECG and C-ECG groups were 63.7 (SD 18.4) and 58.1 (SD 12.4), respectively. Of the 36 enrolled patients, 33 (92%) were included in this study. One of the excluded patients wanted to drop out of the study due to disorientation. In one participant from each group, there were errors in the time measurements due to study violation. The average age of the 33 final participants was 61.06 (SD 15.8) years. Moreover, 14/33 (42.4%) patients were women, and the most common Korean Triage and Acuity Scale was 3. The other characteristics did not show significant intergroup differences (Table 1).

Intergroup differences in age, sex, and vital signs were small. Although 12/17 (70%) of the C-ECG group had a Korean Triage and Acuity Scale of 3, this was not meaningful because the participants were randomly assigned to each group.

Table 1. Demographic information of the study participants.

Characteristics	C-ECG[a] group (n=17)	SP-ECG[b] group (n=16)	*P* value
Age (years), mean (SD)	63.7 (18.4)	58.1 (12.5)	.32
Sex, n (%)			
Female	6 (35)	8 (50)	
Male, N	11 (65)	8 (50)	
KTAS[c], n (%)			.80
1	0	0	
2	3 (18)	6 (38)	
3	12 (70)	5 (31)	
4	2 (12)	5 (31)	
5	0	0	
Heart rate (beats per minute), median (SD)	79.4 (17.9)	79.3 (12.6)	.99
Body temperature (°C), median (SD)	36.7 (0.5)	36.7 (0.4)	.82
Respiratory rate (breaths per minute), median (SD)	18.5 (2.7)	18.1 (1.7)	.61
Systolic blood pressure (mmHg), median (SD)	133.4 (18.4)	129.8 (18.2)	.57
Diastolic blood pressure (mmHg), median (SD)	79.7 (14.3)	81.3 (14.6)	.75

[a]C-ECG: conventional electrocardiography.

[b]SP-ECG: single-patch 12-lead ECG.

[c]KTAS: Korean Triage and Acuity Scale.

Main Outcome

Timeliness of the ECG Types

Figure 4 shows the timing distribution of the 2 study groups. The average times for the C-ECG group are 23 minutes and 68 minutes for each test, and the average times for the SP-ECG group are 15 minutes and 32 minutes for each test. The recorded ECG time for each patient assigned to the C-ECG group and SP-ECG group can be seen in Table 2.

For the first follow-up ECG, the timeliness values of the recordings in the SP-ECG and C-ECG groups were 13/16 (81%) patients and 7/17 (41%) patients, respectively (*P*=.74). At the second follow-up, it was 10/16 (63%) patients and 6/17 (35%) patients, respectively (*P*=.71). Overall, the accuracies were 81.2% and 41.1%, respectively (*P*=.62).

Figure 4. Timing of electrocardiography measurements (gray areas indicate accurate time intervals). C-ECG: conventional electrocardiography (ECG); SP-ECG: single-patch 12-lead ECG.

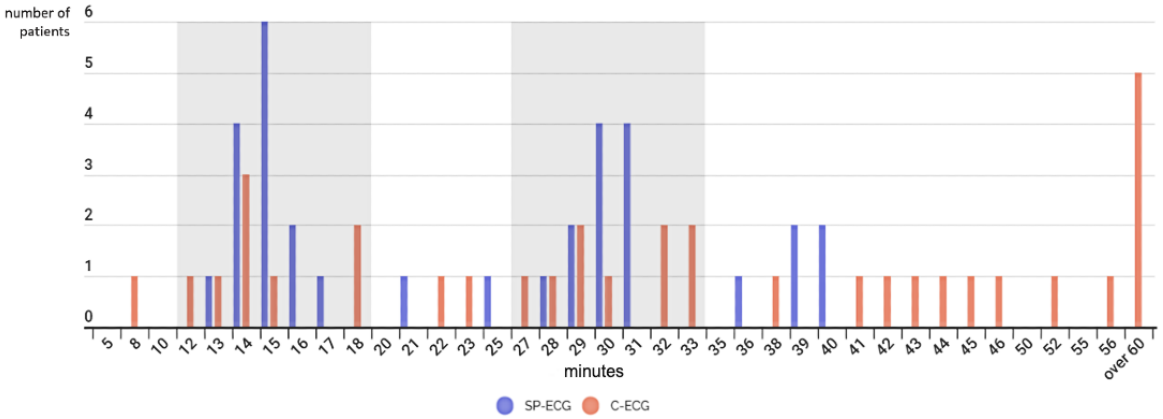


Table 2. Recorded electrocardiography (ECG) time for each patient assigned to the conventional ECG (C-ECG) group and the single-patch 12-lead ECG (SP-ECG) group.

C-ECG group			SP-ECG group		
Patient	1st follow-up ECG	2nd follow-up ECG	Patient	1st follow-up ECG	2nd follow-up ECG
S01	23	45	S02	15	30
S06	42	56	S03	15	31
S09	8	27	S04	15	31
S10	14	32	S08	29	44
S14	12	28	S11	16	30
S15	39	61	S12	17	32
S16	13	52	S13	15	39
S17	29	43	S18	14	40
S20	18	33	S19	15	31
S22	29	75	S21	14	31
S25	44	266	S23	14	28
S26	14	32	S24	15	30
S27	14	33	S28	15	30
S29	15	46	S30	16	29
S31	22	180	S32	20	35
S33	18	18	S36	16	31
S35	30	131	N/A[a]	N/A	N/A

[a]N/A: not applicable.

Figure 4 also illustrates that the C-ECG group's timing is not only outside the targeted time window, but it is significantly more delayed than that of the C-ECG group. It is also noteworthy that the ECG was recorded for 4 participants from the C-ECG group more than one hour after Time 0.

The C-ECG group consisted of 6/17 (35%) women and 11/17 (65%) men, whereas the SP-ECG group consisted of 8/16 (50%) women and 8/16 (50%) men. In the C-ECG group, the average time of the first follow-up ECG in women (n=6) was 22 (SD 6.35) minutes, while that of the second follow-up ECG was 82.5 (SD 55.20) minutes. For men (n=11), the average time of the first follow-up ECG was 22 (SD 12.55) minutes, while that of the second ECG was 60 (SD 66.28) minutes. In the SP-ECG group, the average time for women's (n=8) first follow-up ECG was 15 (SD 1) minutes, while that of the second ECG was 32 (SD 3.98) minutes. For men in the SP-ECG group (n=8), the average time for the first follow-up ECG was 17 (SD 4.58) minutes, while that for the second follow-up ECG was 32 (SD 4.71) minutes.

Discussion

Principal Findings

Wireless and single-patch ECGs were obtained from patients with chest pain at a more accurate time than C-ECG in clinical settings. Through this, we confirmed significant results on the time accuracy of wireless and single-patch ECG.

Patients with chest pain were enrolled in the ED and divided into 2 groups to examine whether the timeliness with SP-ECG was superior to that with C-ECG. The results showed that timeliness was significantly higher in the intervention group, implying its usefulness in complex ED environments.

This study is the first randomized controlled trial comparing wireless and single-patch ECG, and we arrived at meaningful results. Additionally, we did not impede complex processes and workflows in the ED. It was possible to perform other tests, such as chest x-rays or laboratory tests, while the device was placed, minimizing interference with the protocols of the ED. None of the patients dropped out of this study to undergo other procedures. Moreover, none of the patients or medical staff complained that its placement interfered with the other examinations.

Limitations

This study has some limitations. First, as this was a single-center study, the patient population was not fully representative. Therefore, our data should be validated across other institutions to draw generalizable conclusions. Second, this study was conducted over a relatively short period of time. Additionally, due to a lack of follow-up observations, the impact of the procedure in the ED could not be directly confirmed. SP-ECG has not yet been verified, and minor problems have been identified. In addition, human error occurred in 4 subjects in the SP-ECG group during the device setup and study.

Future Directions

To prevent the error of attaching a wireless electrocardiogram to the patient inappropriately during application, the provider should receive adequate training. Additional methods to compensate for the error of attaching a wireless electrocardiogram to the patient inappropriately should be explored in the future. The use of SP-ECG is expected to reduce the demand for human resources. In this study, only time accuracy was compared and evaluated. However, it was impossible to determine the effect of improving ED problems, such as staff shortage, the complexity of the emergency room medical environment, satisfaction with the test provider, the effect on the patient's overall diagnosis, and outcome of applying SP-ECG. Therefore, further research is required [18] to fill these gaps.

Conclusions

ECG is the most important and frequently performed test for patients with chest pain. Additionally, continuous checks, rather than one-time checks, are often required. The timing of ECG may influence patient outcomes. However, ECG recordings are sometimes delayed in the ED due to congestion and lack of human resources. To increase their timeliness, the development and use of medical devices that capture measures automatically and constantly without interfering with ED activities is required. Although our study on SP-ECG revealed that it required correction of minor device imperfections and training of medical staff before it could be used in a clinical setting, we identified significant improvement in the examination timeliness and demonstrated that it minimally disrupted the treatment processes in the ED.

Acknowledgments

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Conflicts of Interest

None declared.

Multimedia Appendix 1
CONSORT (Consolidated Standards of Reporting Trials) flowchart.
[PDF File (Adobe PDF File), 129 KB - ijmr_v11i2e36335_app1.pdf]

Multimedia Appendix 2
CONSORT-eHEALTH checklist (V 1.6.2).
[PDF File (Adobe PDF File), 85 KB - ijmr_v11i2e36335_app2.pdf]

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Abbreviations

C-ECG: conventional ECG
CONSORT: Consolidated Standards of Reporting Trials
ECG: electrocardiography
ED: emergency department
SP-ECG: single-patch 12-lead ECG

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Original Paper

An Analysis of PubMed Abstracts From 1946 to 2021 to Identify Organizational Affiliations in Epidemiological Criminology: Descriptive Study

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Abstract

Background: Epidemiological criminology refers to health issues affecting incarcerated and nonincarcerated offender populations, a group recognized as being challenging to conduct research with. Notwithstanding this, an urgent need exists for new knowledge and interventions to improve health, justice, and social outcomes for this marginalized population.

Objective: To better understand research outputs in the field of epidemiological criminology, we examined the lead author's affiliation by analyzing peer-reviewed published outputs to determine countries and organizations (eg, universities, governmental and nongovernmental organizations) responsible for peer-reviewed publications.

Methods: We used a semiautomated approach to examine the first-author affiliations of 23,904 PubMed epidemiological studies related to incarcerated and offender populations published in English between 1946 and 2021. We also mapped research outputs to the World Justice Project Rule of Law Index to better understand whether there was a relationship between research outputs and the overall standard of a country's justice system.

Results: Nordic countries (Sweden, Norway, Finland, and Denmark) had the highest research outputs proportional to their incarcerated population, followed by Australia. University-affiliated first authors comprised 73.3% of published articles, with the Karolinska Institute (Sweden) being the most published, followed by the University of New South Wales (Australia). Government-affiliated first authors were on 8.9% of published outputs, and prison-affiliated groups were on 1%. Countries with the lowest research outputs also had the lowest scores on the Rule of Law Index.

Conclusions: This study provides important information on who is publishing research in the epidemiological criminology field. This has implications for promoting research diversity, independence, funding equity, and partnerships between universities and government departments that control access to incarcerated and offending populations.

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KEYWORDS

epidemiological criminology; PubMed; offenders; justice health; affiliations; health database; research output; criminology; publication; open research; research promotion; epidemiology research; research database

Introduction

Prisoner populations experience poor health, including chronic diseases, exposure to bloodborne viruses, sexually transmissible infections, and mental health problems [1]. Increased all-cause mortality has been described in those exposed to prisons, with the immediate postrelease period a time of heightened vulnerability to suicide and drug overdose [2,3]. The health disparity between prisoners and the general population has been attributed to socioeconomic factors and high-risk health behaviors, including smoking, drinking, and substance use [1,4,5].

Research is necessary to identify the health needs and challenges of prisoners and develop interventions aimed at improving health, welfare, and justice outcomes. The emerging discipline operates at the nexus of the health and criminal justice systems, with a focus on the prevalent health issues that affect offender and incarcerated populations. Epidemiological criminology (or epicriminology) seeks to apply the scientific principles of epidemiology and public health thinking to criminal justice outcomes by framing crime and offending as a public health issue [6]. This involves examining factors such as drug use, mental health, and behavioral conditions to explain and prevent patterns of offending.

Given the increased interest in epicriminology research, it is important to better understand which stakeholders are contributing to this discipline. This may highlight the relative importance that different organizations place on this area and which topics are deemed important to pursue in terms of developing the evidence base. Recognizing who conducts research has implications for impartiality and bias, as it is recognized that those responsible for the development of programs and interventions tend to find more favorable outcomes of such programs than independent evaluators [7]. It may not be in an organization's best interests to publish negative findings about a program or intervention, but it is important for governments to be accountable to the public they serve; independent university-affiliated researchers may provide such impartiality. Indeed, the independence of research has become a prominent societal issue but generally relates to companies and government agencies that influence research priorities and processes to satisfy investor or political agendas. Perceived independence is an important factor for gaining public trust in research findings [8]. Although independence and conflicts of interest have been extensively discussed in health and medical science literature [8], they remain underexamined in the criminology and justice health fields.

Research productivity is often quantified by summary indices and used to rank countries, institutions, and individuals against each other [9]. This helps inform national and international funding strategies. Universities, perhaps more than other sectors, are highly focused on performance metrics as they impact government, industry, and philanthropic funding and attract students. Research outputs are encouraged to be published in peer-reviewed literature and indexed in large bibliographic databases covering disciplines such as medicine (MEDLINE), sociology (Sociological Abstracts), and psychology (PsychINFO). These, in turn, are accessed by metasearch engines such Scopus, Google Scholar, ProQuest, and LexisNexis, allowing disciplines to be compared between countries, institutions, and individuals. However, niche disciplines such as those focusing on specific populations and emerging fields—as with justice health—tend not to feature in these high-level metrics, thus making it difficult to assess performance.

The advent of big data and the availability of digital data sets makes it possible to conduct large-scale research using those bibliographic databases. PubMed is one such database developed by the National Library of Medicine, which is part of the National Institutes of Health (NIS) and designed to provide access to millions of citations from biomedical journals [10]. For example, there are more than 23,000 articles in the justice health field that report on different epidemiological findings, with more than 13,000 articles published in the last 10 years. However, it is unclear which actors (eg, countries, sectors, and agencies) contribute to this field in terms of peer-reviewed publication outputs.

The aim of this study was to determine the countries and organizations responsible for leading the research in the field of epidemiological criminology. We semiautomatically analyzed the lead author's affiliation in 23,904 peer-reviewed published outputs from PubMed and mapped them to the World Justice Project Rule of Law Index to better understand how outputs could relate to performance measures of the "functionality" of countries' justice systems [11].

Methods

Research Query

Epidemiological criminology studies are indexed in bibliographical databases related to medicine such as PubMed. Thus, a literature search based on an original query [12] was carried out in PubMed to identify studies relevant to this discipline comprised by 3 parts.

First, we wanted to capture epidemiological studies; thus, we utilized a Medical Subject Headings (MeSH) term (ie, epidemiology) to ensure maximum specificity in the search. Second, since we were focusing on epidemiological studies conducted with offending/incarcerated populations, we used a wide variety of terms that described this marginalized population (eg, "delinquent," "remandee," or "offender") as well as its correctional setting (eg, "prisons," "correctional facilities," or "gaols"). This prevented articles that made only passing reference to prison work from entering the data set and resulted in a high-quality corpus for analysis.

Third, to be able to inspect the related affiliations, the search was restricted to English language articles, only as it is the most common language in PubMed.

The full query, which was run on April 20, 2021, was (prison or borstal or jail or jails or gaol or gaols or penitentiary or custody or custodial or (corrective and (service or services)) or ((correctional or detention) AND (centre or centres or center or centers or complex or complexes or facility or facilities)) or (closed AND (setting)) or prisoner or prisoners or incarcerated or criminals or criminal or felon or felons or remandee or remandees or delinquent or delinquents or detainee or detainees or convict or convicts or cellmate or cellmates or offenders or offender or ((young or adolescent) AND (offender or offenders)) or ((delinquent or incarcerated) AND youth) or (juvenile AND (delinquents or delinquent or delinquency or detainee or detainees or offender or offenders)) or ((young) and (people) and (in) and (custody)) or ((justice) and (involved) and (youth)) or ((incarcerated) and (young) AND (people or person or persons)) or ((juvenile or juveniles) and (in) and (custody)) AND english[lang] AND ("epidemiology"[Subheading] or "epidemiology" [MeSH Terms] OR epidemiology [Text Word]).

Affiliation Processing

We used the PubMed "save" function to download the query results in the "PubMed format." We automatically processed the files by developing a Python script that identified the first author's affiliation in each article, as stated under the field "AD," a designated PubMed heading that indicates affiliation. Usually, the first and last authors belong to the same institute, so we used the first author as a proxy for capturing the institution responsible for carrying out the research.

We automatically added the country associated with the first author's affiliation to provide a geographical context to the study by searching through a list of countries and determine whether there was a match in the affiliation. Articles with no country in their affiliation were manually inspected by 2 authors (GK and WL), and the country was manually inserted where possible. Articles with countries that no longer exist (eg, Yugoslavia), those belonging to disputed regions (eg, Northern Cyprus), or those with no other information indicated a country were classified as "miscellaneous."

The affiliations were classified into 5 groups that represent various sectors that conduct research in the epicriminology field:

- The first group comprised universities, including institutes/centers that are part of universities as well as teaching and affiliated hospitals (eg, "The Kirby Institute" is part of the "University of New South Wales" in Australia).
- The second group consisted of prisons, jails, departments of corrective services, and probation and health-related services (administered by departments of corrective services).
- The third group consisted of government (ie, noncorrectional) departments, agencies, and institutes (eg, the "National Institutes of Health" in the United States).
- The fourth group comprised military departments, agencies, and centers including related hospitals and universities (eg, "Second Military Medical School" in China).
- The fifth group consisted of hospitals (public and private), health/medical centers, and clinics that are not affiliated with academia (eg, "Taipei City Hospital" in Taiwan).

The classification was conducted automatically by employing key word search for each group (eg, "university," "prison") (Multimedia Appendix 1). Affiliations that could not be mapped to any of these 5 groups were classified as "miscellaneous" (sixth group). An inspection of 50 randomly selected classified affiliations to determine whether they were classified in the wrong group did not return any errors, although it is possible that misclassification could have occurred. If so, these were later rectified after the manual inspection of all classified affiliations (see Data Standardization section).

Affiliations with no identifiable key word were put into the miscellaneous group. All groups were inspected by 2 authors (GK and TB) for misclassification errors. For example, the affiliation *California, Berkeley* refers to the *University of California, Berkeley* but did not contain any university-related words. Cases like these were manually assigned the value *University of California, Berkeley* and placed into the appropriate group. This approach was applied to the other 4 groups.

In addition, when authors GK and TB encountered affiliations related to nonprofit organizations (eg, *Médecins Sans Frontieres*) and industry entities including law firms, pharmaceutical corporations, and consultants (eg, *Juniper Associates*), they manually assigned those into 2 new groups that reflected this ("nonprofit organization," "industry"). Nevertheless, several affiliations (eg, *Center for Criminology*) remained unclassified due to ambiguity or lack of any identifiable information (ie, address, country) and subsequently remained in the "miscellaneous" group. To ensure consistency in this process, we calculated the interannotator agreement as the absolute agreement rate [13] between the 2 annotators (GK and TB) in a random sample of 50 affiliations resulting in 90%, thus suggesting reliable results. Table 1 shows classification examples of first-author affiliations into the 8 groups.

If an article had more than 1 first-author affiliation (marked with the presence of several separators ie, ";," "/," "and," ","), the affiliations were manually assigned to their respective groups (Multimedia Appendix 2).

Table 1. Examples of first-author affiliations that were classified semiautomatically into the 6 initial affiliation groups including those added (ie, industry, nonprofit) after the manual classification.

First-author affiliation	Key word	Affiliation group	Country
School of Psychiatry, University of New South Wales, Sydney, NSW[a], Australia	University	University	Australia
Indiana women's prison, Indianapolis, Indiana 46214, USA	prison	Prison	United States
Epidemiology unit, Ministry of Health, Gaborone, Botswana	Ministry	Government	Botswana
Mental health department, Israel Defense Forces, Tel Hashomer	Defense	Military	Israel
Rampton hospital, Retford, Notts	hospital	Hospital	United Kingdom
ABT Associated Inc, Cambridge, MA[b] 02138-1168, USA[c]	N/A[d]	Industry	United States
Médecins Sans Frontières, 7 Bougainvillea Close, Palmerstone, Mutare, Zimbabwe[c]	N/A	Nonprofit organization	Zimbabwe
Centre for Criminology	N/A	Miscellaneous	Unknown

[a]NSW: New South Wales.

[b]MA: Massachusetts.

[c]Originally assigned in the "miscellaneous" group, these were further inspected by authors GK and TB and manually assigned an additional affiliation group (industry, nonprofit).

[d]N/A: not applicable.

Data Standardization

Each affiliation group was manually inspected by the 2 aforementioned authors (GK and TB) to normalize (when possible) the values of each affiliation and thus enable a suitable presentation of the data for descriptive statistics. Common acronyms were manually expanded (eg, *UNSW* to *University of New South Wales*, *UCL* to *University College London*), synonyms were eliminated (eg, *University of NSW* to *University of New South Wales*), and affiliations that were written in languages other than English (eg, Spanish, Italian) were translated to English (eg, *Universidade Federal do Rio de Janeiro* to *FederalUniversityof Rio deJaneiro*, *Università Cattolica del Sacro Cuore* to *Sacred Heart Catholic University*).

In addition, some affiliations existed under (or within) specific parent organizations. For example, *National Drug and Alcohol Research Centre, UNSW, Sydney, Australia* was assigned initially into the miscellaneous group, but a manual inspection showed that it is part of the *University of New South Wales*, so its group was changed to university and its value as *University of New South Wales*. Table 2 presents examples of affiliations that were reclassified into other groups following manual inspection. Figure 1 shows an overview of the semiautomated approach that was used to classify and standardize the first-author affiliations.

For reporting purposes, we combined under 1 umbrella term various campuses for big university networks in the United States. For example, affiliations related to the various campuses of *University of California* (ie, San Diego, San Francisco, Berkeley, Davis, Irvine, Los Angeles, Merced, Riverside, Santa Barbara, and Santa Cruz) were all classified as *University of California*.

Table 2. First-author affiliations reclassified after manual inspection.

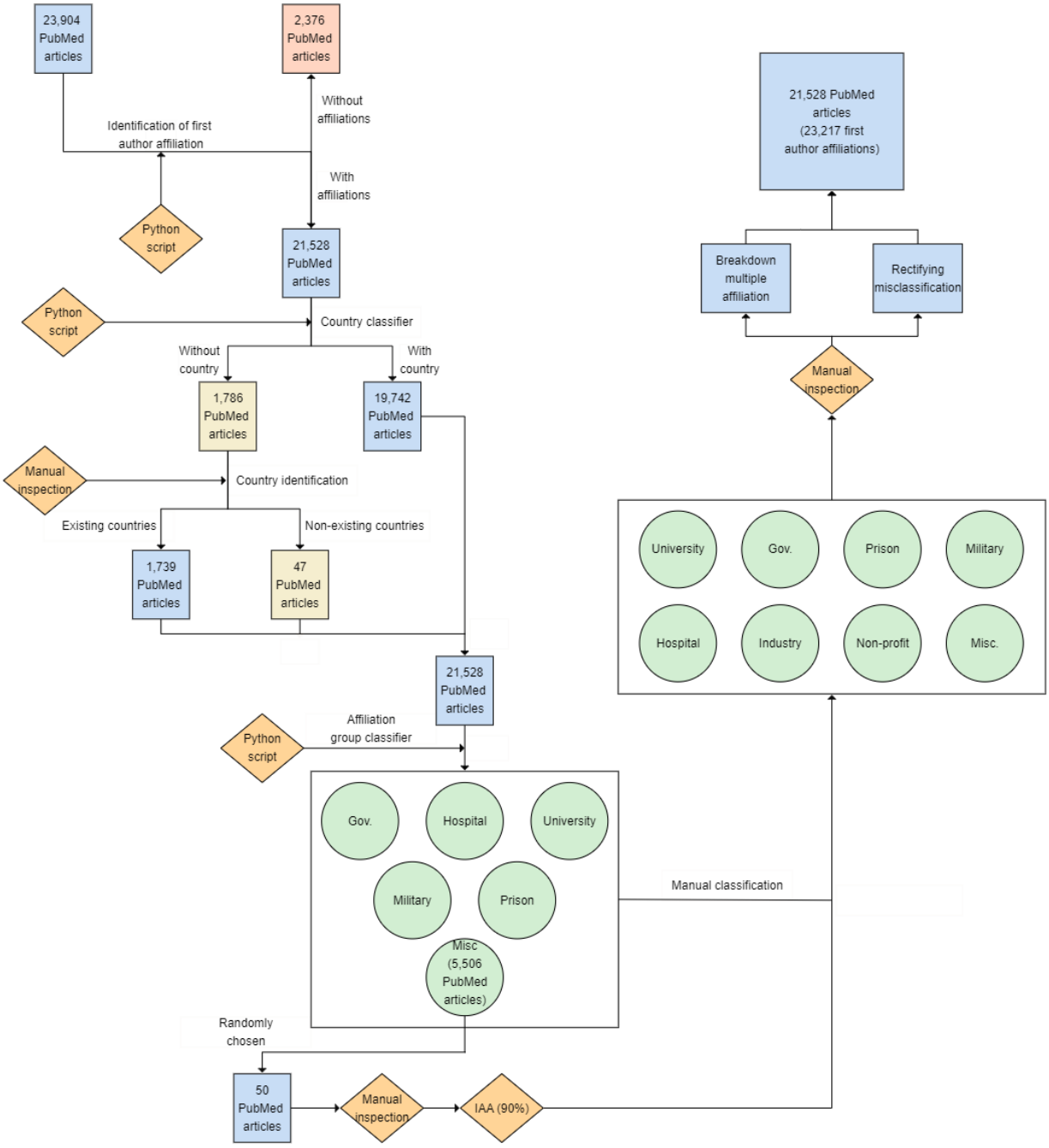
First-author affiliation	Key word	Initial affiliation group	Affiliated institution	New affiliation group	Country
Department of Emergency Medicine, Tri-Service General Hospital, National Defense Medical Center, Taipei, Taiwan	Hospital	Hospital	National Defense Medical Center	Military	Taiwan
National Drug and Alcohol Research Centre, UNSW[a], Sydney, Australia	N/A[b]	Miscellaneous	University of New South Wales	University	Australia
Mathari Hospital, Ministry of Health, PO[c] Box 40663, Nairobi, Kenya	Ministry	Government	Mathari Hospital	Hospital	Kenya
Office of Public Health, Louisiana Dept of Health and Hospitals, New Orleans	Hospital	Hospital	Louisiana Department of Health and Hospitals	Government	United States

[a]UNSW: University of New South Wales.

[b]N/A: not applicable.

[c]PO: post office.

Figure 1. An overview of the semiautomated approach used for the classification and standardization of the first author affiliations from 21,528 PubMed articles. Gov: government; IAA: Inter Annotator Agreement; Misc: miscelleneous.



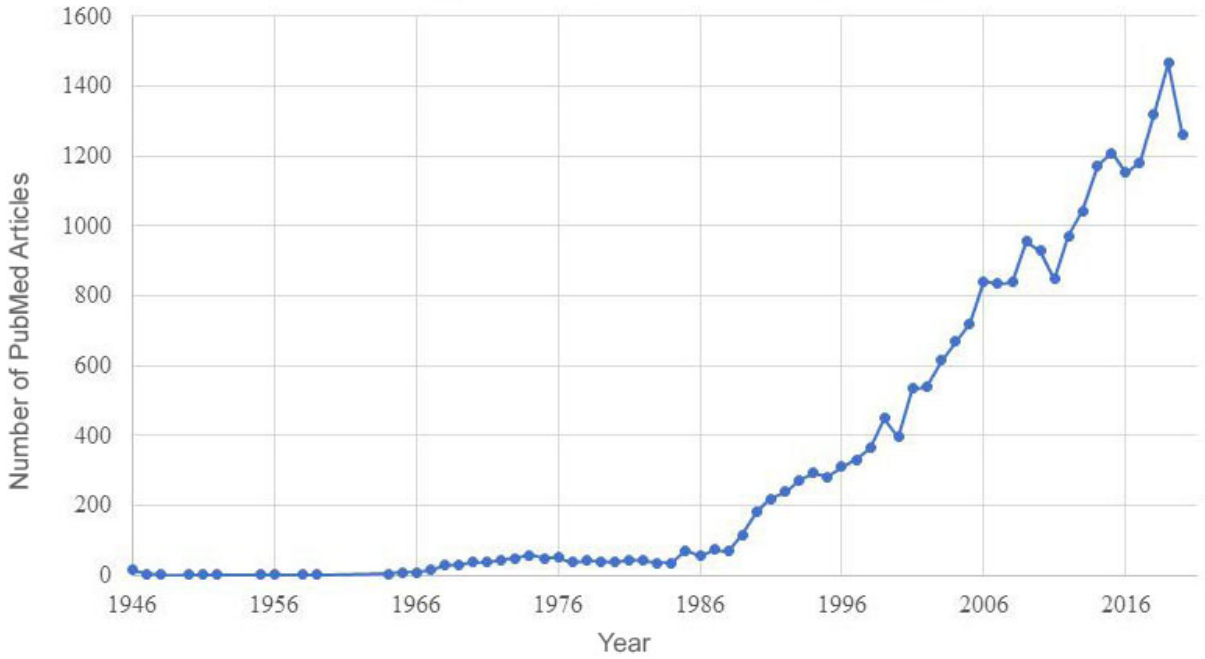
Results

Query Results

The query returned 23,904 studies, with the earliest study recorded in 1946. The number of returned studies showed a 95% increase in articles published between 1990 and 2021 (Figure 2).

Almost 1 in 10 articles (n=2376, 9.9%) did not have any author affiliation. Following a manual inspection of 30 randomly chosen articles from the group with no “AD” field, we verified that these articles indeed did not have a first author (or any, for that matter) affiliations, thus reducing our final data set to 21,528 (90.1%) articles (Figure 1). In 1786 (8.2%) articles, the country was manually inserted, and 47 (0.2%) articles had a country status of “miscellaneous.” A total of 5506 (25.5%) affiliations with no identifiable key word were put into the miscellaneous group.

Figure 2. Number of articles related to prisoner health published in PubMed between 1946 and 2020. Since the query was implemented in April 2021, results from that year were not reported.



Almost half (n=9188, 42.6%) of the 21,528 articles had first-author affiliations mapped to the United States, followed by United Kingdom (n=2040, 9.4%) and Australia (n=1288, 5.9%) (Table 3). Only 1 country each from South America (Brazil) and Africa (South Africa) appeared in the top 20 publishing countries in epicriminology, whereas Europe had 6 countries in the top 10 (ie, United Kingdom, France, Sweden, Netherlands, Italy, and Germany).

However, to account for the size of the country population, which we assumed to be broadly linked to the size of its prisoner population (Pearson r=0.73), and this in turn being a likely driver of research interest reflected by the number of publications, we derived a publication rate based on the average prisoner population size over the period of 2000 to 2020 [14] and calculated a rate per 1000 prisoner population. The rate significantly changed the country ranking in terms of peer-reviewed publication output, with the Nordic entries (ie, Sweden, Finland, Norway, and Denmark) occupying the top 4 spots, while the United States dropped to number 15 (Table 3). When further examining countries that ranked 21 to 30 in terms of peer-reviewed publication outputs and calculating their corresponding publication rate, we found that South Africa, India, Brazil and China were not among the top 20, while Hong Kong (crude rank: 11; publication rate rank: 13.8), Belgium (crude rank: 12; publication rate rank: 13.7), Israel (crude rank: 13; publication rate rank: 9.8), and Greece (crude rank: 14; publication rate rank: 7.9) entered the top 20.

Of the 21,528 articles, 902 (4.2%) had more than 1 first-author affiliation, bringing the total number of affiliations to 23,217. In terms of the affiliation groups responsible for publications across countries, among the 21,528 articles that we examined, first authors affiliated to universities had the highest proportion of peer-reviewed publications (n=15,800, 73.3%) (Table 4). First authors attached to government agencies (n=1928, 8.9%) and hospitals (n=1787, 8.3%) were each responsible for less than 10% of publications, while prison-affiliated first authors were linked to 1% (n=220) of the publications.

A total of 1893 unique universities were identified in our data set. Five countries occupied the top 20 positions with 12 universities based in the United States (Table 5). In terms of crude publication outputs, the *University of California* and *Harvard University* were ranked number 1 and 2, respectively, with the *University of New South Wales* ranking number 3. However, when accounting for the size of the prisoner population in each country, Sweden's *Karolinska Institute* was ranked the number 1 university in the world in terms of peer-reviewed publication outputs, with the *University of New South Wales* and *University of Melbourne* in second and third place, respectively.

Among the 1928 articles whose first-author affiliation was government related, the *US Centers for Disease Control and Prevention* was the most common government agency, with a publication rate rank of 7 when considering the US prisoner population size (Table 6). The *Norwegian Institute of Public Health* was ranked number 1 (3.6%), followed by the *Justice Health New South Wales (NSW)* (2.9%; Australia) and the *Victorian Institute of Forensic Mental Health* (1.5%; Australia). To more accurately reflect the impact of certain government agencies that have a state focus, we used state prisoner populations rather than national prisoner populations in several instances (see footnote [e] in Table 6). For example, the *New York City Department of Health and Mental Hygiene* is likely to serve New York rather than the whole United States.

Table 3. Top 20 countries with the highest number of published articles in PubMed (1946-2021) in the epicriminology field along with their respective region, number of articles, prisoner population (average 2000-2020), article rate per 1000 prisoners, and publication rate.

Crude rank	Country	Region	Articles, n (%)	Prisoner population[a]	Article rate per 1000 prisoners[b]	Publicationrate rank
1	United States	North America	9292 (43.2)	2,156,813	4.3	15
2	United Kingdom	Europe	2070 (9.6)	79,564	26	9
3	Australia	Oceania	1289 (6)	30,685	42	5
4	Canada	North America	1077 (5)	38,321	28.1	8
5	France	Europe	493 (2.3)	62,158	7.9	11
6	Sweden	Europe	488 (2.3)	6303	77.4	1
7	Netherlands	Europe	483 (2.2)	14,470	33.4	7
8	Italy	Europe	427 (2)	56,090	7.6	12
9	Germany	Europe	393 (1.8)	68,437	5.7	13
10	China	Asia	367 (1.7)	1,633,561	0.2	20
11	Brazil	South America	346 (1.6)	509,602	0.7	18[c]
12	Spain	Europe	330 (1.5)	61,715	5.3	14
13	India	Asia	267 (1.2)	385,832	0.7	18[c]
14	Switzerland	Europe	250 (1.2)	6257	40	6
15	Finland	Europe	226 (1)	3233	70	2
16	Japan	Asia	215 (1)	65,397	3.3	16
17	Denmark	Europe	195 (0.9)	3742	52.1	4
18	Norway	Europe	192 (0.9)	3289	58.4	3
19	South Africa	Africa	191 (0.9)	164,629	1.2	17
20	New Zealand	Oceania	185 (0.9)	8051	23	10

[a]Average prisoner population 2000 to 2020 (Source: World Prison Brief [14]).

[b]Rate per 1000 prisoners

[c]Equal rank between University of Michigan, University of Maryland, and Emory University.

Table 4. Number of PubMed articles (1946-2021) with classified first-author affiliations[a].

Affiliation group	PubMed articles, n (%)
University	15,800 (73.3)
Government	1928 (8.9)
Hospital	1787 (8.3)
Miscellaneous	953 (4.4)
Nonprofit organization	695 (3.2)
Industry	282 (1.3)
Prison	220 (1)
Military	164 (0.7)

[a]In cases where the first author had more than 1 affiliation listed (eg, a hospital and a university), this was counted as both a hospital and university affiliation unless the hospital was affiliated with the same university, in which case it was counted as 1 affiliation.

Table 5. Top 20 universities with the most published articles in PubMed (1946-2021) in the epicriminology field along with their respective country, number of articles, prisoner population (average 2000-2020), and article rate per 1000 prisoners and publication rate.

Crude rank	University	Country	Articles, n (%)	Prisoner population[a]	Article rate per 1000[b]	Publication rate rank
1	University of California	United States	599 (2.8)	2,156,813	0.3	9
2	Harvard University	United States	252 (1.2)	2,156,813	0.1	10
3	University of New South Wales	Australia	246 (1.1)	30,685	8	2
4	Texas University	United States	242 (1.1)	2,156,813	0.1	11
5	Johns Hopkins	United States	239 (1.1)	2,156,813	0.1	12
6	University of Washington	United States	214 (1)	2,156,813	0.1	13
7	Yale University	United States	192 (0.9)	2,156,813	0.1	14
8	Kings College London	United Kingdom	188 (0.9)	79,564	2.4	6
9	Columbia University	United States	184 (0.9)	2,156,813	0.1	15
10	Karolinska Institute	Sweden	184 (0.9)	6303	29.2	1
11	University of North Carolina	United States	179 (0.8)	2,156,813	0.1	16
12	Brown University	United States	159 (0.7)	2,156,813	0.1	17
13	Oxford University	United Kingdom	145 (0.7)	79,564	1.8	7
14	University of British Columbia	Canada	140 (0.7)	38,321	3.7	4
15	University of Toronto	Canada	132 (0.6)	38,321	3.4	5
16	University of Melbourne	Australia	127 (0.6)	30,685	4.1	3
17	Emory University	United Kingdom	119 (0.6)	2,156,813	0.1	18[c]
18	University College London	United States	118 (0.5)	79,564	1.5	8
19	University of Michigan	United States	118 (0.5)	2,156,813	0.1	18[c]
20	University of Maryland	United States	118 (0.5)	2,156,813	0.1	18[c]

[a]Average prisoner population 2000 to 2020 (Source: World Prison Brief [14]).

[b]Rate per 1000 prisoners.

[c]Equal rank between University of Michigan, University of Maryland, and Emory University.

Table 6. Top 20 government departments with the most published articles in PubMed (1946-2021) in the justice health field along with their respective country, number of articles, prisoner population (average 2000-2020), article rate per 1000 prisoners, and publication rate.

Crude rank	Government	Country	Articles, n (%)	Prisoner population[a]	Article rate per 1000[b]	Publication rate rank
1	Centers for Disease Control and Prevention	United States	268 (1.2)	2,156,813	0.124	7
2	Justice Health NSW[c]	Australia	35 (0.2)	11,889[d]	2.94	2
3	New York City Department of Health and Mental Hygiene	United States	33 (0.2)	91,000[d]	0.36	5
4	Health Protection Agency	United Kingdom	30 (0.1)	79,564	0.377	4
5	Chinese Centers for Disease Control and Prevention	China	28 (0.1)	1,633,561	0.017	10
6	National Center for Injury Prevention and Control	United States	23 (0.1)	2,156,813	0.011	11
7	National Center for Infectious Diseases	United States	21 (0.1)	2,156,813	0.010	12
8	National Development and Research Institutes	United States	20 (0.1)	2,156,813	0.009	13
9	World Health Organization	World	18 (0.1)	11,500,000[e]	0.002	16
10	Public Health England	United Kingdom	18 (0.1)	79,564	0.226	6
11	National Institute of Health	United States	18 (0.1)	2,156,813	0.008	14
12	National Cancer Institute	United States	17 (0.1)	2,156,813	0.008	14
13	Public Health Service	Netherlands	16 (0.1)	14,470	1.106	4
14	South African Medical Research Council	South Africa	16 (0.1)	164,629	0.097	8
15	Ministry of Social Affairs and Health	Finland	16 (0.1)	3233	0.008	14
16	Ministry of Public Health	Thailand	13 (0.1)	251,695	0.008	14
17	Norwegian Institute of Public Health	Norway	12 (0.1)	3289	3.649	1
18	National Institute on Alcohol Abuse and Alcoholism	United States	11 (0.1)	2,156,813	0.005	15
19	California Department of Health Care Services	United States	11 (0.1)	117,000[d]	0.09	9
20	Victorian Institute of Forensic Mental Health	Australia	10 (0)	6466[d]	1.55	3

[a]Average prisoner population 2000 to 2020 (Source: World Prison Brief [14]).

[b]Rate per 1000 prisoners.

[c]NSW: New South Wales.

[d]Based on available state incarcerated population data.

[e]World prisoner population used (Source: World Prison Brief [14]).

Publication Rate and the Rule of Law Index

To examine the association between performance measures of justice systems and publication outputs in the justice health arena, we used the 2021 World Justice Project Rule of Law Index [11]. This is a composite index of 8 factors that describe the rule of law through the lens of constraints on government powers, absence of corruption, open government, fundamental rights, order and security, regulatory enforcement, civil justice, and criminal justice [11].

The Index draws on over 400 variables based on country-wide polling and surveys of in-country experts in law and public health, with scores ranging from 0 to 1 (1 being the strongest adherence to the rule of law). Factor 8 of the index focuses on criminal justice and ranks countries based on measures of the effectiveness of criminal justice systems, including whether the "criminal justice system is effective in reducing criminal behavior" and "correctional institutions are secure, respect prisoners' rights, and are effective in preventing recidivism" [11]. We identified a very high negative correlation (–0.82) between Factor 8 (criminal justice) and the publication rate rank, indicating that countries that ranked the highest in terms of publication rate (eg, Norway, Finland) were also placed higher in terms of the Rule of Law Index (Factor 8) (Denmark: –0.9, Finland: –0.88, Norway: –0.9, Sweden: –0.86).

The bottom 10 ranked countries in the Rule of Law Index (Afghanistan, Cambodia, Democratic Republic of Congo, Egypt, Haiti, Mauritania, Nicaragua, Pakistan, Venezuela, and Cameroon) had a total of 123 publications between 1946 and 2021.

Discussion

Principal Findings

The aim of this study was to explore agencies, academic institutions, and industry groups responsible for peer-reviewed, published research outputs in the epicriminology area by analyzing first-author affiliations of PubMed epidemiological studies involving offending and incarcerated populations between 1946 and 2021. We obtained and processed the first-author affiliations of 23,904 PubMed articles using a semiautomated approach to determine which countries produced the most peer-reviewed publications.

Overall, the United States had the highest crude number of published articles in the period between 1946 and 2021, with most from the *University of California* and *Harvard University.* This is consistent with the SCImago Journal and Country rankings, in which the United States leads in terms of citable documents across most subject areas [15]. This is most likely due to the United States having many well-funded universities (second highest number of universities in the world after India [16]) and strong university-industry partnerships (eg, according to SciVal for the period of 2016-2021 in the United States, 4.7% of peer-reviewed publications had an academic-industry collaboration, as opposed to 2.7% for the rest of the world). The United States also has the largest prisoner population in the world, with 25% of the world's prisoners held in prisons and jails. Therefore, it might be expected to have a greater number of research outputs. However, when the publication rate was calculated based on an estimate of each country's prisoner population, the United States fell to number 15 overall. Countries with smaller general populations and correspondingly smaller prisoner populations were ranked in the top 10 worldwide in terms of research output. The Nordic countries of Sweden, Finland, Denmark, and Norway occupied the top 4 spots, and Australia ranked fifth. Nordic countries are often regarded as having some of the most progressive approaches to prisoner and offender rehabilitation, with proportionally lower numbers of incarcerated persons and recidivism rates compared to other countries [17-20]. Our findings suggest that conducting research within the prison setting may be a contributing factor in the reduction of recidivism.

We also examined publications in terms of a metric used to rank countries legal systems' functionality (the Rule of Law Index), which integrates measures of reducing criminal behavior, respecting prisoners' rights, and recidivism [11]. We found a strong correlation between high scores on the Rule of Law Index and the publication rate rank, suggesting a relationship between publications and country rank in terms of this index. This likely reflects an openness to research and embracing evidence generation by specific countries, which manifests in improved justice outcomes. Countries with lower Rule of Law Index scores had very low corresponding publication rates in our sample, with the lowest 10 (ie, Afghanistan, Cambodia, Cameroon, Democratic Republic of Congo, Egypt, Haiti, Mauritania, Nicaragua, Pakistan, and Venezuela) having a total of only 123 publications between 1946 and 2021. Notably, these nations represent low-income countries with histories of political instability and colonialism that have impeded the translation of economic and social development plans into research activity. Within such a climate, it is unlikely that prisoner health research represents a priority.

We found significant variation in institutions across first-author affiliations, in that 28% (n=6029) of first-author affiliations were not associated with an academic institution. Instead, they were affiliated with government agencies (n=1928, 8.9%) and hospitals/medical centers (n=1787, 8.3%), while 5.3% (n=1141) of the remaining affiliations were linked to nonprofit organizations, the military, and industry. Our findings demonstrate that universities are overwhelmingly responsible (n=15,800, 73.3%) for published peer-reviewed outputs, underscoring their importance and subsequent contribution to the justice health area. This maybe be somewhat surprising, given the Herculean challenges of conducting research in the prison setting [1,3,21]. For example, researchers must navigate multiple ethics committees responsible for providing approvals to conduct research in prison, with approval sometimes taking several years, which could lead to research being abandoned in some cases [21-23].

With universities responsible for undertaking most research in this area and the importance of research independence, a question is raised as to whether government agencies ought to divert funding from their own internal research departments to universities to pursue research on behalf of the public. Identifying the key research groups in a field with poor transparency can potentially enhance dialogue and promote knowledge transfer between universities, government, and prison departments. This can potentially improve health, justice, welfare, and economic outcomes for this highly marginalized population and the community [24].

While first authors from prison-related affiliations represented only 1% (n=220) of our publication data set, this could be due to a preference to conduct in-house research for internal evaluation and consumption. Notwithstanding this, peer review is a marker of research excellence and scientific integrity and an indication that independent expert peers have endorsed the research's hypotheses, methodology, analytical approach, results, and conclusions and thus ought to be encouraged. However, publications in this area around the effectiveness of applied programs are usually not peer reviewed, mainly because independent researchers may detect negative findings which could reflect poorly on the prison system. However, these are publicly funded agencies; thus, accountability and transparency to the public are imperative. To improve this, program and intervention development should involve universities to minimize the risk of implementing programs with a poor or a nonevidence base and to limit wasting public funds.

Challenges

The application of a semimanual methodology to classify the first-author affiliation comes with certain challenges. While the first iteration of the classification of affiliations was automated, manually investigating affiliations that remained unclassified (n=5506, 25.5%) and attempting to determine their related group and whether they were part of a larger organization posed a challenge, considering their large number. Several affiliations

that were classified as miscellaneous (n=953, 4.4%) had no information (ie, address, type of department, country) that could assist with further identification (eg, *Center for Prisoner and Human Rights*, *Institute of Public Health*), which might have an impact in the order and context of our findings.

This highlights a more generic issue of how problematic the lack of a standardized format in reporting affiliations is. Affiliations are written according to the format of each journal or other publishing authority and might make use of acronyms (eg, *UNSW*, *UCLA*), lack clarity (eg, *HIV/AIDS Asia Regional Program*, *Departments of Emergency Medicine*), refer to only a city or a street address (eg, *Ottawa Ontario*; *2075 Bayview Ave*, *FG52*, *Toronto*, *Ontario*, *M4N 3M5*, *Canada*, *No 25*), neglect to report the affiliation's country (eg, *National Chung Cheng University*), or describe a certain affiliation in several ways (eg, *University of New South Wales*, *New South Wales University*, *UNSW*, or *University of NSW*).

In addition, some articles (n=1146, 5.3%) had more than 1 first-author affiliation. A specific challenge was to dismantle those, as affiliations can be separated by a semicolon (eg, *University Department of Psychiatry; Royal Edinburgh Hospital*, *Morningside Park*), a backslash (eg, *Igenomix Valencia/Incliva*, *Valencia*, *Spain*), or a connecting preposition (eg, *Naval Medical Center San Diego and University of California San Diego School of Medicine*), among others. To avoid misclassification of these additional affiliations, cases like these were inspected manually. Furthermore, despite focusing only on English results from our PubMed query, some affiliations were written in a different language (ie, Spanish, German, and Indonesian), making it difficult for the authors to manually classify them, especially when acronyms were used (eg, *INSERM*, *CIBERESP*).

These observations indicate that the myriad ways in which affiliations can be reported might cause problems in determining key organizations, thus potentially impacting performance metrics based on affiliation [25]. Such attempts at identifying the necessary organization within an affiliation depend on correct spelling, translation of related affiliations, and appropriate expansion of acronyms, which is what this study attempted to do [26]. Publishing journals should consider adopting a standard or common format (s) for reporting affiliations that at a minimum, reference the lead agency, city, and country.

Limitations

Our study has several limitations. PubMed articles might not be sufficient to capture an accurate picture for offending and incarcerated populations, as relevant government articles and reports often do not publish in academic journals. Moreover, studies with a more sociological and criminal focus are unlikely to appear in journals covered by PubMed. Thus, our data set likely underestimates the total number of research outputs in this area. In addition, our query may not be broad enough to capture all related articles in this area due to the use of a MeSH term (ie, "epidemiology"). The inclusion of extra MeSH terms such as "clinical trial" and "observational study" could potentially increase the number of articles which could provide potentially a different picture.

The use of first-author affiliations might obscure the true extent of research collaboration and likely underrepresent some groups (eg, prison, nonprofit organizations). Some articles might be the product of a collaboration between different departments and organizations that, while their related research might be conducted by an academic first author, usually contain input from professionals in nonacademic areas that do not necessarily contribute heavily to the publication of academic research. Senior or last author status is often a sought-after spot in a list of authors, and, at this stage, we did not explore this, as we consider the first author to be the person who is (often) responsible for driving the research.

Finally, this study carries the risk of English-language bias because including non-English articles presented resource challenges in terms of prospective costs, time, and expertise in non-English languages. The inclusion of non-English articles would help ensure greater generalizability and reduce bias [27].

Conclusions

Conducting epidemiological research with offending and incarcerated populations has a well-documented list of challenges. However, for transparency reasons and to identify robust research to improve health and justice outcomes, it is important to understand which types of organizations and agencies are conducting research in this area and quantify how much they contribute to this field. We employed a semiautomated approach to classify the first-author affiliations from 23,904 PubMed epidemiological studies between 1946 and 2021. Nordic countries appear to be generating peer-reviewed output research proportional to their incarcerated population ranking, followed by Australia. Interestingly, more functional legal systems correlated with an increased research output rate. Universities appear to be punching above their weight, with almost three quarters of all published articles in PubMed having first-author affiliations related to a university. *Karolinska Institute* (first rank) and the *University of New South Wales* (second rank) lead the publication rate worldwide, while government departments (n=1928, 8.9%) and prisons (n=220, 1%) were overall in the second and seventh position, respectively. While challenges exist in organizing affiliations into 8 distinct organizational groups, this semimanual meta-analysis provides valuable insights into the epicriminology field that can complement more traditional ranking systems.

Conflicts of Interest

None declared.

Multimedia Appendix 1

Key words used to search and classify the first author affiliations of 21,528 PubMed articles into five groups (university, prison, government, military, hospital).
[DOCX File , 29 KB - ijmr_v11i2e42891_app1.docx]

Multimedia Appendix 2
Examples of first author affiliations with more than one affiliation classified into eight groups.
[DOCX File , 29 KB - ijmr_v11i2e42891_app2.docx]

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Abbreviations

MeSH: Medical Subject Headings
NIH: National Institutes of Health
NSW: New South Wales

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Original Paper

American Anesthesiology Residency Programs: Website Usability Analysis

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Abstract

Background: The Association of American Medical Colleges has recently issued recommendations for the upcoming 2022-2023 application cycle that residency programs should conduct all interviews for this upcoming application cycle over the web. In light of these recommendations, many students will have limited exposure to anesthesiology programs and will rely on information gleaned digitally. This change means that the aspects of program websites used to provide information, such as size, structure, location, requirements, and contact information, will be crucial in helping prospective residents decide where and how to apply in the future. An evaluation of website usability, which includes initial appearance along with factors that influence its ease of navigation and convenience of use, can thus be applied to anesthesiology residency websites. Areas of need can be targeted to increase web presence and provide effective pathways to exhibit the different attributes of their programs to future applicants.

Objective: This study aimed to compile a list of US anesthesiology residency programs and their websites while objectively analyzing the websites using a formally published usability scoring system, as well as to identify positive and negative trends to offer areas of improvement among anesthesiology residency websites.

Methods: We included only 114 US anesthesiology residency program websites in our sample set, since some websites we analyzed showed errors or inconclusive. Website usability was separated into 4 distinct categories for analysis based on methodology outlined in previous literature on both health care website usability and residency website usability. The 4 categories were Accessibility, Marketing, Content Quality, and Technology. Each website was then analyzed and scored based on key components highlighted within the 4 categories. The multiple factors were then graded using a percentage system to create a comprehensive score for each program.

Results: The highest scoring category was Content Quality (mean 4.7, SD 2.48, SE 0.23). The lowest scoring category was Technology (mean 0.9, SD 0.38, SE 0.04).

Conclusions: Through the application of a health care website usability framework, multiple anesthesiology residency programs were analyzed and scored in the areas of Accessibility, Marketing, Content Quality, and Technology, which allowed us to determine the effectiveness of the usability of these websites to convey information to their end user. Websites must communicate vital information, with usability at the forefront, to continue to grow, especially as the United States faces challenges due to the COVID-19 pandemic. Our recommendation is that anesthesiology programs should strive to improve website usability to increase the ease by which applicants can collect vital information about anesthesiology programs. A few proposed solutions include

making changes such as decreasing error pages on websites, migrating away from using in-line cascading style sheets, and improving web page loading speeds to improve the Technology category.

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KEYWORDS

medical student education; education in anesthesia; technology in education; quality improvement; communication

Introduction

Background

Due to the changes that the coronavirus disease brought to the medical education landscape, medical students and residency programs have had to adapt to the rapidly shifting residency application process. This change was predominantly a result of limited in-person contact, which not only affected opportunities for audition rotations but also in-person interviews for this upcoming application cycle. For the current residency cycle of 2022-2023, the Society of Academic Associations of Anesthesiology and Perioperative Medicine and Association of Anesthesiology Core Program Directors recommended that all anesthesiology residency programs commit to web-based interviews and virtual visits for all applicants [1].

Based on how guidelines have changed in the past and continue to change regarding away rotations and virtual interviews, both medical students and anesthesiology residency programs will be placing greater emphasis on different resources in their decision-making process compared to previous years. There are some factors that will be difficult for programs to change, such as the current circumstances regarding the COVID-19 pandemic along with a program's nonmodifiable elements (ie, city, program size, and patient population). Digitally, there are opportunities for programs to better showcase their strengths by optimizing program website usability. The purpose of this research was to inform administrators of anesthesiology residency programs on how to best reach a wide audience of applicants.

Website Usability for Anesthesiology Residency Programs

Usability is not limited to a website's appearance; it also incorporates factors of "user experience" such as understandability, layout, and the accuracy of information [2,3]. Previous research has examined website usability for library websites, e-commerce, government websites, and even mobile news apps [3-7]. Website usability has also been used to analyze health care websites such as those of children's hospitals, digital health care centers, hospitals, and cancer centers [7-11]. Increased usability on websites is typically correlated with higher level of engagement by users. As a result, industries unrelated to health care have created regulated guidelines to measure usability in 4 different areas: Accessibility, Marketing, Content Quality, and Technology [11-14]. Health care websites have been facing increasing pressure to conform to industry standards of user experience [14-16].

Due to the increasing role of anesthesiology residency program websites in engaging potential applicants, usability is becoming more relevant. Residencies within the specialties of neurosurgery, dermatology, general surgery, diagnostic and interventional radiology, urology, physical medicine and rehabilitation, orthopedic surgery, otolaryngology, radiation oncology, vascular surgery, cardiothoracic surgery, and plastic surgery have all had their websites previously analyzed for content quality [16-27]. To date, we believe that no analysis of anesthesiology residency website usability has been completed. The International Organization for Standardization has defined usability as "the extent to which a system, product, or service can be used by specific users to achieve specified goals with effectiveness, efficiency, and satisfaction in a specified context of use" [28]. In our study, we are using the term website usability as outlined by Huerta et al [7,9,10]. Although this definition deviates from the typical definition used by web developers, it is a proxy for user-based usability testing; the definitions by Huerta et al [7,9,10] are the only ones that have been published specifically for health care website usability. Through this study, we propose that anesthesiology programs have placed less emphasis on website development metrics due to the rapid shift and pace of technological advancements. We hope that this paper will educate anesthesiology residencies on how to showcase themselves to applicants and better optimize their web presence.

Objectives

The primary goals of this study were to (1) compile a list of US anesthesiology residency programs and their websites while objectively analyzing the websites using a formally published usability scoring system; and (2) identify positive and negative trends to offer areas of improvement among anesthesiology residency websites.

Methods

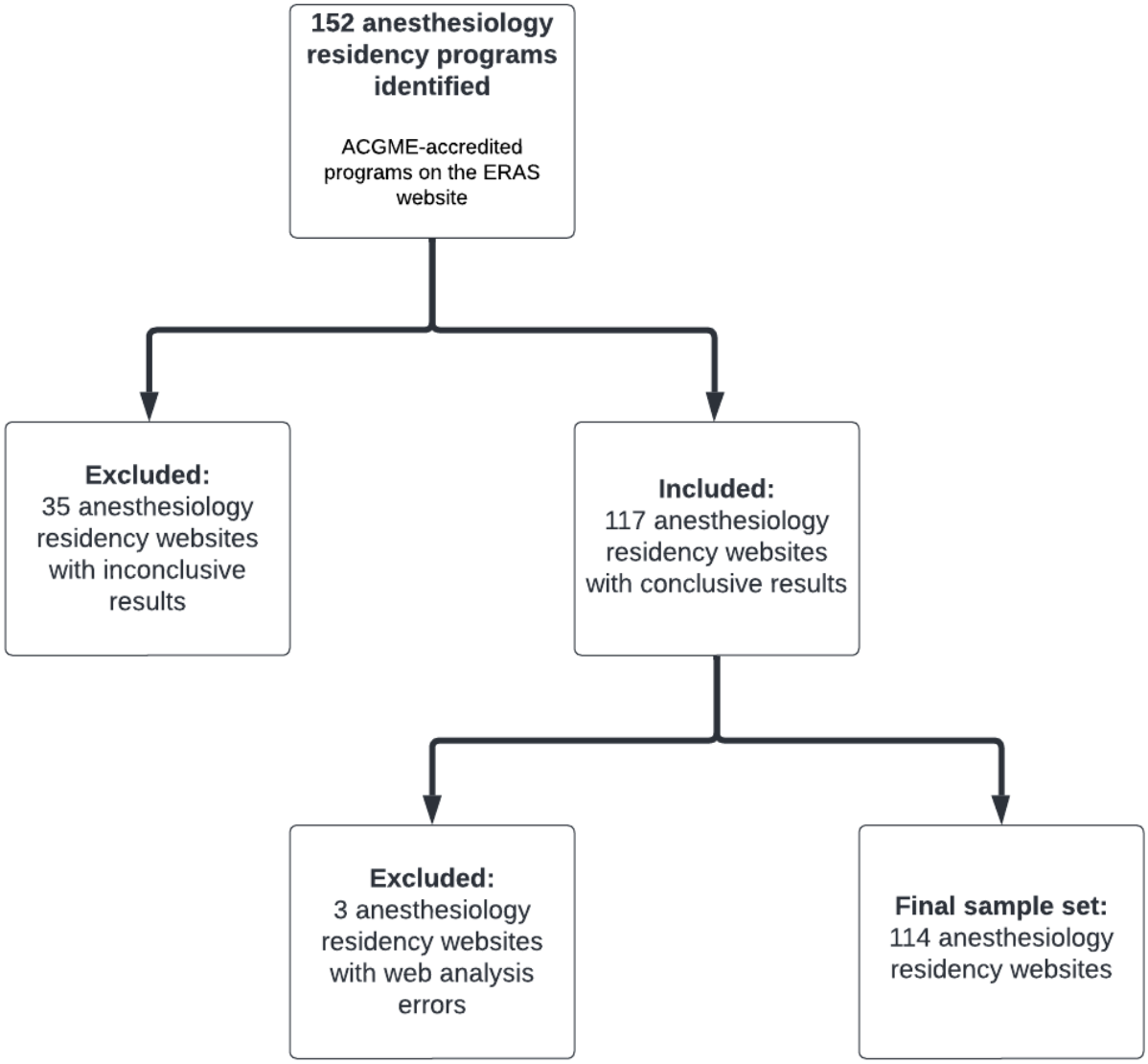
A cross-sectional usability audit of US anesthesiology residency websites was performed.

Sample Selection

US anesthesiology residency programs were the target website population. We initially identified 152 anesthesia programs listed on the Electronic Residency Application Service that were accredited by the Accreditation Council for Graduate Medical Education (ACGME). Our sample set included only programs with their own primary domain or subdomain. Upon studying the limitations of the study by Fundingsland et al [27] due to program websites being subpages of a larger domain, we realized that our methodology could be modified to expand the inclusion criteria. We included a backslash to websites that were part of larger domains (ie, hospital or university) to limit the amount of non–residency-related content. This method ensured that all scores were accurate across all websites, regardless of the pages possibly being under a larger primary domain. If a

website was analyzed and showed errors or had inconclusive results, they were excluded. An inconclusive result was defined as being unable to collect all data points with the tools. Commonly, this result was because of the inability to appropriately index a website by a web crawler due to blocking or website connection issues. Our final sample set included 114 US anesthesiology residency programs, with the selection process represented in Figure 1.

Figure 1. Sample selection criteria for anesthesiology residency websites. Inconclusive results are outlined in the Limitations section. ACGME: Accreditation Council for Graduate Medical Education; ERAS: Electronic Residency Application Service.



Overview

Between March 12 and April 18, 2021, all data pertaining to website usability were acquired using tools assessing each programs' website usability. Anesthesiology residency websites were ranked using the methodology and definitions previously defined by Calvano et al [8], Huerta et al [7,9,10], and Fundingsland et al [27]. Based on previous literature on website usability, 4 categories of website usability were both characterized and classified as follows:

1. Accessibility: the capability of users with minimal technology literacy to navigate web pages
2. Marketing: the ease with which websites can be accessed via search engines
3. Content Quality: the regularity of informational updates, readability, relevant content, and proper grammar
4. Technology: the excellence of the website's coding, configuration of the website, and website loading speed [7-9]

Analysis

All ACGME-accredited anesthesiology residency programs were compiled into a single database if they had a primary domain or subdomain. Each website was then scored, corresponding to the different tools defined by Calvano et al [8] and used by Fundingsland et al [27], as shown in Table S1 in Multimedia Appendix 1. The tools collected information on certain metrics, such as the number of missing texts, error pages, or missing files, that were quantified and then categorized. The main tool for extracting information was a web crawler. The web crawler analyzed websites and their respective subpages via URL to create an outline for metadata, errors, and improper

links. Two authors (NS and JB) were trained by the expert author (JC) on both websites rating and data gathering. To ensure that the data collected were both replicable and exact, the raters also studied the instruction manuals related to each web tool. Each author was then assigned the tools they were the most confident in and collected the appropriate data for the tools used. When specifically examining factors dependent on internet speed, 2 separate tools were used with the results averaged to minimize the variability that could possibly be influenced by the authors' internet connection. Each tool was run by either NS or JB on their respective computers. Both computers had the exact same specifications to minimize possible errors that could be introduced by differences in technology.

The selected usability tools were then applied and used to score each website. The results were then placed into 4 separate categories: (1) Accessibility, (2) Marketing, (3) Content Quality, and (4) Technology. Taking into account a variety of key factors relating to the 4 different categories, a General Usability score was then calculated. The different program websites were then ranked according to an Overall Usability score.

Accessibility

Accessibility represents the ability of a website to engage with a varied population. Accessibility consists of the following components: readability, functionality, overall layout, and meta description. Readability was calculated by using tools that measured reading difficulty and approximated the grade level necessary to comprehend a web page. Functionality explores features that allow users of varying literacy proficiency to comprehend a website's content. Accessibility encompasses the use of assistive technologies for those with visual impairments and those who would benefit from tools such as magnifiers or screen readers. A meta description is the brief outline produced when a website is found through a search engine. The results from the metrics used to analyze Accessibility were applied to an algorithmic scale to create a ranking list for program websites. Websites were ranked based on the estimated reading level needed for an appropriate understanding along with the ease of reading.

Marketing

Marketing explores the difficulty of finding a particular website. This category was quantified by focusing on the website's search engine results page (SERP). SERP is the placement of websites when searched through a search engine such as Google. As outlined in Table S1 in Multimedia Appendix 1, the analysis tool used was a combination of publicly available algorithms including Ahrefs (Ahrefs Pte Ltd) and Alexa ranking (Amazon).

Content Quality

Content Quality examines the items and content on a website and a user's ability to derive information from them. This category encompasses content such as the use of imagery/videos, metadata, analysis of text, and pertinence of text. When examining multimedia on web pages, the quality of images and the number of images were considered. Metadata serves as support for the presented content. Content Quality studies both the grammar and spelling of the written text. The pertinence of text evaluates the accuracy of information concerning certain topics. In our study, we evaluated anesthesiology residency websites based on their capability to present information that was grammatically correct along with the ease of deriving important information from each web page.

Technology

Technology examines the technical performance of each anesthesiology residency website. Technology explores a website's quality of technical design and performance. This category encompasses the comfort of use, user interface, server management, and server coding. User experience encompasses users' emotions, preferences, and perception about a website, which can be influenced by the user interface. We were able to gauge the ease of use for the websites based on their ability to perform consistently across different devices, the general layout, and dissecting facets of HTML. This examination included ensuring that links on the websites lead to active pages while avoiding error pages. Server coding is the programming code implemented to ensure that websites run smoothly. Back-end design investigates that appropriate in-line cascading style sheets link to separate web pages. Loading time for websites is important not only for retaining users but also to ensure that the websites are accessible to new users.

General Usability

The General Usability metric incorporates Accessibility, Marketing, Content Quality, and Technology. The score given is a summation of the applied percentages attributed to certain metrics outlined in previous research by Huerta et al [7,9,10]. It was created to quantify the overall quality of a health care website and produce a baseline for anesthesiology residencies to compare their own websites.

Overall Usability

Overall Usability was a calculation used to encompass the major and minor factors of the preceding 5 categories to create a rank list. The different factors in each category were then given a certain percentage according to their weight to create an all-encompassing ranking. The percentages were calculated from previously published research by Huerta et al [7,9,10]. A summation and description of the categories is shown in Table S1 in Multimedia Appendix 1.

Results

From our initial set of 152 websites, 38 websites were removed. A majority (35/38, 92%) of the removed programs were due to limitations associated with the web crawler or security measures implemented on the websites to prevent crawling technology. A majority (35/38, 92%) of the problems were due to difficulties with the web crawler, because it occasionally lacked the ability to explore more than the opening web page. In other cases, there was not enough computing power for the web crawler to explore the thousands of subpages on a website. The remaining (n=114) anesthesiology residency websites were then scored based on our grading system by looking at their Accessibility, Marketing, Content Quality, Technology, and General Usability.

Content Quality was the highest average scoring category with a score of 4.7 (SD 2.48, SE 0.23). The overall lowest category was Technology, with a mean score of 0.9 (SD 0.38, SE 0.04). Accessibility had a mean score of 1.8 (SD 0.65, SE 0.06). Marketing had a mean score of 1.7 (SD 0.75, SE 0.07). Finally, General Usability had a mean score of 1.3 (SD 0.59, SE 0.06). Summary statistics of all categories are shown in Table 1.

Table 1. Anesthesiology residency websites: summary statistics from usability analysis.

Category	Mean (SD)	Standard error	Minimum	Maximum
Accessibility	1.8 (0.65)	0.06	0.00	6.47
Marketing	1.7 (0.75)	0.07	0.51	8.30
Content Quality	4.7 (2.48)	0.23	–2.23	20.48
Technology	0.9 (0.38)	0.04	0.67	4.91
General Usability	1.3 (0.59)	0.06	0.14	6.71

Discussion

Principal Findings

After studying the various aspects of website usability, Content Quality was the highest scoring category, whereas Technology was the lowest. Most anesthesiology programs also scored extremely low in General Usability. Anesthesiology residency programs with low General Usability scores indicate a shortcoming in comprehending the various components needed for a high-quality website. Superficially, websites might appear to be high quality; however, the necessary changes needed to truly optimize websites must be explored by conducting a usability analysis.

One way to improve Marketing is through search engine optimization (SEO). Many corporations use SEO to influence their SERP to market products. Applying SEO within anesthesiology programs can also increase their web presence and ability to share information.

According to our data in Content Quality, anesthesiology residency websites appeared to prioritize precise information about their programs. Thus, we can infer that anesthesiology residency websites are focused on the information they provide on the web.

The lowest ranked category on average was Technology, which indicated that anesthesiology residency programs had placed little emphasis on using new digital technology. The insufficient prioritization of technology manifests itself as websites that are seldom analyzed or have subpar server space. We acknowledge that the use of technology might be an area of greater difficulty for program administrators to address due to its technical nature, but it can be an area of growth within programs. By encouraging interprofessional collaboration between programs and their information technology departments, anesthesia programs would be better equipped for the rapidly changing technological world.

Comparison With Prior Work

When comparing our study to related research that assessed the website usability of different specialties and residency programs, the areas for improvement appear to be uniform across all specialties. They all shared similar deficits and strengths in their websites, regardless of specialty. Although other studies assessed different residency websites using mechanisms or measurements that differed from our methodology, they all showed a need for the development of web presence for residency websites [18-27,29].

Our study used the same methodology that was previously performed by Calvano et al [8], which ranked the website usability of emergency medicine residencies. Previous research has enabled the authors to analyze usability trends related to health care, including children's hospitals, digital health care centers, and hospitals [7-9]. Content Quality is still the highest scoring category when comparing previous usability research [7-9]. Similar to our study, Technology consistently appears as the lowest ranked category in previous studies [7,8]. Our results also show the Technology category having the lowest score, and this finding could be a result of a variety of problems such as missing files on web pages, slow loading times, and missing headers on web pages. One way to improve Technology is by advocating for greater collaboration between anesthesia programs and their information technology staff.

One point of divergence when comparing our study with previous findings appeared when examining children's hospital websites. In children's hospital websites, Accessibility was the lowest category instead of Technology [9]. Accessibility has also been ranked low in older studies [7,8]. Generally, Accessibility has tended to be lower in other studies but ranked second in our research. It could be presupposed that those who use residency websites already have the necessary educational background to appropriately comprehend the information presented; however, an objective of this study was to promote a common baseline for assessing websites. Health care has neglected the standardization of website analysis and now must double its efforts to be on par with other industries that have placed a greater importance on this area [11-13].

Health care is rapidly changing through the use of technology to not only improve care but also minimize expenses. As a result, usability is now becoming a vital part of evaluating health care websites, which also encompasses medical education and training. In addition, the COVID-19 pandemic and its unprecedented effects on the 2021-2022 application cycle and interview season highlight the importance of anesthesiology residency program websites.

Limitations

We recognize the limitations of this study. The largest limitation is the decreased number of anesthesiology residency websites that were evaluated. Only 114 anesthesiology program websites out of the 152 ACGME-accredited anesthesia residencies met the inclusion criteria. With limited consumer-level analysis tools, multiple websites could not be properly analyzed for our study. Additionally, the web crawler was unable to examine many residency websites due to the random access memory demand from the tools and limited computing access by the data collectors.

Assessing the social media presence of the various programs proved to be a minor limitation. A large number of programs lacked direct links to their social media profiles. Consequently, we had to use the search engines within Facebook and Twitter. Further convoluting the process, the targeted pages often appeared lower on result pages, which introduced a concern about whether the correct, official social media pages were properly evaluated. This uncertainty underscored the importance of integrating appropriate and working social media links.

Another limitation was the measurement of each website's loading time. Data were collected using a single computer and network to minimize confounding factors. The data were accumulated over 37 days, and the information collected might have changed since our initial examination of the websites.

Finally, the last limitation encountered was the small amount of research that applied this framework to health care websites. We recognize that website usability analyses are not universal, but we believe that further efforts should be focused on creating a database of health care website usability to increase relevance.

Conclusion

The results of our study provide anesthesiology residencies a chance to critically examine their web presence and target areas that could use improvement. The average General Usability score of 1.3 indicates a need for overall improvement for anesthesiology residency program websites. Examining our data, anesthesiology programs do well with the Content Quality category, but there is room for improvement for the Technology category. Through this study, we advise anesthesiology residency programs to use recurring reviews of usability on their websites to ensure optimization in all categories of website usability.

Acknowledgments

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Conflicts of Interest

SH is on the advisory board for Covid Act Now and Safeter.App; is a co-founder and on the executive board of ConductScience Inc; is on the committees of the American College of Emergency Physician Supply Chain Task Force; receives research funding from the Foundation for Opioid Response Efforts (FORE); and receives personal fees from Withings Inc, Boston Globe, American College of Emergency Physicians, Maze Eng Inc, ConductScience Inc, and Curative Medical Associates. No other disclosures are reported. All other authors declare no other conflicts of interest.

Multimedia Appendix 1
Anesthesiology residency websites: factors that were assessed on anesthesia residency websites and the tools used to evaluate each website that were previously used in Calvano et al [1] and Fundingsland et al [27].
[PDF File (Adobe PDF File), 121 KB - ijmr_v11i2e38759_app1.pdf]

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Abbreviations

ACGME: Accreditation Council for Graduate Medical Education

SEO: search engine optimization
SERP: search engine results page

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Tutorial

Creating the Map of Interactive Services Aiding and Assisting Persons With Disabilities (MSAADA) Project: Tutorial for the Novel Use of a Store Locator App

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Abstract

Background: An estimated 15% of the global population is living with a disability. In Kenya, children with disabilities remain among the most vulnerable populations, experiencing substantial barriers to wellness and inclusion. Smartphone ownership and internet access have been increasing across sub-Saharan Africa, including in Kenya. Despite these advances, online or mobile resources remain limited and difficult to find and navigate.

Objective: This paper aims to describe the novel use of a store locator app to develop an interactive map of organizations that provide medical, educational, and socioeconomic resources to individuals with disabilities in Kenya. The target audience is individuals with disabilities, medical professionals, and organization leaders.

Methods: A comprehensive list of organizations, government county offices, educational assessment and resource centers, and institutions was compiled. Organizations were contacted via email, WhatsApp, or in person for semistructured interviews. Based on the services offered, each organization was assigned categorical search tags. The data were entered into a third-party store locator app. The resulting map was inserted into a page on the Academic Model Providing Access to Healthcare (AMPATH) website.

Results: The Map of Interactive Services Aiding and Assisting Persons With Disabilities (MSAADA; this abbreviation is also Swahili for “help”) was launched in July 2020 in both English and Swahili. The map included 89 organizations across Kenya. Of these, 51 were reached for an interview (for a 57% response rate). Interviewees cited limited paid staff and dependence on grant-based funding as primary challenges to growth and sustainability.

Conclusions: MSAADA is an interactive, virtual map that aims to connect individuals with disabilities, medical professionals, and organization leaders to resources in Kenya. The novel use of a store locator app to compile resources in remote settings has the potential to improve access to health care for a wide variety of specialties and patient populations. Innovators in global health should consider the use of store locator apps to connect individuals to resources in regions with limited mapping.

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KEYWORDS

map; virtual; interactive; disability; resources; inclusion; mHealth; Kenya; global health; public health

Introduction

Background

According to the World Health Organization, an estimated 15% of the world's population is living with a disability. Globally, individuals with disabilities have worse health outcomes, encounter more barriers to education and employment, and experience increased levels of poverty compared to individuals without disabilities [1]. Children with disabilities are among the most vulnerable populations. An estimated 11.2% of children and adolescents have a disability, and nearly 95% reside in low- and middle-income countries [2].

The prevalence of disability in Kenya reflects global trends. An estimated 10.3% of Kenyans have some form of disability, including difficulty with seeing, hearing, mobility, cognition, self-care, or communication [3]. In 2003, the government of Kenya passed the Persons with Disabilities Act, prohibiting discrimination against persons with disabilities and improving access to care, education, and employment [4]. Despite these legislative changes, children and adults with disabilities in Kenya continue to experience significant barriers to wellness and inclusion, including barriers to education [5], barriers to employment [6], and poorer health outcomes compared to individuals without disabilities [1].

Individuals with disabilities in sub-Saharan Africa experience multiple barriers to accessing health care and services. These barriers include stigmas associated with disability, a lack of awareness about disability, the inability to access transportation, and other poverty-related factors [7]. Few accessible resources exist to directly help individuals with disabilities navigate therapy and equipment needs. Additionally, due to limited availability, few health care professionals and skilled providers are knowledgeable about referral and equipment resources for families caring for individuals with disabilities [7,8]. Based on this understanding, we identified a need to compile resources in a centralized place where families could easily access them.

We recognized the growing share of Kenyans with access to smartphones and the internet as a potential pathway for connecting Kenyans to resources for individuals with disabilities. Smartphone ownership and internet access have been increasing across sub-Saharan Africa, including in Kenya [9]. Approximately 80% of Kenyans own a mobile phone, 30% own a smartphone, and 39% use the internet, including more than half of Kenyans between the ages of 18 and 29 years [9]. Despite these increases in access to information via the internet, many online resources are difficult to find and navigate.

Objectives

This paper aims to describe the novel use of a store locator app to develop an interactive map of organizations that provide medical, educational, and socioeconomic resources to individuals with disabilities in Kenya. The project is titled MSAADA (Map of Interactive Services Aiding and Assisting Persons With Disabilities); the Swahili word *msaada* translates to the English word "help." The target audience is individuals with disabilities, medical professionals, and organization leaders with access to needed services.

Methods

Setting: the Academic Model Providing Access to Healthcare Project in Western Kenya

In 1990, the Indiana University School of Medicine began a partnership with Moi Teaching and Referral Hospital, located in Eldoret, Kenya. In 2001, other universities joined to establish a long-term partnership known as the Academic Model Providing Access to Healthcare (AMPATH). The mission of AMPATH is to address needs for care, training, and research to improve the health of individuals globally. Within this tripartite mission, care remains most important and central to AMPATH. The model prioritizes the bilateral exchange of medical doctors, residents, students, and researchers to serve together in Kenya and North America. Every project based in Kenya must be care centered, sustainable, and locally led [10].

We are a team of 2 pediatricians (1 from Kenya, 1 from the United States) and 2 medical students (1 from Kenya, 1 from the United States). Much like other initiatives started within AMPATH, this project was formed to fill a gap in patient care. Health care providers at Moi Teaching and Referral Hospital were having difficulty connecting their patients with disabilities to available resources and services in their communities. The reasons for this were complex. In part, disability is an umbrella term for various conditions, meaning that a resource that supports one family may not be the best fit for another family. Additionally, Moi University Teaching and Referral Hospital is a large referral center, so providers in Eldoret may not be aware of resources for their patients in Kabsabet. In a setting where transport is limited, proximity is crucial. Finally, existing search engines and maps often do not contain updated or detailed information from organizations in Kenya; this missing information remains a major barrier to accessing these resources.

Ultimately, the team decided to make MSAADA available through the AMPATH website for two reasons. First, this academic partnership already has various long-term connections with organizations that could be added to the site. Many of the organizations that were added were known by the pediatric research team based in Kenya, given their experience living and working alongside children with disabilities and their families. Second, adding MSAADA to the AMPATH site allows for opportunities for trainees from both Kenyan and US institutions to help update the map over time. A critical component of this resource is that it is regularly updated to be sustainable. Having undergraduate and graduate students actively involved in this project allows for greater consistency overall.

Creating a Database

The first step to developing MSAADA was to create a database of organizations, institutions, and government offices that provide resources for persons with disabilities in Kenya. This step was conducted using various methods. The team started with a list of organizations that were commonly known by the pediatric research team at Moi Teaching and Referral Hospital. Subsequently, the team used common search engines to start to find other organizations. With continued searching, the team was able to find several directories; however, many

organizations' contact information and services were not up-to-date. In some cases, the organizations in the directory no longer existed. The team compiled a comprehensive list. Organizations with an email address or WhatsApp number were contacted for a virtual interview to verify basic information and discuss the services provided by the organization. The information gathered included the organization's name, address, email address, website URL, social media links, phone number, primary contact, longitude and latitude, services offered, payment options, requirements for enrollment, and transport services (Multimedia Appendix 1). After these interviews were conducted, a team member based in Kenya traveled to Nairobi to conduct interviews with other organizations in person. All information gathered in these interviews was stored in a shared database for the map.

Selecting Storepoint: a Store Locator App

The next step was selecting a way to feature each of the resources in a single map that would be easy to use and manageable to update regularly. Storepoint is a user-friendly, customizable mapping feature that can be incorporated into any website. Its original purpose was as a store locator app that allowed businesses to display each of their locations on a map. It allows consumers to input their city name or zip code to find the nearest business location. It also has features on the map that allow consumers to filter locations based on specific characteristics. While Storepoint has a monthly cost, it is relatively intuitive to use and requires no prior knowledge or expertise in coding. After considering other comparable options, we chose Storepoint to host MSAADA, as it gave the team the greatest opportunity for customization without imposing the burden of having to train students in highly technical skills. From a sustainability standpoint, the cost to use Storepoint was allocated in the monthly research budget.

Adding and Editing Organizations

The following steps detail how to add and edit organizations in Storepoint after gaining membership. On the main dashboard, users can select "Add Location" to add 1 location or "Bulk Import Locations" to use a spreadsheet to add multiple locations at once. For MSAADA, every location in Storepoint represents an organization. The fields on the form for organization name, email address, location, social media links (eg, Twitter, Facebook, and Instagram), photograph, logo, and "tags" (see the "Adding Search Categories" section of this paper) are filled in and these items are featured on the map. Location can be either determined by a street address or by coordinates for longitude and latitude; this choice provides flexibility and precision for organizations in this setting that do not have a traditional street address. To edit an organization, users can select "Search Locations" to find the organization they want to edit and click on it to update or change any information.

Adding Search Categories

One useful feature of Storepoint is the ability to categorize organizations by various features that can help the user more easily locate a specific resource. This step involves "tagging" organizations within a "tag group." Users can click a tag group drop-down menu in the search bar above the map and filter by a specific tag. For instance, there is a tag group called "Select by Cost" with the tags "$," "Free," "NHIF" (ie, the National Hospital Insurance Fund), and "Private Insurance." Users can potentially click "Select by Cost" and then "Free" if they only want organizations that have free services to be shown on the map. Storepoint allows adding tags by selecting "Manage Locations" and then selecting "Tags and Filters." To add a tag group, users click "Add A Tag Group" at the top. To add a tag to a location, users can add it to the information for a specific location under "Tags" (see the section "Adding and Editing Organizations" in this paper).

We created tag groups before we interviewed the organizations and adjusted our methods as the interviews progressed to reflect the types of resources offered by each organization. An unlimited number of tags and tag groups can be created and added for each organization. The tag groups and tags included for the initial phase of the map can be found in Multimedia Appendix 2. The filter can be set up with AND or OR operators when multiple tags are chosen. We have it set to AND for MSAADA. For example, a user might select "free" AND "speech and language therapy" AND "cerebral palsy" as tags. In this search, only organizations with all 3 of these tags would appear, meaning they offer free speech and language therapy for individuals with cerebral palsy. Since the map already has hundreds of organizations featured, this allows individuals to easily search for specific resources of interest.

Embedding in the Website

This final step discusses how to incorporate a Storepoint map into a website. This step involves going to "Embed Locator" on the Storepoint dashboard. An embed link is provided that can be copied into the website HTML. Any changes made in the Storepoint account will automatically be reflected, so the embedded code does not need to be adjusted. For our team, this was an added benefit for this project, since we were not personally managing the website. AMPATH generously allowed the team to use a URL connected to their domain for MSAADA and helped us to create a functional site for users.

Additional Features

In addition to the interactive map, the web page provides access to 3 other valuable resources: a disability card infographic, Kenya Disability Resource, and Kenya Disability Directory. The disability card infographic was created by the team to explain and illustrate the process for obtaining the government card issued to individuals with disabilities in Kenya, as shown in Figure 1. This infographic was also translated to Swahili and made accessible on the website.

Kenya Disability Resource is a website dedicated to providing information, creating awareness, and building community around disability in Kenya. Kenya Disability Directory is a directory in the PDF format created by Handicap International in 2010 that includes hundreds of organizations.

Figure 1. Representation of a downloadable step-by-step guide to obtaining a disability card in Kenya created for this study.

Functionality of MSAADA

Throughout the Methods section of this paper, the primary format has been a step-by-step tutorial on how to use the store locator app to develop an interactive resource map in a remote setting. Here, we will briefly describe how the target audience could use MSAADA. Any individual with internet access can log on to the map using the URL created by AMPATH to host the web page [11]. At the top of the page, users can select "Unazungumza Kiswahili?" which will take them to the same resource map translated into Swahili. If English is preferred, users can continue to the map.

After scrolling down, users can type in their location by inputting their village, city, or region. The location search bar will auto-populate options to provide additional choices. They can then use the drop-down menu to choose how many kilometers they are willing to travel from their selected location, with options ranging from 5 to 100 kilometers. In Figure 2, "Nairobi, Kenya" has been typed in and "25 km" has been selected from the drop-down menu.

The remaining drop-down menus allow users to select from the various criteria listed earlier as tags. In this case, "verified," under "verification status," and "occupational therapy," under "select by therapy," have been selected, which will show all organizations that provide verified occupational therapy services within 25 kilometers of Nairobi. In this search, 4 organizations are shown, as seen in Figure 3.

Figure 2. Screenshot of the interactive map with settings to show all resources within 25 km of Nairobi, as selected in the search bar at the top of the map. Map data from OpenStreetMap.

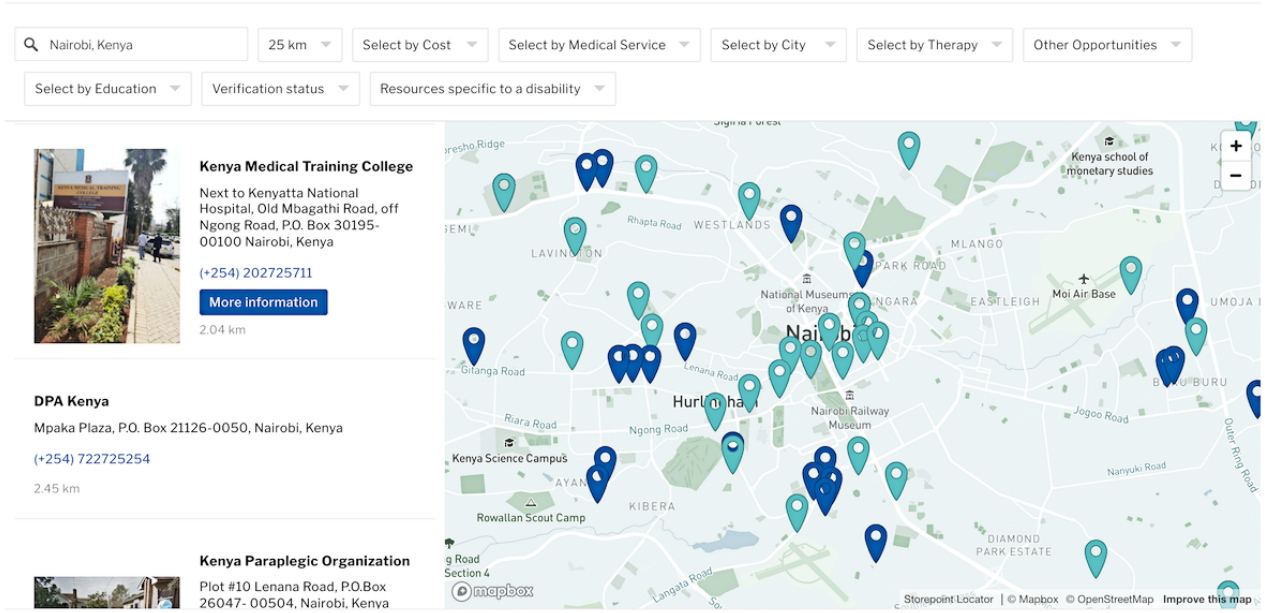
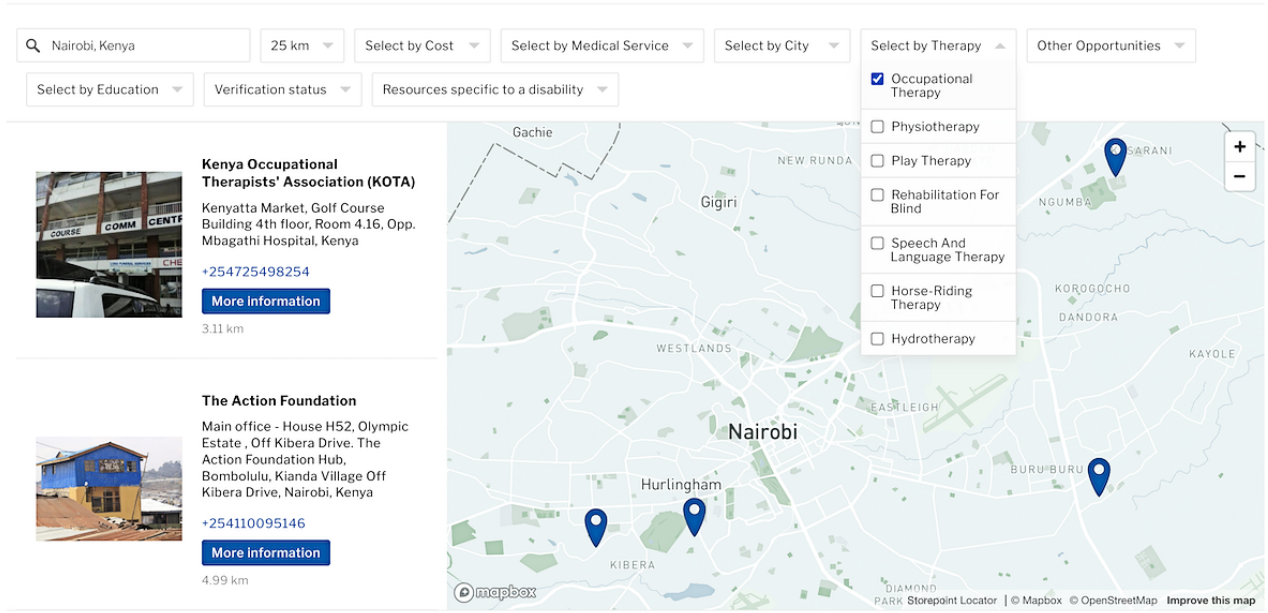


Figure 3. Screenshot of the interactive map with settings to show all resources that are verified and offer occupational therapy services within 25 kilometers of Nairobi. Map data from OpenStreetMap.



Results

MSAADA was launched in July 2020 in both English and Swahili. The team compiled a list of 219 organizations and institutions within Kenya that offered services to individuals with disabilities. Of these organizations, 89 had an email address or WhatsApp account to which the team was able to send an introductory email to set up an interview. Of the 89 organizations that were contacted, 12 agreed to conduct interviews. An additional 39 were reached in person and completed an interview. In total, interviews were conducted with 51 of the 89 organizations, giving a response rate of 57%. In the interviews, the organization representatives mentioned limited staff and volunteers and grant-based (ie, short-term) funding as the primary challenges to the growth and sustainability of their services. When asked about features that would be valuable for the site, the majority of organization representatives mentioned the need for it to be accessible to all individuals with disabilities.

Discussion

Advantages

Translation to Multiple Languages

One of the most valuable features of Storepoint is that the map can be translated into multiple languages. Each translation of

the map has a unique embedded code that can be inserted into a website. The 2 official languages in Kenya are English and Swahili, but over 30 distinct languages and dialect clusters are also spoken. Originally, MSAADA was developed in English, and members of the team in Kenya then translated the site features and additional documents on the site into Swahili. Additionally, since the team originally created MSAADA, the AMPATH website has added an accessibility feature called UserWay, which is visible as a small widget icon in the lower right-hand portion of the screen. Among many accessibility features that are detailed later in this tutorial, this widget can translate the entire site into 42 additional languages.

New Organization and Feedback Forms

Another key feature of the website is a form for organizations not yet featured on the map to add their organization and provide key information. The site also includes a link to a form for organizations to provide feedback on the map and make updates to information specific to their organization. Upon submission, both surveys are automatically sent directly to an individual on the team who consistently updates the map. This feature allows new organizations and already featured organizations to ensure that the information on MSAADA is accurate and up-to-date.

Disadvantages and Limitations

Grant-Based Funding

A major challenge noted by several organizations was that projects and services are highly dependent on grant funding. As a result, a specific service may only be offered for 1 to 5 years, based on the length of the grant. This presents an obstacle for both health care providers and individuals with disabilities because the resources that exist are constantly evolving. The benefit to having an interactive map is that changes can be quickly made by the team, and these changes are reflected immediately in MSAADA for its users.

Communication With Organizations

Another challenge for the development of MSAADA was communication with organizations, as seen with the low initial response rate. This is likely due to several factors, including outdated contact information, limited access to the internet, and limited time of staff or volunteers. During the interviews, many organizations noted they had a limited number of employees or were completely operated by volunteers, making it difficult for them to respond or devote time to an interview. This presented a challenge to obtaining information that was verified and accurate. Additionally, most of the communication was initially conducted via email, WhatsApp, and video chat from the United States. To further develop relationships with organizations, a member of the team based in Kenya visited 39 organizations in Nairobi to meet with employees and volunteers in person. This aided greatly in verifying contact information from several organizations within a short timeframe, but it may not be feasible for every organization across Kenya on an annual basis. However, we found that through this relationship-based model, we were able to gather updated information that could not be found online elsewhere.

Reliance on Human Endeavor

A final limitation of this model that should be noted is that it relies heavily on human endeavor to keep updated. To develop MSAADA, 1 research team member input the data collected in the virtual and in-person interviews and from the 2 Google forms. Updating will be done on a weekly basis by checking the 2 Google forms and making edits to the Storepoint page. In the future, this may be automated, but at this time, the human component allows for two major advantages: (1) we can build a relationship with the organization, and (2) we can review and revise any errors before uploading information to the public. Additionally, we have a sustainable internal system for updating the site. There are always at least 2 to 4 medical students or graduate students on the research team at any given time. Every semester, a student will be assigned the responsibility of working with Kenyan colleagues and organizations to maintain MSAADA.

Future Improvements

Increased Accessibility and Inclusivity

A crucial component of MSAADA is that is remains an accessible and inclusive resource for all users. Currently, the AMPATH website uses UserWay, which includes a dictionary; screen reader; functions for contrast, highlighting, text sizing, and spacing; dyslexia-friendly options; and cursor formatting. These features improve usability for individuals who have visual impairments or difficulty reading written text on a computer screen. Another key accessibility feature is ensuring that the site remains financially accessible to users across Kenya. Thus, this resource will remain free for users to avoid excluding anyone based on socioeconomic status. Additionally, since the internet remains a major expense, a long-term goal is to investigate the possibility of creating a smartphone app version of MSAADA that could be downloaded and used without internet access. Finally, at this time, the map is limited to organizations and institutions within Kenya. To make it more geographically accessible, the map could be expanded to include locations in neighboring countries in East Africa, such as Uganda and Tanzania.

Information Guides

In the next phase of MSAADA, another goal is to have more detailed information about each resource that is organized for individuals with disabilities, medical professionals, and organization leaders. One proposal is to create clear, easy-to-refer-to information guides about each organization. For instance, a medical professional could use this guide to find free speech and language therapy for individuals with cerebral palsy and be able to provide the contact information, website, and address of the organization. Moreover, if the medical professional could use the information guide to direct the patient to a 1-page chart with more detailed information about when or how to qualify for the program, the guide could be a valuable extension of the map. These could be created in a standard format, translated to multiple languages, and uploaded as downloadable files to the web page.

Promotion and Evaluation

Another next step for MSAADA will be to seek feedback in order to evaluate the usability of the interactive map. The team plans to introduce MSAADA to groups of individuals in the target audience. A survey or short interview guide will be developed in order to gain feedback from individuals and to evaluate areas for improvement. Eventually, the team plans to use the "Locator Analytics" feature of Storepoint, which allows users to create a heat map of popular search areas, develop a chart of locator views and searches over time, and obtain the average distance individuals travel to their destination. By publishing this data, MSAADA will not only benefit those currently using it, but also provide organizations with data on how to better reach individuals with disabilities in the future.

Conclusion

This paper describes the novel use of a store locator app to develop an interactive map of organizations that provide medical, educational, and socioeconomic resources to individuals with disabilities in Kenya. The use of a store locator app to compile resources in remote settings has the potential to improve access to health care for a wide variety of specialties and patient populations. Innovators in global health should consider the use of store locator apps to connect individuals to resources in regions with limited mapping.

Acknowledgments

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Conflicts of Interest

None declared.

Multimedia Appendix 1
Interview guide to verify organizations.
[DOCX File , 16 KB - ijmr_v11i2e37036_app1.docx]

Multimedia Appendix 2
Search tags for organizations.
[DOCX File , 14 KB - ijmr_v11i2e37036_app2.docx]

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Abbreviations

AMPATH: Academic Model Providing Access to Healthcare
MSAADA: Map of Interactive Services Aiding and Assisting Persons With Disabilities

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Original Paper

The Characteristics of Student SARS-CoV-2 Cases on an Urban University Campus: Observational Study

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Abstract

Background: Academic institutions are central hubs for young adults, laden with academic and social interactions and communal living arrangements, heightening the risk of transmission of many communicable diseases, including COVID-19. Shortly after the start of the fall 2020 academic year, institutions of higher learning were identified as hot spots for rises in COVID-19 incidence among young adults.

Objective: This study aims to identify the characteristics of student SARS-CoV-2 cases, identify the extent to which the student population adhered to preventative strategies, and examine behaviors that would put them at higher risk of contracting or spreading COVID-19.

Methods: This observational study comprises 1175 university students at The George Washington University in Washington, DC, with a confirmed COVID-19 diagnosis between August 3, 2020, and November 30, 2021. Case investigation and contact tracing tools were developed by the Campus COVID-19 Support Team and captured in REDCap (Research Electronic Data Capture). Trained case investigators were notified of a case and attempted to contact all cases within 24 hours of the case receiving their lab result. Associations between case characteristics and number of contacts were examined using Wilcoxon rank sum tests. Knowledge of exposure, behaviors since exposure, student residence status, and fraternity and sorority life affiliation were examined using chi-square tests.

Results: Positive student cases reported a median of 3 close contacts, and 84.6% (993/1175) reported at least one symptom with a median of 4 COVID-19 symptoms. Congestion (628/1175, 53.4%), cough (530/1175, 45.1%), and headache (484/1175, 41.2%) were the most frequently reported symptoms. Moreover, 36% (415/1160) reported that they did not know how they were exposed to the virus. Among those aware of contact with a COVID-19 confirmed case, 55.1% (109/198) reported the contact was a close friend or family member, and 25.3% (50/198) reported that it was someone with whom they lived. Athlete (vs nonathlete; $P<.001$), on-campus (vs off-campus; $P<.001$), and undergraduate (vs graduate; $P=.01$) students all reported a significantly higher number of contacts. Students living on campus were more likely to report attending campus events in the 2 days prior to symptom onset or positive test result ($P=.004$). Students with fraternity or sorority affiliation were more likely to report attending campus events in the 2 days prior to symptom onset or positive test result ($P<.001$).

Conclusions: COVID-19 cases have not yet stabilized to a predictable state, but this study provides case characteristics and insights for how academic institutions might prepare to mitigate outbreaks on their campuses as the world plans for the transition from pandemic to endemic COVID-19.

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KEYWORDS

COVID-19; SARS-CoV-2; college; university; students; young adult; youth; communicable disease; prevention; school health; outbreak prevention; contact tracing; pandemic

Introduction

The world has witnessed major disruption in all domains of life since the World Health Organization declared the novel SARS-CoV-2 outbreak a global pandemic in March 2020. Although children and young adults were initially reported to be at lower risk for severe disease or death from COVID-19, emerging evidence suggested a rise in cases among 18- to 22-year-olds [1]. Academic institutions are central hubs for young adults of this age group, and the congregate settings, academic and social interactions, and communal living arrangements inherent to college heighten the risk of transmission of many communicable diseases, including COVID-19 [2].

In spring 2020, colleges and universities across the United States transitioned to virtual learning to curb the transmission of SARS-CoV-2. However, for the fall 2020 semester, several institutions returned to some form of in-person instruction or campus living. By September 2020, 4% of colleges were conducting full in-person instruction, 23% were primarily in person, while the remaining majority implemented remote or hybrid learning [3]. Shortly after the start of the fall 2020 academic year, institutions of higher learning were identified as hot spots for rises in COVID-19 incidence among young adults [4]. A county-level analysis comparing 21-day periods before and after classes began in fall 2020 revealed that large colleges and universities with remote instruction observed a 17.9% decrease in COVID-19 incidence, and those with in-person instruction experienced a 56% increase in COVID-19 incidence [5].

Evidence is suggestive of young adults being less likely to adhere to COVID-19 preventive measures than any other age group [1,6]. Additionally, a traditional on-campus academic experience typically includes extracurricular group activities and social gatherings, which are difficult to monitor for adherence to public health measures to prevent outbreaks. During August to September 2020, a university in Arkansas reported 965 cases, with 31% of these cases reporting involvement in fraternity and sorority activity; 91% of the gatherings identified in network analysis were linked by participation in fraternity and sorority activities [7]. SARS-CoV-2 can also spread quickly among college athletes [8], and outbreaks among university sports teams have received a great deal of media attention; however, the extent to which these are due to contact during sports activities is unclear. For an outbreak among men's and women's soccer teams in a university, 73% of the cases were living in shared housing, and approximately 60% attended at least one social gathering, including a birthday party, visits to friends' dormitories or apartments, and outdoor lake gatherings [9].

The George Washington University (GWU), an urban campus with its largest campus in Washington, DC, prepared for a limited reopening of its campus in fall 2020 and put into place multiple strategies to mitigate the spread of SARS-CoV-2 including the following: (1) requiring physical distancing and face coverings and limiting gatherings to less than 10 people; (2) return to campus monitoring and testing for on-campus residential students on arrival and 5 days later, including quarantine of residence hall students pending 2 negative polymerase chain reaction (PCR) tests; (3) mandatory weekly SARS-CoV-2 PCR testing for on-campus students, faculty, and staff, and thrice weekly testing for athletes; (4) mandatory daily symptom monitoring for all on-campus students, faculty, and staff; (5) on-campus investigations to quickly identify transmission pathways and intervene early via quarantine and testing of suspected close contacts of the cases; (6) clinical follow-up, quarantine, and testing at any point for any member of the campus community who develops symptoms; (7) per rules of the District of Columbia Health Department, a 14-day quarantine of anyone returning to campus from states defined by them as "high risk"; and (8) mandatory influenza vaccine [10,11].

This analysis aims to identify the characteristics of student SARS-CoV-2 cases at GWU, identify the extent to which the student population adhered to preventative strategies, and examine health behaviors that would put them at higher risk of contracting or spreading COVID-19. Lessons learned can contribute to refining COVID-19 protocols and pandemic programming in academic institutions.

Methods

Participants and Data Collection

This observational study comprises 1175 university students at GWU with a confirmed COVID-19 diagnosis between August 3, 2020, and November 30, 2021. GWU has over 26,000 undergraduate and graduate students, yet most of these individuals were learning remotely during the 2020-2021 academic year. Individuals authorized to be on campus during the fall 2020 and spring 2021 semesters were required to participate in weekly surveillance testing and to complete daily symptom screening surveys [11]. The student population approved to live in residence halls on campus or having access to campus was identified based on enrollment (in a small number of classes that continued to be delivered in person) and active ongoing research; student athletes; hardship students with

limited alternative housing resources; or being employed as student workers in essential on-campus jobs. The on-campus student population that was required to participate in the weekly surveillance program comprised approximately 500 individuals in fall 2020 and increased to approximately 2500 individuals in spring 2021 owing to reopening more residence hall space, as well as increased on-campus instruction and research. In addition, starting in October 2020, approximately 13,000 students who were not authorized to be on campus (ie, students who lived near GWU) were able to access voluntary testing for travel or if they were experiencing symptoms. By fall 2021, the university had welcomed back more than 20,000 in-person students who were required to participate in twice-monthly surveillance testing. Surveillance testing, contract tracing, and outbreak response strategies are described elsewhere [10,11].

Case investigation and contact tracing tools were developed by the GWU Campus COVID-19 Support Team, comprised of public health experts. All data were captured in REDCap (Research Electronic Data Capture), a secure web application for web-based surveys and databases [12]. Trained GWU case investigators, or contact tracers, were notified of a case and attempted to contact all cases within 24 hours of the case receiving their result. A single case investigation took approximately 30 minutes to complete, soliciting information on case demographics, symptoms, underlying health conditions, risk-reduction behaviors, known exposures within the 48 hours before symptom onset or a positive test, campus authorization, and campus affiliation.

Statistical Analysis

We used univariate analyses to examine the frequencies and percentages of categorical variables, as well as medians and distributions of continuous variables. We examined the bivariate relationships between selected case characteristics and number of contacts using Wilcoxon rank sum tests. Additionally, bivariate relationships were examined between knowledge of exposure and behaviors since exposure, student residence status and knowledge and behaviors since exposure, and fraternity and sorority life affiliation using chi-square tests. All hypothesis tests were 2-sided, and the level of significance was set to an alpha of .05. Analyses were performed using SAS, version 9.4 (SAS Institute Inc).

Ethical Considerations

All students provided informed consent to participate in the GWU COVID-19 surveillance program, and the GWU Institutional Review Board concluded that these were non–research-related activities.

Results

Between August 3, 2020, and November 30, 2021, the university public health lab performed 219,919 SARS-CoV-2 PCR tests for our student population, resulting in 1175 cases, which represents 84% (1175/1399) of the total university cases during the study period. Table 1 presents the characteristics of students found to be infected with SARS-CoV-2. The median age of students who tested positive for COVID-19 was 21 years. Moreover, out of the 1175 student cases, 831 (70.7%) cases were White, 707 (60.2%) self-identified as female, 877 (74.7%) were undergraduates, 862 (73.4%) lived off campus, and 945 (80.4%) reported as never smoking. Only 92 (8%) cases were student athletes, and 337 (28.7%) were affiliated with fraternity or sorority life. Students who tested positive for COVID-19 reported a median of 3 close contacts. Nearly 85% (993/1175) of students reported at least one symptom with a median of 4 COVID-19 associated symptoms being reported.

The top 3 most reported symptoms among the 1175 cases were 628 (53.4%) reporting congestion, 530 (45.1%) reporting cough, and 484 (41.2%) reporting headache. Just over 15% (n=181) of cases reported experiencing no symptoms (Figure 1). Underlying health conditions were somewhat common, with 224 (19.1%) students reporting one or more underlying medical conditions that put them at higher risk for COVID-19 complications.

Table 2 presents knowledge and behaviors 48 hours prior to testing positive. Out of the 1160 cases, 415 (35.8%) reported they did not know how they were exposed to the virus. Of the 198 cases aware of prior contact with a COVID-19 confirmed case, 109 (55.1%) reported the contact was a close friend or family member, and 50 (25%) reported that it was someone with whom they lived. When asked about preventative health behaviors 48 hours prior to the onset of symptoms or positive test result, 44 (5%) out of 846 reported not having used personal protective equipment (PPE) such as masks on campus. In addition, of 1159 cases, 242 (20.9%) reported domestic travel in the 2 days prior to symptom onset or their positive test result. Moreover, 402 (35.6%) of 1128 cases reported using local transport in the form of city buses, city trains, or ride sharing services such as Lyft or Uber. Additionally, 251 (21.4%) out of 1175 reported being around people from campus in the 2 days prior to symptom onset or their positive test result.

Table 3 presents the median number of contacts by select case characteristics. Athletes reported a median of 5 (IQR 3-11) contacts compared to 3 (IQR 1-5) for nonathletes (P<.001). Students living on campus reported a median of 4 (IQR 2-7) contacts compared to 3 (IQR 1-4) reported by those living off campus (P<.001). Undergraduate students reported a median of 3 (IQR 2-6) contacts compared to 3 (IQR 1-4) reported by graduate students (P=.01). There were no significant differences in the number of contacts by self-reported gender identity or fraternity and sorority life (FSL) affiliation.

Table 1. Case characteristics of students (N=1175).

Characteristics	Values
Age (years), median (IQR)	21 (20-23)
Gender, n (%)	
Woman	707 (60.2)
Man	456 (38.8)
Non–gender conforming	8 (0.7)
Missing	4 (0.3)
Race, n (%)	
Asian	123 (10.5)
Black or African American	97 (8.3)
Multiracial	44 (3.7)
Native Hawaiian or other Pacific Islander	1 (0.1)
White	831 (70.7)
Other	76 (6.5)
Missing	3 (0.3)
Student status, n (%)	
Undergraduate	877 (74.7)
Graduate	278 (23.7)
Other	16 (1.4)
Missing	4 (0.3)
Athlete, n (%)	
Yes	92 (7.8)
No	1083 (92.2)
Fraternity and sorority life, n (%)	
Yes	337 (28.7)
No	838 (71.3)
Student residence, n (%)	
On campus	313 (26.6)
Off campus	862 (73.4)
Smoking status, n (%)	
Current	122 (10.4)
Former	89 (7.6)
Never	945 (80.4)
Missing	19 (1.6)
Number of contacts, median (IQR)[a]	3 (2-5)
Number of symptoms, median (IQR)	4 (2-6)
Underlying conditions, n (%)	
None	907 (77.2)
One or more	224 (19.1)
Missing	44 (3.7)

[a]N=837.

Figure 1. Frequency of reported symptoms among student COVID-19 cases (N=1175).

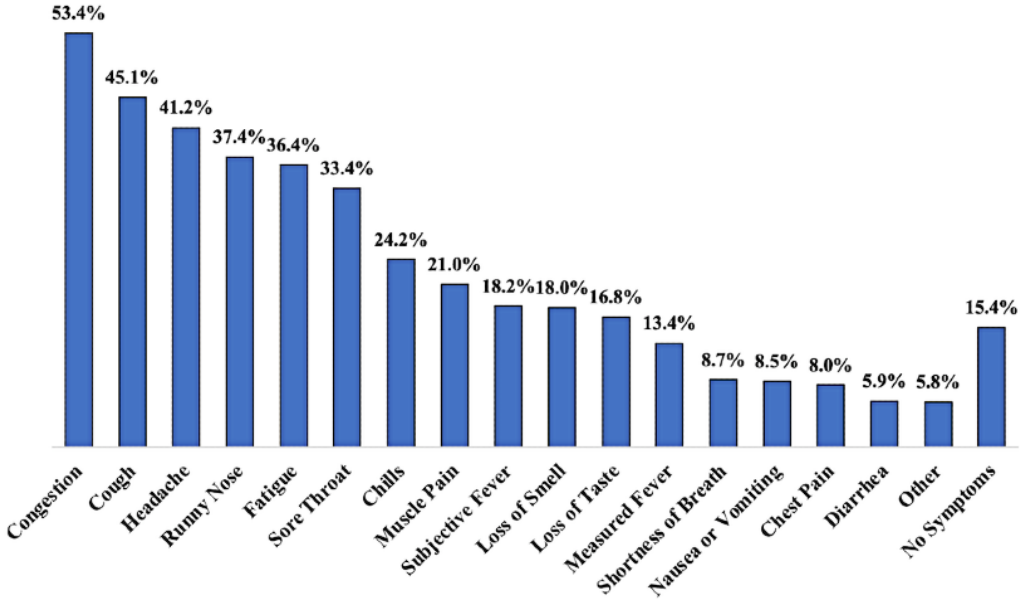

Table 2. Knowledge and behaviors prior to a positive COVID-19 test.

Knowledge and behaviors	Values, n (%)
Knowledge of exposure (n=1160)	745 (64.2)
Prior contact with confirmed case (n=198)	
A close friend or family	109 (55.1)
Classmate	8 (4.0)
Coworker	5 (2.5)
Someone you live with	50 (25.3)
Other[a]	23 (11.6)
Missing	3 (1.5)
Traveled within the United States 2 days prior to symptom onset or test date (n=1159)	242 (20.9)
Used any local transportation 2 days prior to symptom onset or test date (n=1128)	402 (35.6)
Did not use any PPE[b] on campus 2 days prior to symptom onset or positive test result (n=846)	44 (5.2)
Were around other people on campus 2 days prior to symptoms starting or positive test results (ie, training, conferences, concerts, parties, dinner, etc; n=1175)	251 (21.4)

[a]Other includes those met during travel, friend of friends, and teammate.

[b]PPE: personal protective equipment (eg, masks, hand-made masks, and gloves).

Table 3. Median number of contacts by select case characteristics.

Characteristics	Median (IQR)	*P* value
Gender (n=826)		.61
Woman	3 (2-5)	
Man	3 (2-5)	
Student status (n=826)		.01
Undergraduate	3 (2-6)	
Graduate	3 (1-4)	
Athlete (n=837)		<.001
No	3 (1-5)	
Yes	5 (3-11)	
Fraternity or sorority (n=837)		.55
No	3 (1-5)	
Yes	3 (2-5)	
Student residence (n=837)		<.001
On campus	4 (2-7)	
Off campus	3 (1-4)	

Table 4 presents exposures and behaviors by student residence (on campus versus off campus). Students living on campus were more likely to report using any PPE (eg, masks, hand-made masks, and gloves) on campus in the 2 days prior to symptom onset or positive test result compared to students living off campus (*P*=.006). Not surprisingly, students who lived on campus were more likely to report attending campus events in the 2 days prior to symptom onset or positive test result (*P*=.004). There were no statistically significant differences between living on campus or off campus in terms of domestic travel, local transportation use, or knowledge of exposure in the 2 days prior to symptom onset or positive test result.

Table 5 presents student exposures and behaviors by FSL affiliation. There were no statistically significant differences between FSL affiliation in terms of knowledge of exposure or using PPE in the 2 days prior to symptom onset or positive test result. Those reporting no FSL affiliation were more likely to report using domestic travel or local transportation in the 2 days prior to symptom onset or positive test result (*P*<.001 and *P*<.001, respectively). However, students reporting an FSL affiliation were more likely to report attending campus events (*P*<.001) in the 2 days prior to symptom onset or positive test result.

Table 4. Exposure and behaviors by student residence.

Exposure and behaviors	Off campus, n (%)	On campus, n (%)	*P* value
Knowledge of exposure (n=1160)			.06
Yes	562 (65.8)	183 (59.8)	
No	292 (34.2)	123 (40.2)	
Used any PPE[a] (n=846)			.006
Yes	554 (93.4)	248 (98.0)	
No	39 (6.6)	5 (2.0)	
Travel within the United States (n=1159)			.33
Yes	183 (21.6)	59 (19.0)	
No	665 (78.4)	252 (81.0)	
Used local transportation (n=1128)			.33
Yes	286 (34.8)	116 (37.9)	
No	536 (65.2)	190 (62.1)	
Attended any campus events (n=1042)			.004
Yes	282 (37.0)	131 (47.0)	
No	481 (63.0)	148 (53.0)	

[a]PPE: personal protective equipment.

Table 5. Exposure and behaviors by fraternity and sorority life (FSL) affiliation.

Exposure and behaviors	Non-FSL, n (%)	FSL, n (%)	*P* value
Knowledge of exposure (n=1160)			.17
Yes	519 (63.0)	226 (67.3)	
No	305 (37.0)	110 (32.7)	
Used any PPE[a] (n=846)			.61
Yes	573 (94.6)	229 (95.4)	
No	33 (5.4)	11 (4.6)	
Travel within the United States (n=1159)			<.001
Yes	201 (24.3)	41 (12.2)	
No	623 (75.6)	294 (87.8)	
Used local transportation (n=1128)			<.001
Yes	323 (40.2)	79 (24.4)	
No	481 (59.8)	245 (75.6)	
Attended any campus events (n=1042)			<.001
Yes	262 (35.2)	151 (50.7)	
No	482 (64.8)	147 (49.3)	

[a]PPE: personal protective equipment.

Discussion

Principal Findings

The findings from this study contribute to the limited understanding of how COVID-19 uniquely presents itself in a population of university students by describing the case characteristics, risk and protective behaviors, and adherence to preventive strategies among students on a large university campus. Most students in this analysis reported being aware of their exposure and reported that the exposure resulted from a close friend or family member outside of an academic setting. It should be noted that, to date, we have not identified any significant, unexplained classroom transmission, which is suggestive that indoor masking, along with rigorous case investigations, contact tracing, and surveillance testing were successful in preventing widespread transmission within

classrooms. This is an especially important finding as campuses weigh web-based or hybrid learning during future COVID-19 surges. Additionally, athletes reported a higher number of contacts, while on-campus students, along with students affiliated with FSL, reported that they were more likely to attend events, potentially increasing their own exposure risk or exposing others.

Comparison With Prior Work

Our results are consistent with previous research that suggests extracurricular groups and social gatherings such as fraternity and sorority activities can be hot spots for spreading SARS-CoV-2 [7]. These groups are traditionally together a lot, and by nature this could put them at higher risk. We observed FSL affiliates more likely to attend social events, and it is difficult to monitor adherence to public health measures during these events. To help reduce spread among extracurricular group activities, public health campaigns should be designed in concert with and specifically for such groups (ie, athletes and FSL leaders) where gathering or close contact is sometimes necessary during interactions. Additionally, increased testing of specific groups (eg, athletes or FSL members) during periods of high transmission should be implemented to quickly detect a rise in cases and move individuals into isolation or quarantine to mitigate further spread. Public health ambassadors can be deployed to work specifically with these groups to promote risk reduction behaviors, monitor results, and mitigate spread if outbreaks are detected.

It has been suggested that riskier behaviors and certain settings, such as unmasked events or parties and communal living with limited space to social distance, place college campuses at greater risk for outbreaks of COVID-19 and becoming "super spreaders" for neighboring communities [8]. Despite exposure locale, we recognize that college campuses can harbor "super spreader" situations due to college settings encompassing groups of individuals that potentially spend a lot of time together, such as athletes, FSL affiliates, and communal living spaces where transmission can be difficult to contain. Thus, primary prevention efforts during waves of high transmission must be a cornerstone of campus safety to mitigate the spread. This should include the following: strong support and continuous communication for greater adherence to indoor masking in campus buildings; increased ventilation; having proper hand hygiene; carrying out social distancing where possible; eliminating buffets in dining halls; de-densifying campuses and classrooms; and frequent cleaning to further mitigate the spread of the virus within classrooms and academic settings [13,14].

Strengths and Limitations

While this study provides insights into COVID-19 case characteristics on an urban university campus, there are limitations that should be considered before generalizing to other university or college settings. First, there is potential bias from cases self-reporting underlying conditions, behaviors, and perceived symptoms. To mitigate self-reporting bias, we used prompts, listed out and read a list of underlying conditions and symptoms, and provided important dates during the interview for recalling behaviors during the interviewees' infectious period or when symptoms may have started. Second, our survey evolved over the course of the pandemic, and some study questions, such as participation in FSL, were not asked until later versions of the survey. To address FSL affiliation for cases prior to fall 2021, we obtained a roster from our division of student affairs, which may have included some discrepancies of people not continuing in FSL for a whole semester. Third, our study participants may have also experienced recall bias or social desirability bias concerning their behaviors before becoming infected with SARS-CoV-2. To mitigate any potential social desirability bias, we reviewed statements of confidentiality with cases and reminded them throughout the interview that their answers would not impact their standing at the university in any way. Finally, our sample was predominately White and female, which corresponds to the university's demographics of 77.2% White (n=20,849) and 60.7% female (n=16,798). However, we acknowledge that these results are not generalizable to a larger population, and results should be interpreted with caution before generalizing to other populations.

Future Directions

Despite many colleges and universities requiring the COVID-19 vaccine prior to the fall 2021 semester, we must continue primary prevention efforts and testing, accompanied by isolation of cases and quarantine of individuals not up to date with current vaccines, to reduce the spread of variants of concern and subsequent further mutations [15]. The weekly surveillance measures put into place for this study setting were instrumental in maintaining a relatively low daily positivity rate for the university community. During the study period, the daily positivity rate at GWU ranged between 0.00% and 5.45%, whereas the larger Washington, DC daily positivity rate reached 24.6% [16]. As an urban college campus, it is our responsibility to strive to keep our students and the larger community safe and make concerted efforts to mitigate COVID-19 transmission on our campuses [17]. We can continue to provide a traditional college experience, and we can remain in classrooms together, but we must implement masking, testing, and other risk reduction procedures to keep our campuses safe.

Conclusions

Along with its devastating health outcomes, COVID-19 also sparked an *education pandemic* with lockdowns disrupting the lives of children, adolescents, and young adults. While much attention has been placed on K-12 education and SARS-CoV-2 transmission, less is known about the college or university context. Further, as the world continues to experience repeated outbreaks of different COVID-19 variants, it underscores the importance of understanding the behaviors of students on a college campus. COVID-19 cases have not yet become stabilized to a predictable state, but this analysis provides case characteristics and insights for how academic institutions might prepare to mitigate outbreaks on their campuses as the world plans for the transition from pandemic to endemic COVID-19 and having to deal with evolving variants. It is imperative that colleges and universities continue to plan for waves of increased COVID-19 transmission on campuses and have surge capacity in place to maintain a certain level of operational procedures during times of increased transmission. Faculty must be prepared

to adapt instruction to account for themselves or their students potentially missing up to 10 days of classes.

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Data Availability

The data sets generated or analyzed during this study are available from the corresponding author on reasonable request.

Conflicts of Interest

None declared.

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Abbreviations

FSL: fraternity and sorority life
GWU: The George Washington University
PCR: polymerase chain reaction
PPE: personal protective equipment
REDCap: Research Electronic Data Capture

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Original Paper

How Face Masks Affect the Use of Echolocation by Individuals With Visual Impairments During COVID-19: International Cross-sectional Online Survey

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Abstract

Background: Although a critical safety measure, preliminary studies have suggested that the use of a face mask may pose a problem for some users with disabilities. To date, little is known about how the wearing of a traditional face mask may pose a barrier to individuals with visual impairments who draw on auditory cues and echolocation techniques during independent travel.

Objective: The goal of this study was to document the difficulties, if any, encountered during orientation and mobility due to the use of a face mask during the COVID-19 pandemic and the strategies used to address these barriers.

Methods: In total, 135 individuals aged 18 years and older who self-identified as being blind, being deafblind, or having low vision and who could communicate in either English or French completed an anonymous cross-sectional online survey between March 29 and August 23, 2021.

Results: In total, 135 respondents (n=52, 38.5%, men; n=83, 61.5%, women) between the ages of 18 and 79 (mean 48.22, SD 14.48) years participated. Overall, 78 (57.7%) self-identified as blind and 57 (42.3%) as having low vision. In addition, 13 (9.6%) identified as having a combined vision and hearing loss and 3 (2.2%) as deafblind. The most common face coverings used were cloth (n=119, 88.1%) and surgical masks (n=74, 54.8%). Among the barriers raised, participants highlighted that face masks made it more difficult to locate people (n=86, 63.7%), communicate with others (n=101, 74.8%), and locate landmarks (n=82, 60.7%). Although the percentage of those who used a white cane before the pandemic did not substantially change, 6 (14.6%) of the 41 participants who were guide dog users prior to the pandemic reported no longer working with a guide dog at the time of the survey. Moreover, although guide dog users reported the highest level of confidence with independent travel before the pandemic, they indicated the lowest level of confidence a year after the pandemic began.

Conclusions: These results suggest that participants were less able to draw on nonvisual cues during independent travel and social interactions due to the use of a facemask, contributing to a reduction in perceived self-confidence and independence. Findings inform the development of evidence-based recommendations to address identified barriers.

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KEYWORDS

visual impairment; echolocation; COVID-19; orientation and mobility; vision rehabilitation; online survey; rehabilitation; face mask; visual disability; vision disorder; quality of life; health intervention

Introduction

Background

The COVID-19 pandemic has had a significant impact on the lives of individuals worldwide. Measures have been implemented to mitigate the spread of the virus, including physical distancing, the use of face masks, and avoiding all nonessential travel [1]. Though critical, such measures also adversely impact the quality of life and increase social isolation [2]. It is projected that the pandemic will carry negative consequences for the mental and physical health and self-care of individuals, especially for persons with disabilities, including those with visual impairments [3-5]. Many individuals with visual impairments (ie, those who are blind or who have low vision) already experience higher levels of social isolation due to factors such as inaccessible physical environments and the inability to rely on vision during independent travel [6-11]. Vision rehabilitation practitioners are health care professionals who provide training and support for individuals with a congenital or acquired visual impairment. A variety of techniques and strategies are used to regain or maintain independence for activities of daily living, including the use of a white cane for independent travel in indoor and outdoor environments. Although an essential safety measure, initial evidence indicates that the use of a face mask may impair the ability of individuals with visual impairments to use echolocation and other auditory strategies by either muffling self-generated sounds (eg, speech) or obstructing vital environmental cues that reach the ears (eg, the sound of parallel traffic) [12,13]. Despite the urgency of these concerns, there is a lack of research on the effect of face masks on echolocation or on the potential safety implications that may arise during the COVID-19 pandemic. These questions will remain important to facilitate planning for additional waves of the current pandemic and for strengthening strategies to better prepare for future pandemics. This study explored the nature and extent of problems caused by face masks within the visually impaired population and gathered information about the strategies that individuals with visual impairments have used to circumvent these barriers. The findings will be used to develop recommendations for rehabilitation centers and governments on how to effectively assist clients during both current and future pandemics.

The Population: Individuals With Visual Impairments

According to the World Health Organization (WHO), it is estimated that there are 405.5 million individuals with mild-to-severe visual impairments worldwide and 36 million who are blind [14]. The term “visual impairment” includes both low vision and blindness. As the majority of the cortex is devoted to visual perception and processing, vision is the primary sense that is used for performing most daily tasks [11]. Individuals with visual impairment may therefore encounter a variety of obstacles in their daily lives. Vision loss is associated with decreased mobility, thus contributing to higher levels of social isolation and depressive symptoms for those who have not adopted compensatory techniques [6-11,15]. To mitigate these challenges, individuals with visual impairments use a variety of techniques, including the use of a white cane or a guide dog [16].

Echolocation and Auditory Cues as Compensatory Strategies

One of the major challenges faced by individuals with visual impairments relates to orientation and mobility. For individuals with little or no vision, the ability to perceive objects from a distance and to navigate within space depends primarily on auditory and spatial information [17]. It has now been established that the human brain has a remarkable ability to adapt to changes in the environment due to its plasticity. For example, individuals with congenital blindness experience cortical reorganization early in life, which allows them to recruit the unused visual cortex during nonvisual tasks [18-21]. Studies have shown that such cortical plasticity is associated with enhanced auditory spatial abilities and echolocation skills and that this improved performance is experience dependent [14].

In general, echolocation represents the ability for an individual to locate objects and obstacles by interpreting the reflected echoes of sounds that bounce off them. There are two overarching categories of echolocation. On the one hand, active echolocation refers to the self-generation of sounds via tongue clicking, whistling, humming, and talking or externally via finger snapping, the tapping of a white cane, or other noises to gain information on object/obstacle localization through reflected echoes. On the other hand, passive echolocation refers to when individuals use the reflected echoes of sounds that naturally occur and that provide auditory cues and landmarks to help interpret the environment (eg, the sound of parallel traffic, people talking, or sounds that emerge from nearby businesses) [19,20,22,23]. Evidence suggests that passive echolocation is more commonly used than active echolocation because individuals with visual impairments are often reluctant to self-generate sounds due to the stigma associated with these behaviors [24]. Data show that echolocation allows visually impaired individuals to locate objects, differentiate between objects of various sizes and shapes, and in some cases differentiate between objects of various textures [20]. Auditory cues (eg, the sound of others speaking) also provide vital information to help orient individuals to others during social interactions. Although echolocation is generally unconsciously used by individuals with visual impairments, active echolocation techniques must typically be taught [25,26]. For the purposes of this study, echolocation is defined as both the active and the passive use of sounds for travel and social interactions. In addition to the use of sound during independent travel, individuals with visual impairments also draw on other sources of sensory information, including texture, olfactory, and tactile cues and residual vision [12,16,27].

Face Masks and COVID-19

COVID-19 is transmitted through respiratory droplets or through the mouth, nose, or eyes after direct contact with a contaminated surface [1,3]. Recent studies indicate that individuals with a visual impairment are more susceptible to COVID-19 due, in part, to the fact that they may rely on assistance of others for certain tasks and may be less able to easily avoid others in public in order to maintain physical distancing [4,5,26]. Initial reports suggest that face masks introduce new barriers for individuals with a visual impairment who use echolocation during independent travel to detect obstacles and to navigate more easily [14]. From a social interaction perspective, it is unknown whether the use of face masks may impair the ability of blind individuals to use auditory cues to determine where others are located, which may further increase anxiety when navigating in public during the pandemic and increase social isolation. Though not focusing on face masks, prior studies have demonstrated that difficulties due to audition (eg, loud environments) can be cognitively demanding and stressful to visually impaired individuals (and even more so for those with dual sensory impairments) who may not be aware of when they are being spoken to or who may be less able to rely on visual cues during social interactions [28]. Though anecdotal, it has also been suggested that the use of face masks may pose unique communication challenges for guide dog users by muffling the vocalization of handlers when commands are being communicated [29,30]. Although guide dogs are not trained to rely on facial expressions and instead rely on a combination of verbal and physical commands [31,32], it is known that dogs read subtle muscle changes that indicate a twitch or a smile, which may facilitate communication [29,33]. The inability to use echolocation is especially concerning, as individuals with visual impairments are less able to rely on alternative options, such as the use of sighted guides and volunteers during the pandemic, due to physical distancing measures [3,5,26,34,35]. There is thus an urgent need for research that explores the potential impact of face masks on both independent travel and social interaction in order to guide rehabilitation practitioners and others on how to best advice and support individuals with visual impairments during this time.

Objectives and Research Questions

Although a critical safety measure, recent studies have explored how the use of traditionally designed face masks may pose unique challenges to other disability groups. Most notably, face masks prevent individuals with hearing impairments from relying on lip- and speech-reading techniques, leading to the development of clear face masks as more effective alternatives [36-38]. Although concerns have been raised about the use of face masks among individuals with visual impairments [12,13], there is no prior research that gathers evidence on the nature and extent of this issue or the possible solutions that exist. The objectives of this study were therefore to:

- Explore the nature and extent of problems caused by face masks among individuals with a visual impairment.
- Determine whether demographic variables (eg, level of vision, age of onset, visual diagnosis, mobility aids used, and age) are characteristics of participants who experience these problems.
- Understand the strategies that individuals have used to overcome these barriers.

Methods

Ethical Considerations

Ethical approval was obtained from the Institutional Review Board of the Université de Montréal in March 2021 (CERC-21-019-D).

Participants

Eligibility Criteria

To take part in this study, participants had to be at least 18 years of age; self-identify as an individual who is blind, is deafblind, or has low vision; and be able to communicate in English or French (one of the survey language options). Given that the use of face masks may pose barriers to individuals regardless of where they reside and that data were gathered through an online survey, no restriction based on geographic location was imposed.

Sample Size

Given the lack of prior research in this domain, this study was exploratory in nature. Therefore, no traditional power analysis was conducted during the proposal stage. Based on a previous international online survey geared toward individuals who are blind, are deafblind, or have low vision, conducted by members of this research team [39], a sample size of more than 150 was estimated. Though obtaining a sufficient sample size is often difficult in blindness research due to the low incidence of visual impairment [40], members of the research team have drawn on an extensive list of social media platforms to assist with recruitment, which has resulted in sample sizes of more than 400 in similar research based on a survey instrument [39]. Additionally, experts with visual impairments served as core members of the research team to guide research design, ensure greater accessibility and inclusion, and facilitate recruitment.

Recruitment

Recruitment was carried out using 3 main approaches: social media announcements and outreach to blindness consumer groups, collaboration through vision rehabilitation centers, and snowball sampling [41]. Participants were primarily invited through announcements on social media platforms geared toward individuals who are blind, have low vision, or are deafblind (Facebook, Twitter, and email groups). A list of over 150 social media groups was compiled by the research team to assist with recruitment. Where moderator approval was required before posting to a specific social media group, this permission was requested in advance.

In addition, the study was promoted through different media outreach activities, including interviews on blindness media platforms [42,43]. Finally, snowball sampling (whereby participants were asked to refer anyone else they know who may be interested) provided additional reach beyond these initial contacts [44].

Materials and Procedure

Data were gathered through an anonymous, online, voluntary survey that required an average of 36 minutes (SD 29.75) to complete. It contained 35-58 questions in total, depending on participant responses, because certain questions were conditional on the participant's response. Although the options to allow participants to go back or perform a completeness check before submitting their answers were not available, the survey was built in a way that participants could not go to the next question without completing the previous one. It was first piloted by 2 users (1 blind and 1 with low vision) to ensure accessibility. The survey was available between March 29 and August 23, 2021. Participants provided informed consent in accordance with the Declaration of Helsinki and Public Health by selecting the "I agree" button to proceed with the survey [45].

We did not report unique visitors' information. The survey was anonymized, and as such we did not track IP addresses, nor were cookies or other mechanisms used to block repeated submissions from a single IP address, computer, or web browser. There was a risk that either mechanism might block legitimate users from accessing the survey (eg, multiple respondents from a single rehabilitation center). Moreover, we do not have information about the unique survey visitors versus unique site visitors because the survey was advertised through a wide range of platforms (and via email links); therefore, they did not all arrive at the survey from a single site that could be tracked directly. However, our participation rate for the survey (visitors who agreed to participate/unique first survey page visitors) was 9%. Our completion rate for the survey (users who finished the survey/who agreed to participate) was 49.1%.

Survey Instrument

The survey was developed and executed using the LimeSurvey software package and hosted on servers provided by the Université de Montréal. This platform was chosen because it is known to be accessible to users who are blind or have low vision and enables the collection of data through a secured, encrypted internet channel. The survey was available in both English and French, and responses were collected through a combination of closed- and open-ended questions. At the start of the survey, participants were asked to answer questions about their age and level of vision to ensure that they met the eligibility criteria, prior to moving on to subsequent sections.

Section 1 of the survey (14-20 questions) gathered demographic information from participants, including information about the level and nature of visual impairment and living arrangements both before and since the pandemic began. Section 2 (9-15 questions) gathered information about the orientation and mobility history and behaviors of participants, including mobility aids used (eg, guide dog, white cane), their level of confidence with independent travel both before and after the pandemic began, and echolocation techniques used by participants while traveling. Section 3 (7-13 questions) gathered information about the barriers encountered due to the use of a face mask, including barriers related to independent travel (the ability to use auditory and other nonvisual cues in the environment) and those related to social interaction (the ability to communicate with others and maintain physical distancing). Section 4 (2-7 questions) asked participants what strategies they have used to address these barriers, if any. The final section provided participants with the option to indicate whether they wished to receive a summary of the results, participate in a draw, or provide any final comments about their experiences while using a face mask. Participants had the option at the end of the survey to include their name in a draw for the chance to win a CA $100 (US $72.71) Amazon gift card and to request an email summary of the results once the study is complete, but in such cases, contact information was separated from survey responses (see Multimedia Appendix 1 for the full survey instrument).

Data Analysis

The aim of this study was to explore the barriers encountered due to the use of a face mask among individuals with visual impairments and the strategies used to address identified barriers. For these reasons, descriptive statistical analysis for quantitative data was primarily used. Mixed within-between analyses of variance were performed to test the existence of a statistically significant difference before and after the onset of the pandemic, as well as between participant groups based on demographic variables. Only completed surveys were analyzed.

Results

Demographics

Table 1 summarizes the demographic characteristics of the 135 participants in the study, who were between the ages of 18 and 79 (mean 48.22, SD 14.47) years. Age of onset for visual impairment ranged from birth to 59 years of age (mean 9.45, SD 14.24). Figure 1 shows the number of participants who reported the most common diagnoses. Of the 16 (11.9%) participants who reported a hearing impairment, age of onset of hearing impairment ranged from birth to 66 years of age (mean 31.04, SD 25.89).

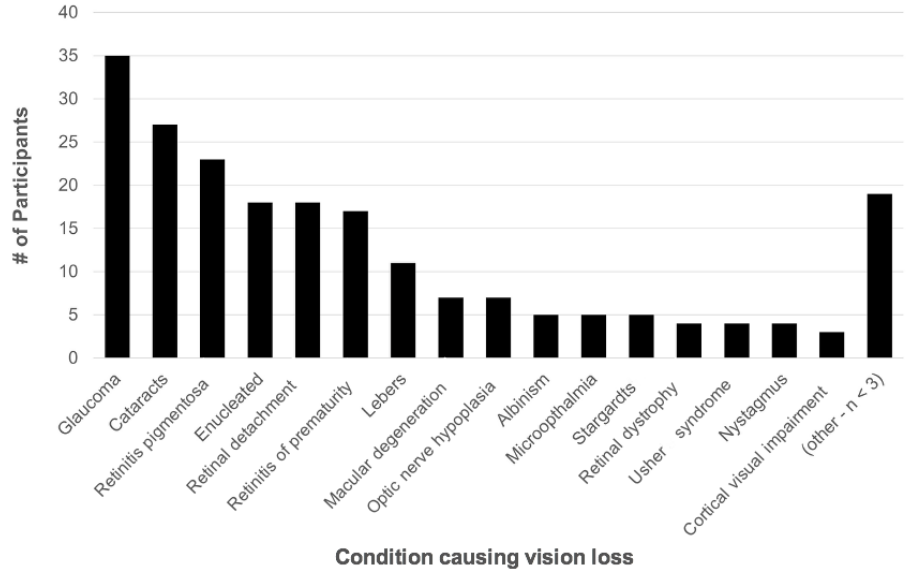
Table 1. Demographic characteristics of participants (N=135).

Characteristics	Participants, n (%)
Sex	
Female	83 (61.5)
Male	52 (38.5)
Gender	
Female	86 (63.7)
Male	48 (35.6)
Nonbinary	1 (0.7)
Level of vision impairment[a]	
Blind	78 (57.8)
Low vision	57 (42.2)
Level of hearing impairment[a]	
Hard of hearing	13 (9.6)
Deaf	3 (2.2)
Country of residence	
Canada	85 (63.0)
United States	32 (23.7)
France	11 (8.1)
England	2 (1.5)
Morocco	1 (0.7)
Italy	1 (0.7)
Australia	1 (0.7)
Sri Lanka	1 (0.7)
Tunisia	1 (0.7)
Highest completed level of education	
Some high school	6 (4.4)
High school diploma	14 (10.4)
Vocational/professional education	6 (4.4)
Community college or Collège d'enseignement général et professionnel diploma	31 (23.0)
Undergraduate degree (eg, bachelor's)	42 (31.1)
Graduate degree (eg, master's or PhD)	36 (26.7)
Employment status	
Self-employed	10 (7.4)
Full-time employee	42 (31.1)
Part-time employee	13 (9.6)
Student	15 (11.1)
Retired	29 (21.5)
Unemployed	26 (19.3)
Face coverings used[b]	
Cloth masks	119 (88.1)
Surgical masks	74 (54.8)
N95 respirators	21 (15.6)

Characteristics	Participants, n (%)
Face shields	11 (8.1)
Glasses	6 (4.4)

[a]Some participants may have reported both vision and hearing losses; these 2 categories are not mutually exclusive.
[b]Participants could mark all that apply for face coverings used.

Figure 1. Number of participants reporting each of the most common medical diagnoses. N>135 as many participants reported having multiple diagnoses.



Orientation and Mobility

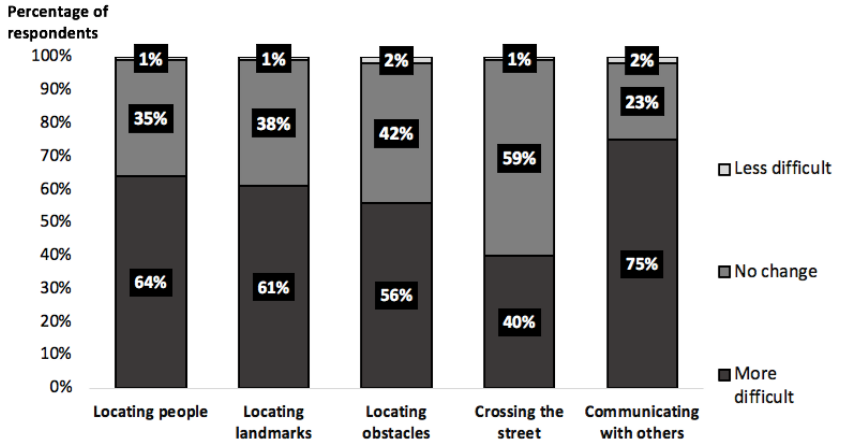
Table 2 summarizes the travel techniques used by the participants in the study. Findings indicate that 85 (63%) participants used a white cane pre–COVID-19 compared to 84 (62.21%) participants who reported still using a white cane post–COVID-19. Conversely, 41 (30.4%) participants identified as guide dog users pre–COVID-19 compared with only 35 (25.9%) who reported working with a guide dog after the pandemic began. The majority of participants found that common orientation and mobility tasks, such as locating people and landmarks, were made more difficult by the use of face masks (see Figure 2).

Table 2. Travel techniques and tools used for orientation and mobility, and navigation (N=135).

Technique	Participants, n (%)[a]
Passive echolocation	
In outdoor environments	109 (80.7)
In indoor environments	100 (74.1)
Active echolocation	
Cane tapping	66 (48.9)
Finger snapping	18 (13.3)
Tongue clicking	17 (12.6)
Tactile feedback (from white cane or feet)	105 (77.8)
Olfactory cues	91 (67.4)
Estimation of distance	84 (62.2)
Residual vision	66 (48.9)

[a]The 135 participants may have selected more than 1 travel technique.

Figure 2. Selected orientation and mobility tasks and the change in difficulty experienced by travelers on account of the use of a face mask.



Impact on Travel Frequency and Confidence

The frequency at which participants traveled independently significantly decreased between the period before and after the pandemic began (see Figure 3). A repeated-measures analysis of covariance revealed that there was a statistically significant difference in the frequency of travel before versus after the pandemic began ($F_{1,128}$=6.51, P=.012, η^2=0.014) but not when controlling for age ($F_{1,128}$=0.192, P=.66).

The confidence with which participants traveled independently (measured on a scale wherein 1=not confident at all, 2=somewhat confident, 3=confident, and 4=very confident) also decreased between the period before and after the pandemic began (see Figure 4). A repeated-measures analysis revealed that there was a statistically significant difference in the frequency of travel before versus after the pandemic ($F_{1,133}$=24.09, P<.001, η^2=0.051) but not when controlling for age ($F_{1,133}$=0.930, P=.34). The most common explanations given by those who indicated that they were “not confident’ or were only “somewhat confident” included difficulty communicating with other people (n=86, 63.7%); barriers to using sighted guide assistance, when required, due to physical distancing requirements (n=58, 43%); impairment of the ability to detect landmarks, such as bus shelters or intersecting hallways (n=57, 42.2%); impairment of the ability to hear ambient noises in the environment (n=55, 40.7%); and interference with the use of active echolocation techniques, such as tongue clicking (n=28, 20.7%).

The level of confidence of participants who were deafblind (compared to those who were blind or who had low vision) was particularly negatively impacted (see Figure 5). A repeated-measures analysis of variance showed that mean confidence differed significantly between time points for all groups ($F_{1,132}$=133.02, P<.001, η^2=0.229), with those who self-identified as deafblind experiencing a significantly greater loss of confidence in comparison with participants who had low vision and were blind.

Likewise, the level of confidence of guide dog users was especially negatively impacted compared to the level of confidence of those using a cane or no mobility aids (Figure 6). A repeated-measures analysis of variance showed that mean confidence differed significantly between time points for all groups ($F_{1,132}$=179.77, P<.001, η^2=0.275), with guide dog users exhibiting a significantly greater loss of confidence in comparison with cane users and those who did not use a mobility aid.

Figure 3. Frequency of travel prior to versus during the COVID-19 pandemic.

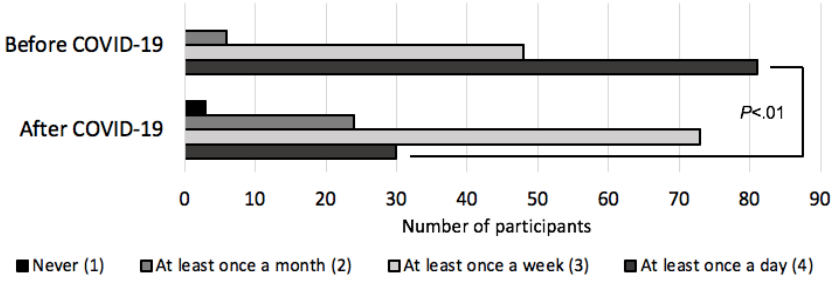


Figure 4. Degree of confidence in independent travel prior to versus during the COVID-19 pandemic.

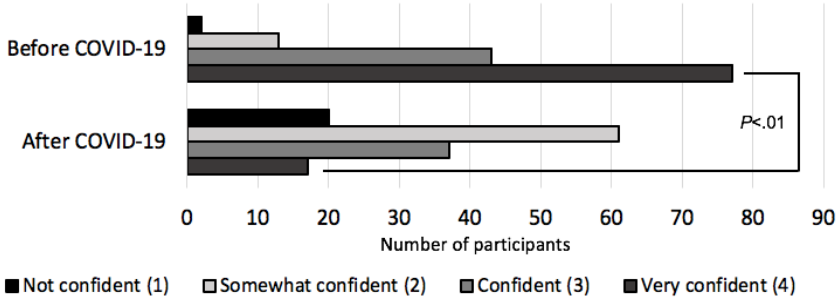


Figure 5. Level of confidence pre- and post–COVID-19 by level of vision loss. Confidence was measured on a scale wherein 1=not confident at all, 2=somewhat confident, 3=confident, and 4=very confident.

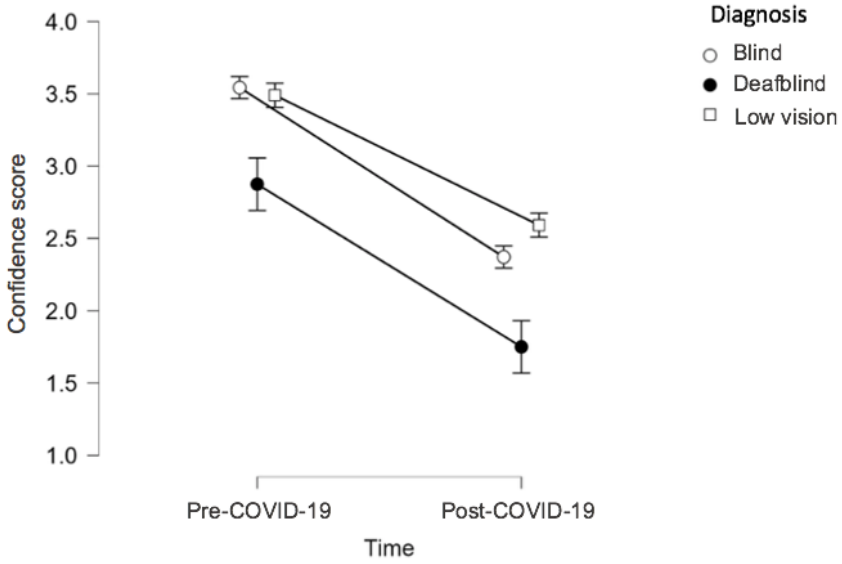
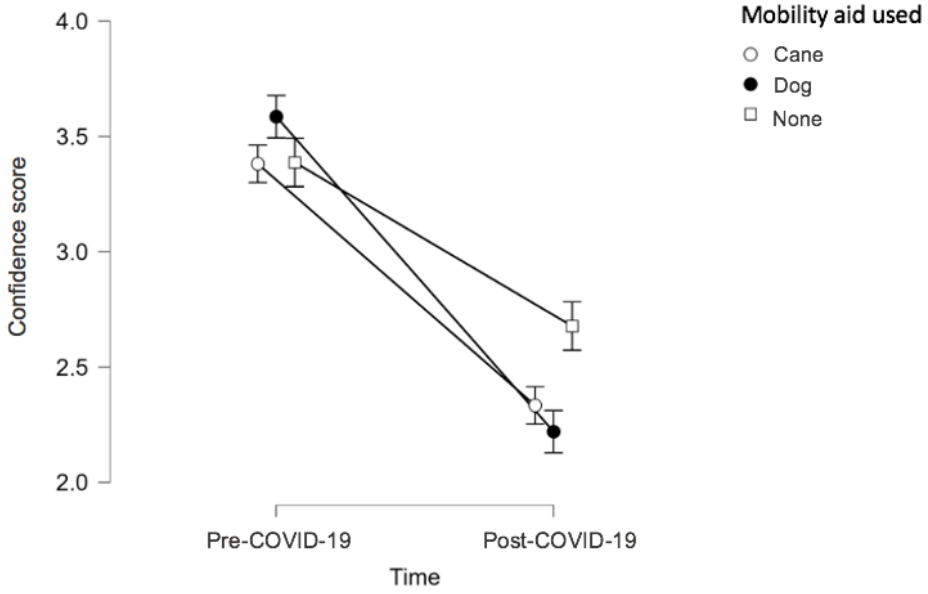


Figure 6. Level of confidence pre- and post–COVID-19 by mobility aid. Confidence was measured on a scale wherein 1=not confident at all, 2=somewhat confident, 3=confident, and 4=very confident.



Strategies for Overcoming Barriers

Table 3 outlines the different strategies that participants have used to overcome the barriers posed by the use of face masks. The results show that most of the strategies used were the use of other senses, delivery services, and sighted guides (where a person with a visual impairment holds the arm of a sighted guide while walking through a physical environment). In addition, few people asked for help from rehabilitation centers (n=7, 5.2%). However, a recurring theme in the comments from participants was that it was more difficult to get sighted guide

assistance since the beginning of the pandemic, as expressed by these quotes:

While traveling independently has been made more difficult, getting assistances has also diminished. People are hesitant to touch or be close.

Before the pandemic people were more agreeable to providing human guide assistance.

Table 3. Number of participants identifying various barriers to travel while wearing a face mask, and the strategies used to overcome the identified barriers (N=135)[a].

Barriers	Other senses, n (%)	Delivery services, n (%)	Sighted guide, n (%)	Phone app, n (%)	Rehabilitation services, n (%)	Nothing, n (%)
Communicate with others (n=17)	7 (41.2)	5 (29.4)	5 (29.4)	3 (17.6)	0	5 (29.4)
Locate people around (n=87)	40 (46.0)	31 (35.6)	38 (43.7)	8 (9.2)	1 (1.1)	26 (29.9)
Locate landmarks (n=82)	43 (52.4)	38 (46.3)	48 (58.5)	15 (18.3)	7 (8.5)	16 (19.5)
Locate obstacles (n=76)	44 (57.9)	30 (39.5)	42 (55.3)	12 (15.8)	4 (5.3)	16 (21.1)
Crossing streets (n=55)	27 (49.1)	26 (47.3)	32 (58.2)	9 (16.4)	6 (10.9)	12 (21.8)

[a]The counts and percentages in each row add up to more than the number of respondents who identified a particular barrier, as respondents used more than 1 strategy to overcome said barrier.

Discussion

Principal Findings

The aim of this study was to explore the challenges caused by the use of traditional face masks for individuals with visual impairments and to determine the strategies used to overcome these barriers. Overall, findings confirm that individuals with visual impairments continue to experience a variety of barriers related to orientation and mobility during the pandemic and that this is especially true for those with lower levels of vision and those who use a guide dog. The results also highlight a significant decrease in confidence and in the frequency of travel that has persisted since the pandemic began, raising concerns about the ability of individuals with visual impairments to access services and maintain social participation as the pandemic persists. Although participants highlight the use of sighted guide as a strategy to overcome barriers during independent travel, access to sighted support is limited due to physical distancing measures. Moreover, although the majority of participants rely on online and delivery services in place of independent travel, the accessibility of these online services remains a persistent barrier despite the existence of international web accessibility standards. Despite these challenges, most participants have not sought support from existing rehabilitation services.

Problems Caused by Face Masks

Although no significant decrease in white-cane usage was reported after the pandemic began, 6 of the 41 guide dog users reported no longer using a guide dog now. In some instances, this decrease may be due to the natural retirement of service dogs due to advancing age or other circumstances not directly related to the pandemic, such as behavioral or health issues [46]. However, evidence also indicates that border closures during the pandemic have significantly impeded the ability of guide dog handlers to receive support when issues arise with guide dog usage and have prevented those who require successor dogs from pursuing training [47,48]. To address these persisting barriers, several dog guide–training organizations have implemented virtual services to provide training support from a distance, where feasible, or are in the process of hiring staff who live closer to geographic areas with a high density of guide dog users [49]. Despite these measures, guide dog organizations report a notable decrease in the number of service teams they have been able to serve during the pandemic and mounting wait lists that will require several years to resolve [46,49]. Moreover, border closures have led to an increase in requests for domestic guide dog training and support. The Canadian National Institute for the Blind Foundation, which serves individuals within Canada, for instance, recently noted that demand for services has increased by at least 300% during the pandemic [34]. Although there is no clear guideline to address such service disruptions, advocates continue to highlight the need for governments to recognize dog guide training as an essential service during current and future pandemics.

The inability to access support explains, in part, the significant decrease in confidence experienced by guide dog users. These issues are compounded by the inability of guide dog handlers to regularly work their dogs during lockdowns and other isolation measures, as routine reinforcement in training is essential to maintain guide work skills, particularly for dogs that are younger and more recently attributed [50,51]. These findings highlight the need for orientation and mobility specialists and guide dog–training programs to proactively collaborate to ensure that clients who use guide dogs can access emergency support during times of a pandemic and international crises. In particular, evidence of best practices for virtual service delivery and methods for coordinating with local rehabilitation centers, where feasible, will be important to address. To this end, a number of dog guide organizations have developed online tools to educate members of the public on how to assist guide dog users during the pandemic while maintaining physical distancing [52]. In addition to this vital information, there is a need for an increased number of guide dog service providers as well [46,53,54].

Participants indicated that the wearing of a traditional face mask impeded the ability to locate others in the environment, locate landmarks, and communicate with others. Although the wearing

of a face mask appears to interfere with the use of echolocation, participants also highlight that the ability to draw on other senses, including olfactory cues from the environment, is diminished. The results also demonstrate that there has been a significant decrease in the frequency and level of confidence during independent travel before and after the beginning of the pandemic. These findings highlight the need to reinforce and improve universal accessibility measures within physical environments, particularly as individuals may be limited even further in their ability to draw on nonvisual senses and may need to rely even more heavily on environmental cues, such as tactile floor indicators, braille and large-print signage, and audible pedestrian signals [55]. Although many countries, including Canada [56] and the United States [57], maintain legislation that requires that public places incorporate universal design principles, it is evident that such accessibility measures are not consistently integrated into all spaces. The findings of this research are particularly noteworthy in Canada, where the newly implemented Accessible Canada Act aims to address existing gaps within accessibility and inclusion at the federal level [58].

Impact of Demographic Variables

Results show that although guide dog users were the most confident while traveling alone prior to the pandemic, they were the least confident after the pandemic began. Prospective guide dog users must typically demonstrate existing orientation and mobility skills in order to qualify for a guide dog, which may explain why this group exhibited the highest level of confidence prior to the pandemic when compared to other mobility aid users [59]. This is due, in part, to the fact that dog guides are trained to navigate around obstacles, but it is the responsibility of the handler to maintain a mental map of where they wish to go and to communicate those instructions to their dog [60]. However, physical distancing measures introduced with the pandemic may be especially challenging for this population, given that dog guides are not typically trained to maintain physical distancing while in public places [61]. This further highlights the need for those around guide dog users to maintain physical distancing and to recognize these challenges when providing assistance.

In addition, Figure 5 indicates to which extent participants with lower levels of vision, including those with dual sensory impairments, reported experiencing the most significant decrease in the level of confidence since the pandemic began. This finding might be due to the fact that these participants have less vision to rely on, which increases challenges if the use of echolocation and other auditory cues is limited. This is especially noteworthy, given that there is a growing prevalence of individuals with age-related dual sensory impairment due to a rapidly aging population in developed countries [62]. Governments, including rehabilitation agencies and allied services, should ensure that there are virtual opportunities to maintain social participation and access essential services, especially since many individuals with dual sensory loss are also in older age groups that already experience higher levels of isolation [63]. In response, some rehabilitation centers have implemented virtual peer support groups and social activities where individuals can socialize and receive support [64-67]. Although such measures are no doubt crucial during the pandemic, the enhancement of telehealth and rehabilitation services provide new opportunities to more effectively address the needs of individuals who live outside urban areas, including indigenous communities that often remain underserved and isolated. It will be important to consider the long-term maintenance of such new measures even after the pandemic subsides.

Strategies That Individuals Have Used to Overcome the Barriers Raised

The most common strategies used to circumvent identified barriers included the use of a sighted guide, the use of other senses, and the use of online delivery services. However, participants reported the limited availability of sighted assistance during the pandemic due to physical distancing measures. Moreover, many online delivery services remain either partially or wholly inaccessible to users with visual impairments who access content through electronic braille, auditory, or magnification software [68,69]. Screen-reading software is one of the most common assistive technologies used by individuals with visual impairments to access information [69]. Although international standards for web accessibility exist [70], the accessibility of websites and apps remains a pervasive problem, limiting usability for individuals with diverse needs. For example, many platforms incorporate images and other graphical content that cannot be interpreted by screen-reading software, without the inclusion of alternative captioned text to make this content accessible to users without sight. When such inaccessible features are embedded within online delivery services (eg, online restaurant menus), such services are inherently unusable to individuals with visual impairments [71,72]. Ensuring that such universal design standards are proactively incorporated and maintained across all online services is especially vital during times of international crises and pandemics, when individuals may have even less access to services to address their basic safety needs. Indeed, the International Council on English Braille recently called upon governments and organizations to ensure the accessibility of information, pointing not only to access to services but also to information about rising infection rates and safety measures [73]. The findings of this study also indicate that only a minority of participants (5%) turned to vision rehabilitation services for assistance, perhaps suggesting that individuals are unaware of how such agencies can provide support. Although not a replacement for mainstream accessibility and inclusion measures, for example, some organizations provide services to assist individuals with daily tasks, ranging from grocery shopping to reading mail. This study further underscores the need for vision rehabilitation centers to go beyond the services they can provide and to develop public education resources to train mainstream service providers (health care providers, store clerks, etc) on how to effectively guide and assist individuals with visual impairments while maintaining physical distancing measures. As evidenced by some efforts in this domain, such training could incorporate strategies for providing effective verbal information and the use of modified sighted guide techniques [52,74,75].

Limitations

Although this is among the first studies to explore the impact of traditional face masks on orientation and mobility during COVID-19 among individuals with visual impairments, a number of limitations should be noted. First, language could have had an impact on the number of participants as the survey and the media announcements were only available in French or English. Second, data collection primarily consisted of announcements circulated through online social media platforms and email mailing lists. It is therefore possible that this may have limited participation from those within the blind and low-vision community who do not have access to technology or who lack the technical competence to complete an online survey. However, to circumvent these concerns, participants had the option to request assistance by phone, and efforts were made to advertise the survey to diverse groups within the population, including consumer groups geared toward older adults with acquired vision loss, and through more traditional methods, such as radio and TV announcements. In addition, given the descriptive nature of the study, we did not calculate a power analysis in order to determine an optimal sample size. Instead, we followed the recruitment approach of a previous study [39], where we obtained an impressive sample of 466 participants with visual impairments. Although we did not recruit as many participants as in the previous study, we were content with a sample of 135 participants.

Implications for Practice

These results contribute to the development of recommendations on how to address identified barriers. These recommendations include the accessibility of online and remote services (a health equity issue) by reviewing websites to ensure they comply with provincial and federal accessibility legislation and international web accessibility standards [55,70,76]. This includes the need to ensure that accessible information about the pandemic (including infection rates and safety measures) is available to those within the community who are most vulnerable, including people with disabilities [73]. Training for sighted guide and service providers on human guide techniques that respect physical distancing measures must be expanded [77]. Research and practice initiatives are needed that more closely explore the feasibility of where and when to provide remote assistance for rehabilitation and orientation and mobility services [64,67]. Finally, it is critical to reconsider designing guide dog–training services to better support and address user needs during times of international crises, including the feasibility of remote assistance, strategies for maintaining physical distancing when using a guide dog, and methods for educating the public on how to interact with guide dog users during COVID-19.

Conclusion

The pandemic has introduced new problems for all individuals but poses even greater issues for equity-seeking groups who already encounter barriers within society. For persons with visual impairments (including those who are deafblind), navigating through physical environments may be impeded by various accessibility challenges (eg, inaccessible environments). During the pandemic, the use of a traditional face mask may pose new problems, including the inability to rely on echolocation techniques and external auditory cues from the environment. For those with little or no sight, and for those who use guide dogs, such challenges may pose significant safety concerns and lower the level of confidence during independent travel. Despite the barriers raised, no existing research has explored the impact of traditional face masks on mobility among individuals with visual impairments during the COVID-19 pandemic. This study highlights the extent of the difficulties that individuals with vision impairment have continued to face during the pandemic and stresses the importance of implementing solutions to better circumvent identified barriers. Although the wearing of face masks is essential to prevent the transmission of COVID-19, it is evident from these findings that a number of strategies can address the difficulties encountered by users with visual impairments. Ensuring the accessibility of online services, expanding access to remote and virtual support, and educating members of the public will address many of the barriers raised to improve the lived experiences of individuals both during and after the current pandemic.

Acknowledgments

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Data Availability

The anonymized data set as well as its corresponding data labels and questionnaire items are available through the Open Science Framework.

Conflicts of Interest

None declared.

Multimedia Appendix 1
Survey instrument.
[DOCX File , 43 KB - ijmr_v11i2e39366_app1.docx]

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Original Paper

Frailty, Comorbidity, and Associations With In-Hospital Mortality in Older COVID-19 Patients: Exploratory Study of Administrative Data

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Abstract

Background: Older adults have worse outcomes following hospitalization with COVID-19, but within this group there is substantial variation. Although frailty and comorbidity are key determinants of mortality, it is less clear which specific manifestations of frailty and comorbidity are associated with the worst outcomes.

Objective: We aimed to identify the key comorbidities and domains of frailty that were associated with in-hospital mortality in older patients with COVID-19 using models developed for machine learning algorithms.

Methods: This was a retrospective study that used the Hospital Episode Statistics administrative data set from March 1, 2020, to February 28, 2021, for hospitalized patients in England aged 65 years or older. The data set was split into separate training (70%), test (15%), and validation (15%) data sets during model development. Global frailty was assessed using the Hospital Frailty Risk Score (HFRS) and specific domains of frailty were identified using the Global Frailty Scale (GFS). Comorbidity was assessed using the Charlson Comorbidity Index (CCI). Additional features employed in the random forest algorithms included age, sex, deprivation, ethnicity, discharge month and year, geographical region, hospital trust, disease severity, and International Statistical Classification of Disease, 10th Edition codes recorded during the admission. Features were selected, preprocessed, and input into a series of random forest classification algorithms developed to identify factors strongly associated with in-hospital mortality. Two models were developed; the first model included the demographic, hospital-related, and disease-related items described above, as well as individual GFS domains and CCI items. The second model was similar to the first but replaced the GFS domains and CCI items with the HFRS as a global measure of frailty. Model performance was assessed using the area under the receiver operating characteristic (AUROC) curve and measures of model accuracy.

Results: In total, 215,831 patients were included. The model using the individual GFS domains and CCI items had an AUROC curve for in-hospital mortality of 90% and a predictive accuracy of 83%. The model using the HFRS had similar performance

(AUROC curve 90%, predictive accuracy 82%). The most important frailty items in the GFS were dementia/delirium, falls/fractures, and pressure ulcers/weight loss. The most important comorbidity items in the CCI were cancer, heart failure, and renal disease.

Conclusions: The physical manifestations of frailty and comorbidity, particularly a history of cognitive impairment and falls, may be useful in identification of patients who need additional support during hospitalization with COVID-19.

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KEYWORDS

COVID-19; coronavirus; SARS-CoV-2; frailty; comorbidity; mortality; death; hospitalization; hospital admission; hospitalisation; patient; age; sex; ethnicity; disease; hospital; cancer; heart; heart failure; weight loss; weight; renal disease; support; geriatric; older adult; elder; descriptive statistics; machine learning; model

Introduction

Various studies have been conducted to look at the factors that contribute the most to poorer outcomes for people with COVID-19. In both community-based and hospital-based studies, age has consistently been found to be the strongest predictor of mortality in people with COVID-19 [1]. However, distinguishing between the effects of chronological age and the effects of age-related changes in health status linked to frailty and comorbidities could improve patient-centered care and health care resource allocation [2-5].

Many previous studies of frailty in COVID-19 have used the Clinical Frailty Scale (CFS) to assess frailty status [6-11]. CFS-assessed frailty has been found to be consistently associated with mortality risk in COVID-19 patients [12]. However, as a clinical tool, the CFS score is usually not recorded in large databases, and these studies tend to be of relatively small cohorts. A recent systematic review of studies using the CFS identified a strong link between frailty and mortality but noted that most studies were at high risk of bias and suggested that further studies were warranted [13]. Larger studies have been conducted, but have often focused on specific cohorts of patients, such as those in critical care [14,15].

A number of tools have been developed to identify frailty and comorbidity from large administrative databases, including some developed using artificial intelligence algorithms [16,17]. A recent review [12] identified 5 such tools, including the electronic Frailty Index [18] (for use in primary care), the Hospital Frailty Risk Score (HFRS) [19], the Global Frailty Scale (GFS) [20], and the Charlson Comorbidity Index (CCI) [21]. Such tools rely on coded diagnostic data and may help provide insights beyond those that can be obtained from smaller clinical studies of COVID-19 patients.

The aim of this study was to assess the potential of an administrative database of patients aged 65 years or older to explore the relationship between frailty and comorbidities (defined using coded diagnostic data) and COVID-19 in-hospital mortality. We used machine learning algorithms to analyze the data. Machine learning offers a flexible approach to exploratory analysis, as it makes no a priori assumptions about the hierarchy of variables or their relationships. This allowed us to assess the relative importance of the various frailty and comorbidity features in relation to in-hospital mortality. It is particularly important to be able to identify the relative importance of these frailty and comorbidity features, which are typically long-term in nature, relative to admission-specific items.

Methods

Ethical Considerations

Ethical approval was not sought for the present study because it did not directly involve human participants. Consent from individuals involved in this study was not required for this analysis of the Hospital Episodes Statistics (HES) administrative data set. Guidance from National Health Service (NHS) Digital for the use and reporting of HES data for research purposes was followed, with anonymization to the level required by the ISB1523 Anonymisation Standard for Publishing Health and Social Care Data [22]. This study was completed in accordance with the Helsinki Declaration as revised in 2013.

Study Design and Data Collection

This was a retrospective, exploratory analysis of HES data. HES data are collected by NHS Digital for all NHS-funded patients admitted to hospitals in England. Data are entered by trained clinical coders in each hospital trust; data collection and reporting are mandatory. The data collected include demographics, the nature and timing of admission and discharge, diagnoses, and procedures undertaken.

Timing, Case Ascertainment, and Inclusion and Exclusion Criteria

We reviewed HES data for all completed episodes of hospital care in England with a discharge date from March 1, 2020, to February 28, 2021, that involved a diagnosis of COVID-19. We only considered completed episodes of care in which the patient had been discharged and their outcome (died or survived) was known. Patients aged <65 years were excluded. Cases of COVID-19 were identified using the International Statistical Classification of Disease, 10th Edition (ICD-10) codes (2019 version) U07.1 (ie, presence of COVID-19 has been confirmed by laboratory testing) and U07.2 (ie, clinical or epidemiological diagnosis of COVID-19 where laboratory confirmation is inconclusive or not available). The diagnoses were made either on admission or during the stay and could be primary or secondary. These 2 codes were created by the World Health Organization to code COVID-19 data [23].

Where a patient had multiple admissions during the study period, only the chronologically last admission was retained. This ensured that all admissions were independent of one another at

a patient level and avoided biasing the data by including cases where the outcome was predefined by virtue of a subsequent admission.

Outcomes

The outcome of interest was in-hospital mortality, as recorded by the Office for National Statistics. All data were available to us though NHS Digital and linked at a patient level using a pseudonymized patient identifier. An in-hospital death was recorded if the date of death was the same as or within 1 day of the hospital discharge date. Data on length of stay were also extracted and used to compare the relationship between these 2 patient outcomes.

Features

Frailty/Comorbidity Features

The HFRS was categorized as none, mild, moderate, or severe for the descriptive analysis and as a continuous score in the machine learning algorithm [19]. The HFRS is calculated from 109 ICD-10–coded diagnoses during the index admission of any admission in the previous 2 years to give a weighted score. The HFRS gives a global assessment of frailty status and cannot be broken down into individual domains. It has been validated for use in a number of settings. [19,24-26]

The GFS defines 7 domains of frailty (dementia and delirium; mobility problems; falls and fractures; pressure ulcers and weight loss; incontinence; and anxiety and depression) based on ICD-10 codes for hospital admissions during the previous year [20]. The GFS is closely aligned with the key clinical subdomains of frailty and considers the impact of manifestations of frailty on functional ability. It was developed by considering the relationship between the frailty domains and long hospital stays, 30-day nonelective readmission, and in-hospital mortality. It has not been validated outside of the original development study. The domain of dependency/care was not used, as an exploratory analysis suggested that the 2 ICD-10 codes used to define it (Z74 and Z75) were used in HES to identify patients who had survived to discharge but could not be discharged due to an unmet social care need.

The CCI identifies 14 specific medical conditions identified as secondary diagnoses in the index admission and primary or secondary diagnoses in any admission during the previous year. The conditions are peripheral vascular disease, congestive heart failure, acute myocardial infarction, cerebrovascular disease, dementia, chronic pulmonary disease, connective tissue disease/rheumatic disease, peptic ulcer, liver disease (mild and moderate/severe), diabetes (with and without chronic complications), paraplegia/hemiplegia, renal disease, cancer (primary and metastatic), and HIV/AIDS [21]. It has been extensively validated [27].

An index admission diagnosis of obesity was based on ICD-10 code E66.

Non–Frailty/Comorbidity Features

Age was categorized as bands (65-69 years, 70-79 years, and 80 years or older) for descriptive analysis and as a continuous variable when input into the machine learning algorithm.

Sex was categorized as female or male.

Ethnicity was categorized as White, Black or Black British, South Asian or South Asian British, other Asian or other Asian British, mixed, or other. For a number of patients, an ethnicity category was not recorded. In these cases, the HES database was searched for the most recent prior hospital admission for the same patient where ethnicity had been recorded and this value was used.

The index of multiple deprivation (IMD) score (2019 version) was used to categorize relative deprivation. It is measured in England by assigning each of England's 32,844 lower layer super output areas (LSOAs) a deprivation score calculated from a weighted average of 7 deprivation-related domains: income (22.5%), employment (22.5%), health deprivation and disability (13.5%), education or skills training (13.5%), crime (9.3%), barriers to housing and services (9.3%), and living environment (9.3%) [28-30]. The IMD score is reported as deciles in the descriptive analysis and used as a continuous variable in the machine learning algorithm.

Hospital trusts typically run between 1 and 4 NHS hospitals covering a geographically defined catchment.

NHS regions include London; the southeast, southwest, and east of England; the Midlands; the northeast and Yorkshire, and the northwest.

The individual ICD-10 codes recorded in the diagnostic record during the hospital stay were included as binary features.

Data Analysis and Model Building

Data were analyzed using the Python programming language (version 3.9, Python Software Foundation). Descriptive statistics techniques were used to summarize the data in the covariate categories described above.

All machine learning models were developed using the scikit-learn library. Random forest classifiers were used to identify key covariates associated with in-hospital mortality. Random forest classifiers are ensemble classifiers that fit decision trees to portions of the data and average over all decision trees. This is of particular importance if a machine learning model is to provide useful information about the relationship between the features and the outcome variable to clinicians. Machine learning has an advantage over traditional statistical models because it does not make any assumptions about the nature of the model. Machine learning has shown benefits in analyzing health care data [31-33].

To identify the most important features for each model, we used the SHAP (Shapley additive explanation) feature importance method [34]. Feature importance values were calculated using TreeSHAP, an efficient estimation approach for tree-based models. The SHAP feature importance method allows for the identification of the nature of the relationship between the individual features and the output variable [35]. In a plot of SHAP values, each dot in the plot represents a patient. The dots are colored red or blue. The color of the dot represents the size of the feature relative to the range of values that feature can take, with red representing large feature values and blue low feature values. A positive SHAP value can be interpreted as

meaning the feature is associated with in-hospital mortality. A negative SHAP value can be interpreted as meaning the feature is associated with the patient surviving to discharge. The features are ranked by the mean of the absolute value of the SHAP values.

Two different random forest models were constructed to classify patients according to mortality status, and their predictive accuracy was compared. The models differed in their choice of features. Model 1 included age, sex, deprivation, ethnicity, region, NHS trust, ICD-10 codes, the 14 CCI items, and the GFS domains. Model 2 included the same items as model 1, except the HFRS bands were added as a feature and the CCI items and the GFS domains were removed. The 2 models allowed a comparison of the performance of a model that included individual frailty domains and comorbidities (model 1) and one that included a single global measure of frailty. All listed variables were included in the final model, although only the most important features are described.

To avoid collinearity, features with a high degree of correlation (ie, a bivariate correlation coefficient >0.5) were excluded. The dementia item from the CCI and the dementia/delirium item from the GFS had a correlation coefficient of 0.6. As the GFS item had the broader definition, this was used as a covariate and the CCI item was excluded. No other items were excluded due to high correlation.

For data preprocessing, the data set was randomly split at a ratio of 70:15:15 into a training set, a testing set, and a validation set, respectively. All 3 data sets contained patients who had died and patients who had survived. The machine learning algorithm was trained on the training set and its performance was evaluated based on how well it could predict mortality in the test set. To ensure that the model did not simply classify according to the majority outcome (ie, survival), the training set was reduced further by randomly removing patients who had survived to ensure that there were an equal number of patients who had died and who had survived in the training set. This eliminated the effect of the class imbalance on the model performance and ensured that the model had sufficient exposure to patients who died. However, the test set on which the trained model was evaluated was not balanced, increasing the model's external validity. The validation set was used to tune the hyperparameters of the random forest. There are several hyperparameters specific to the random forest classifier that can be tuned. The combination of hyperparameters with the highest area under the receiver operating characteristic (AUROC) curve was selected. The optimal hyperparameters were found by using the Bayesian optimization library. The hyperparameter ranges used are listed in Table S1 in Multimedia Appendix 1. These hyperparameters included the number of trees (n=112), the minimum samples per split (n=8) and the minimum samples per leaf (n=1). The AUROC curve was plotted as sensitivity versus 1–specificity [36].

Categorical variables were one-hot encoded. This involved creating a binary column for each value that the variable could take. For example, for NHS region, a patient treated in the Midlands would have a value of 1 in the Midlands column, but a value of 0 in the other regional categories. The algorithm for model 1 was used to construct a model of the relationship between length of stay and in-hospital mortality.

In the sensitivity analysis, the performance of the random forest classifier was compared to extreme gradient boosting (XGBoost) and multivariable logistic regression models.

Other than for ethnicity (see "Features"), missing data were relatively rare, and no attempt was made to impute missing values. Patients with missing data were omitted from the analysis. The number of missing values for each variable is given in Table 1.

Table 1. Demographic characteristics and in-hospital deaths of patients.

Characteristics	Number of patients (N=215,831)	In-hospital deaths (n=77,738)	Chi-square (*df*)	*P* value
Age band (years), n (%)			4213.2 (2)	<.001
65-69	27,401 (12.7)	6431 (23.5)		
70-79	73,568 (34)	23,277 (31.6)		
≥80	114,862 (53.2)	48,030 (41.8)		
Sex[a], n (%)			1646.9 (1)	<.001
Female	101,989 (47.3)	32,351 (31.7)		
Male	113,826 (52.7)	45,382 (40)		
Deprivation decile[b], n (%)			16.2 (9)	.06
1 (most deprived)	25,053 (11.6)	8862 (35.4)		
2	24,937 (11.3)	8679 (35.6)		
3	23,320 (10.8)	8441 (36.2)		
4	21,756 (10.1)	7884 (36.2)		
5	21,044 (9.8)	7701 (36.6)		
6	21,004 (9.7)	7732 (36.8)		
7	20,149 (9.3)	7273 (36.1)		
8	19,787 (9.2)	7212 (36.4)		
9	18,764 (8.7)	6724 (35.8)		
10 (least deprived)	17,012 (7.9)	6123 (36)		
Region in England[c], n (%)			246.1 (6)	<.001
East	22,934 (10.6)	9096 (39.7)		
London	35,912 (16.6)	12,617 (35.1)		
Midlands	44,590 (20.7)	16,072 (36)		
Northeast and Yorkshire	34,850 (16.1)	12,187 (35)		
Northwest	35,281 (16.3)	12,971 (36.8)		
Southeast	29,562 (13.7)	10,554 (35.7)		
Southwest	12,028 (5.6)	4085 (34)		
Ethnicity[d], n (%)			46.1 (5)	<.001
White	181,453 (84.1)	65,440 (36.1)		
Black or Black British	5794 (2.7)	2108 (36.4)		
South Asian or South Asian British	10,216 (4.7)	3910 (38.3)		
Other Asian or other Asian British	2659 (1.2)	953 (35.8)		
Mixed	963 (0.4)	342 (35.5)		
Other	4484 (2.1)	1488 (33.2)		
Disease severity, n (%)				
Pneumonia	144,206 (65.9)	66,323 (46.6)	18,757.8 (1)	<.001
Renal disease	55,155 (25.6)	29,353 (53.2)	9512.3 (1)	<.001
Blood clotting	6836 (3.2)	3017 (44.1)	201.8 (1)	<.001
Cardiology/circulation	4967 (2.3)	2529 (50.9)	489.7 (1)	<.001
Neurology	6986 (3.2)	3022 (43.3)	164.2 (1)	<.001
Digestive system	235 (0.1)	134 (57)	45 (1)	<.001

Characteristics	Number of patients (N=215,831)	In-hospital deaths (n=77,738)	Chi-square (*df*)	*P* value
Sepsis	16,327 (7.5)	9534 (58.4)	3837.6 (1)	<.001

[a]There were 16 missing values.

[b]There were 3545 missing values.

[c]There were 674 non–National Health Service providers.

[d]Not stated in 10,262 values.

Results

The data extraction process resulted in a data set of 215,831 patients (Figure S1 in Multimedia Appendix 1). The crude mortality rate was 36% (77,738/215,831). The breakdown of patient numbers and the associated mortality rate is presented by age, sex, deprivation decile, region, ethnicity, and disease severity marker in Table 1 and by GFS domain and CCI item in Table 2. Higher in-hospital crude mortality rates were seen in older age groups, men, and in almost all comorbidity and frailty groups, except those with mild liver disease and anxiety or depression. There was no obvious relationship between in-hospital mortality and deprivation and a relatively modest difference between the different ethnic groups, with South Asian patients having the highest in-hospital mortality rate. The median length of hospital stay was 10 (IQR 5-20) days in patients who survived to discharge and 9 (IQR 4-17) days in those who died in hospital.

Table 2. Mortality rates by comorbidity/frailty measure. Significance was tested using the chi-square test with significance set at 5%. For each comorbidity and frailty item, the number of patients with the condition is given together with the number of in-hospital deaths.

Comorbidity/frailty items	Patients (N=215,831), n (%)	In-hospital deaths (n=77,738), n (%)	Chi-square (*df*)	*P* value
Charlson Comorbidity Index				
Peripheral vascular disease	15,519 (7.2)	6663 (42.9)	358.9 (1)	<.001
Congestive heart failure	42,370 (19.6)	20,433 (48.2)	3412.8 (1)	<.001
Acute myocardial infarction	26,670 (12.4)	11,416 (42.8)	611.2 (1)	<.001
Cerebrovascular disease	28,773 (13.3)	11,241 (39.1)	137.9 (1)	<.001
Dementia	44,036 (20.4)	18,749 (42.6)	1098.1 (1)	<.001
Chronic pulmonary disease	63,244 (29.3)	24,298 (38.4)	227.3 (1)	<.001
Connective tissue/rheumatic disease	7867 (3.6)	2964 (37.7)	8.2 (1)	.004
Peptic ulcer	1979 (0.9)	764 (38.6)	7.0 (1)	.008
Mild liver disease	7402 (3.4)	2664 (36)	0 (1)	.92
Moderate or severe liver disease	1706 (0.8)	975 (57.2)	344.9 (1)	<.001
Diabetes without chronic complications	59,815 (27.7)	22,704 (38)	133.5 (1)	<.001
Diabetes with chronic complications	7190 (3.3)	2864 (39.8)	43.2 (1)	<.001
Paraplegia and hemiplegia	5667 (2.6)	2253 (40)	38.2 (1)	<.001
Renal disease	55,652 (25.8)	24,947 (44.8)	2533.5 (1)	<.001
Primary cancer	21,822 (10.1)	9764 (44.7)	864.1 (1)	<.001
Metastatic carcinoma	8095 (3.8)	3675 (45.4)	378.3 (1)	<.001
HIV/AIDS	72 (0.03)	19 (26.4)	7.4 (1)	.006
Obesity	14,766 (6.8)	5222 (35.5)	5.4 (1)	.02
Global Frailty Scale				
Dementia and delirium	76,669 (35.5)	32,011 (41.8)	1696.6 (1)	<.001
Mobility problems	29,191 (13.5)	11,207 (38.4)	82.6 (1)	<.001
Falls and fractures	81,805 (37.9)	31,957 (39.1)	530.7 (1)	<.001
Pressure ulcers and weight loss	23,249 (10.8)	10,814 (46.5)	1245.5 (1)	<.001
Incontinence	15,359 (7.1)	6095 (39.9)	96.4 (1)	<.001
Anxiety and depression	25,268 (11.7)	8123 (32.1)	186.0 (1)	<.001

The training data set included 151,081 patients, the test data set included 32,374 patients, and the validation data set included 32,376 patients. Table 3 shows the performance of the random forest classifier on the test set in the 2 models developed. The best performing model was model 1, which included the GFS domains and CCI items and had an accuracy of 83%, an AUROC curve of 90%, and a true positive rate of 81%. Model 2 had slightly poorer performance, with an accuracy of 82%, an AUROC curve of 90%, and a true positive rate of 80%. The AUROC curve for model 1 is shown in Figure S2 in Multimedia Appendix 1.

Figure 1 shows the SHAP value dot plots for the 30 most important features for model 1. The most important disease severity items that the random forest identified as predictive of mortality were pneumonia, renal failure, and sepsis. The most important frailty items were dementia and delirium, falls and fractures, and pressure ulcers and weight loss. The most important comorbidities were renal disease, heart failure, and primary cancer. Figure 2 shows the probability of in-hospital mortality as calculated by the random forest algorithm as a function of length of stay. In-hospital mortality risk was low for those with length of stay less than 3 days, was relatively stable between 3 and 20 days, and declined with increasing length of stay thereafter. Figure 3 shows the SHAP value dot plots for the 30 most important features for model 2. The HFRS band ranks as one of the most important features.

Table 3. Performance of the random forest classifier on the various models. For each model, the random forest classifier accuracy, the area under the receiver operating characteristic curve, and the true positive rate are listed. The true positive rate is the fraction of patients who died who were predicted to have died by the model.

Model	Random forest accuracy, %	Area under the receiver operating characteristic curve, %	True positive rate, %
1	83	90	81
2	82	90	80

Figure 1. Shapley value dot summary plot for model 1. Each dot in the plot represents a patient. The x-axis indicates whether there is a positive or negative correlation between the value of the feature and its contribution to the model prediction of a patient dying. The color of the dot represents the size of the feature relative to the range of values that feature can take, with red representing large feature values and blue low feature values. The horizontal axis represents the association of the feature value with the outcome. A positive SHAP value means the feature is associated with mortality. A negative SHAP value means the feature contributes to the patient surviving to discharge. The features are ranked by the mean of the absolute value of the SHAP values. CCI: Charlson Comorbidity Index; GFS: Global Frailty Scale; ICD-10: International Statistical Classification of Disease, 10th Edition; IMD: index of multiple deprivation; SHAP: Shapley additive explanation.

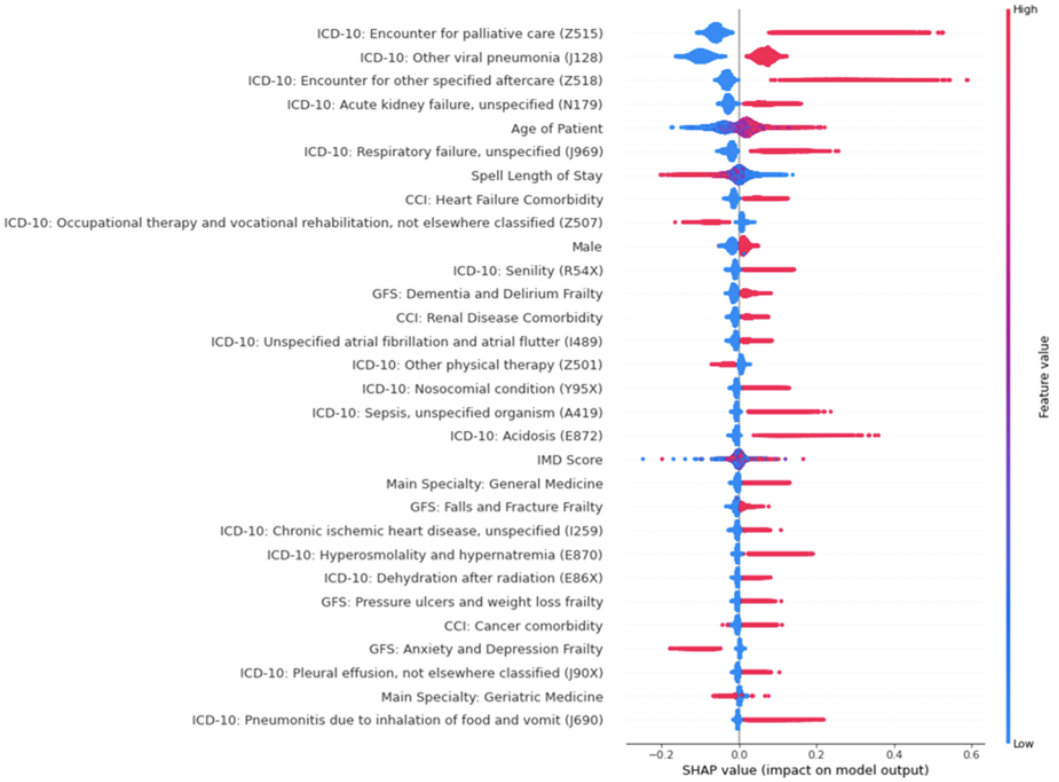

Figure 2. Plot of the predicted probability of death as a function of the length of stay.

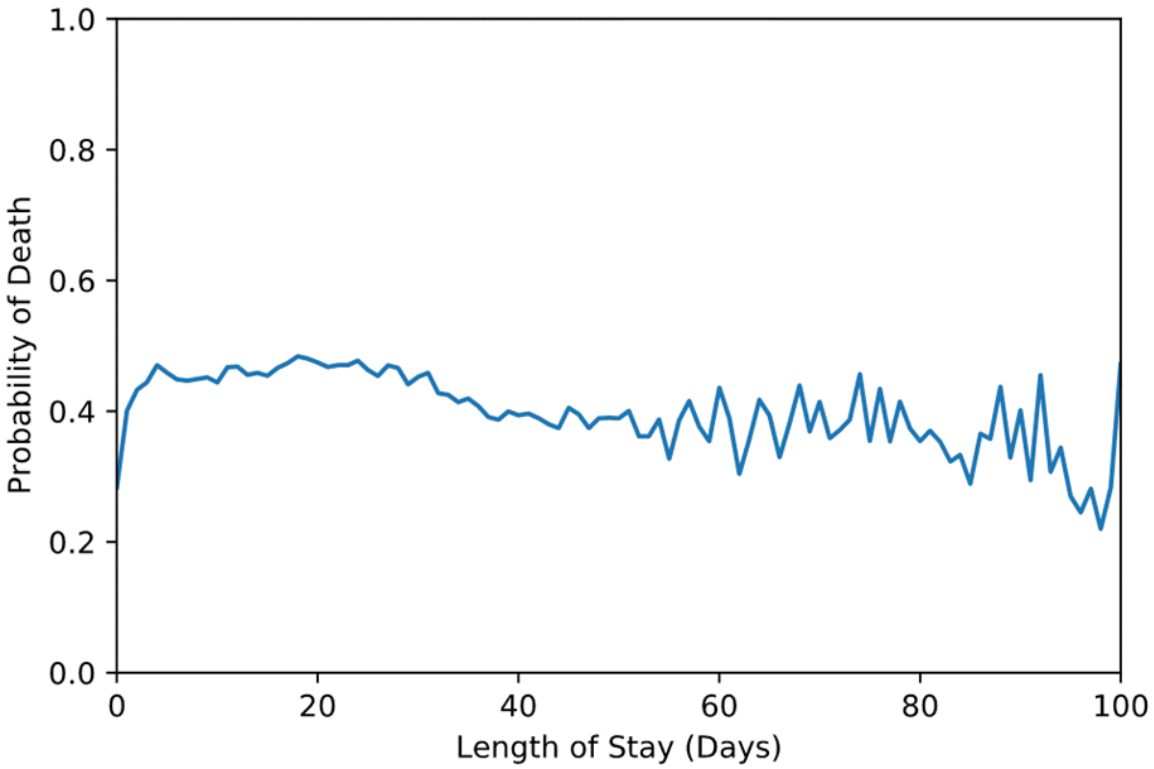

Figure 3. SHAP value dot summary plot for model 2. Each dot in the plot represents a patient. The x-axis indicates whether there is a positive or negative correlation between the value of the feature and its contribution to the model prediction of a patient dying. The color of the dot represents the size of the feature relative to the range of values that feature can take, with red representing large feature values and blue low feature values. The horizontal axis represents the association of the feature value with the outcome. A positive SHAP value means the feature is associated with mortality. A negative SHAP value means the feature contributes to the patient surviving to discharge. The features are ranked by the mean of the absolute value of the SHAP values. HFRS: Hospital Frailty Risk Score; ICD-10: International Statistical Classification of Disease, 10th Edition; IMD: index of multiple deprivation; SHAP: Shapley additive explanation.

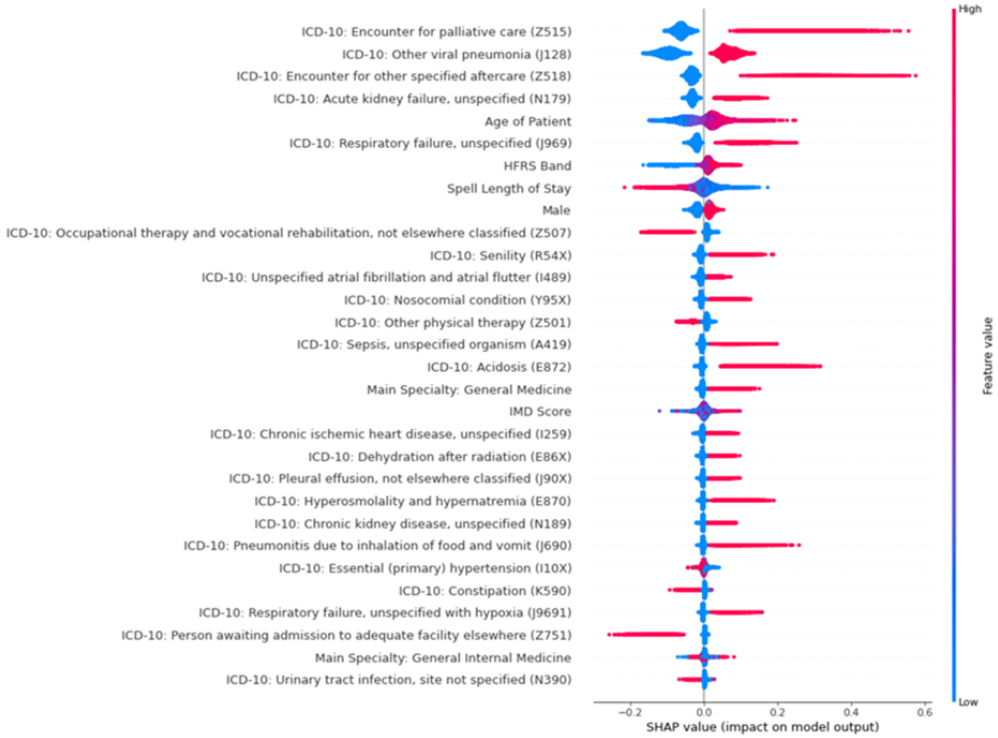

Figure S3 in Multimedia Appendix 1 shows the critical care admissions by age band, with the decline in critical care use for older patients reflecting decisions regarding ceilings of care. Figure S4 in Multimedia Appendix 1 shows the time series of the number of hospital admissions and deaths over the course of the study period; higher patient numbers and lower in-hospital mortality rate in the second wave during winter 2020-2021 are apparent. Figures S5 to S7 in Multimedia Appendix 1 are plots of the random forest classifier's prediction of the probability of mortality as a function of age for patients with and without dementia and delirium, pressure ulcers and weight loss, and falls and fractures. The presence of each domain of frailty was associated with a higher mortality rate for all domains. Figures S8 to S10 in Multimedia Appendix 1 are plots of the random forest classifier's prediction of the probability of mortality as a function of age for patients with and without cancer, heart failure, and renal disease. Patients with any of these comorbidities had a noticeably higher risk of mortality. Figure S11 in Multimedia Appendix 1 shows the prediction of mortality as a function of age for the 4 HFRS bands and shows the association between greater frailty and in-hospital mortality risk across all age bands.

From the sensitivity analysis, Table S2 in Multimedia Appendix 1 details the AUROC curve for the XGBoost and multivariable logistic regression models. Both models had an AUROC curve of 89%.

Discussion

Our study is one of very few to use machine learning techniques to explore the role of frailty and comorbidities in COVID-19 outcomes in hospitalized older adults, and by far the largest to date [37]. Measures such as the CFS and HFRS give a global measure of frailty but give little detail on the role of specific aspects of frailty and comorbidity in determining outcomes [38]. As such, their use in guiding decision-making has been questioned [39]. Our study provides a different perspective and explores specific domains of frailty and comorbidities associated with COVID-19 mortality using an administrative data set.

In our study, preexisting dementia, falls and fractures, pressure ulcers and weight loss, renal disease, heart failure, and cancer were all important features in the model.

Dementia/delirium was found to be the most important feature of all the frailty and comorbidity items investigated, with a consistent relationship between dementia/delirium across all ages. Studies from Italy and Brazil have found a higher COVID-19 mortality rate in those with delirium than those without [40,41]. An Italian study of 332 patients found that neurological comorbidities, which included dementia, were associated with a 2-fold increase in mortality, though dementia was not considered in isolation [42].

Various studies have found that patients who have suffered from fractures are at increased risk of dying from COVID-19 [43,44], with one study noting that even though the volume of fracture patients admitted to hospital had decreased during the pandemic, the mortality rate had increased [45]. Respiratory diseases and cardiovascular diseases have been identified as associated with increased COVID-19 mortality risk in other studies [46]. In our study, we identified a substantial increase in the probability of death among patients with falls and fractures compared to those without.

A previous study by members of our team using HES data for all hospitalized adults in England found that all comorbidities in the CCI, except mild liver disease and peptic ulcer, were strong predictors of in-hospital mortality [47]. This is broadly supported by other studies of large administrative databases [48-53].

Age and male sex were important features in all models, which is consistent with previous reports [9,54-56]. The deprivation score was one of the most important features in both our models. Previous studies are inconsistent on the relative importance of deprivation in COVID-19 mortality [57,58]. However, there is a strong relationship between deprivation, ethnicity, age, and other covariates, and it is likely that different modeling approaches address the relationship in different ways.

We found that length of stay had a strong relationship with in-hospital mortality. The risk of death increased between 0 and 3 days before decreasing again after 20 days.

This study has numerous strengths. The use of the HES data set ensures that all hospital activity in England over the first year of the pandemic was captured, minimizing collider bias. We have demonstrated that a random forest classification algorithm is able to predict mortality with reasonable accuracy from an administrative data set. The accuracy of this work can be demonstrated by comparing the true positive rate of model 1 (81%) to the QCOVID risk algorithm, which had a sensitivity of 75.7% for identifying deaths within 97 days in the top 5% of at-risk patients [59]. An external validation of the QCOVID prediction algorithm found the sensitivity in predicting mortality to be 65.94% for men and 71.67% for women in the top 5% of most at-risk patients [60]. Model 1 is clearly comparable to these, despite being trained on an administrative data set lacking clinical details regarding presentation. The risk model for QCOVID used clinical markers for disease severity. It was not our aim to develop a risk prediction algorithm, and we would caution against using our findings to do so, given concerns over data poverty and model accuracy in underrepresented groups (eg, non-White ethnicities). However, provided these concerns can be addressed (eg, through the use of transfer learning in model development [61]), there is clear potential to use large administrative data sets to develop highly accurate models.

There are also limitations to our study, mainly related to the nature of the HES data set. Comorbidities may only be coded if they are deemed relevant to the patient's condition. As such, the reported prevalence of various domains of frailty and comorbidities is likely to underestimate their true prevalence. For example, it is possible that only the most severe cases of dementia/delirium were recorded in the HES database, which could explain the strong association in our study. Coding of COVID-19 will have been less consistent at the start of the pandemic, particularly with limited testing capacity. For this reason, we included patients diagnosed on clinical grounds, as well as those with a positive test.

We also acknowledge that some secondary diagnoses may have been recorded in the HES database more commonly than others. Issues arise when different trusts' coding teams code to a different depth of information and when some long-term conditions (eg, diabetes or dementia) are mandatory [62]. We also recognize that in cases of patient transfer to a different trust for treatment, the first admission would have been recorded in our data set as an earlier admission and removed. Thus, the admission period would appear shorter than it actually was. Issues around coding consistency across countries were identified during the GFS development study [20]. This could have impacted the reported relative importance of each frailty/comorbidity feature in the model.

In summary, machine learning has proven useful in understanding the impacts of frailty and comorbidity on mortality. Our findings should help clinicians to identify which COVID-19 patients are most at risk of poor outcomes and help guide treatment strategies during future case surges. Artificial intelligence systems have already found use in guiding treatment strategies for palliative care. [63] A similar approach could be used to triage patients with COVID-19, building on insights from our work.

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Data Availability

This report does not contain patient identifiable data. Consent from individuals involved in this study was not required. Requests for any underlying data cannot be granted by the authors because the data were acquired from data under license and a data sharing agreement from National Health Service Digital, for which conditions of use and further use apply. Individuals and organizations wishing to access Hospital Episodes Statistics data can make a request directly to National Health Service Digital.

Conflicts of Interest

None declared.

Multimedia Appendix 1
Supplementary tables and figures.
[DOCX File , 817 KB - ijmr_v11i2e41520_app1.docx]

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Abbreviations

AUROC: area under the receiver operating characteristic
CCI: Charlson Comorbidity Index
CFS: Clinical Frailty Scale
GFS: Global Frailty Scale
HES: Hospital Episodes Statistics
HFRS: Hospital Frailty Risk Score
ICD-10: International Statistical Classification of Disease, 10th Edition
IMD: index of multiple deprivation
LSOA: lower layer super output area
NHS: National Health Service

SHAP: Shapley additive explanation
XGBoost: extreme gradient boosting

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Original Paper

The Physical Activity Assessment of Adults With Type 2 Diabetes Using Accelerometer-Based Cut Points: Scoping Review

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Abstract

Background: Incorporating physical activity into lifestyle routines is recommended for individuals with type 2 diabetes. Accelerometers offer a promising method for objectively measuring physical activity and for assessing interventions. However, the existing literature for accelerometer-measured physical activity among middle-aged and older adults with type 2 diabetes is lacking.

Objective: This study aims to identify research studies in which accelerometer-based cut points were used to classify the physical activity intensity of middle-aged to older adults with type 2 diabetes as sedentary, light, moderate, vigorous, and very vigorous, and to determine if validated accelerometer cut points specifically for this population exist.

Methods: We followed the Joanna Briggs Institute methodology for scoping reviews. Between June 23 and July 12, 2020, two reviewers independently screened records from four databases (PubMed, Web of Science, Embase, Engineering Village) and the ActiGraph Corp web site for eligible studies that included patients with type 2 diabetes with a sample mean age ≥50 years, used research-grade accelerometers, applied cut points to categorize objectively measured physical activity, and were available in English. We excluded studies reporting exclusively steps or step counts measured by accelerometers or pedometers and conference abstracts or other sources that did not have a full text available. Data extraction was completed using Microsoft Excel. Data for the following variables were tabulated based on frequency distributions: study design, accelerometer type, device placement, epoch length, total wear time, and cut points used. Study aims and participant demographic data were summarized.

Results: A total of 748 records were screened at the abstract level, and 88 full-text articles were assessed for eligibility. Ultimately, 46 articles were retained and analyzed. Participants' mean ages ranged from 50 to 79.9 years. The ActiGraph accelerometer and the Freedson et al and Troiano et al counts-per-minute cut points were the most frequently used across the literature. Freedson et al and Troiano et al counts-per-minute cut points for light, moderate, and vigorous activity correspond to <1952, 1952-5724, and ≥5725, and 100-2019, 2020-5998, and ≥5999, respectively. The Lopes et al cut points were developed by calibrating the ActiGraph in middle-aged and older adults with overweight/obesity and type 2 diabetes. These counts-per-minute thresholds are ≥200 (light), ≥1240 (moderate), and ≥2400 (vigorous), and were applied in 1 interventional study.

Conclusions: An assortment of accelerometer cut points have been used by researchers to categorize physical activity intensity for middle-aged and older adults with diabetes. Only one set of cut points was validated and calibrated in our population of interest. Additional research is warranted to address the need for diabetes-specific cut points to inform public health recommendations. This includes confirmation that the Lopes et al cut points reflect clinically meaningful changes in physical activity for adults with diabetes who have comorbidities other than overweight/obesity and the development of relative intensity cut points that may be more suitable for those with suboptimal physical functioning.

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KEYWORDS

accelerometer; cut points; type 2 diabetes; physical activity

Introduction

Background

Approximately 462 million individuals are affected by type 2 diabetes (T2D) globally [1], and the vast majority of the estimated 37 million Americans with diabetes have T2D [2]. Physical inactivity is a known risk factor for diabetes complications, yet about 38% of adults with diabetes achieve less than 10 minutes per week of moderate or vigorous activity [3]. These individuals generally engage in lower levels of physical activity duration and intensity [4], and have lower physical functional capacity compared to adults without diabetes [5].

Rationale

While many interventions for individuals with diabetes promote reducing sedentary time by increasing physical activity, accurate assessment of physical activity remains a challenge. Self-report questionnaires have traditionally quantified physical activity in numerous research studies but are subject to recall bias and lack of standardization [6]. In the last decade, accelerometers have shown promise for their ability to objectively measure the body's acceleration in at least one of three orthogonal planes (anteroposterior, mediolateral, and vertical) and convert it into activity counts, also reported as counts per minute. These counts, which are proportional to the amount of physical activity performed by an accelerometer wearer, can be further used to categorize exercise into intensity levels (light, moderate, vigorous) [7]. Intensity thresholds, or cut points, have commonly been determined from regression equations relating accelerometer-recorded counts per minute and simultaneous measurement of energy expenditure (as metabolic equivalents of task [METs]) during laboratory and free-living activities [8].

For people with T2D, exercise can help lower blood glucose levels, lipid levels, and blood pressure, thus improving diabetes outcomes [9]. Several population-specific thresholds have been established to define physical activity intensity using accelerometers such as the ActiGraph monitors, which comprise ≥50% of activity monitors globally [10]. Existing reviews related to this topic are limited to only consumer-wearable activity trackers [11], randomized controlled trials (RCTs) [12,13], or walking measured as steps per day [14,15]. Determining the most appropriate protocols for capturing accelerometer data in this population to accurately inform disease-specific public health recommendations is critical. This scoping review is comprehensive and aims to describe the use of accelerometer-based cut points for assessing physical activity intensity of adults with T2D.

Review Questions

We address two questions: (1) which cut points, if any, have been used to objectively categorize the physical activity intensity of adults with T2D (mean age ≥50 years) and (2) do accelerometer thresholds specifically validated for this population exist in the literature?

Methods

This scoping review was conducted following the Joanna Briggs Institute Manual for Evidence Synthesis [16] using the following protocol: a limited search of relevant databases with an analysis of title and abstract keywords, and of article index terms; a comprehensive search using identified keywords and index terms across all databases; and a search of the reference lists of all full-text articles included in the review.

Inclusion Criteria for Sources of Evidence

The criteria in Table 1 define eligibility of sources included in this scoping review. Publications were included if all, or a clear subset of, participants were selected for the study on the basis of a T2D diagnosis with an allowance for comorbidities. Abstracts that indicated use of research-grade activity monitors to objectively measure the physical activity of participants with T2D were included. Studies that exclusively reported steps or step counts measured by accelerometers or pedometers were excluded. Conference abstracts and other sources that did not have the full text available were also excluded. In accordance with the average age of diabetes diagnosis [17], a mean age threshold of ≥50 years was implemented. Full-text articles were included if authors used specific accelerometer thresholds to categorize physical activity by intensity.

Table 1. Screening eligibility criteria.

Screening stage	Inclusion criteria
Abstracts	• Participants selected for study on basis of type 2 diabetes diagnosis • Research-grade (nonpedometer) accelerometers used to objectively measure physical activity • Source is not conference abstract and full text is available • Physical activity not tracked exclusively as steps or step counts • Study sample has mean age ≥50 years
Full-text articles	• Metabolic equivalents of task or counts-per-minute cut points reported/cited by authors and used to categorize physical activity intensity

Search Strategy

First, a limited pilot search of PubMed and Web of Science was conducted using the Medical Subject Headings terms "accelerometry" and "diabetes mellitus, type 2," and all related entry terms from the database. Two reviewers individually selected and analyzed 10 abstracts at random to identify recurrent keywords. Subsequently, a comprehensive search was conducted across five sources including PubMed, Web of Science, Embase, Engineering Village, and the ActiGraph Corp website research database. Finally, the reference lists of all full-text articles eligible for the review were scanned for additional original sources of evidence. Full details regarding the search strategy for each database can be found in Multimedia Appendix 1.

The PubMed search contained the major terms "accelerometry," "diabetes mellitus, type 2," and "exercise" as well as all related subentry terms. Results were controlled using the filter "Middle Aged + Aged: 45+" to maximize efficiency during the screening process given the age inclusion criterion stated in Table 1. All records published prior to June 23, 2020, were included, as this was the most recent date the database was accessed. The Embase search was conducted using the terms "accelerometer," "diabetes mellitus type 2," and "physical activity" as well as all of the related terms that automatically populate when selected. The filters "middle aged," "aged," and "very elderly" were used to maximize efficiency for the screening process given the age criterion in Table 1. All records published prior to July 6, 2020, were included in the screening and selection process. The Web of Science search was conducted using the complete list of terms searched in PubMed and included all articles published prior to July 12, 2020, when this search was concluded. In Engineering Village, a platform featuring multiple engineering databases such as Compendex and Inspec, records were searched using "diabetes," "accelerometer or accelerometry or actigraph or actigraphy," and "exercise or physical activity," and were limited to journal articles published prior to July 12, 2020. ActiGraph, LLC produces several models of wearable activity and sleep monitors, which have been used in numerous clinical trials. The ActiGraph Corp website has a research database with various publications mentioning the use of these activity and sleep monitors. After completing the comprehensive search of the major databases mentioned hitherto, we conducted a final search for records in the ActiGraph Corp website's research database page under the category "diabetes." We screened all of the abstracts filed under this category with a publication date prior to July 12, 2020. Across all databases, only articles published in English were considered for inclusion.

Source of Evidence Screening and Selection

Two reviewers independently screened all abstracts and full texts for inclusion using the predefined criteria, seeking consensus or the opinion of a third reviewer in cases of disagreement. Initially, the title, name of first author, publication year, and database name of all identified records were collected using Excel (Microsoft Corporation). Abstracts were then screened against our criteria. In cases where abstracts met the first four inclusion criteria from Table 1 but did not clearly state the age of participants, reviewers consulted the full text to confirm full eligibility. Abstract information was organized in Excel to track their original source and avoid redundant screening of duplicate records. Afterward, full texts of available abstracts were accessed and assessed for eligibility. Finally, the reference lists of all eligible full-text articles were scanned to identify any additional studies that could be included in our final pool of eligible articles. The complete screening spreadsheet is in Multimedia Appendix 2.

Data Extraction

Two reviewers independently performed data extraction from full-text articles using a form created in Excel, with one reviewer extracting data and the other verifying it (Multimedia Appendix 3). We collected the following variables: author or authors, publication year, country, study aims and design, participant demographics, accelerometer type, placement, epoch length, total wear time, cut points, and physical activity outcomes/results. Information relevant to the accelerometer methodology that was presented in the discussion section of each study was also collected. Reviewers accessed cited articles or supplementary material if prompted by authors and necessary for data extraction.

Synthesis and Presentation of Results

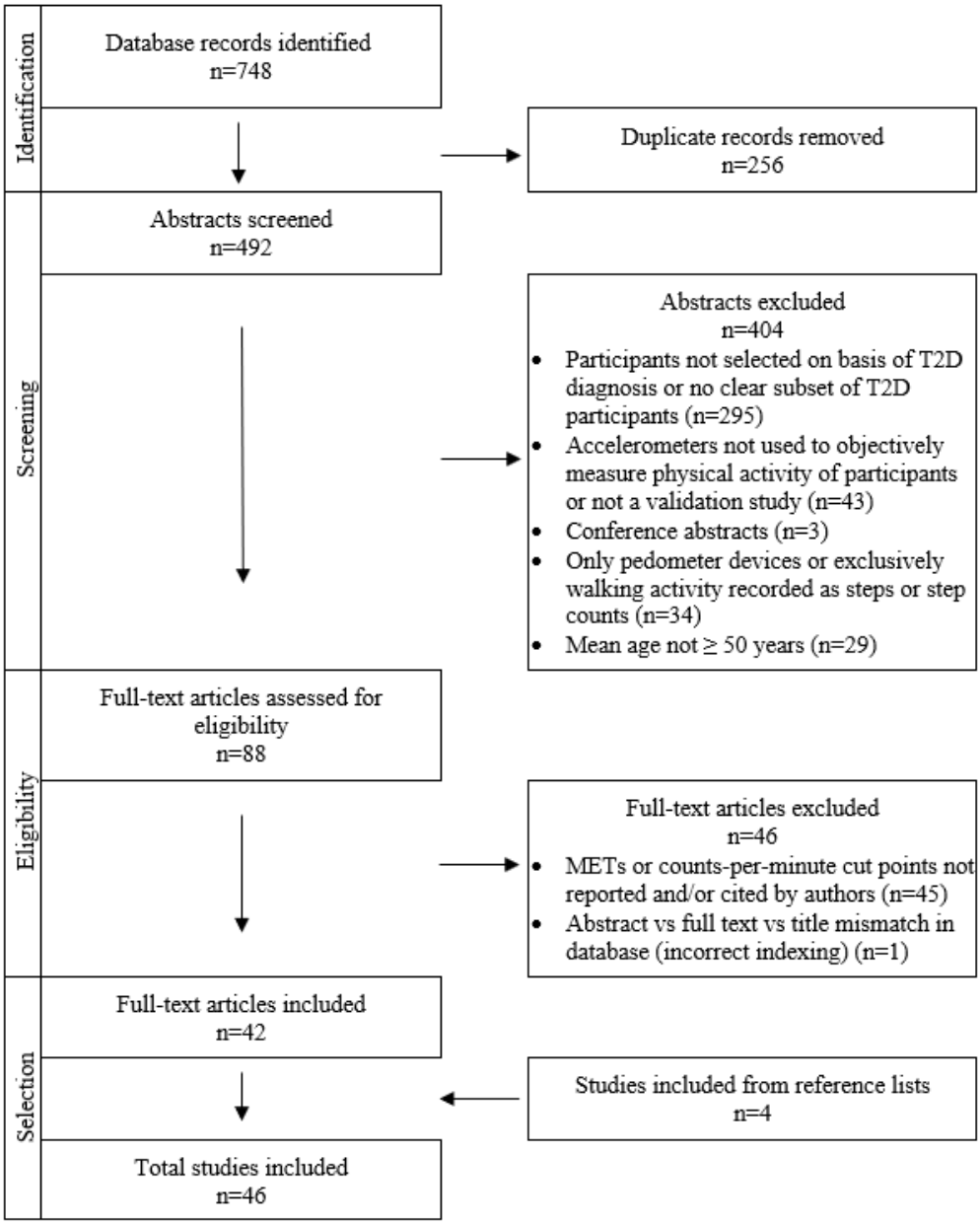
Extracted data were tabulated based on frequency distributions for the following variables: study design, accelerometer type, device placement, epoch length, total wear time, and cut points used. Study aims were consolidated into broad themes and participant demographic data were summarized and presented as a narrative. A qualitative description follows all tabulated results to relate the findings to the objectives of this review.

Results

Search Results

The scoping review search yielded 748 records across the five databases (158 in PubMed, 201 in Embase, 309 in Web of Science, 36 in Engineering Village, and 44 in the ActiGraph Corp website). After removal of duplicates and subsequent screening of the remaining 492 abstracts, 88 full-text articles were assessed for eligibility. Of those, 42 articles met our inclusion criteria. The reference lists of these articles were then searched for additional sources of evidence, yielding 4 new articles. Ultimately, 46 articles were retained and analyzed (Figure 1 [18]).

Figure 1. PRISMA-ScR (Preferred Reporting Items for Systematic Reviews and Meta-Analyses Extension for Scoping Reviews) flowchart of screening and selection process with reasons for elimination. MET: metabolic equivalent of task; T2D: type 2 diabetes.



Source of Evidence Characteristics

Complete data extraction details are available in Multimedia Appendix 4. Most sources were cross-sectional studies (n=24), followed by RCTs (n=13), calibration/validation studies (n=2), and prospective longitudinal cohort studies (n=2). The remaining studies were correlational, mixed methods, descriptive, pretest to posttest, and case-control (Table 2). Article publication years ranged from 2008 to 2020. Of the research published in the United States, all but 2 studies had an even distribution of male and female participants, exceptions included Vanden Bosch et al [19], which enrolled only middle-aged female participants, and Whipple et al [20] whose participants were mostly male participants (80%). Among the 11 of 13 American studies that reported race/ethnicity data, 1 was comprised of at least 50% African American or Black participants [21], while the remaining 10 featured a predominantly White study population. Our age criterion captured 26 study samples with a mean age of 50 to 59.9 years, 18 samples with a mean age of 60 to 69.9 years, and 2 samples with a mean age of 70 to 79.9 years.

Table 2. Distribution of sources by study design (N=46).

Study design	Study, n (%)
Cross-sectional	24 (52)
Randomized controlled trial	13 (28)
Calibration/validation	2 (4)
Prospective longitudinal cohort	2 (4)
Mixed methods	1 (2)
Descriptive	1 (2)
Case control	1 (2)
Pre-to-post	1 (2)
Correlational	1 (2)

Accelerometer Parameters

Selected RCTs examined the effect of various interventions on either physical activity (n=11) or on diabetes control (n=2), while non-RCTs similarly evaluated associations of physical activity (or lack thereof) on physical health; 2 studies conducted accelerometer calibration/validation. From an assortment of 16 different accelerometers identified across the literature, the ActiGraph was the most popular brand with its triaxial GT3X (n=10) and uniaxial GT1M (n=10) models being equally favored in 22% of studies (Table 3).

Researcher-dependent parameters for accelerometer data collection and analysis are presented in Table 4. In most studies, the accelerometer device was secured on the participant's waist (n=23, 50%) during active data collection. Alternative placement options included the hip, wrist, chest, and on a neck strap. A total of 29 (63%) studies collected movement data in 60-second epochs (data acquisition intervals), and 23 (50%) required participants to wear the accelerometer for 7 days during data collection. Corresponding to the observed preference for ActiGraphs, various versions of the ActiLife software were used to conduct data reduction and analysis.

Table 3. Accelerometer devices used across research studies (N=46).

Accelerometer	Number of axes	Study, n (%)	Studies
GT3X, ActiGraph, LLC; Pensacola, FL	Triaxial	10 (22)	Poppe et al [22], Júdice et al [23], Mathe et al [24], Welch et al [25], Garcia et al [26], Castonguay and Miquelon [27], Britto et al [28], Do et al [29], Hamer et al [30], de Moura et al [31]
GT1M, ActiGraph, LLC; Fort Walton Beach, FL	Uniaxial	10 (22)	Vanden Bosch et al [19], Winkler et al [32], Eakin et al [33], Eakin et al [34], Cooper et al [35], Falconer et al [36], Healy et al [37], Goode et al [38], Lee et al [39], Falconer et al [40]
AM7164, ActiGraph, LLC; Pensacola, FL	Uniaxial	6 (13)	De Greef et al [41], Evenson et al [42], Lopes et al [43], De Greef et al [44], Loprinzi and Pariser [45], Loprinzi and Ramulu [46]
MyWellnessKey, Technogym; Cesena, Italy	Uniaxial	4 (9)	Balducci et al [47], Balducci et al [48], Balducci et al [49], McGinley et al [50]
ActiGraph, Manufacturing Technology, Inc; Fort Walton Beach, FL	Uniaxial	2 (4)	Allen et al [51], Allen et al [52]
HJA-350IT, Omron Healthcare; Kyoto, Japan	Triaxial	2 (4)	Miyamoto et al [53], Miyamoto et al [54]
RT3 Accelerometer, StayHealthy; Monrovia, CA	Triaxial	2 (4)	Unick et al [55], Jakicic et al [56]
Actiheart, CamNtech; Cambridge, United Kingdom	Triaxial	2 (4)	Guo et al [57], Cichosz et al [58]
Polar AW200 Activity Watch, Polar Electro Oy; Kempele, Finland	Uniaxial	1 (2)	Karjalainen et al [59]
MT-KT01, Terumo; Tokyo, Japan	Triaxial	1 (2)	Miyauchi et al [60]
GT9X Link, ActiGraph; Pensacola, FL	Triaxial	1 (2)	Wooldridge et al [61]
Actiwatch-Score, Philips Respironics; Bend, OR	Multidimensional	1 (2)	Fritschi et al [21]
GT3X+, ActiGraph, LLC; Fort Walton Beach, FL	Triaxial	1 (2)	Sardinha et al [62]
Fitbit Charge HR, Fitbit Inc; San Francisco, CA	Triaxial	1 (2)	An et al [63]
GT3X-BT, ActiGraph, LLC; Pensacola, FL	Triaxial	1 (2)	Whipple et al [20]
Active Style Pro HJA-750C, Omron Healthcare; Kyoto, Japan	Triaxial	1 (2)	Nishida et al [64]

Table 4. Parameters for accelerometer data collection and analysis (N=46).

Protocol variables	Studies, n (%)
Device placement	
Waist	23 (50)
Hip	14 (30)
Wrist	4 (9)
Unknown	3 (7)
Neck strap	1 (2)
Chest	1 (2)
Epoch length (seconds)	
15	2 (4)
30	2 (4)
60	29 (63)
Not reported or not applicable to device	13 (28)
Total wear time (days)	
<1	1 (2)
3	3 (7)
4	2 (4)
5	3 (7)
6	3 (7)
7	23 (50)
10	2 (4)
14	2 (4)
16	1 (2)
21	1 (2)
28	1 (2)
84	1 (2)
127	1 (2)
180	1 (2)
183	1 (2)
Analysis software	
ActiLife (various versions)	11 (24)
SAS (various versions)	9 (20)
SPSS (various versions)	9 (20)
STATA (various versions)	4 (9)
KineSoft (Saskatoon, SK)	3 (7)
MAHUffe Analyser (various versions)	3 (7)
ActiGraph (DOS RIU256K.EXE)	2 (4)
BI-LINK, Omron Healthcare, Kyoto, Japan	1 (2)
JMP Ver. 11.0.0 (SAS Institute, Japan)	1 (2)
MATLAB (MathWorks)	1 (2)
MeterPlusTM (Santech, San Diego, CA)	1 (2)
MyWellnessKey online portal	1 (2)

Protocol variables	Studies, n (%)
SAS Programs for Analyzing NHANES 2003-2004 Accelerometer Data (National Cancer Institute)	1 (2)
Respironics Actiware (Philips Respironics, Bend, OR)	1 (2)
StayHealthy	1 (2)
Not reported	1 (2)

Cut Points and Data Interpretation

This scoping review included studies in which cut points for METs or counts per minute were applied to accelerometer-measured physical activity with the aim of categorizing movement as sedentary, light physical activity (LPA), moderate physical activity (MPA), vigorous physical activity (VPA), very vigorous physical activity (VVPA), moderate-to-vigorous physical activity (MVPA), and nonlocomotive physical activity. Table 5 contains all cited cut points; some authors referenced more than one set of cut points for their data analysis. A total of 9 articles used one or more thresholds derived from the 2011 Compendium of Physical Activity, a comprehensive codebook standardizing self-reported energy expenditure into MET intensity levels [65]. These absolute cut points quantify physical activity into sedentary behavior (1.0-1.5 METs), LPA (1.6-2.9 METs), MPA (3.0-5.9 METs), VPA (6.0-8.9 METs), and VVPA (≥9.0 METs) [66,67].

The Freedson et al [67] cut points relate to the aforementioned MET intensity ranges by the regression equation shown in Multimedia Appendix 5. Per Freedson et al [67], the aforementioned MET values for LPA, MPA, and VPA correspond to <1952 counts per minute, 1952-5724 counts per minute, and ≥5725 counts per minute, respectively. Almost half (n=20) of the studies included in this scoping review used the Freedson et al [67] cut points. Of those using an ActiGraph device, 18 also used the study by Freedson et al [67] to categorize activity intensity. The Matthews et al [68] cut point for sedentary time (<100 counts per minute) compliments Freedson et al [67] but differentiates sedentary behavior from LPA when used concurrently.

The Troiano et al [69] cut points, cited in 8 articles, categorize LPA as 100-2019 counts per minute, MPA as 2020-5998 counts per minute, and VPA as ≥5999 counts per minute. Of the remaining cut points identified through this scoping review, the ones calibrated by Lopes et al [43] are intended to reflect the expected metabolic capabilities of older adults with T2D with overweight or obesity. The thresholds for sedentary-light, light-moderate, and moderate-vigorous activity are 200, 1240, and 2400 counts per minute, respectively (see Multimedia Appendix 5 for the corresponding regression equation). The Lopes et al [43] cut points were applied in 1 additional study to determine the effects of an aerobic exercise intervention on physical activity levels in adults with T2D [31].

Table 5. Frequency distribution for cited cut points (N=46).

Source	Cut points	Studies, n (%)
Counts per minute		
Freedson et al [67]	SED[a] and LPA[b]: <1952 MPA[c]: 1952-5724 VPA[d]: ≥5725	20 (43)
Matthews et al [68]	N/A[e]	11 (24)
Troiano et al [69]	LPA: 100-2019 MPA: 2020 - 5998 VPA: ≥5999	8 (17)
Matthew [8]	LPA: 100-759 MVPA[f]: ≥760	2 (4)
Lopes et al [43]	SED: ≤200 LPA: 201-1239 MPA:1240-2399 VPA: ≥2400	2 (4)
Unknown source	SED: <200 LPA: 202-1800 MVPA: >1800	1 (2)
Unknown source	MVPA: ≥2296	1 (2)
Aguilar-Farías et al [70]	SED: ≤200 LPA: 201-2690 MPA: 2691-6166 VPA: 6167-9642 VVPA[g]: ≥9643	1 (2)
Spierer et al [71], Crouter et al [72], Harvey et al [73]	SED: <20 MVPA: >20	1 (2)
Hamer et al [30]	SED: ≤199 LPA: 200-1998 MVPA: >1999	1 (2)
Metabolic equivalent of task		
Ainsworth et al (if used) [65]	SED: <1.5 LPA: 1.5-2.9 MPA: 3-5.9 VPA: ≥6	9 (20)
Unknown source	MPA: 2-5 VPA: >5	1 (2)
Oshima et al [74]	N-LPA[h]: ≥1.5	2 (4)

[a]SED: sedentary.
[b]LPA: light physical activity.
[c]MPA: moderate physical activity.
[d]VPA: vigorous physical activity.
[e]N/A: not applicable.

[f]MVPA: moderate-to-vigorous physical activity.

[g]VVPA: very vigorous physical activity.

[h]N-LPA: nonlocomotive physical activity.

Discussion

Principal Findings

Among 46 peer-reviewed publications that met our inclusion criteria, this scoping review revealed that an assortment of accelerometer cut points have been used by researchers to categorize physical activity intensity for middle-aged and older adults with T2D. We found that the ActiGraph models GT3x and GT1M were most frequently used for data collection, and the Freedson et al [67] cut points were most applied for analysis. Of the 2 validation/calibration studies identified, one [43] calibrated new ActiGraph cut points with our population of interest.

Challenges in Accelerometer Use

The current literature identifies certain limitations to accelerometer-based cut points that may lead to an underrepresentation of meaningful changes in physical activity. For example, the Freedson et al [67] thresholds were originally validated with a sample of healthy young adults (mean age 24.8, SD 4.2 years for male participants and 22.9, SD 3.8 years for female participants). In comparison, the mean age of study participants in this review ranged from 50 to 79.9 years. The Freedson et al [67] cut points are derived from the simultaneous measurement of activity counts with an accelerometer and metabolic cost with open circuit spirometry during graded treadmill exercises. Therefore, when these cut points are used to assess physical activity interventions among individuals with lower physical capacity, such as middle-aged or older adults with T2D, they potentially underestimate time spent performing MVPA. Miller et al [75] found that, when expressed relative to an individual's maximal aerobic capacity, MPA intensity levels are not consistent across all ages of adulthood. Results revealed a substantial difference between the amount of MPA captured for older (60-69 years) and younger (20-29 years) age groups, 2847-5376 counts per minute versus 4573-6786 counts per minute, respectively. Thus, LPA intensity for a 20- or 40-year-old can be considered MPA intensity for a 60-year-old. With almost half of the studies in our scoping review favoring the application of the Freedson et al [67] cut points for data analysis, it is necessary to consider the implications of using these cut points to interpret physical activity data in populations with ages and abilities different than those of the original population used to validate them.

Multiple authors in our review [21,24,27,42] also noted that data collection is limited by device location, and accelerometers are therefore unable to capture the entire spectrum of human movement, potentially causing a misrepresentation of physical activity quantity and intensity (eg, a waist-worn device may record upper body strength training as sedentary behavior). In addition, the lack of standardization in data collection protocols, as evidenced in our review by the variety of choices for device placement, epoch length, and total wear time, makes it difficult to compare physical activity data across studies. Furthermore, as previously exemplified with the Freedson et al [67] thresholds, the choice of cut points directs data interpretation. Some authors [24,25,55,59,76] recognize that absolute cut points are not sensitive to variations in individual fitness level, which is affected by age and health status. Physical activity data for adults who are older and have chronic diseases like T2D may be disproportionately affected by the use of absolute cut points originally validated with data from their younger and healthier counterparts.

Limitations

Our scoping review is subject to limitations. First, relevant articles may have been omitted due to our inclusion criteria and our specific research questions. For example, populations with lower physical fitness and chronic disease other than T2D were excluded. In addition, our studies were limited to those published in English and available at the time of screening. We eliminated abstracts exclusively reporting step counts; however, walking studies were acceptable if cut points were used to determine intensity. Second, we recognize an inherent potential for bias because we consulted the ActiGraph Corp website research database as the final step of our search strategy. A total of 25 unique articles were identified through this website but were subsequently excluded from analysis after failing to meet our screening criteria. Therefore, our final analysis was not impacted by the decision to search the website. Third, statistical analysis extends beyond the framework of scoping reviews, so we did not perform a quality assessment of the best cut points to use or methodology to follow for future physical activity interventions in our population of interest.

Conclusion

The use of appropriate accelerometer cut points for the measurement of physical activity in middle-aged and older adults with T2D is critical in guiding clinically meaningful public health recommendations for T2D management in these populations. While the Lopes et al [43] cut points have been documented and were used in 1 other study, more interventional research applying them is warranted to confirm if they reflect clinically significant changes in physical activity for adults with diabetes and comorbidities other than overweight/obesity. Alternatively, relative cut points, rather than absolute cut points, could provide a more appropriate determination of physical activity based on individual fitness. Ultimately, there remains a need to develop and further test diabetes-specific cut points that can precisely and accurately assess physical activity interventions and guide public health recommendations.

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Conflicts of Interest

Author SEM holds equity in an early-stage company, See Yourself Health Inc. She has presented sponsored lectures on relationship-centered care sponsored by Merck & Co, which are unrelated to the presented research. See Yourself Health Inc and Merck & Co have no relationship to the research presented in this manuscript.

Multimedia Appendix 1
Narrative description of scoping review search strategy.
[DOCX File , 276 KB - ijmr_v11i2e34433_app1.docx]

Multimedia Appendix 2
Scoping review screening results.
[XLSX File (Microsoft Excel File), 101 KB - ijmr_v11i2e34433_app2.xlsx]

Multimedia Appendix 3
Data extraction form.
[XLSX File (Microsoft Excel File), 9 KB - ijmr_v11i2e34433_app3.xlsx]

Multimedia Appendix 4
Scoping review data extraction.
[XLSX File (Microsoft Excel File), 44 KB - ijmr_v11i2e34433_app4.xlsx]

Multimedia Appendix 5
Regression equations.
[DOCX File , 12 KB - ijmr_v11i2e34433_app5.docx]

Multimedia Appendix 6
Completed PRISMA-ScR (Preferred Reporting Items for Systematic Reviews and Meta-Analyses Extension for Scoping Review) checklist.
[PDF File (Adobe PDF File), 3278 KB - ijmr_v11i2e34433_app6.pdf]

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Abbreviations

LPA: light physical activity
MET: metabolic equivalent of task
MPA: moderate physical activity
MVPA: moderate-to-vigorous physical activity
RCT: randomized controlled trial
T2D: type 2 diabetes
VPA: vigorous physical activity
VVPA: very vigorous physical activity

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Original Paper

Challenges of Type 2 Diabetes Mellitus Management From the Perspective of Patients: Conventional Content Analysis

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Abstract

Background: Patients with type 2 diabetes mellitus (T2DM) face significant challenges in the treatment process, which can have a negative impact on disease management. Proper management of the disease can reduce symptoms and complications, improve glycemic indices, and reduce mortality and readmission.

Objective: Given the influential role of patients in prevention and self-care, this study was conducted to explore the challenges of diabetes management from the perspective of patients.

Methods: Two rounds of focus group discussions with T2DM patients were conducted. The principal investigator of the study and a research assistant compiled a list of volunteer patients with names and contact information and selected participants based on their medical information. Participants were chosen via a purposive sampling technique. The questions were designed to encourage patients to share their views on how the treatment team communicates and participates in treatment, how they are trained, and the health care system. The discussion continued until data saturation. During 2 rounds of focus group discussions, the voices of the participants were recorded by 2 voice recorders, and one of the team members was a transcriber. After discussion, participant views were transcribed, and common issues were identified, sorted, and reported as categories and subcategories.

Results: According to the conventional content analysis, 88 primary codes were extracted from the detailed and in-depth description of the participants. The codes were summarized after repeated readings and classified based on their similarities and semantic relevance. Through analysis and comparison, 4 categories and 7 subcategories were identified: communication challenges (poor medical staff communication, lack of psychological support), challenges to participation in treatment (lack of patient participation), educational challenges (training program bugs, inadequate training), and challenges of the health care system (inefficiency of the care system, caregiver inefficiency).

Conclusions: This study showed that the treatment team members should pay more attention to the challenges of care and treatment from the perspective of patients with T2DM. Therefore, recommendations for future policies to overcome these obstacles include establishing a multidisciplinary health care team; using trained health care workers to provide organized treatment and care services; holding individual counseling sessions with patients in need of counseling; and providing counseling services, involving patients in the treatment and self-care process, and designing a comprehensive diabetes education program with an emphasis on education. Necessary information should be provided to the patients, and effective communicate should address patient concerns.

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KEYWORDS

diabetes mellitus; challenges; conventional content analysis; disease management; Iran

Introduction

Type 2 diabetes mellitus (T2DM), with all its complications and consequences, constitutes the most critical problem for health systems worldwide. It is estimated that in 2014, 422 million adults lived with diabetes compared to 108 million in 1980 [1], which shows an almost 4-fold increase over a 34-year period. The prevalence of T2DM is expected to increase to 592 million adults worldwide in 2035 and 642 million adults by 2040 [2,3].

The prevalence of T2DM has affected all areas of the world, but the prevalence of T2DM is higher in low- and middle-income countries. It is estimated that about 12% of the total health expenditure in the world is spent on treatment of T2DM and related complications, and most countries spend 5% to 20% of their national health budgets on this disease [4]. In Iran, a national prevalence of 11.4% means that there are 4 million adults with diabetes. It is estimated that this number will reach 9.2 million by 2030 [5].

Management of diabetes is one of the most important priorities of the World Health Organization [6]. Diabetes complications threaten the health of patients and cause an economic burden on societies [7]. Studies have shown that for better management of diabetes complications and improvement of self-care, educational and counseling interventions should be provided by health workers [8,9]; however, patients' knowledge and management of their disease are not always improved by educational interventions [10]. Evidence has shown that interventions based on lifestyle modification can be very efficient and effective in managing diabetes [11,12]. These interventions mostly rely on patient knowledge, attitude, behavior, and self-care to increase patient self-management, the strength of these interventions.

In other words, diabetes control requires a multidisciplinary care approach with a focus on self-management, in which the patient and family are at the center and the activity of all members of the treatment team is necessary to identify and cover the treatment and care needs of the patient and family [13]. Medical prescriptions and education are important dimensions of self-management, but behavioral and emotional dimensions are important as well. These dimensions are mainly focused on the patient and their emotions. Patients neglect their feelings and emotions when receiving the mass of information and education from health workers and cannot fully manage the condition. Patients must understand the disease, have a chance to adapt to the disease, and adjust the dimensions of their life with this disease. Multidisciplinary care can provide timely and effective care to patients [14]. Studies have shown that to achieve an effective prevention program and a comprehensive care program, understanding patients' feelings and opinions about health conditions is essential. When adopting a comprehensive approach to diabetes care, we must consider patients' feelings, concerns, fears, and expectations in our plans [15]. Because focus groups are used to explore perspectives on health issues, programs, interventions, and research [16], we used focus group semistructured discussions with groups of 4 to 12 people to examine a set of issues [17]. Managers usually start the discussion by asking broad questions about the topic of interest before asking focal questions. Although participants answer the facilitator's questions individually, they are encouraged to talk and interact with each other [18]. This technique encourages respondents to explore and clarify individual and share perspectives [19].

One of the most important factors in controlling chronic disease is the participation of patients in disease management. Therefore, patients with diabetes and their families should learn about measures such as monitoring blood glucose, choosing an appropriate diet, and increasing physical activity [18]. Most of the studies have been conducted on the views of health workers regarding the disease and self-management of diabetes [17]. However, the patients who live with the disease must adapt to its symptoms and complications and manage the disease. Therefore, behaviors and feelings of patients are important dimensions of self-management and should be given prominence as an important indicator of the patient's condition and compliance with treatment. Due to the pivotal and effective role of patients in the multidisciplinary team for the care and control of T2DM, the aim of this study was to investigate the challenges of T2DM management from the perspective of the patients.

Methods

Study Design

In this study, a qualitative methodology was selected and focus group discussion (FGD) was used as the study method. FGD is a qualitative research method in which the facilitator asks questions and participants volunteer their opinions, creating opportunities to extract information on a topic through group discussion. This also encourages participants to interact and exchange information about their experiences and perspectives

[20-22]. Due to the interaction and effects of individuals on one another, FGDs show the dimensions of perception and knowledge of individuals, which are inaccessible through other methods of data collection [23]. A consolidated criteria for reporting qualitative research (COREQ) checklist is used to write the article [16].

Participant Selection

Patients with T2DM were included in the study. Inclusion criteria were the ability to participate in the FGD without assistance (ie, understanding and speaking in Persian language and not having a cognitive impairment, which makes the interview difficult). Patients suffering from mental or physical disability were excluded from the study. After coordinating with the clinic supervisor, patients were simultaneously invited to participate in the FGD. Sampling was purposive. Two investigators (principal investigator and research assistant) selected study participants based on medical information. Background disease, disease duration, marital status, education level, type of drugs (oral antidiabetic drugs and insulin), and history of diabetes complications including retinopathy, nephropathy, diabetic foot ulcer, neuropathy, and cardiovascular diseases were recorded by the researchers. The researchers determined the time and place of the meetings in the clinic. The researchers had no previous relationship with any of the study participants, and they did not work at the clinic where this study was conducted.

Setting

This study was performed at the Diabetes and Metabolic Diseases Clinic affiliated with Tehran University of Medical Sciences (Tehran, Iran). After providing written informed consent, participants were invited to participate in the FGDs. We arranged the patients in a circle position to improve group interactions and accurately record their voices. Each round of FGDs took less than 2 hours. At the beginning of each session, the principal investigator explained the objectives of the study to the participants and described their participation and activities in detail. The research assistant helped record the interviews, observe group interactions, take notes, and facilitate the discussion with probing questions.

Data Collection

One researcher (ie, the principal investigator of the project) was as facilitator during the 2 rounds of FGDs, while another researcher took notes on the topics discussed and recorded participant reactions. Participants were asked to follow instructions explained to them at the beginning of each round of FGDs: each participant should introduce themself at the beginning, and they should not interrupt each other. Thus, the FGDs began with open-ended questions about challenges from the perspective of patients with T2DM.

The following questions were asked during the FGDs:

- What is your experience with how health care providers communicate?
- How do you feel about your participation in the management (both care and treatment) of your disease?
- What are your health care providers' views on diabetes education?
- What are your main challenges in dealing with the health care system?

The facilitator encouraged the participants to express their opinions and experiences on related topics. The next questions were asked based on the answers of the participants. General promotional questions were asked to enrich the data: "What do you mean?" "Can you explain more?" "Can you give an example?" and "Would you like to mention anything else?"

The responses of the participants were recorded through 2 voice recorders and note-taking. We held 2 FGD rounds, with each round lasting less than 2 hours. First, 12 patients were selected. Two patients did not participate due to lack of time; 10 patients participated in the first round, and the same 10 patients participated in the second round. At the end of each FGD round, participants were asked to state what else they thought was important in the process of diabetes management and care.

Data Analysis

The FGDs were ended when data saturation was reached. In other words, we continued the discussion until no new ideas were expressed or when the responses were similar or repetitive [24]. Conceptual transcription and mining were performed simultaneously. Conventional content analysis was done based on the 3 main steps of preparing, organizing, and reporting the analysis [25-27].

In the preparation phase, all recorded FGDs were transcribed. In case of any doubts on understanding the responses or any disagreement, the third researcher was consulted or a member check was applied. The transcribed FGDs were then read several times, and codes were identified. In the next step, similar open codes were classified into subcategories. Based on similarity and semantic relevance, subcategories were then divided into categories, and finally, categories, subcategories, open source, and key phrases were extracted from transcripts. In the final step, the analysis was reported.

Trustworthiness

Trustworthiness is one of the most important dimensions of qualitative studies. According to Bowen [28], 4 reliable criteria including credibility, transferability, consistency, and conformability were considered in this study.

To ensure credibility, researchers tried to communicate well, spend enough time, and gain participants' trust in data collection process. In order to do a member check, the results were returned to the participants to check the opinion of members and ensure the accuracy of the collected data. The research team also had a considerable conflict with qualitative data. In order to maintain transferability, we tried to avoid homogeneous participation by having the maximum variety in terms of age, sex, type of medication, disease duration, and history of diabetes complications, including retinopathy, nephropathy, neuropathy, cardiovascular diseases, and diabetic foot ulcer. To ensure consistency, all stages and research process were recorded and reported as thoroughly as possible.

Ethics Approval

This study was approved by the research ethics committee of Tehran University of Medical Sciences in 2019 (approval: IR.TUMS.MEDICINE.rec.1397.847). All participants signed the written informed consent forms. Participants agreed to having their voices recorded, and the researchers made sure the data were anonymous and confidential at all times. The researchers promised that the information would remain confidential and the files and transcripts of interviews and voice records would be deleted at the end of the investigation.

Results

Participant Characteristics

Table 1 shows the characteristics of study participants. According to this table, 5 out of 10 participants were men aged 34 to 77 years, and 7 participants were married and lived in urban areas. Duration of the disease was between 10 and 27 years (Table 1).

According to the conventional content analysis, 88 codes were extracted from the rich and in-depth descriptions of the participants. The codes were summarized after repeated readings and classified on the basis of their similarities and semantic relevance. Through analysis and comparison, 4 categories and 7 subcategories were identified as shown in Table 2.

Table 1. Characteristics of the study participants.

No.	Gender	Age (years)	Marital status	Education level	Residential status	Type of medications	Disease duration (years)	Complications of diabetes
1	Man	50	Married	High school	Urban	Oral tablets and insulin	20	• Cardiovascular disease
2	Woman	34	Single	High school	Urban	Oral tablets and insulin	10	• Obesity • Cardiovascular disease
3	Woman	60	Married	High school	Urban	Oral tablets and insulin	14	• Retinopathy • Hypertension • Dyslipidemia
4	Woman	71	Married	High school	Urban	Oral tablets	26	• Retinopathy • Cardiovascular disease • Skin dryness • Skin itching
5	Man	53	Married	College	Urban	Oral tablets	14	• Hyperthyroid
6	Man	77	Married	High school	Urban	Oral tablets	12	• Retinopathy • Nephropathy • Cardiovascular disease • Diabetic foot
7	Man	63	Married	College	Urban	Oral tablets	11	• Retinopathy • Hypertension • Dyslipidemia
8	Woman	74	Widow	High school	Rural	Oral tablets	22	• Retinopathy • Cardiovascular disease • Hypertension
9	Woman	61	Widow	High school	Rural	Oral tablets and insulin	27	• Retinopathy • Hypertension • Dyslipidemia • Digestive problems
10	Man	74	Married	Illiterate	Rural	Oral tablets and insulin	17	• Retinopathy • Cardiovascular disease • Hypertension • Dyslipidemia • Anorexia • Gastrointestinal upset

Table 2. Categories, subcategories, and codes discovered in the study.

Category/Subcategory	Code
Communication challenges	
Poor medical staff communication	• Insufficient understanding and empathy • Unkindness and disrespect • No face-to-face communication • Inflexibility of health staff
Lack of psychological support	• Creating fear in the patient about signs and consequences of the disease • Change of doctor due to inappropriate behavior of the doctor • Lack of individual counseling • Lack of suitable space for consultation and haste of health staff
Challenges to participation in treatment	
Lack of patient participation	• Not giving the patient the right to comment • Lack of explanation about the treatment process: complications, alternative therapies and duration of treatment • The patient is not involved in nutrition
Educational challenges	
Training program bugs	• Continuity of training programs • Training programs do not start on time • Advertising for fellow physicians in training programs
Inadequate training	• Dissatisfaction with the educational information provided and its duration • Get additional information from other educational resources • Providing information in an authoritarian manner • Lack of adequate training in the diagnosis and treatment and complications of the disease • Not giving enough training in self-care • Not teaching about traditional medicine
Challenges of the health care system	
Inefficiency of the care system	• Short visit by a doctor • Not seeing a doctor even by paying for a visit • Lack of access to the relevant specialist (in person or by phone) • Do not do specialized patient work as a team • Duplicate record making for the patient
Caregiver inefficiency	• Do not follow the patient's treatment

Communication Challenges

Poor communication by medical staff included insufficient understanding and empathy, unkindness and disrespect, lack of face-to-face communication, and inflexibility of health workers. Patients expressed their opinions that health personnel do not care about patients and the disease, and members of the diabetes treatment team did not have a close relationship with and did not listen to patients.

Disrespect by the medical staff was expressed from the patient's point of view.

> *The patient who cried while talking and said I live alone and I'm nervous. I would like them to talk to me and support me.* [Participant 6]

Patients wanted the doctor to pay attention and make eye contact when talking to them.

> *The doctor is also working on his computer while talking to me and this behavior bothers me.* [Participant 5]

Lack of psychological support was another subcategory. Patients were worried about their symptoms and illness, and the health care staff did not address their complaints or spend enough time to listen to them (see examples in Textbox 1). Patients sometimes changed doctors because of this.

Communication problems between patient and health care provider are caused by various factors. The patient's condition and perspective help to determine these factors. Patients with diabetes have many different meetings with health care providers due to the symptoms and control of the disease, and the issue of communication is of great importance for these patients. On the other hand, many doctors and nurses do not answer the questions of these patients because they believe that they received enough training.

Therefore, communication problems can be an obstacle in the process of patient management and cause noncompliance with treatment. It is necessary to solve this problem by considering the patient and the patient's emotions and feelings.

Textbox 1. Illustrative quotations about lack of psychological support.

- My blood sugar drops late at night and I don't know what to eat. [Participant 3]
- When I eat something, my blood sugar rises to 300 at once and I get very worried. When I tell my problem, they tell me to eat less. [Participant 6]
- When I have hypoglycemia, I feel very drowsy. I do not have the patience to talk to anyone, I feel very hot, and it's hard to breathe so I open the windows. [Participant 4]
- I have severe dry mouth, this symptom annoys me a lot. [Participant 1]
- Lack of appetite control and overeating. Sometimes I overeat and I like to eat everything and I don't pay attention to what people around me say. [Participant 2]
- I do not feel like going to exercise, even though I know I should be physically active. [Participant 8]
- I get full early when I eat. [Participant 7]
- I get very nervous when my blood sugar rises. [Participant 9]
- Sometimes my toe hurts and sometimes at night my feet get very cold and my toes get cold and hot. [Participant 5]
- I worked for a food company. I had severe itching and bleeding from scratching, and I did not know what to do. I went to the doctor. He asked about my workplace and then said "You are miserable because your blood sugar is above 400. Do not eat sweets at all." I was very scared. Good behavior of the doctor in the office with the patient is very important. A patient complained about the doctor's bad behavior and had to change his doctor. [Participant 10]
- I had to change my doctor because of uncaring behavior. He didn't answer my questions and got angry and threw me out of his office once. [Participant 8]

Challenges to Participation in Treatment

Challenges to participation in treatment has one subcategory, lack of patient participation, which originates from not giving the patient the right to comment; lack of explanation about the treatment process including complications, alternative therapies, and duration of treatment; and not involving the patients in nutrition programs and physical activity.

Patients like to participate in the treatment and care process, including the type of medications, nutrition, and exercise. They also like the health care providers to explain why these things should be done for them. They stated that decisions are often made for them without considering the their opinion.

> *The doctor did not allow me to comment on my illness and kicked me out of the room.* [Participant 3]

Nonparticipation in treatment, changing medications, and lack of a diet program were challenges some patients encountered.

> *The medical staff made a quick decision about how to treat my illness. At first, I only took pills for diabetes. When my A1C was close to 10, they told me to take my insulin first, and they did not give me any training or consultation.* [Participant 8]
>
> *They did not involve me in how to eat with diabetes; they just gave me a plan and told me to do it.* [Participant 9]
>
> *I have a lot of appetite and I am not satisfied with the diet that the health staff has prepared for me without my consultation and participation.* [Participant 1]

Not paying attention or listening and neglecting the patient creates a mental burden for the patient. The patient feels that the doctor repeats the medication orders in a routine and usual manner. Involving the patient in the treatment process can strengthen the trust and relationship between patient and treatment team.

Educational Challenges

Participants cited educational challenges in the form of training program bugs, such as continuity of training programs, not starting training programs on time, and advertising for fellow physicians in training programs. In addition, patients stated that training programs should be continued and sometimes training programs are not held. Training programs usually do not start on time. In training programs, doctors advertise to their colleagues and this is not acceptable.

> *Training programs do not start on time and are advertised for another doctor.* [Participant 6]
>
> *Training programs are not held regularly.* [Participant 9]

Complaints of inadequate training consisted of dissatisfaction with the educational information provided and its duration; difficulty getting additional information from other educational resources; and inadequate training in the diagnosis, treatment, and complications of the disease and about self-care. Additional complaints were raised about not teaching traditional medicine and providing information in an authoritarian manner. The patients complained that they were not given enough and correct information about the time to take pills in the educational programs. They also liked to be given information about the use of herbal medicines.

> *They do not teach me about taking drugs. I took diuretic pills at night. I had frequent urination. Today, when I had a problem, I was taught that I should take this pill in the morning. When the training here is not complete, we have to use virtual space to find answers to our questions, which we do not know are valid.* [Participant 10]

Patients also complained of insufficient training and incomplete education about self-care.

> *A few years ago, when my blood sugar was high, they told me that I had diabetes and they gave me 300 ml of vitamin B1, and they told me to walk more, and they did not teach me about diet and disease.* [Participant 7]
>
> *The first time I had high blood sugar and they said I had diabetes, my blood sugar was 180 and they gave me half a pill of Goli Bin Kalamid and they did not tell me what to eat and what not to eat and they just told me not to eat sweets.* [Participant 9]
>
> *When I was diagnosed with diabetes, I was only taught to walk and I was not taught about nutrition.* [Participant 8]
>
> *They do not teach about traditional medicines.* [Participant 1]
>
> *They do not answer me when I talk about using herbs to lower blood sugar.* [Participant 2]

Challenges of the Health Care System

Inefficiency of caregivers and the care system were identified as challenges in the health care system. According to the patients, insufficiency of the care system included short visits with the doctor, not seeing a doctor even if paying for a visit, lack of access to relevant specialists (in person or by phone), lack of provider team work, and duplicate record making for the patient.

> *The duration of the doctor's visit is very short. The doctor's visit time is very short. The doctor quickly examines and prescribes medicine, and this makes me very uncomfortable in every visit. Whenever I protest, he says that he should visit other patients as well.* [Participant 1]

Patients also complained that sometimes they paid for a doctor's visit but were not visited by a doctor.

> *Although we pay for a doctor's visit, and sometimes we even pay for two doctor visits, but we do not see the doctor, and then the survey form is texted that you are satisfied with the doctor? And they expect me to fill in the evaluation form.* [Participant 5]

In addition, the patients were upset that things were not done by the team in an organized manner, and they had to visit several times to get services.

> *Things are not done as a team. I have to visit a doctor once and another day for nutrition counseling.* [Participant 2]

Patients were dissatisfied with the medical record filing system, and the system was not working well. Each new group that comes to the clinic creates a new file for the patient.

> *I have a record in this diabetes clinic for 18-17 years. The new people who came filed a record for me again.* [Participant 4]

Another challenge was caregiver insufficiency. The most important issue raised by patients regarding caregiver efficiency was follow-up.

> *The first time my blood sugar was high, the doctor told me to get rid of stress and adjust my diet and walk for an hour a day. The next time I went, he said my blood sugar was low and I did not take any further action because the doctor did not insist on taking medication. He did not follow up and the next time I went; my blood sugar was so high that I had to inject insulin.* [Participant 9]

Discussion

Principal Findings

Due to the important and effective role of patients in better prevention and self-care, focus group meetings were held to review the challenges of patients with diabetes for disease management. The results showed their challenges in 4 main categories including communication challenges, challenges to participation in treatment, educational challenges, and challenges of the health care system.

Communication problems in the treatment staff and training program indicate ineffective communication and inadequate patient education. The results of a study investigated the barriers to diabetes care in a developing country. This study showed that patients need more time to understand the content of the educational program provided by the treatment team, and the treatment team needs to allocate more time to patients [29]. Another study found that communication discordance with the health care members was an obstacle to understanding diabetes education [30]. Another study determined that communication skills of health system employees are very important in the management of patients with diabetes, and they may be able to have a greater impact on the patient's perception through effective communication skills [31]. A third study reported that according to the patients' experiences of communication with health care providers, factors such as trust and confidence, willingness to communicate, attention to the patient's emotional dimension, and the appropriateness of the meeting time and conditions are essential in effective communication [32]. Therefore, it seems that communication is a key for achieving better self-management in patients. In several previous studies, unprofessional behavior of the medical staff with patients was not directly mentioned, but in this study, patients complained of insufficient understanding and empathy, unkindness and disrespect, and lack of face-to-face communication and flexibility of the medical staff, all of which are classified as communication challenges [33-36].

One of the most important factors in controlling this disease is the participation of patients in the treatment [37]. The results of the study showed that in order to achieve an effective prevention program and comprehensive care program, the presence, feelings, and understanding of patients about their health condition are necessary [15]. Our study highlighted that one of the challenges in the management of the patients with T2DM was lack of patient participation. Review of the literature also showed that patient activation and patient involvement in

treatment play a crucial role in self-management of patients with T2DM [38-40]. Recent review article determined that patient activation can be used as a reliable tool for improving T2DM self-management and clinical outcomes [38]. Another study was found a relationship between patient empowerment, self-management education, and lifestyle modification in the management of patients with diabetes [39]. Patient empowerment can cause more coordination between the treatment staff and the patients. In addition, the awareness of the patients about their condition and disease increased by empowering them.

Our study showed that patients face educational challenges in the management of diabetes. In a study on barriers to self-care, diabetics requested more time for visits and counseling. They also needed to continue their education in different ways and update their information on diabetes care [41]. Another similar study on barriers to self-care education for diabetics from the perspective of nurses and patients showed that one of the main reasons for inadequate self-management in patients with diabetes is the existence of barriers in educating these clients [42]. A study in Bangladesh found that to better understand patients' views on diabetes and drug beliefs and identify psychological stress, health care providers should provide quality health education interventions and more up-to-date information to patients [43]. A study in Pakistan on patients' perspectives, experiences, and barriers toward diabetes-related self-care reported that counseling by health care providers is the key enabler that encourages study participants to adhere to diabetes-related self-care practices [44]. Lack of understanding about diabetes medication management and long-term safety of diabetes medications could be the examples of poor inadequate training [30].

The results of this study showed that obstacles in the management of diabetes from the patients' view are problems related to the care system and health system. Lack of support for patients was one of the most important problems mentioned in previous studies [31,43,45]. Financial and social support can effectively help to better manage the disease [46]. The lack of support for patient caregivers was also an obstacle to disease management from the patients' view [47]. The results of the study showed that patients need to talk to the treatment team about emotions, such as anxiety, frustration, and inattention, and need their support. This may be more the case in developing countries where there is a shortage of specialist clinics and time constraints on multidisciplinary diabetes treatment teams. Studies also require group consultation with patients and experiences. One of the main reasons for inadequate self-management in diabetics is the existence of barriers in educating these clients. The care system provides insufficient support for patients in the field of medications and therapeutic interventions. Diabetes is a chronic disease requiring medication regimens and regular visits to providers. Therefore, support measures such as insurance coverage and reduction the number of drugs and treatment costs should be considered for these patients [48].

Limitations

The most important limitation of this study was related to the nature of the study methodology. The generalizability of the qualitative study is limited. Another limitation was that only 2 rounds of FGDs were held, fewer than the researcher expected. In qualitative studies, data saturation is a definite determinant of ending the study. In this study, due to the similarity in patients' opinions and the lack of a new opinions and ideas after 2 rounds of FGDs, this factor may not affect the findings.

Conclusions

The results showed that patients pay more attention to nontherapeutic issues than therapeutic issues. Communication with the patient, patient education, proper support from the health system, and adequate participation in treatment were challenges that made the process of treatment and self-management difficult for patients. Therefore, it is necessary to pay attention and check these cases in the management of the patient. A comprehensive training program should be designed to address these patient concerns.

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Authors' Contributions

SN was responsible for the conceptualization and design of the study, data collection, statistical analysis, and writing the first draft of the manuscript. NM, TNG, MKM, and BL contributed to study design. RH and MA were involved in data collection. NM and TNG performed data analysis. All authors contributed equally to interpretation of the results. MN reviewed the manuscript and edited the final version.

Conflicts of Interest

None declared.

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Abbreviations

COREQ: consolidated criteria for reporting qualitative research
FGD: focus group discussion
T2DM: type 2 diabetes mellitus

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Original Paper

Predicting Therapeutic Response to Unfractionated Heparin Therapy: Machine Learning Approach

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Abstract

Background: Unfractionated heparin (UFH) is an anticoagulant drug that is considered a high-risk medication because an excessive dose can cause bleeding, whereas an insufficient dose can lead to a recurrent embolic event. Therapeutic response to the initiation of intravenous UFH is monitored using activated partial thromboplastin time (aPTT) as a measure of blood clotting time. Clinicians iteratively adjust the dose of UFH toward a target, indication-defined therapeutic aPTT range using nomograms, but this process can be imprecise and can take ≥36 hours to achieve the target range. Thus, a more efficient approach is required.

Objective: In this study, we aimed to develop and validate a machine learning (ML) algorithm to predict aPTT within 12 hours after a specified bolus and maintenance dose of UFH.

Methods: This was a retrospective cohort study of 3019 patient episodes of care from January 2017 to August 2020 using data collected from electronic health records of 5 hospitals in Queensland, Australia. Data from 4 hospitals were used to build and test ensemble models using cross-validation, whereas data from the fifth hospital were used for external validation. We built 2 ML models: a regression model to predict the aPTT value after a UFH bolus dose and a multiclass model to predict the aPTT, classified as subtherapeutic (aPTT <70 seconds), therapeutic (aPTT 70-100 seconds), or supratherapeutic (aPTT >100 seconds). Modeling was performed using Driverless AI (H2O), an automated ML tool, and 17 different experiments were iteratively conducted to optimize model accuracy.

Results: In predicting aPTT, the best performing model was an ensemble with 4x LightGBM models with a root mean square error of 31.35 (SD 1.37). In predicting the aPTT class using a repurposed data set, the best performing ensemble model achieved an accuracy of 0.599 (SD 0.0289) and an area under the receiver operating characteristic curve of 0.735. External validation yielded similar results: root mean square error of 30.52 (SD 1.29) for the aPTT prediction model, and accuracy of 0.568 (SD 0.0315) and area under the receiver operating characteristic curve of 0.724 for the aPTT multiclassification model.

Conclusions: To the best of our knowledge, this is the first ML model applied to intravenous UFH dosing that has been developed and externally validated in a multisite adult general medical and surgical inpatient setting. We present the processes of data collection, preparation, and feature engineering for replication.

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KEYWORDS

heparin; activated partial thromboplastin time; aPTT; predictive modeling; machine learning; personalized medicine

Introduction

Background

Unfractionated heparin (UFH) is a parenteral anticoagulant used for the prevention and treatment of arterial and venous thromboembolic diseases [1,2]. UFH consists of a heterogeneous mixture of polysaccharides with varying molecular lengths and weights; therefore, direct monitoring of serum drug concentrations to guide optimal dosing is not possible [3,4]. Instead, a surrogate of bleeding time, activated partial thromboplastin time (aPTT), is used to monitor the dose-dependent response [5]. The initial bolus and maintenance doses of UFH are estimated by clinicians using weight-based formulas (units of UFH/kg for bolus and units or UFH kg/hour for maintenance), with the aim of achieving a defined therapeutic aPTT range. Future doses are continually adjusted to maintain this therapeutic range (TR) [6-8], which varies depending on the therapeutic indication [1]. An aPTT value below the TR (subtherapeutic) is linked to reduced efficacy (high probability of recurrence or progression of thromboembolic events), whereas values above the TR (supratherapeutic) are linked to the risk of bleeding [9,10]. For patients with life-threatening thromboembolic events, clinicians aim to rapidly achieve a therapeutic aPTT and maintain a TR for the duration of UFH therapy. In the hospital setting, UFH therapy commences with a bolus (loading) dose followed by a maintenance infusion, and an aPPT is quantified within 12 hours [1,6]. This result provides guidance for further dosing, and clinicians often rely on dosing nomograms (Multimedia Appendix 1).

UFH is an extremely complex and difficult drug to accurately dose. The UFH molecules are distributed freely throughout the body; bind to many physiological sites including clotting factors, endothelial cells, and macrophages [4]; and are eliminated from the body via several physiological pathways. This creates marked variation in its pharmacokinetics and dose response between patients, such that there is no standardized *one-dose-fits-all* strategy [8-11]. Despite the use of nomograms to optimize dosing, it is difficult to achieve and maintain a TR that places patients at risk. For example, excessive dosing may result in up to 5.5% of patients having a bleeding event [12]. Studies evaluating metrics of safety and effectiveness, such as time to TR, time within TR, and percentage of patients within TR, have demonstrated an inability to predict optimal dosing with confidence [13-15]. The time to TR after initiation of UFH can be as long as 60 hours in some studies, and a recent local study of 200 patients showed a median time to TR of 36 hours [16]. In another study, only 29% of the patients had 2 consecutive therapeutic aPTTs [15] throughout the duration of treatment. Even in large clinical trials with strict patient monitoring, the percentage of patients attaining aPTT in TR within 48 hours is less than 50% [17-19]. Clearly, many factors influence bodily responses to UFH, which are independent of body weight and are not accounted for in current dosing strategies [7].

Related Work

Machine learning (ML) is a subset of artificial intelligence that identifies patterns in large data sets and encodes them into models to predict new data [20,21]. ML has great potential for providing decision support tools in modern health care [20,22-24], which are developed using large volumes of digitized patient data contained within electronic health records (EHRs) [25-27]. To achieve optimal dosing of UFH, ML methods can potentially be used to develop models that make accurate predictions for the target aPTT in response to UFH dosing. However, there have been few studies to date on how to use ML to optimize UFH dosing [28]. A recent systematic review [28] identified 8 studies using ML for UFH. Out of these, 4 studies predicted aPTT [29-32]; 1 study [33] reported out-of-TR surrogates for aPTT, including bleeding and clotting events; and the remaining 3 studies [34-36] evaluated UFH dosing in hemodialysis patients [28]. To date, 5 studies [29,30,32,33,36] have been conducted in the intensive care units (ICUs) of hospitals in the United States using retrospective data and 3 studies in the dialysis setting [34-36].

A variety of modeling approaches were reported. Four studies reported supervised learning methods including random forests, adaptive boosting, extreme gradient boosting, and neural networks [30,32,34,36]. One study used an unsupervised approach to train the model, which was then fine-tuned using a supervised approach [34]. Three studies also used regression analysis [29,30,34], 2 studies used a reinforcement learning approach to develop their models [33,36], and 1 study [31] compared neural networks with nonlinear mixed-effects modeling methods. Studies have reported a wide range of performance metrics including accuracy, precision, recall, area under the receiver operating characteristic curve (AUC), F_1-score (a combination of precision and recall), and coincidence rates. The study by Su et al [32] reported the best model accuracy at 88%. Ghassemi et al [29,30] reported 2 studies on modeling for the prediction of UFH dosing, with 1 study reporting a model developed using multinomial regression to predict subtherapeutic and supratherapeutic aPTT, which had superior performance to ML methods. Their later work explored 4 modeling methods, including reinforcement learning and neural networks, with modest accuracies ranging from 0.56 to 0.6. Overall, the multinomial regression model outperformed the ML methods and was a more appealing model because of its clinical interpretability, which is important in the context of implementation and stakeholder engagement. All studies provided limited reporting of reproducibility, and, except for one study by Smith et al [31], none were validated in a new cohort. Most recently, Li et al [37] reported the development and validation of a multiclass aPTT model and subsequent dose prediction application for use in the ICU setting using a shallow neural network approach. The top 5 features for both data sets

included a patient's baseline aPTT, patient weight, total UFH administered, serum creatinine, and age. The model reported performance metrics similar to those of prior studies, with an F_1-score of 0.887 to 0.925. As with prior studies, the study population was limited to ICU patients and may not be generalizable to other clinical settings. It also does not provide guidance on the exact dose changes that clinicians desire at the point of care.

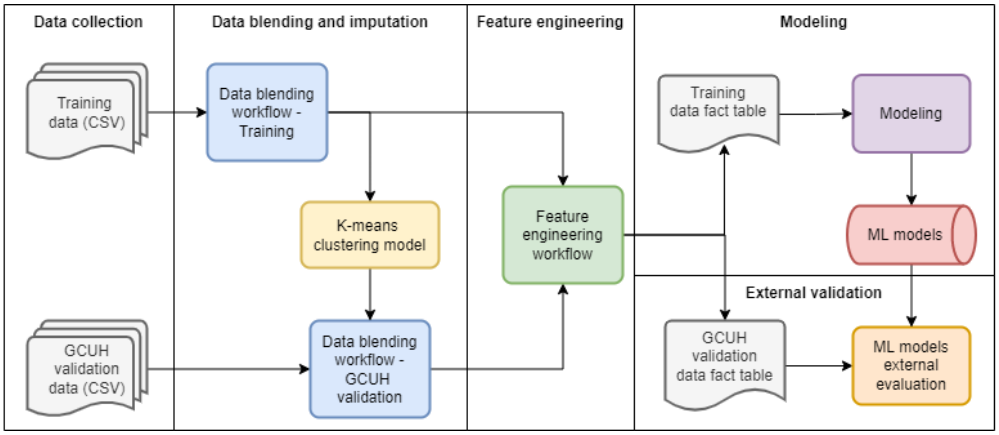
As evidenced by a recent systematic review [28], no identified models had their impact evaluated within routine clinical practice, and research remains limited and of variable quality. In this body of work, we aimed to develop a model that could be used in hospital general medical and surgical wards, which overcomes the limitations of previous studies with regard to methods, reporting, and external validation.

Methods

Data Flow

Figure 1 depicts the data flow and architecture of the project, which is divided into 5 phases. Phase 1 outlines the data collection in which data files were extracted from EHRs from 5 hospitals, of which 4 were used in model development and the fifth was retained for external validation. In phase 2, the 2 data sets underwent the same phase 2 transformations and mapping process (data blending and imputation), except that the clusters built using the training data set were used unchanged in the validation data set to prevent outcome leakage, where parts of the training data used to create a model were not available at the time of prediction. After data blending, we conducted feature engineering in phase 3, which was again applied to both data sets using the same process. The outputs from the feature-engineering workflow were 2 fact tables: the engineered training data, which were input into the H2O Driverless AI tool to build the ML models (phase 4), and the validation data used to validate the model predictions (phase 5). The same pipeline structure, as shown in Figure 1, was applied in developing and validating a regression model to predict the exact aPTT value and a multiclass model to predict the aPTT class (subtherapeutic, therapeutic, and supratherapeutic), with minor differences in data blending to prepare the outcome columns.

Figure 1. Experiment setup including training and validation processes. GCUH: Gold Coast University Hospital; ML: machine learning; CSV: comma separated values.



Ethics Approval

This research work was granted a low-risk research protocol approval and a waiver of consent by the Metro South Health (MSH) Human Research Ethics Committee for ethical and scientific review (reference number LNR/2019/QMS/54581). We confirm that the work completed in this project is consistent with ethics approval of the acquired research.

Data Collection

EHR data were collected retrospectively for patients admitted between 2017 and 2020 on consecutive admissions to 5 digital hospitals (one health district) in Queensland, Australia, in which UFH was administered for therapeutic purposes. Model development and external validation were undertaken within the Clinical Informatics Division of MSH. We collected data on UFH that were prescribed using a power plan, which is an EHR decision support tool for specific clinical scenarios that facilitates timely ordering of laboratory tests, medication prescribing, and interdisciplinary communication. Four adult-specific power plans that MSH clinicians use, which were used to identify patients eligible for study inclusion, were acute coronary syndrome, deep vein thrombosis or pulmonary embolism, bridging therapy for oral anticoagulants (warfarin replacement), and low–target-range aPTT anticoagulation for neurosurgical patients. This initial patient cohort was then filtered based on the selection criteria defined by the clinician authors:

- Inclusion criteria: adult patients administered a UFH bolus dose and a maintenance infusion for more than 48 hours, had a documented power plan, and had an aPTT result recorded within 12 hours of the UFH bolus dose.
- Exclusion criteria: ICU patients as ICUs use an ICU-specific EHR that is not linked or integrated into the general EHR system in MSH.

A total of 2783 hospital admissions were identified, involving 2470 patients at the 4 hospitals in MSH whose data were used for model development and 236 hospital admissions involving 221 patients at the hospital where data were used for external validation.

Next, we determined the data tables to be collected from the EHRs and generated an initial list of features. Using previous studies in the literature and the content expertise of collaborating clinicians, we identified 15 data tables that were intentionally inclusive at this stage, while recognizing that some would be removed later if found to be irrelevant or if the data were incomplete. Multimedia Appendix 2 lists the tables showing the number of features extracted from each table before and after the feature-engineering phase.

Data Blending and Imputation

Using the identifier codes of enrolled patients, an aPTT fact table was built by blending UFH bolus dose administration with subsequent aPTT assay results. The rules for inclusion were defined in collaboration between data scientists and clinician researchers to be consistent with the existing literature and to eliminate data noise and ensure data consistency. The following rules were applied:

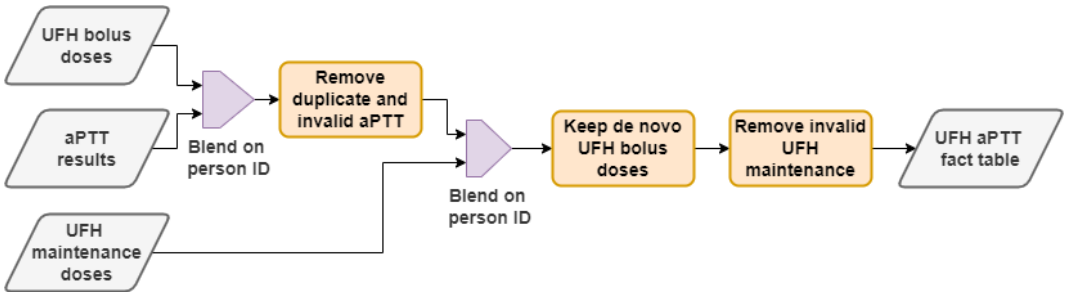
- A UFH bolus dose was included if it was a de novo (first) dose or was administered after at least 6 hours following prior UFH therapy cessation (equal to approximately 5 UFH elimination half-lives to ensure that no drug remained) [38].
- The aPTT results recorded for the first time after 12 hours of the UFH bolus dose were considered invalid.
- UFH maintenance infusions (maintenance dose) were considered invalid if they were not administered or intravenous infusions were completed, stopped, or paused for more than 1 hour before aPTT testing [39].

The generation of the aPTT fact table is illustrated in Figure 2. The data blending process was completed in 6 steps, used patient identifiers, and recorded time stamps to connect and filter the data records. The blending process was performed to satisfy the inclusion or exclusion rules previously defined, resulting in a data set of 2158 records for the model development data set and 236 records for the external validation data set.

During the blending of UFH and aPTT data, several features were identified based on clinician input as listed in Textbox 1. For the other tables (Figure S1 in Multimedia Appendix 2), we excluded all records documented after the time the target aPTT had been performed, as derived from the fact table. Looking at the counts, we excluded 3 tables as they had an insufficient number of examples to incorporate into the model, with each having less than (278/2783, 9.98%) of the total records in the fact table. During the blending process, we first identified the columns of interest in each of the remaining tables. For some features, such as age and sex, data were added to the aPTT fact table with minor or no processing. Other features, to be useful, required data to be aggregated, grouped, or converted in some way. For example, a less granular mapping was applied to 166 distinct order catalogs of medications to categorize them into medication classes. However, during modeling, only the antimicrobial group was used because of uneven distributions across the data set for the other groups. A complete feature list with details of the applied processing is included in Table S2 in Multimedia Appendix 2.

Dealing with missing data was the next step after blending all the identified tables into a single fact table (Table 1; Figure S2 in Multimedia Appendix 2 provides more detail on all features and definitions). In general, we used clinician expertise to decide on the imputation methods for achieving the most accurate representation of missing values. Imputing the missing baseline aPTT (Table 1) assumed a normal physiological aPTT value of 30 seconds on the basis of the literature [40] and the median result derived from our training data set. Missing values of patients height and weight were imputed to the mean value of the cohort after grouping by age (bin interval of 10 years), sex, and marital status.

Figure 2. Unfractionated heparin and activated partial thromboplastin time tables blending. aPTT: activated partial thromboplastin time; UFH: unfractionated heparin.



Textbox 1. Features identified during blending of activated partial thromboplastin time (aPTT) and unfractionated heparin (UFH) administration data.

Feature and description

- Baseline aPTT: aPTT result preceding the current (target) aPTT
- Baseline aPTT minutes: time (in) between the baseline aPTT and target aPTT
- UFH bolus minutes: time (in) between the bolus dose and target aPTT
- UFH maintenance minutes: time (in minutes) between the maintenance start and target aPTT

Table 1. Missing data handling.

Features	Imputation
Baseline aPTT[a] and baseline aPTT minutes	Missing values and values completed more than 24 hours before UFH[b] bolus administration were imputed to 30 seconds, whereas baseline aPTT minutes are imputed to 1440 (24 hours) minutes for those records.
Weight and height	Encounters with no measurements were imputed to the averages for their age, marital status, and sex (as recorded in the patient electronic health record).
Vital Signs features	If the results are missing or occurred more than 12 hours before the target aPTT, they are imputed using centroid values of k-means clustering with k=10.
Pathology results	If the results are missing or occurred more than 1 week before the target aPTT, they are imputed using k-means clustering using centroid value with k=10.
Waterlow score and ADLs[c]	Imputed to 0 where missing or older than 1 week before target aPTT.

[a]aPPT: activated partial thromboplastin time.

[b]UFH: unfractionated heparin.

[c]ADL: activity of daily living.

Feature Engineering and Data Transformation

In this phase, the blended and imputed aPTT fact table was used initially to conduct univariate analysis and data visualization, which aimed to inform decisions about building new features and transforming data. However, this process was not separate from data modeling; rather, it was an iterative process where ML models were built on initial features that changed and evolved, thus serving as new feature inputs to the next cycle of modeling. Multimedia Appendix 3 provides details and visualizations of Pearson correlations between features and outcomes in our aPTT fact table.

Table 2 summarizes the demographic data and important features that are most relevant to the blended (training) data set. The definitions of diagnoses were based on the International Classification of Diseases (ICD)-10 codes; however, we were only able to include categories with large frequencies; that is, ACS and VTE. Other diagnoses were grouped as other. All patients' recorded codes during their admission were used in the grouping process.

The reported aPTT result showed a distribution heavily skewed to the right (Figure 3) and contained outliers, which negatively impacted the performance of a regression model. Although several statistical methods, such as quadratic mean learning [41], can be used to correct this, we chose, on the basis of clinician expertise, to reduce the negative impact of skewness by introducing a floor and ceiling value to target aPTT of 30 and 150. Values less than 30 seconds reflect normal physiological values. The impact of using floor and ceiling values is visualized in residual graphs in Figure S1 in Multimedia Appendix 3, and more feature analysis information is presented in Figures S3-S5 in Multimedia Appendix 2.

Four calculated features were introduced. The first one was the UFH maintenance dose where, unlike the single bolus dose administration, the cumulative maintenance dose was derived based on the total units in the syringe, the infusion period, and the total infusion time before the target aPTT test was performed, excluding any stoppage periods of the infusion (calculation described as follows):

$$UFHMaintinance = (UFH\ syringe\ size / Total\ infusion\ period) \times (infusion\ time\text{-}infusion\ stop)$$

The standard amount of UFH contained in a syringe was 25,000 units (50 mL syringe, 500 IU/mL), and this, together with the total time for the syringe to be emptied with no interruption, indicated the infusion rate as the number of UFH units infused per minute. The second part of the equation (infusion time—infusion stop) aimed to calculate the exact infusion period in minutes. The 3 other calculated features were body size, UFH bolus time, and UFH bolus time; body size is calculated using the following equations:

$$Size = Weight / Height$$

$$UFH\ Bolus\ Time = UFH\ Bolus\ Dose / Time\ to\ aPTT$$

$$UFH\ Bolus\ Time\ and\ Size = Size \times UFH\ Bolus\ Time$$

Finally, we added a cosine cyclical transformation of aPTT time to build 3 features representing the aPTT day of the week, hour of the day, and month of the year. At the end of this phase, we obtained 93 features in the aPTT fact table. Depending on the data distributions, continuous variables were scaled using the Yeo-Johnson transformation [42] from the SciPy Python library [40] or a min-max transformation. Details about the transformation method applied for every feature are provided in Figure S2 in Multimedia Appendix 2, and equation details are available in Multimedia Appendix 4.

Table 2. Baseline characteristics of training data set (all records, N=2783).

Feature	Values
Sex, n (%)	
Male	1898 (68.2)
Female	885 (31.8)
Diagnosis, n (%)	
ACS[a]	818 (29.4)
VTE[b]	540 (19.4)
Age (years), mean (SD)	65.8 (14.6)
Weight (kg), mean (SD)	87.8 (26.7)
Baseline aPTT[c] (seconds), mean (SD)	36 (11.1)
UFH[d] bolus dose (units), mean (SD)	4713 (1467)
UFH maintenance (units), mean (SD)	6767 (4993)
Time between UFH bolus and aPTT (minutes), mean (SD)	364.1 (149)

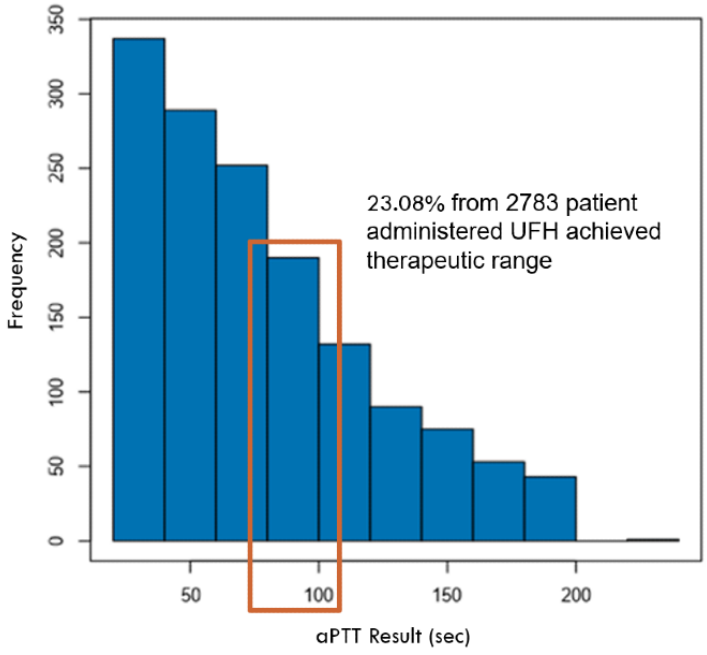
[a]ACS: acute coronary syndrome.

[b]VTE: venous thromboembolism.

[c]aPTT: activated partial thromboplastin time.

[d]UFH: unfractionated heparin.

Figure 3. Frequencies of target activated partial thromboplastin time results with bin size=20. aPTT: activated partial thromboplastin time.



Modeling

Outcomes and Setup

In this phase, 2 models were developed: a regression model for predicting the target aPTT result and a multiclassification model for predicting the aPTT class as subtherapeutic, therapeutic, or supratherapeutic. To identify the optimal model in each case, several models were iteratively tested, with each iteration evaluated using 3-fold cross-validation involving 67 by 33 data splits, where all cases could be used for both model training and internal validation. Cross-validation was repeated 3 times to ensure that the validation metrics were robust, as the training data sets were relatively small. The predictive metrics of all iterations were averaged to obtain the overall results for the model.

The modeling process was completed using the H2O Driverless AI tool, which is an auto-ML tool that takes tabular data as input and builds supervised models automatically using the available open-source ML libraries in Python and R. It also automates model validation, tuning, and selection to achieve an accuracy level equivalent to that of the manually built models. The tool also performs an iterative feature evolution process during

modeling to discover new features. Supervised ML models supported by H2O Driverless AI include XGBoost [43], LightGBM [44], generalized linear models [45], TensorFlow [42], RuleFit [46], and FTRL [47] (followed by the regularized leader) [48]. The tool will generate and test large numbers of models by using different open-source algorithms, undertake hyperparameter tuning, try different feature subsets, and combine models using different methods. After generating hundreds of different models and combinations (ensembles), the tool recommended the most accurate model built for deployment.

Ensemble Regression Model

We built an ensemble regression model to predict aPTT values within 12 hours of a UFH bolus dose. The optimized performance metric was the root mean square error (RMSE). Other reported metrics include the mean absolute error and coefficient of determination (R^2).

During this experiment, 1126 alternative models were trained, including constant predictions, the LightGBM [44] and XGBoost [43] algorithms, and ensemble models. After the feature evolution process, the 93 original features were converted into 188 features, with the contributing features on every model automatically selected by the H2O Driverless AI tool during the training process. We built several baseline regression models, against which the performance of the H2O Driverless AI ensemble model was compared. For all these baseline models, we used the same set of features used to build the ensemble model, except for those evolved during the modeling process using the H2O Driverless AI tool. The first baseline model was built using the tool but as a single model rather than an ensemble. The best model returned by the tool is the XGBoost model. The other baseline models were developed using the Python scikit-learn library, where we tested 3 different linear regression models: Ridge [49], Lasso [50], and ElasticNet [51].

Ensemble Multiclassification Model

We built a multiclassification model using the same training data set to predict the target aPTT class, where aPTT<70 seconds was considered subtherapeutic, aPTT between 70 and 100 seconds as therapeutic, and aPTT>100 seconds as supratherapeutic. In this modeling process, we optimized the accuracy and reported several other metrics relevant to multiclassification, including macroprecision, macrorecall, macro–F_1-score, and macroaverage one class vs rest classes AUCs [52].

In total, 457 different models were trained and tested using the H2O Driverless AI tool. Similar to the regression models, the tool tested constant predictions, the LightGBM [44] and XGBoost [43] algorithms, and ensemble models. The evolved and original features used in the modeling process totaled 2196 features. The tool ranked the models based on their performance and recommended the best performing model producing the best accuracy. The other baseline models were developed using the Python scikit-learn library: logistic regression, logistic regression with recursive feature elimination, support vector machine [53] using a linear support vector classifier [54], and support vector machine using polynomial support vector classifier.

External Validation

External validation was performed using data obtained from patient records at a fifth hospital (Gold Coast University Hospital), which had an exact schema and table structure as the training set. The final data set comprised 236 records, after applying the same inclusion or exclusion criteria as the training data set. We used the method proposed by Archer et al [55] to calculate the sample size sufficient to validate the proposed model and achieve a preselected target for the CI of R^2. The equations and calculation details are provided in Multimedia Appendix 4. The equation generated a minimum sample size of at least 235 participants, which was achieved.

Results

Ensemble Regression Model

The best performing model was an ensemble of 4x LightGBM models that were linearly blended. LightGBM is a gradient-boosting framework that uses tree-based learning algorithms [44]. The model relied on 134 features, some of which are well-established as influencing responses to UFH, such as weight and baseline aPTT, with others first identified in this experiment, of which the most important was the time between when the bolus dose was administered and when the aPTT was measured (Table 3). The bolus dose time, baseline aPTT, age, and bolus dose were also relatively important. Weight, size (weight divided by height), and hematological and biochemical parameters, including serum creatinine level, as a measure of renal function, were also among the top 20 features. Table 4 shows the description and selected list of the LightGBM hyperparameters.

The performance metrics of our ensemble and all the baseline models are listed in Table 5. The H2O Driverless AI ensemble model had best performance with RMSE 31.35 (SD 1.37), residual charts provided in Figure S1 in Multimedia Appendix 3. In addition, this baseline model outperformed all other Python-based linear regression models because the tool tested several algorithms, as previously mentioned, and evolved additional features during the modeling process.

Table 3. Top 10 most important features with relative importance scores.

Feature	Relative importance
Minutes between UFH[a] bolus and aPTT[b]	1
UFH bolus time	0.58
Baseline aPTT	0.41
Age	0.37
UFH bolus dose	0.3
Height	0.25
UFH maintinance	0.23
UFH bolus size calculated	0.22
Weight	0.21
Size calculated	0.195

[a]UFH: unfractionated heparin.

[b]aPTT: activated partial thromboplastin time.

Table 4. Descriptions of contributing models in the final regression ensemble model.

ID	Model type	Model weight	Fitted features	Feature fraction	Max leaves	Learning rate	Max bins	Lambda L1	Lambda L2
0	LightGBM	0.3333	65	0.6	16	0.01	128	0	0.5
1	LightGBM	0.1042	69	0.6	16	0.01	128	0	0.5
2	LightGBM	0.1667	95	0.8	64	0.01	256	0	10
3	LightGBM	0.3958	134	0.4	16	0.01	64	0	2

Table 5. Performance of regression models for predicting activated partial thromboplastin time results.

Tool	Model	Mean absolute error	Root mean square error	R^{2a}
H2O DAI[b]	Final ensemble model	*24.61* [c]	*31.35*	*0.355*
H2O DAI	XGBoost	25.51	32.33	0.31
SKlearn[d]	Linear regression	26.89	33.8	0.244
SKlearn	Ridge regression	26.93	33.79	0.244
SKlearn	Lasso regression	26.93	33.68	0.249
SKlearn	Elasticnet regression	27.15	33.72	0.247

[a]R^2 coefficient of determination.

[b]DAI: Driverless AI.

[c]Minimum error rate.

[d]SKlearn: a machine learning library in Python.

Ensemble Multiclassification Model

The best performing model was a linear blend ensemble of 4 different models with different weights, 2 XGBoost models and 2 LightGBM models (Table 6).

The performance metrics of the ensemble multiclassification model and baseline models built using the SKlearn library in Python are presented in Table 7, with the ensemble model showing superior performance across all metrics, with an accuracy of 0.599 and macro–F_1-score of 0.613. The simple logistic regression model in Python was the second-best performer, highlighting the efficiency of using auto-ML tools for feature engineering, evolution, and model tuning and blending.

Figure 4 shows the confusion matrix for the ensemble model, demonstrating very good accuracy (0.88) for the subtherapeutic class aPTT<70 seconds, intermediate accuracy (0.512 for the supratherapeutic class aPTT>100 seconds, and poor accuracy (0.098) for the therapeutic class aPTT 70 to 100 seconds. This lower accuracy is most likely a result of class imbalance due to the underrepresentation of the therapeutic class in the data set. Nevertheless, predicting patients at risk of recurrent thromboembolic events from underdosing or at risk of bleeding from overdosing is important for clinicians and patients.

For the multiclassification ensemble model, the validation set returned an accuracy of 0.568 (95% CI 0.538-0.598) and an AUC of 0.724 (95% CI 0.714-0.734), which also compares favorably with the corresponding values for the training set cross-validation of 0.599 and 0.735, respectively. In surveying the confusion matrix (Figure 5), the model demonstrated similar accuracy for each class as the training model: 0.899 for the aPTT class <70 seconds, 0.492 for the aPTT class >100 seconds, and 0.078 for the aPTT class 70 to 100 seconds.

Table 6. Descriptions of contributing models in the final multiclassification ensemble model.

ID	Model type	Model weight	Fitted features	Feature fraction	Max leaves	Learning rate	Max bins	Lambda L1	Lambda L2
0	XGBoost	0.3067	1900	0.2	8	0.01	128	0	0.5
1	XGBoost	0.2	1914	0.5	8	0.01	256	0	5
2	LightGBM	0.4	78	0.6	16	0.01	64	0	0.5
3	LightGBM	0.0933	183	0.8	64	0.01	256	0	0

Table 7. Performance of multiclassification models in predicting activated partial thromboplastin time class.

Tool	Model	Accuracy	Macroprecision	Macrorecall	Macro–F_1-score	Macro-AUC[a]
H2O DAI[b]	Final ensemble model	*0.599* [c]	*0.554*	*0.686*	*0.613*	*0.735*
SKlearn	Logistic regression	0.562	0.51	0.56	0.52	0.691
SKlearn	Logistic regression with RFE[d]	0.557	0.49	0.56	0.5	0.687
SKlearn	SVM[e]—linear SVC[f]	0.535	0.51	0.54	0.517	0.679
SKlearn	SVM—polynomial SVC	0.451	0.46	0.45	0.457	0.614

[a]AUC: area under the receiver operating characteristic curve.

[b]DAI: Driverless AI.

[c]Best calculated accuracy.

[d]RFE: recursive feature elimination.

[e]SVM: support vector machine.

[f]SVC: support vector classifier.

Figure 4. Multiclassification confusion matrix. aPTT: activated partial thromboplastin time.

		Predicted			
		aPTT<70	100≥aPTT≥70	aPTT>100	Total
Actual	aPTT<70	1216	32	134	1382
	100≥aPTT≥70	381	63	199	643
	aPTT>100	324	46	388	758
	Total	1921	141	721	2783

Figure 5. Multiclassification confusion matrix for external validation. aPTT: activated partial thromboplastin time.

		Predicted			
		aPTT<70	100≥aPTT≥70	aPTT>100	Total
Actual	aPTT<70	98	2	9	109
	100≥aPTT≥70	30	5	29	64
	aPTT>100	31	1	31	63
	Total	159	8	69	236

Discussion

Principal Findings

This study reports the development and external validation of an ML model for the prediction of aPTT following bolus and maintenance dosing with UFH. The ML models were developed using EHR data from 4 Australian hospitals with the best performing approach, producing an ensemble with 4x LightGBM models with an RMSE of 31.35. As a multiclassification task, the ensemble model achieved an accuracy of 0.599 and an AUC of 0.735. External validation in a new patient cohort at a fifth hospital showed similar results, with an RMSE of 30.52 for the prediction model and an accuracy of 0.568 and AUC of 0.724 for the multiclassification model.

The final model relied on 93 features, including body weight, baseline aPTT, and bolus dose, with others novel to this study and contemporary clinical knowledge, such as hematological and biochemical features (Multimedia Appendices 2 and 3). The most important clinically informative novel features were the time between administration of the bolus dose and aPTT, age, and baseline aPTT. Baseline aPTT, maintenance UFH dose, and time between bolus administration and aPTT as a grouped feature, which had the highest relative importance (Table 3). UFH is considered a high-risk drug with a narrow therapeutic window, and therefore requires patient-specific dosing to ensure safety and effectiveness [1,7]. Determining the optimal initial bolus and maintenance dosing for UFH therapy is challenging because of the many unknown physiological variables that may contribute to its anticoagulant response. Initial bolus dosing based on body weight is currently preferred [19]; however, other variables must influence the response [56,57]. Nomograms and regular aPTT monitoring, which guide subsequent dose adjustments, increase the proportion of patients achieving a target therapeutic aPTT range [6,8]. Unfortunately, local data derived from 2783 patient episodes suggest that this target is achieved in as few as 23.08% of the patients administered UFH.

As UFH is difficult to administer, new anticoagulants have been introduced in the health setting. Although these new anticoagulants, such as direct-acting oral anticoagulants and low–molecular-weight UFHs, have similar effectiveness to UFH in thromboembolic disease, UFH retains an extensive role in hospital practice because of its several advantages [1,2]. Current dosing is based on nomograms, drug action can be quickly reversed if required, the response can be monitored using aPTT, and its short half-life ensures that the drug is quickly eliminated if urgent surgery is required, or bleeding occurs. As per our data, UFH is still a commonly used drug that requires better dosing and monitoring to ensure patient safety than what is currently achievable. Using ML to derive a predictive model offers a possible approach to more accurately predict individual responses to an initial bolus dose of UFH. This information will assist clinicians in estimating the optimal bolus dose. Developing, testing, and deploying these models is becoming more feasible with the advent of large, digitized data sets such as EHRs [22,26,58]; systems that have been implemented in most large hospitals in Australia. Our study demonstrates that many other features exist beyond the traditional weight-based calculations to determine the best UFH bolus dose. This has the potential to improve the safety profile of UFH. EHR data now afford the opportunity to start using model-based dosing strategies and the ability to develop continuous learning ML models in the future [59].

ML is increasingly being used in early phase drug development [22,26,58] and postmarketing dose design, particularly for other high-risk drugs with narrow therapeutic windows, such as warfarin [56,57,60,61], insulin [62], digoxin [63], immunosuppressants, and chemotherapeutics [64]. Using ML models to guide dosing of UFH in acutely ill, unstable medical and surgical patients to minimize thromboembolic events and bleeding events is an important advancement. In developing such models, as shown in our study, a collaborative approach whereby clinicians and data informaticians work in close consultation is essential. Our study used researchers, data engineers, hematologists, pharmacists, and medical practitioners in its design and conduct. This is essential for developing usable artificial intelligence solutions in hospital settings [65].

Comparison With Prior Work

In this study, an ensemble approach with supervised learning was used. Five other studies have reported using supervised learning in developing models to assist with UFH dosing [29,30,32,34,36]. To date, although 3 report accuracy [32,33,37] superior to that of our ensemble approach, these models were restricted to ICU data sets from the United States and China and are, therefore, not generalizable to the general medical and surgical wards of hospitals where UFH is most frequently administered. Furthermore, compared with all existing studies of ML in UFH dosing, ours was the only one, apart from one small external validation in a hemodialysis setting [31,66], to evaluate model performance when applied to new unseen data. External validation is considered an essential step before assessing the efficacy in controlled clinical trials and subsequent implementation in routine practice [65,67].

Future Work

The stage is now set for a feasibility study, the implementation of the model in hospital clinical workflows, and, if successful, further evaluation of clinical utility in a trial comparing current standard practice with model-guided bolus dosing. Implementing the model in routine practice requires an easily accessible decision support platform that can prepopulate most, if not all, the features within the model from the EHR without the need for manual input by clinicians. The model will need to rapidly provide guidance at the exact time of decision-making and will not require end users to undertake extensive training in its use [68,69].

Limitations

Our model was developed and validated using data from EHRs of 5 hospitals and, therefore, should be tested in other health care systems that use EHRs. The modeling approach only applies to adult inpatients admitted to general medical and surgical specialties. ICU patients were excluded from this study. Furthermore, this modeling approach was intended for the prediction of aPTT after a prespecified bolus and maintenance

dose, and as such, further work is required to allow dose calculation and adjustment.

Some features (such as activities of daily living assessments), which were included in the 93 influential features, may not always be available at the time of dosing UFH, and appropriate surrogates should be considered in future iterations of the model. It is also important to consider the level of data standardization within the EHR data sets, which may limit the applicability and usefulness of ML-derived models [70]. For example, differences in how features are measured (eg, the weight and height using different scales), differences in aPTT assays, or different locations of data in EHR may affect model performance and generalizability.

Finally, similar to many other dosing regimens for intravenous drugs, a perfect algorithm for UFH is probably not achievable, as UFH interacts with a myriad of hematological and physiological factors that may affect its anticoagulant effect. Many of these cannot be measured or remain unknown. The goal of our study was to produce and validate a predictive model for UFH dosing that is significantly more accurate than the current weight-based nomograms that have been in use for many years.

Conclusions

This study reports the development and validation of an auto–ML-built ensemble modeling approach for predicting aPTT results and determining their therapeutic classification within 12 hours of administration of a de novo UFH bolus accompanied by a UFH maintenance infusion. ML models were developed using retrospective data from the EHRs of the 4 hospitals. These models were shown to have a consistent performance when applied to an external data set from a fifth hospital. To our knowledge, this is the first study of ML regression and multiclassification models applied to UFH dosing that has used auto-ML tools in model development and conducted external validation. Future work should include the optimization of model performance and its redesign and incorporation into a dose calculation software tool that can be easily used by clinicians at the point of care.

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Data Availability

Access to the data used in this project is restricted to the research team and for the duration of the research project, as outlined in the national statement on ethical conduct in human research 2007, the Australian code for the responsible conduct of research, and Metro South research management policy and procedures. Access to data was granted by Metro South Health Research Governance Committee, Site Specific Assessment reference number SSA/19/QMS/54581.

Conflicts of Interest

None declared.

Multimedia Appendix 1
Dosing and monitoring nomogram used in Queensland, Australia. Retrieved from “State of Queensland (Queensland Health). Heparin intravenous infusion order and administration form for adults. 11th ed. Queensland 2018.”.
[PDF File (Adobe PDF File), 851 KB - ijmr_v11i2e34533_app1.pdf]

Multimedia Appendix 2
Data analysis, description, and processing extra tables.
[PDF File (Adobe PDF File), 279 KB - ijmr_v11i2e34533_app2.pdf]

Multimedia Appendix 3
Data visualizations, heatmaps, plots, and residual graphs.
[PDF File (Adobe PDF File), 492 KB - ijmr_v11i2e34533_app3.pdf]

Multimedia Appendix 4
Metrics equations.
[PDF File (Adobe PDF File), 157 KB - ijmr_v11i2e34533_app4.pdf]

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Abbreviations

aPTT: activated partial thromboplastin time
AUC: area under the receiver operating characteristic curve
EHR: electronic health record
ICU: intensive care unit
ML: machine learning
MSH: Metro South Health
RMSE: root mean square error
TR: therapeutic range
UFH: unfractionated heparin

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Original Paper

Integrating Hepatitis C Care for Opioid Substitution Treatment Patients Attending General Practice: Feasibility, Clinical, and Cost-Effectiveness Analysis

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Abstract

Background: Hepatitis C virus (HCV) infection is common among people who inject drugs, yet well-described barriers mean that only a minority have accessed HCV treatment. Recent developments in HCV diagnosis and treatment facilitate innovative approaches to HCV care that improve access to, and uptake of, care by people who inject drugs.

Objective: This study aims to examine feasibility, acceptability, likely clinical effectiveness, and cost-effectiveness of an integrated model of HCV care for patients receiving opioid substitution treatment in general practice.

Methods: A pre- and postintervention design with an embedded economic analysis was used to establish the feasibility, acceptability, and clinical and cost-effectiveness of a complex intervention to optimize HCV identification and linkage to HCV treatment among patients prescribed methadone in primary care. The "complex intervention" comprised general practitioner (GP)/practice staff education, nurse-led clinical support, and enhanced community-based HCV assessment of patients. General practices in North Dublin were recruited from the professional networks of the research team and from GPs who attended educational sessions.

Results: A total of 135 patients from 14 practices participated. Follow-up data were collected 6 months after intervention from 131 (97.0%) patients. With regard to likely clinical effectiveness, among patients with HCV antibody positivity, there was a significant increase in the proportions of patients who had a liver FibroScan (17/101, 16.8% vs 52/100, 52.0%; $P<.001$), had attended hepatology/infectious diseases services (51/101, 50.5% vs 61/100 61.0%; $P=.002$), and initiated treatment (20/101, 19.8% vs 30/100, 30.0%; $P=.004$). The mean incremental cost-effectiveness ratio of the intervention was €13,255 (US $13,965.14) per quality-adjusted life-year gained at current full drug list price (€39,729 [US $41,857.48] per course), which would be cost saving if these costs are reduced by 88%.

Conclusions: The complex intervention involving clinical support, access to assessment, and practitioner education has the potential to enhance patient care, improving access to assessment and treatment in a cost-effective manner.

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KEYWORDS

hepatitis C; integrated HCV care; people who inject drugs; primary health care

Introduction

Hepatitis C virus (HCV) infection is an important issue for general practice—it is a common infection, often not diagnosed or treated and associated with potentially preventable chronic liver disease [1]. It is estimated that 10 million people who inject drugs globally and 0.7 million people who inject drugs in Europe have been infected with HCV [2]. Despite the high prevalence among people who inject drugs, many are unaware of their infection and few have received treatment for the infection. In Europe, estimates of undiagnosed infection among people who inject drugs range from 24% to 76% [3], while among people who inject drugs diagnosed with chronic HCV, 1%-19% have commenced HCV treatment [3].

In Ireland, 20,000-30,000 people are chronically infected with HCV [4], with injecting drug use the primary risk factor in 80% of cases [5]. Methadone is the only form of opioid substitution treatment (OST) prescribed in Ireland and is provided by addiction treatment centers, specialized general practitioners (GPs), and in prisons, for the treatment of opioid use disorder/opioid dependence [6]. A previous study in Dublin found that 77% (151/196) of patients on OST in general practices had been screened for HCV, and of those who were HCV antibody positive, just 35% (36/104) had received follow-up HCV-RNA testing, 30% (31/104) had been referred to a hepatology clinic, and 3% (3/104) had initiated HCV treatment [7]. Several barriers impede or discourage people who inject drugs from accessing HCV testing, evaluation, and treatment. These include stigma, restrictions around HCV treatment eligibility, not being referred for treatment, fear of HCV investigations (eg, liver biopsy)/treatment side effects, and competing priorities for people who inject drugs [8-11].

The World Health Organization (WHO) has developed a Global Health Sector Strategy (GHSS) to eliminate viral hepatitis as a public health threat by 2030 [12]. Increasing prevention, diagnosis, and treatment is a priority, especially among people who inject drugs. As many people who inject drugs are unaware of their infection, new strategies to reach such individuals are necessary, including testing strategies to increase recognition of HCV and improved care pathways to ensure those diagnosed are successfully linked to HCV evaluation and treatment.

Historically, specialist physicians have provided HCV treatment, usually from tertiary hospital outpatient clinics [1]. However, recent developments in HCV diagnosis and treatment facilitate innovative approaches to community-based HCV care, whereby a patient's treatment pathway can start in community-based clinics and general practices, resulting in improved access to and uptake of care by people who inject drugs. These include point-of-care tests for HCV (including dried blood spot and saliva testing) [13] and transient elastography (FibroScan), which allow specialist evaluation and noninvasive staging of HCV-related liver disease in a community setting [14]. Several European studies have reported on the feasibility of FibroScanning as a screening tool for people who inject drugs, with high rates of acceptance and uptake within various treatment and street outreach settings [14,15]. Furthermore, direct-acting antivirals (DAAs) are taken orally and for shorter periods, associated with fewer side effects, and are therefore more likely to be better tolerated. Cure rates of over 90% have been reported among people who inject drugs [16,17]. In Ireland, DAAs are currently the standard of care for HCV treatment, which is generally provided in specialist hospital services.

Unrestricted access to DAAs and substantial scale-up of treatment are necessary to achieve WHO 2030 targets [18], and engaging people who inject drugs in the continuum of HCV care from testing through to treatment is key to this [18]. The establishment of culturally appropriate and flexible models of care that meet their specific needs and are adapted to the circumstances of people who inject drugs will be essential to optimize HCV diagnosis and linkage to HCV evaluation and treatment among people who inject drugs [18,19].

In Ireland and many European Union countries, primary care is increasingly providing continuing care for people who inject drugs and Irish general practice has been a leader in the introduction and expansion of harm-reduction services, including opioid substitution OST, needle and syringe programs, and naloxone provision. These services have been effective in engaging opiate users in treatment, reducing HIV and HCV transmission, and reducing-drug related morbidities [20]. General practice is therefore an appropriate setting to deliver enhanced HCV care to patients being prescribed methadone. Practitioner education and nurse liaison support can increase rates of HCV screening and referral to specialist HCV care in this setting [21].

The "HepLink" study aimed to develop, implement, and evaluate a complex intervention to integrate primary care and specialist HCV care to enhance HCV identification, evaluation, and treatment among patients being prescribed methadone. While there is no sharp boundary between complex and simple interventions, complex interventions are described as interventions that contain several interacting components [22]. As such, the "HepLink" complex intervention involving practitioner education and HCV nurse outreach/clinical support to primary care was developed and implemented in general practices providing methadone treatment. This paper aims to evaluate the feasibility and acceptability of this intervention to primary care providers and patients, and to determine its likely clinical effectiveness and cost-effectiveness.

Methods

Study Design

A pre- and postintervention design with an embedded economic analysis was used to establish the feasibility, acceptability, and clinical and cost-effectiveness of a complex intervention to optimize HCV identification and linkage to HCV treatment among patients on OST in primary care in North Dublin [23]. A sample of 24 OST-prescribing GP practices were invited to participate in the study from the professional networks of members of the research consortium and from those GPs who attended a series of educational masterclasses on "Advances in Hepatitis C Treatment in the Community." This masterclass symposium series highlighted the benefits of educational seminars as a way of delivering current best practice in the

treatment of HCV infection to a multidisciplinary audience and a useful vehicle for recruiting general practices to the study [24].

Setting

In Ireland, currently there are 2 types of settings in which OST is delivered in the community: specialist addiction clinics and general practice. All patients receiving OST are registered on the Central Treatment List. "Level 1" GPs are responsible for the treatment of stabilized opiate-dependent persons [25] referred from specialist addiction clinics or from "Level 2" GPs. Practice as a "Level 1" GP requires completion of a recognized training program delivered by the Irish College of General Practitioners (ICGP) and regular educational updates. The GP is audited by the ICGP/Health Services Executive (HSE) Audit Committee. "Level 1" GPs can treat up to a maximum of 15 patients. A "Level 2" GP has undergone additional training, can initiate OST, and prescribe for a greater number of patients (up to a maximum of 35 patients or a maximum of 50 in a partnership with 2 or more doctors in their own practice [26]). As of August 31, 2016, there were 9652 patients receiving treatment for opiate use in Ireland (excluding patients in prisons), which included 4150 patients being treated by 350 GPs in the community [27].

The National Hepatitis C Treatment Programme oversees access to DAA treatment and provides HCV screening guidelines to identify risk groups for screening [28]. Prior to 2017, access was organized according to clinical need and restricted to those who were infected with HCV through blood and blood products and those scoring over 8.5 kPa on FibroScan. In early 2017 the criteria were revised to remove this threshold, but a limited health care budget and the high cost of DAAs continue to restrict the numbers who can avail of treatment.

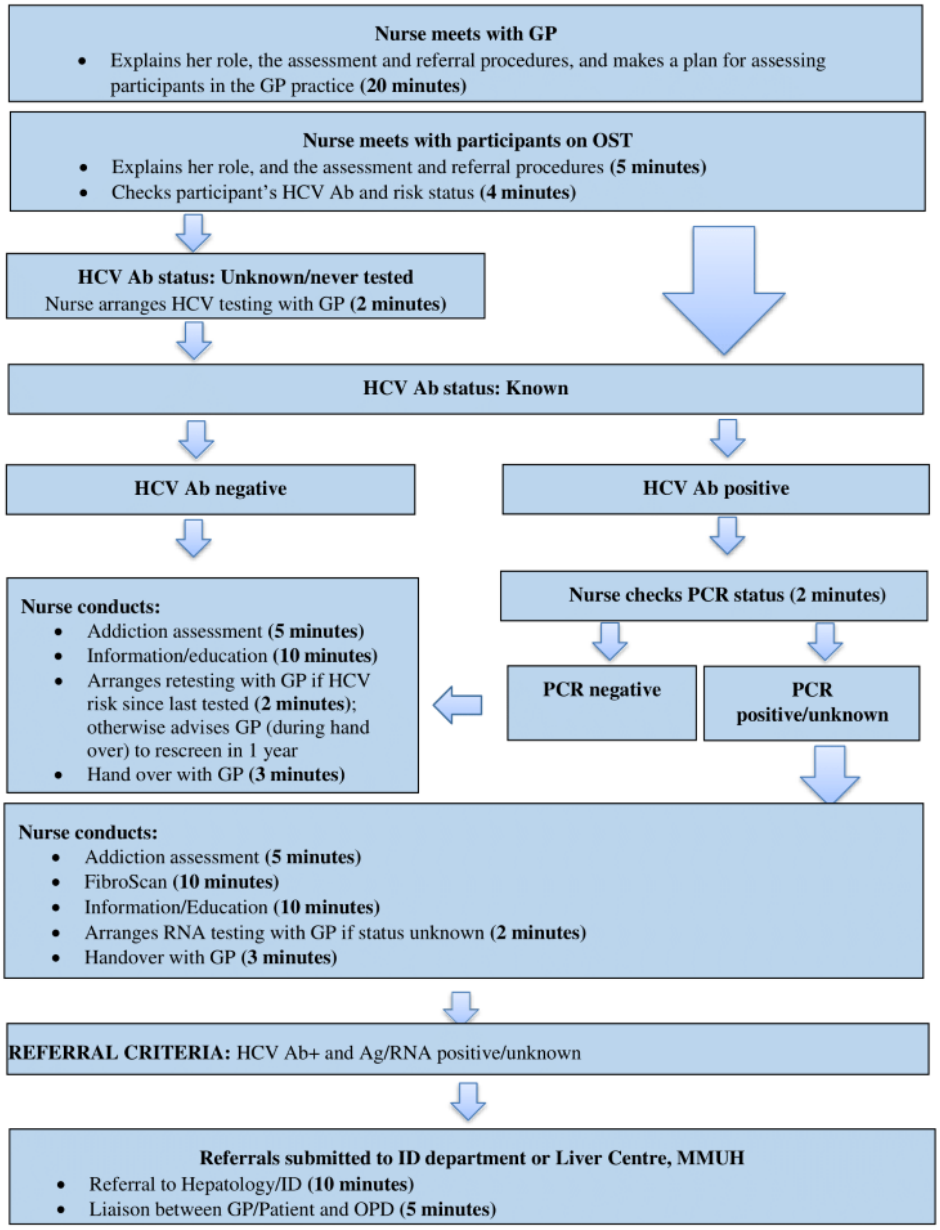
Participants

A total of 14 general practices consented to participate in the study and were asked to recruit 10 consecutive patients on OST (ie, methadone), aged at least 18 years, and who were attending the practice for any reason during the recruitment period. Based on the recommendations for good practice in feasibility studies [29], and our previous feasibility studies among people who inject drugs [30,31], we estimated that 140 patients (attending 14 general practices) would be adequate to estimate recruitment and retention rates (ie, feasibility) and provide data on acceptability of the intervention, to inform a future definitive intervention (trial). This sample size exceeded that recommended for feasibility studies of between 24 and 50 and allowed feasibility assessments within both Level 1 and Level 2 practices [29]. A detailed description of recruitment procedures has been reported separately [32].

Intervention

The complex intervention was delivered to the 14 primary care sites and consisted of outreach by a specialist HCV nurse into primary care sites to optimize interaction and integration between primary and secondary care. Informed by the HepCare Europe Education Masterclass series [24], the nurse provided HCV education, clinical support, and community-based HCV evaluation of patients. The protocol for clinical assessment by the nurse is described in Figure 1.

Figure 1. Flowchart describing nurse-led clinical assessment. Ab: antibody; Ag: antigen; GP: general practitioner; HCV: hepatitis C virus; MMUH: Mater Misericordiae University Hospital; OST: opioid substitution treatment; PCR: polymerase chain reaction.



Data Collection

Clinical records of participating patients were reviewed prior to the implementation of the complex intervention and 6 months after the intervention by a member of the research team (EO'C) and data were extracted on HCV care processes and outcomes. We measured feasibility as the number of practices (14/24) and patients (135/140) who were recruited to the study (recruitment rate) and those on whom follow-up procedures were completed (retention rate). Acceptability of the complex intervention was assessed as uptake of its component interventions by both GPs and patients, which included (1) practitioner education; (2) HCV nurse outreach/clinical support; (3) community-based HCV evaluation of patients, including mobile elastography.

Process/Outcome Measures

In addition to demographic characteristics, the following data on the HCV cascade of care (between diagnosis and sustained virologic response [SVR]) were extracted for each patient from their clinical record immediately prior to the implementation of the intervention and 6 months after the intervention.

Blood-Borne Virus Care

The following were considered: HCV antibody testing and status; HCV RNA and antigen (Ag) testing and status; whether the patient had been referred to a hepatology or infectious diseases specialist; had attended a hepatology or infectious diseases specialist; had been assessed by FibroScan; FibroScan score (kPa); had initiated HCV treatment; had completed HCV treatment; and achieved SVR, which means that the HCV is not detected in the blood 12 weeks or more after completing DAA treatment [33].

Data Analysis

Feasibility and acceptability measures were summarized with counts (percentages) for categorical variables and median (IQR)

for continuous variables. Care process and outcome measures were analyzed using intention-to-treat principles. While the study was not powered to assess effectiveness, the possible impact of the intervention on care process measures was measured by examining the proportion of participants before and 6 months after the intervention who had received HCV testing, and the proportion of HCV antibody–positive patients before and 6 months after the intervention who had ever received follow-up Ag or RNA testing, been referred to a hepatology/infectious diseases service, attended a hepatology/infectious diseases service, been FibroScanned, initiated HCV treatment, and completed HCV treatment. Possible impact of the intervention on care outcomes was measured by examining the proportion of those screened who tested HCV antibody positive and the proportion of patients with HCV antibody positivity achieving SVR before and 6 months after the intervention. Paired binary differences before and 6 months after the intervention for selected process measures were compared using the McNemar test, with *P* values <.05 considered statistically significant. All analyses were done using Stata 15 (StataCorp).

Cost-Effectiveness Analysis

A Markov model of HCV disease progression and treatment was used to estimate the impact and cost-effectiveness of the HepLink intervention compared with the current standard of care pathway of antibody testing and referral by primary care practitioners. The model was used to track disease progression for anyone with chronic HCV and the effect of treatment in reducing levels of liver disease (details in the Supplementary Material entitled “HepLink Cost-Effectiveness Analysis” in Multimedia Appendix 1 [28,34-49]). Health benefits were measured in quality-adjusted life-years (QALYs). Pre-HepLink data suggested that 6% (95% CI 1%-12%) of diagnosed chronically infected patients on OST are treated per year at baseline, which was used as the background treatment rate in both the baseline and intervention scenarios.

HepLink intervention data were used to parameterize the initial fibrosis staging of the intervention cohort and provide subsequent intervention outcomes in terms of proportion of individuals linked to care and treated. Primary cost data for the HepLink intervention (including costs for staff, diagnostics, room rental, overheads, and training) and subsequent HCV treatment were collected through interviews (in 2017 euros) with intervention staff and from financial records. Other model parameters such as disease transition rates, death rates, health utilities, and health care costs for different HCV disease stages, sustained viral response cure rates for treatment, and disease progression rates after SVR came from the existing literature [34-36,50] (see Supplementary Tables 1 and 2 in Multimedia Appendix 1).

The cost-effectiveness analysis was undertaken for full (€39,729 [US $41,857.48] per course) and 10% of HCV drug list price over a 50-year time horizon with a 5% discount rate [37]. The incremental cost-effectiveness ratio (ICER) in terms of the incremental cost per incremental QALYs gained of the intervention was used to determine the cost-effectiveness at Ireland’s willingness-to-pay (WTP) threshold (€30,000 [US $31,607.25] per QALY [37]). We used probabilistic sensitivity analysis (PSA) to determine the effect of parameter uncertainty (distributions given in see Supplementary Tables 1-3 in Multimedia Appendix 1) on the cost-effectiveness projections, and also undertook univariate sensitivity analyses to assess the effect of some of the model and intervention assumptions. This included the effect of the background treatment rate and HCV drug list price on the mean ICER.

Ethics Approval

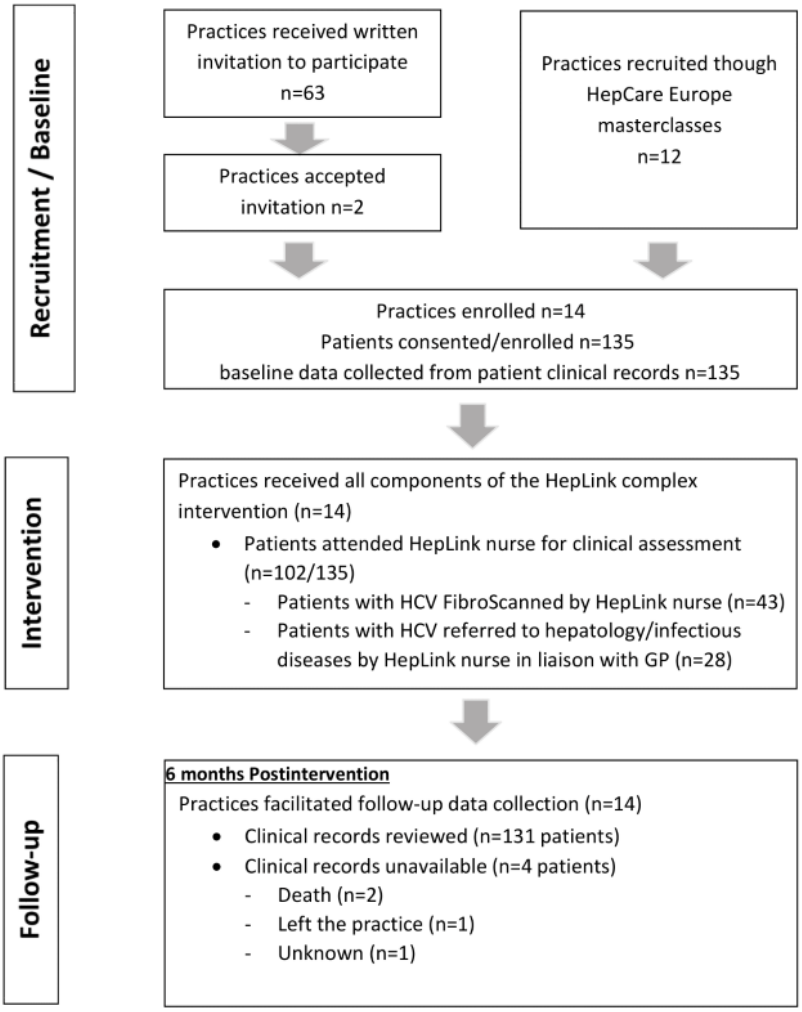
The study has been approved by the Mater Misericordiae University Hospital Research Ethics Committee (Ref: 1/378/1722)

Results

Feasibility

Fourteen practices participated in the study out of 24 practices that were invited, and the 14 practices recruited and obtained consent from 135 patients out of 140 who were invited to participate (Figure 2). All 14 practices facilitated follow-up data collection 6 months after the intervention and follow-up data were collected from the clinical records of 131 (97.0%) patients; clinical records of 4 patients were unavailable at follow-up for the following reasons: the patients were deceased (n=2), had left the practice (n=1), or unknown reason (n=1). As many as 11 (8.4%) of the 131 patients on whom follow-up data were collected had incomplete clinical records for the follow-up period for the following reasons: during the follow-up period they transferred to another GP/addiction service (n=4), were incarcerated (n=2), left the practice (n=1), no longer on OST (n=1), or unknown reasons (n=3).

Figure 2. Study flow diagram. GP: general practitioner; HCV: hepatitis C virus.



Baseline Characteristics of Participants

Of the 14 practices enrolled in the study, 7 were Level 1 prescribers (n=53 patients) and 7 were Level 2 prescribers (n=82 patients). Baseline characteristics of 14 practices and the 135 participating patients are outlined in Tables 1 and 2, respectively, and previously reported by Murtagh et al [32].

Table 1. Baseline characteristics of practices (n=14).

Characteristic	Value, n (%)
Level of training in providing addiction-related care	
Level 1 general practitioner	7 (50)
Level 2 general practitioner	7 (50)
Sex of general practitioner	
Male	10 (71)
Female	4 (29)
Practice nurse	
Yes	14 (100)
No	0 (0)

Table 2. Baseline characteristics of the patients (n=135).

Characteristic	Value
Sex, n (%)	
Male	97 (71.9)
Female	38 (28.1)
Age (years), median (IQR)	42 (38-48)
On opioid substitution treatment, n (%)	135 (100)

Acceptability Measures

Acceptability of the complex intervention was assessed as uptake of its component interventions. The measures included (1) practitioner education, (2) HCV nurse outreach/clinical support, (3) community-based HCV evaluation of patients, including FibroScan. All 14 primary care sites received practitioner HCV education and HCV nurse outreach/clinical support. Community-based HCV evaluation of patients was conducted at all practices, with 102/135 (75.6%) participating patients attending the HCV nurse for an on-site clinical assessment. The clinical protocol involved FibroScanning patients with chronic infection and those with HCV antibody positivity whose RNA/Ag status was unknown. As many as 43 (75%) of the 57 patients who were HCV antibody positive and RNA/Ag positive or unknown were FibroScanned by the HCV nurse. Of the remainder, 5/14 (36%) patients had recently been FibroScanned at the hospital and therefore were not FibroScanned again, 4/57 (7%) patients declined to be scanned, a valid FibroScan reading was unable to be obtained for a further 4/57 (7%) patients, and 1 patient's (2%) FibroScan was deferred until RNA/Ag testing had been conducted by their GP. The median (IQR) liver stiffness score for the 43 patients FibroScanned by the HCV nurse was 7.5 (5.7-13.8) kPa. As many as 19 (44%) of the 43 patients FibroScanned scored over 8.5 kPa and 12/43 (28%) had cirrhosis (scored >12.5 kPa).

Clinical Effectiveness

The proportion of patients tested for HCV did not significantly increase 6 months after the intervention compared with the preintervention screening (128/135, 94.8% vs 128/131, 97.7%; *P*=.25; Table 3). Among those screened for HCV, compared with the preintervention status, there were no significant changes in the proportion with HCV antibody–positive test at 6 months after the intervention (100/128, 78.1% vs 99/128, 77.3%; *P*=.99).

Significant improvements were observed across all steps in the care cascade at 6 months after the intervention (Figure 3). One participant was HCV Ag positive and antibody negative before the intervention and 6 months after the intervention and was included in the analysis of subsequent steps in the care cascade at both time points. Among patients who were Ag/RNA positive or whose RNA/Ag status was unknown, the proportion who had been referred to a hepatology or infectious diseases service was significantly higher 6 months after the intervention (70/101, 69.3% vs 84/100, 84.0%; *P*<.001), as was attendance at a hepatology or infectious diseases service (51/101, 50.5% vs 61/100, 61.0%; *P*=.002). There was a 35% significant increase in the proportion of patients with HCV antibody positivity or Ag/RNA positivity/unknown status who had been FibroScanned (17/101, 16.8% vs 52/100, 52.0%; *P*<.001).

The proportion of patients with Ag/RNA positivity who had started HCV treatment was significantly higher, with 10 additional patients initiating treatment (20/101, 19.8% vs 30/100, 30.0%; *P*=.004). As many as 14 (13.9%) of the 101 patients with HCV Ag/RNA positivity had completed HCV treatment before the intervention and 21/100 (21.0%) had completed HCV treatment 6 months after the intervention (*P*=.16). The proportion of patients with HCV Ag/RNA positivity who had achieved SVR was 14/101 (13.9%) before the intervention and 19/100 (19.0%) 6 months after the intervention (*P*=.16).

Table 3. Baseline/6-month follow-up data.

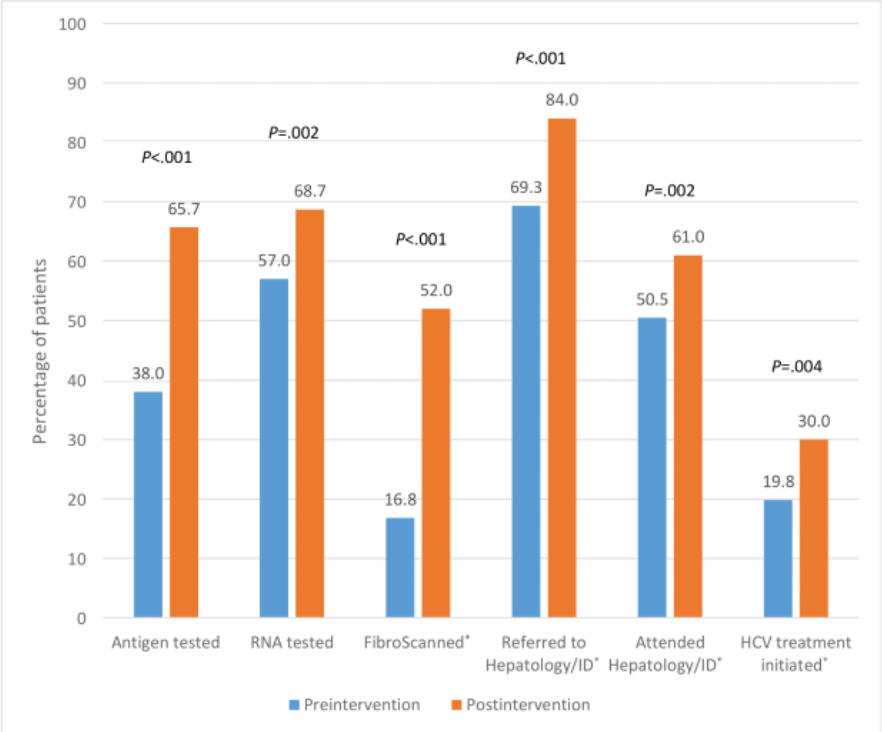
Data	Baseline	Follow-up	*P* value[a]
Patients on whom data were collected, n	135	131	
HCV[b] testing, n	135	131	
HCV antibody test, n/N (%)	128/135 (94.8)	128/131 (97.7)	.25
HCV antibody positive, n/N (%)	100/128 (78.1)	99/128 (77.3)	>.99
Among patients with HCV antibody positivity, n/N (%)			
HCV antigen test	38/100 (38.0)	65/99 (65.7)	<.001
HCV antigen positive	22/38 (57.9)	37/65 (56.9)	
HCV RNA test	57/100 (57.0)	68/99 (68.7)	.002
HCV RNA positive	35/57 (61.4)	37/68 (54.4)	.63
Management of patients with HCV antibody positivity			
FibroScanned, n/N (%)	17/101 (16.8)	52/100 (52.0)	<.001
FibroScan score (kPa)—lifetime, median (IQR)	6.4 (5.6-8.4)	7.4 (5.5-10.9)	
Referral to hepatology or infectious diseases, n/N (%)	70/101 (69.3)	84/100 (84.0)	<.001
Attended hepatology or infectious diseases services, n/N (%)	51/101 (50.5)	61/100 (61.0)	.002
Treatment of patients with HCV antibody positivity, n/N (%)			
HCV treatment initiated	20/101 (19.8)	30/100 (30.0)	.004
HCV treatment completed	14/101 (13.9)	21/100 (21.0)	.16
SVR[c] attained	14/101 (13.9)	19/100 (19.0)	.32

[a]*P* values represent significance levels of the McNemar test.

[b]HCV: hepatitis C virus.

[c]SVR: sustained virologic response.

Figure 3. Proportion of patients with HCV antibody positivity receiving each step in the cascade of HCV care before the intervention and 6 months after the intervention. HCV: hepatitis C virus; ID: infectious disease. *Includes 1 patient who was HCV antibody negative but antigen positive.



Cost-Effectiveness Analysis

Direct costs of the intervention were €85,439 (US $90,016.39) over the 15-month intervention period, with the treatment costs increasing by €223,112 (US $235,065.23; at full treatment cost). The main components of the intervention costs were €59,198 (US $62,369.53) for set up and implementation and €26,241 (US $27,646.86) for the nurse liaison component. Over the intervention, 43/57 (75%) individuals with antibody positivity with positive or unknown RNA/Ag status were FibroScanned by the nurse; 28/57 (49%) of these were referred and 10/28 (36%) started treatment in secondary care. The cost per person FibroScanned was €1507 (US $1587.74; setup costs annualized over 5 years and 43 FibroScanned patients). Model projections suggest savings of €113,769 (US $119,864.17) in HCV-related care and 15 QALYs saved among the 10 additional treated individuals over 50 years. This gives the incremental cost of HepLink as €194,782 (US $205,217.45; direct intervention costs plus treatment costs minus HCV-related care costs saved). At full drug costs, our projections suggest HepLink was cost-effective with a mean ICER of €13,255 (US $13,965.14) per QALY saved and 98% of PSA runs being below the WTP threshold (€30,000 [US $31,607.25] per QALY; see Supplementary Figure 2 and Supplementary Table 3 in Multimedia Appendix 1). Together, uncertainty in the progression rates from Metavir stages F3 and F4 accounted for most of the variation in the ICER (36% and 40%, respectively). The intervention becomes cost saving at 12% of the full drug costs, with all of the PSA runs being below the WTP threshold for Ireland and 48% being cost saving (see Supplementary Figure 3 in Multimedia Appendix 1).

Discussion

Principal Findings

A complex intervention (practitioner education, practice-based assessment, and nurse liaison) may enhance HCV care among patients being prescribed methadone in primary care and is likely to be feasible, acceptable, effective, and cost-effective, with care enhanced specifically for those patients who are HCV positive. By utilizing a liaison nurse to provide HCV education, clinical support, and evaluation of patients, the “HepLink” intervention helps overcome barriers such as patients not being referred for treatment and also patients’ fear of treatment, and provides a more flexible and accessible model of HCV care.

Strengths and Limitations

The key findings from this study provide a better understanding of how to overcome barriers and improve access to care, which can inform policy and service development, and contribute to health both locally and internationally. This study has made an important impact on patient care and supported GPs in making important decisions on HCV testing and onward referral. The strengths of the study are the large numbers who were followed up at 6 months and the uniqueness of the population (OST patients in primary care), which are rarely reported in the literature. The intervention is scalable, and its initial success suggests that it could potentially be implemented elsewhere and used to guide service development and policy internationally.

However, there were limitations to the study design. First, the study used a nonprobability sampling strategy. Although this results in a lower generalizability of findings and inability to calculate CIs or margin of error, we felt it was an appropriate sampling strategy to use for a population consisting of OST patients in primary care, especially when conducting a feasibility study with lower sample sizes that makes probability sampling impractical [51]. Second, there was no control group that prevents the analysis of any preexisting trends or accounting for the possibility that other factors occurred at the same time as the intervention. However, the findings from this feasibility study can inform power calculations for a future large-scale randomized control trial using the “HepLink” complex intervention. The third limitation is that there may be a lack of generalizability to those not in addiction treatment and potential bias may occur from GPs who are more motivated and enthusiastic about the issue under study being overrepresented among those recruited. Because of their interest in the issue, self-selected GPs in the study may be providing better HCV care to their patients than the wider GP population. However, the profile of GPs and patients participating in the study was similar to other Irish studies despite this potential bias [7,52].

Comparison With Prior Work

Our findings, compared with previous studies conducted in Ireland [7,8,21,53], indicate higher attendance and treatment rates than previously reported (Figure 3). In our baseline data these increases reflect the general increase in HCV outreach programs and better education of GPs in Ireland since the introduction of DAAs. However, further increases in our postintervention data indicate the likely effectiveness of the HepCare (HepLink) intervention in enhancing access to specialist assessment and HCV treatment, and better education of GPs in HCV care.

The most significant increase was observed in FibroScan rates: from 16.8% (17/101) before the intervention to 52.0% (52/100) after the intervention. This study also saw an increase in those initiating treatment: 19.8% (20/101) before the intervention versus 30.0% (30/100) after the intervention. This increase is lower than the 31% increase achieved during the HepCATT study intervention year [54]. However, the higher increase achieved in the HepCATT study can be accounted for by the longer intervention period (1 year); the placement of a half-time nurse facilitator to address diagnosis, assessment, and integration within the HCV cascade of care at each clinic undergoing the intervention; and the establishment of local peer champions to support patients.

The success of this intervention in a primary care setting underlines the results of Project ECHO, which suggests HCV care delivered through primary care can be as safe and effective as that provided by specialists at an acute medical center [55]. The ETHOS study suggests that the highly marginalized population of people who inject drugs can achieve a similar adherence to treatment as other populations, with 74% completing their intended duration of treatment [5]. This was also reflected in the results of this study with significant improvements observed across all steps in the care cascade at 6 months after the intervention. The proportions of patients who

had a liver FibroScan, had attended hepatology/infectious diseases services, and initiated treatment were significantly higher 6 months after the intervention. More recently, the role of primary care advanced practice nurses in engaging patients with treatment has been highlighted [56].

Future Directions

The findings from this feasibility study can inform the design of a future large-scale randomized control trial using the "HepLink" complex intervention. Furthermore, incorporating a peer support model to aid and improve access and adherence to the HCV care pathway for the most vulnerable patients could enhance treatment completion rates and SVR outcomes.

Conclusions

The population studied was exposed to the HepLink intervention and thus this study supports further development and broader implementation of the intervention. The HepLink intervention has the potential to impact on patient care, improving access to care and providing quality health care to marginalized populations who might otherwise remain untreated. The data collected enhance the scientific understanding of interventions that contribute to health and social gain and can inform national policy and service development. The authors are actively engaged with key stakeholders and policymakers to ensure that the HepLink project contributes to policy and practice.

Acknowledgments

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Conflicts of Interest

JSL has received nonrestricted grants from Gilead, AbbVie, and Merck Sharp & Dohme for hepatitis C–related educational and research activities; has also received honoraria for advisory board participation on HIV and hepatitis C, organized by Gilead, AbbVie, GlaxoSmithKline, ViiV, and Merck. WC has been a principal investigator on research projects funded by the Health Research Board of Ireland, the European Commission Third Health Program, and Ireland's Health Services Executive and Gilead; been co-investigator on projects funded by AbbVie; and received consultancy fee honorarium from Gilead in respect of participation in the advisory board on hepatitis C. PV has had an honorarium off AbbVie and unrestricted research grants off Gilead, not related to this work. DS received financial support from Gilead for the costs of attendance at the Improving Outcomes in the Treatment of Opioid Dependence 2017 conference.

Multimedia Appendix 1
HepLink Cost-effectiveness Analysis Supplementary Material.
[PDF File (Adobe PDF File), 557 KB - ijmr_v11i2e35300_app1.pdf]

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Abbreviations

Ag: antigen
DAA: direct-acting antiviral
GHSS: Global Health Sector Strategy
GP: general practitioner
HCV: hepatitis C virus
HSE: Health Services Executive
ICER: incremental cost-effectiveness ratio
ICGP: Irish College of General Practitioners
ID: infectious disease
OST: opioid substitution treatment
PSA: probabilistic sensitivity analysis
QALY: quality-adjusted life-year
SVR: sustained virologic response
WHO: World Health Organization
WTP: willingness-to-pay

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Review

Web-Based Interventions to Promote Healthy Lifestyles for Older Adults: Scoping Review

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Abstract

Background: With the aging of the population and rising rates of chronic diseases, web-based interventions could be considered to support older adults in adopting healthy lifestyles. To date, published knowledge syntheses have focused on quantitative studies among older adults aged ≥50 years. However, those aged ≥65 years may have different needs to be met by these interventions because of the biological and physiological changes associated with aging, and qualitative studies could help advance knowledge in this field.

Objective: The objective of this scoping review is to explore the extent of the literature on web-based interventions aimed at promoting healthy lifestyles among people aged ≥65 years.

Methods: A scoping review was conducted based on the framework proposed by Levac et al. Six databases (ie, MEDLINE, CINAHL, PsycINFO, Web of Science, the Cochrane Database of Systematic Reviews, and the Joanna Briggs Library) and gray literature (ie, Google Scholar and OpenGrey) were searched. The final search was conducted on June 23, 2021. The studies were selected by 2 persons (AL and ML) independently. The included studies were systematic reviews and qualitative and quantitative studies focusing on web-based interventions to promote healthy lifestyles in people aged ≥65 years that were published in French or English between 1990 and 2021. Data were extracted in a table and synthesized based on the conceptualization of web-based interventions (ie, according to the use parameters, behavior change techniques, delivery modes, and theories). A thematic analysis was performed.

Results: In total, 20 articles were included in this review, which represents studies focused on 11 distinct interventions. All of the interventions (11/11, 100%) aimed to promote physical activity among older adults. The number of intervention sessions varied from 5 to 16, with a frequency from daily to once every 2 weeks. Diverse delivery modes such as electronic diary, video, and phone call were found. The most used behavior change techniques were instruction, feedback, and self-monitoring. Few interventions (6/11, 55%) were based on a theory. A favorable trend was observed in increasing physical activity, and 5 themes emerged that appeared to be central to behavior change among older adults: motivation, support, tailoring, barriers, and perceptions.

Conclusions: This scoping review provides a better understanding of the components of web-based interventions and their outcomes on the healthy lifestyles of people aged ≥65 years. These findings could provide important guidance for the design and development of future web-based interventions in this field. Further research is needed to continue the development and evaluation of innovative and accessible interventions to promote healthy lifestyles among older adults.

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KEYWORDS

aged; behavior change; components; effects; healthy lifestyle; web-based intervention

Introduction

Background

The number of older adults worldwide (ie, those aged ≥65 years) is expected to almost double over the next 30 years, from 12% to 22% [1]. This significant aging of the population will not be without consequences for health care systems. In fact, this phenomenon will lead to an increase in the rate of chronic diseases considering that the prevalence of these diseases increases with age and that older adults are seriously affected by them [2,3]. In this regard, healthy lifestyle habits (ie, good nutrition, regular physical activity [PA], smoking abstinence, the limiting alcohol consumption, and the management of stress) could help prevent a significant number of diseases in older adults [2], promote longevity [4], reduce frailty [5], and maintain health [3]. For these reasons, older adults should benefit from interventions that support their adoption of healthy lifestyles.

Moreover, with the advances in health technologies, the web is increasingly the preferred method of intervention even among older adults, whose internet use has been growing rapidly in recent years [6-8]. Web-based interventions can be defined as care or treatments that aim to promote behavior change and that are delivered via a web browser over the internet on different technological tools such as computers, tablets, or cell phones [9]. Web-based interventions can take many forms, such as educational programs, disease management programs, and web-based group exercise programs; can include different technologies such as artificial intelligence algorithms or monitoring devices; and can be self-guided or human-assisted [10]. Web-based interventions could be used to support individuals as they adopt healthy lifestyles and would be favorable for older adults [11,12]. In addition, such interventions constitute an economical and accessible alternative for health care systems [13]. In the context of a global pandemic, lifestyle habits such as sedentary behavior and dietary changes may also be disrupted [14], and older adults' access to programs and services to facilitate the adoption of healthy lifestyles, such as gyms, can be limited [15]. As a result, web-based interventions may represent a solution for helping older adults adopt and maintain a healthy lifestyle [15].

In addition, the current global pandemic makes web-based interventions all the more relevant as the modes of intervention delivery need to be reconsidered to promote social distancing [16,17]. The recommendations on social distancing must be followed to preserve the population's health, especially among vulnerable older adults. However, despite the current need for social distancing, we need to ensure that this mode of intervention delivery is as suitable as in-person interventions [16]. In particular, as older adults place a high value on trusting relationships in behavior change, human contact needs to be preserved through any web-based interventions that are introduced to support their adoption of healthy lifestyles [18,19]. Among other things, human contact could be maintained by including the support of a coach, which would also increase the commitment of older adults to the intervention [20]. Although the literature documents numerous web-based interventions, their components and effects are diverse, making it difficult to draw any conclusions about which components promote optimal change outcomes in this population [21]. In this regard, Webb et al [22] developed a framework to facilitate investigations of the components of web-based interventions that will optimally influence behavior change. They found that web-based interventions that incorporate behavior change techniques (BCTs) and that are theoretically grounded lead to better outcomes in terms of health behavior change and that delivery modes could also affect such change [22].

Although some authors have published syntheses of the literature focused on web-based interventions designed to promote lifestyle changes in adults [11,23], to our knowledge, no synthesis of knowledge has focused on people aged ≥65 years. In fact, there appears to have been only 2 systematic reviews conducted on web-based interventions focused on healthy lifestyle habits for people aged ≥50 years [24,25]. The primary studies included in these systematic reviews had small sample sizes with an average age of ≥50 years, which means that they did not focus specifically on a population of older adults [24,25]. There is another review of the literature that examined web-based interventions to promote PA in older adults. This review included primary studies with samples of older adults aged ≥55 years and other age groups as well (ie, adults) [26], which means that the interventions included were not specific to older adults. Although there is no consensus in the literature on the specific age used to define old age, the World Health Organization [2] suggests defining older adults as persons aged ≥65 years. Frequently, it is assumed that interventions designated for young or middle-aged people will be adapted for use with older adults [27]. However, older adults are a heterogeneous group with multiple characteristics, and those aged ≥65 years may have different needs to be met by the interventions because of the biological and psychological changes associated with aging, such as decreased functional capacity, frailty, and changes in social position [2,28]. Moreover, older adults should be able to benefit from accessible health services that are adapted to their needs [29], and any interventions developed for them must consider the challenges associated with aging [27]. In this sense, as the components of the interventions as well as their outcomes could differ for adults aged ≥65 years, it is essential to explore the literature dealing with this specific population.

The 3 syntheses of the literature that we found on web-based interventions among people aged ≥50 or ≥55 years focused only on quantitative studies [24-26]. However, the literature also provides qualitative studies on this subject, and they can make relevant contributions to the components and outcomes of web-based interventions designed to promote healthy lifestyles among older adults. For example, qualitative studies may provide more information about the experiences of older adults who participate in web-based interventions, particularly with regard to the components of the intervention, which is important

for the development of knowledge in this area and for future studies. A scoping review on this topic would appear appropriate as it will permit an exploration of the available literature by including both qualitative and quantitative studies. To our knowledge, no study has explored the extent of knowledge of web-based interventions for people aged ≥65 years by including both qualitative and quantitative studies.

Objectives

Therefore, the purpose of this study is to explore the extent of the literature on web-based interventions aimed at promoting healthy lifestyles among people aged ≥65 years.

Methods

Overview

A scoping review was conducted based on the framework proposed by Levac et al [30]. According to Levac et al [30], a scoping review may be conducted to determine the scope of the research or map the available literature on a phenomenon, which is the purpose of this review. This review followed the 5 steps of the framework developed by Levac et al [30], as presented in the following sections. The protocol for this scoping review is available elsewhere [31].

Identifying the Research Questions

The research questions were identified following a brief review of the initial literature and discussions with the research team, which was composed of a doctoral student (AL), a researcher (VD), and a librarian (RB). This scoping review will seek to answer the following questions: (1) What are the web-based interventions aimed at promoting healthy lifestyles among people aged ≥65 years? (2) What are the components of these interventions (ie, use parameters, BCTs, delivery modes, and theories used)? (3) What are the reported outcomes of these interventions?

Identifying Relevant Studies

To identify relevant studies, the following databases were consulted: MEDLINE, CINAHL, PsycINFO, Web of Science, the Cochrane Database of Systematic Reviews, and the Joanna Briggs Library. These databases were selected for their focus on the social and health sciences, the field related to the topic of this study. Gray literature was searched using the Google Scholar and OpenGrey databases. The reference lists of the identified articles were checked to ensure that all the relevant articles had been included. The authors of the primary studies were contacted when additional information was required.

The search strategy used keywords and descriptors related to the concepts of older adults, lifestyle, and web-based interventions. The complete search strategies for each database are presented in Multimedia Appendix 1. The criteria for inclusion were (1) articles published between 1990 and 2021 as the World Wide Web was created in 1989 [32]; (2) articles published in French or English; (3) articles related to the objective of the scoping review, that is, a web-based intervention delivered via a web browser over the internet addressed to a population of older adults and aimed at promoting healthy lifestyle habits (ie, diet, regular PA, smoking abstention, limiting the alcohol consumption, and management of stress); and (4) primary studies such as experimental studies, quasi-experimental and qualitative studies, systematic reviews, and other documents associated with gray literature (such as government reports and clinical practice guidelines). Research protocols were also included as they often provide a more in-depth description of the intervention studied. For the purpose of this study, web-based interventions were defined as care or treatments aimed at changing behavior and accessed via a web browser over the internet [9]. The scope excluded teleconsultations with health care professionals and websites that provided information without any interaction. Articles were excluded when (1) persons aged ≥65 years were not the population specifically studied; (2) the web component of the intervention was not predominant, such as a face-to-face intervention that was complemented by a web-based component; and (3) healthy lifestyle habits were not primarily targeted by the intervention, such as symptom self-management programs that included some physical exercise. Finally, the identified articles were exported to a data management software program (ie, Covidence) where duplicates were removed. The final database search was performed on June 23, 2021.

Study Selection

The studies were selected by 2 independent persons (AL and ML). An initial selection was made by reading the abstracts and titles of the articles, and then the selected articles were read in full, retaining only those related to the purpose of the study and the research questions and that met the established inclusion and exclusion criteria. In cases where there was disagreement over a selection, a third person (VD) was consulted. As suggested by Levac et al [30], the 2 persons who selected the studies met at the beginning, midpoint, and end of the selection process to clarify any difficulties they had encountered and revise the research strategy. Inclusion and exclusion criteria were clarified in terms of the definition of the web-based interventions (ie, delivered via a web browser over the internet regardless of the technological tool used, such as a tablet or a computer) to be included as well as the population (ie, excluding studies that targeted multiple age groups) and the behavior targeted (ie, excluding web-based interventions for fall prevention that included some exercises). To promote transparency, a PRISMA (Preferred Reporting Items for Systematic Reviews and Meta-Analyses) diagram was used to illustrate the study selection process and present the excluded articles and the reasons for their exclusion.

Charting the Data

Data were extracted into a table including the authors, year and location of publication, purpose, type of study, population and sample, method, intervention and comparison, intervention components, and outcomes. As suggested by Levac et al [30], data from the first 5 papers were extracted independently by 2 persons (AL and ML) to ensure compliance. As the purpose of the review was to explore the breadth of knowledge rather than assess the rigor of the studies identified, the quality of the studies was not assessed.

Collating, Summarizing, and Reporting the Results

To collect, synthesize, and report the results, we used a conceptualization of web-based intervention components proposed by Webb et al [22]. As mentioned previously, this conceptualization seeks to classify the components of web-based interventions into 3 categories: the BCTs used, the delivery modes, and the theories used. Webb et al [22] conceived this framework based on the BCT taxonomy developed by Michie et al [21], on a coding scheme for classifying delivery modes, and on the coding theory scheme by Michie and Prestwich [33]. In its most recent version, the taxonomy by Michie et al [21] details 93 BCTs as strategies used in interventions to promote behavior change, including feedback, action planning, and instruction, among others. The coding scheme for the delivery modes includes additional modes for the web component. It can be used to categorize them as automated functions (eg, video, automated tailored feedback, and automated following messages such as reminders or encouragement), communicative functions (eg, chat session, peer-to-peer access, and "ask the expert facility") and additional modes (eg, email, phone calls, and videoconferencing) [22]. The Michie and Prestwich [33] coding scheme contains questions to assess whether and how theories are used in an intervention. Synthesizing the components of the web-based interventions into these categories (ie, BCTs, delivery modes, and theories) facilitates an understanding of the components that can have an influence on health behavior change. We also used additional items in the CONSORT-EHEALTH (Consolidated Standards of Reporting Trials of Electronic and Mobile Health Applications and Online Telehealth) guidelines proposed by Eysenbach [9] for reporting eHealth trials. This guideline proposes including use parameters such as the number of sessions, duration of the intervention, and frequency when reporting web-based intervention components.

Analysis

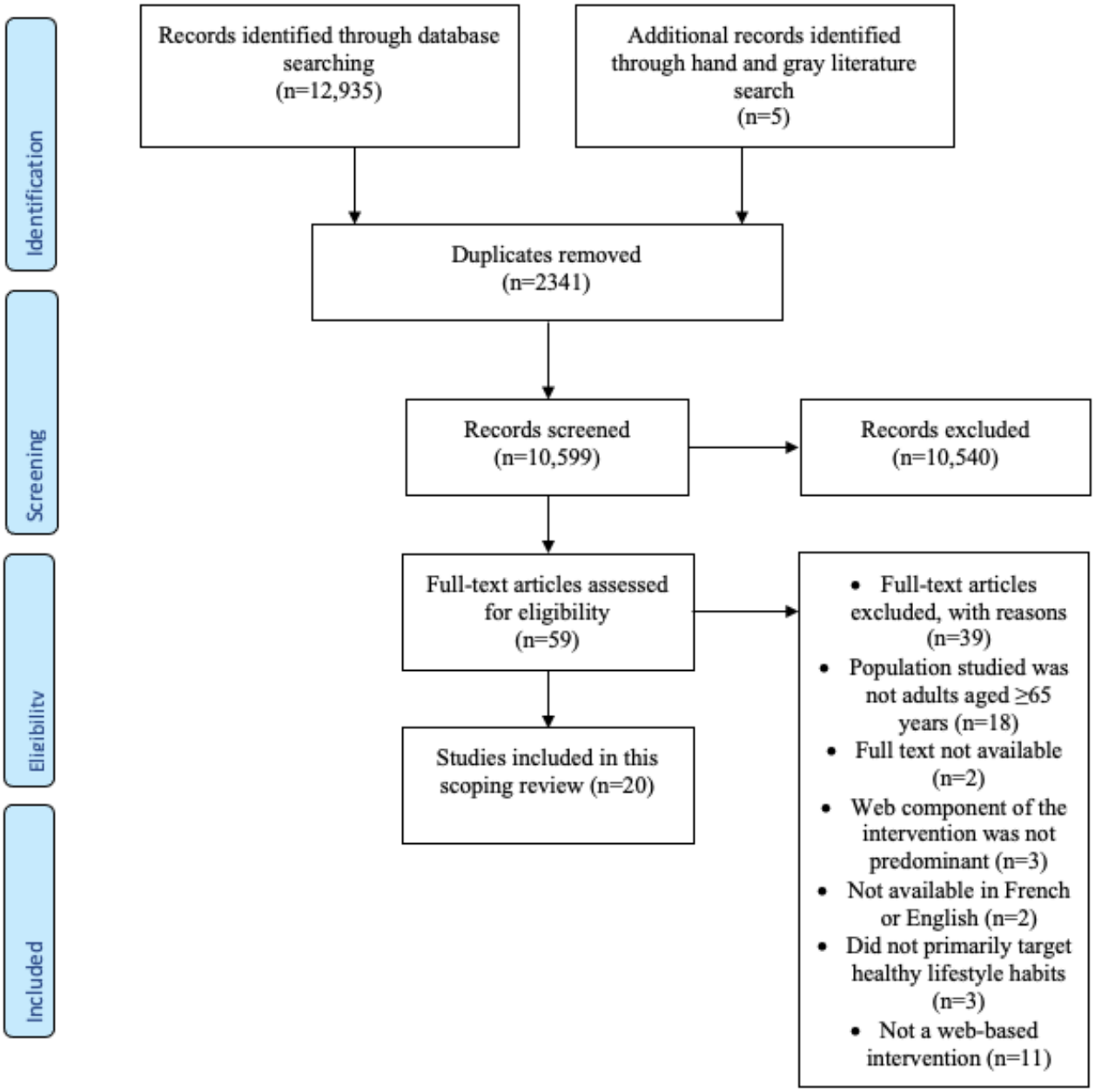
To summarize the data by examining the components and outcomes of the interventions studied, we drew on the method of thematic analysis used by Paillé and Mucchielli [34] to analyze the data. More specifically, components of the web-based interventions were grouped according to their similarity, divergence, complementarity, or recurrence. Themes were identified from the extracted data based on the results of the interventions. Again, these themes were grouped into thematic clusters (ie, groups of themes with common characteristics). For example, the themes "tailored content to each participant" and "personalized advice in regard to preference and condition" could be grouped together into the thematic cluster "tailoring." The analysis was carried out by the first author (AL) and then validated by the second author (VD). The PRISMA-ScR (Preferred Reporting Items for Systematic Reviews and Meta-Analyses extension for Scoping Reviews) checklist [35] was used to ensure that all the key items were reported and promote study replicability (Multimedia Appendix 2). A narrative summary is presented in the next section as an overview of the components and outcomes of the interventions studied.

Results

Search Results

Initially, 12,940 articles were identified. After removing duplicates, 10,599 articles were filtered, and 10,540 (99.44%) of these were excluded by reading the article titles and abstracts based on the inclusion and exclusion criteria. Finally, 0.56% (59/10,599) of the articles were read in their entirety. A total of 20 articles were included in this review. The main reason for excluding an article was when it had a study population that was not specifically older adults aged ≥65 years. The PRISMA diagram shown in Figure 1 summarizes the process used to identify and select the studies.

Figure 1. PRISMA (Preferred Reporting Items for Systematic Reviews and Meta-Analyses) flow diagram of the literature search and article selection process.



What Are the Web-Based Interventions Aimed at Promoting Healthy Lifestyles Among People Aged ≥65 Years?

Among the 20 articles included, we found studies focused on 11 distinct interventions: Active for Life (n=1, 5%), Active Plus (n=2, 10%), Active Plus 65 (n=2, 10%), eMIND (n=2, 10%), Healthy Ageing Supported by Internet and Community (n=1, 5%), Health Aging Through Internet Counseling in the Elderly (n=6, 30%), Life Project (n=1, 5%), MyPlan 2.0 (n=1, 5%), and Otago (n=2, 10%), plus 2 other interventions not named [36,37]. The range of publication years was 2013 to 2021, and most of the studies (19/20, 95%) were published in the last 5 years. These studies were mainly published in the Netherlands (9/20, 45%), France (3/20, 15%), Australia (1/20, 5%), Italy (2/20, 10%), Switzerland (1/20, 5%), Spain (1/20, 5%), Belgium (1/20, 5%), Finland (1/20, 5%), and the United States (1/20, 5%). In total, of the 20 studies, there were 6 (30%) randomized controlled trials, 4 (20%) research protocols, 5 (25%) qualitative studies, 3 (15%) pretest-posttest studies, 1 (5%) randomized pilot study, and 1 (5%) mixed methods study. The sample sizes identified varied from 16 to 2624 participants. The interventions targeted older adults aged ≥65 years living in the community [38] who could walk without technical help (2/20, 10%) [39-41], were prefrail (1/20, 5%) [42], were inactive (3/20, 15%) [36,37,43], had a chronic disease with a disability (2/20, 10%) [44-47], presented 2 or more cardiovascular risk factors or an antecedent of cardiovascular disease (1/20, 5%) [12,19,20,48-50], or were at risk of cognitive decline (1/20, 5%) [51,52]. The average age of the study samples ranged from 68.7 to 83 years, with an average age of 73 years, which means that the studies targeted younger older adults. Indeed, only 20% (4/20) of the studies (3/11, 27% of the interventions) had a sample with an average age of ≥75 years [36,42,46,47].

Most of the articles (9/20, 45%) were focused on evaluating the effects of a web-based intervention on the health behaviors of older adults, including PA and diet, or on other variables, including cardiovascular risk factors such as diabetes, obesity, hypertension, and hypercholesterolemia; self-efficacy [12]; knowledge and skills [38]; and cognitive function [12,51]. Other articles presented a description of the intervention (6/20, 30%) or the experience of the older adults with regard to their participation in the intervention (5/20, 25%), such as the appreciated component, reason for participation, or preferences. All the interventions (11/11, 100%) targeted PA, and 73% (8/11) of them targeted PA as the only behavior. In total, 18% (2/11) of the interventions targeted PA in addition to other behaviors such as nutrition [51,52] and nutrition and alcohol consumption [38]. A total of 9% (1/11) of the interventions targeted all the cardiovascular risk factors such as PA, blood pressure, diabetes, weight, nutrition, and smoking cessation, and participants could choose their health priorities [12,19,20,48-50]. A summary table of the study characteristics is available in Multimedia Appendix 3 [12,19,20,36-52]. The components of the interventions (ie, use parameters, BCTs, delivery modes, and theories) are presented in the following sections.

What Are the Components of These Interventions?

Use Parameters

Use parameters refer to the duration of the intervention, the duration of each session, the number of sessions, and their frequency. In this review, the *duration of the intervention* varied from 5 weeks to 18 months. Only 18% (2/11) of the interventions reported the *duration of each session* [37,39,40]. It would have been helpful to know the duration of each session in the other studies to understand how much time older adults need to spend to complete the sessions. The *number of sessions* varied from 5 (1/11, 9%) [41] to 16 (1/11, 9%) [39,40]. Although the total number of sessions was not specified, in some interventions, the authors proposed an intensity of intervention such as 5-minute daily sessions (1/11, 9%) [37] or free access during the entire study period (2/11, 18%) [36,51,52]. Otherwise, in 45% (5/11) of the interventions, the number of sessions was not reported [12,19,20,38,42,44-50], which does not allow us to understand how many web-based intervention sessions older adults require. The *session frequency* was daily [37], twice per week [39,40], weekly [41], and once every 2 weeks [43]. In 45% (5/11) of the interventions, the frequency of sessions was not reported [12,19,20,38,42,44-50]. These were the same studies that did not report the number of sessions.

BCTs Component

BCTs are the strategies used in interventions to promote behavior change, such as feedback, action planning, or instruction [21]. On the basis of the taxonomy by Michie et al [21] comprising 93 BCTs, we identified 15 different BCTs used in the web-based interventions. The number of BCTs used varied from 1 to 9, with an average of 4.5, meaning that all the interventions except 1 (10/11, 91%) [42] combined multiple BCTs. As the combination of BCTs was varied, it is difficult to establish links between the most used or effective combinations and the results obtained and discern the contribution made by each of them. However, we identified a trend in the combination of instruction, self-monitoring, and feedback (7/11, 64%) despite the fact that this combination was mostly coupled with one or more other BCTs such as action planning or goal setting.

All the interventions (11/11, 100%) used *instructions* on how to perform the behavior. Most of the interventions included *feedback* on the targeted health behavior (9/11, 82%) [12,19,20,36,37,39-41,43-45,48-50] and *self-monitoring* of the behavior (8/11, 73%) [12,19,20,36-41,43,48-52]. Other BCTs used included *action planning* (5/11, 45%) [36,41,43-47], *goal setting* (4/11, 36%) [12,19,20,37,41,43,48-50], *problem solving* (4/11, 36%) [12,19,20,37,41,46-50], *awareness* (1/11, 9%) [46,47], *verbal persuasion* (1/11, 9%) [39,40], *commitment* (1/11, 9%), *self-regulation* (1/11, 9%) [44,45], *prompts and cues* (1/11, 9%), *rewards* (1/11, 9%), *social comparison* (1/11, 9%), and *relapse prevention* (1/11, 9%) [43]. Although common techniques were identified, they were rarely explained by the authors, which makes their definition and application unclear. In fact, only 18% (2/11) of the interventions provided detailed discussions on how the BCTs were used to generate the desired change [41,43]. For example, Alley et al [43] detailed that action planning was used by asking questions about the participants' actions in terms of what, when, and where to perform the behavior. Several other BCTs from the taxonomy by Michie et al [21], such as distraction, self-affirmation, or scheduled consequences, were not identified in this review. For a summary of the BCTs used in each web-based intervention, see Multimedia Appendix 4 [12,19,20,36-52].

Delivery Modes

The delivery modes include every mode in addition to the web component grouped as follows: automated function (eg, video, automated tailored feedback, and automated following messages such as reminders or encouragement), communicative function (eg, chat session, peer-to-peer access, and "ask the expert facility"), and additional modes (eg, email, phone calls, and videoconferencing).

Automated Function

All interventions (11/11, 100%) included behavioral information such as how to stay active, guidelines on PA, a workout plan, and safety when exercising. Some interventions included videos on how to modify behavior (4/11, 36%) [12,19,20,36,38,42,48,49], an electronic diary to track behavior (2/11, 18%) [12,19,20,36,38,42,48,49], a quiz (1/11, 9%) [41], and reminders to use the platform either sent by email (2/11, 18%) [41,43] or provided throughout the platform (1/11, 9%) [12,19,20,48-50]. Many interventions (5/11, 45%) offered automated, tailored feedback based on individual progress either throughout the platform [37,41,43] or by email [44-47]. Among these, in the case of 9% (1/11) of the interventions, a combination of automated and personal feedback was provided [12,19,20,48-50].

Communicative Functions

A total of 27% (3/11) of the interventions included a messaging system that offered the possibility of chats with a coach [12,19,20,39,40,48,49,51,52], and 18% (2/11) proposed a chat forum with peers [38-40]. In 9% (1/11) of the interventions,

participants received written feedback from a physiotherapist [36], but it remains unclear whether this was automated or personal. Some interventions (2/11, 18%) also included in-person meetings, such as an initial meeting with the coach [12,19,20,36,48,49] and a monthly peer mentor meeting [36]. Other interventions included the possibility of training with peers on the web (1/11, 9%) [39,40] and receiving phone calls from a member of the research team (1/11, 9%) [36]. Some interventions (4/11, 36%) also offered participants an opportunity to take part in local group activities [12,19,20,42,44-49], but the authors provided no information on how many participants took part in these activities.

Supplementary Modes

The studies included in this scoping review were focused on a web-based intervention but, as discussed previously, some of them also included a supplementary delivery mode such as email (3/11, 27%) [41,44-47], phone calls (2/11, 18%) [10,17,18,36,48-50], and face-to-face contact (2/11, 18%) [12,19,20,36,48,49]. No intervention used SMS text messaging or videoconferencing. However, as most of the studies that included supplementary modes (7/8, 88%) did not provide information on the impacts of these additional modes on behavior change in older adults, it is difficult to know how such modes influenced the results.

Theory

The coding scheme developed by Michie and Prestwich [33] allows for an assessment of the extent to which the interventions are theory-based. In total, 55% (6/11) of the interventions were based on at least one theory. A total of 18% (2/11) of the interventions were based on 1 theory, whereas 36% (4/11) were based on 2 to 5 theories. The theories used were the theory of planned behavior (2/11, 18%), social cognitive theory (2/11, 18%), precaution adoption process (1/11, 9%), integrated model for change (1/11, 9%), self-regulation theory (3/11, 27%), transtheoretical model (2/11, 18%), self-determination theory (2/11, 18%), motivational interviewing (1/11, 9%), I-Change Model (1/11, 9%), and health action process approach (1/11, 9%).

Among the theory-based interventions, most of the studies (5/6, 83%) did not explicitly state how the theory was used to develop the intervention or how it was integrated into the intervention to lead to the desired change. Therefore, it is difficult to understand the contribution made by the theories used and link them to the results obtained. This was despite the fact that the authors of the papers on all the theory-based interventions specified that they wanted to act on constructs of the theory related to the targeted behavior change, such as self-efficacy, motivation, or attitudes, yet they did not provide definitions of the constructs or explanations of how they operationalized them. Definitions and explanations of the constructs would be needed to understand how the intervention attempted to act on them and lead to behavior change [53]. In only 18% (2/11) of the interventions [41,43] did the authors link theory constructs with the BCTs used. For example, Alley et al [43] indicated that the BCTs instruction and feedback were used to change the attitudes of the participants. In other studies (9/11, 82%), no connection was made between the BCTs and theory constructs when this would have helped us understand how the chosen BCTs would lead to the desired change in terms of the constructs targeted. Otherwise, the authors of the papers on 18% (2/11) of the interventions measured a construct of the theory, such as self-efficacy, as an outcome of the study [12,43]. The authors of the papers on 9% (1/11) of the interventions specified that the theory's constructs were used to tailor the intervention to the participants such that the content of the advice depended on the intrinsic motivation of the participant [44,45]. Table 1 presents a summary of the components of the interventions surveyed.

Table 1. Summary of the intervention components (N=11).

Intervention	Population and behavior	Use parameters	Delivery mode	Behavior change technique	Theory
Active for Life [43]	• Older adults aged ≥65 years who did not meet the recommendations for PA[a] • PA	• Duration of the intervention: 12 weeks • Duration of each session: NR[b] • Number of sessions: 6 • Frequency: bimonthly	• Automated function: tailored feedback on PA via the platform based on the participants' characteristics • Communicative function: none • Additional modes: none	• Instruction • Goal setting • Self-monitoring • Action planning • Prompts and cues • Rewards and relapse prevention • Social comparison • Feedback	• Theory of planned behavior • Social cognitive theory
Active Plus [44,45]	• Older adults aged ≥65 years who had at least one chronic disease that affects mobility and were able to walk 100 m without help • PA	• Duration of the intervention: 4 months • Duration of each session: NR • Number of sessions: NR • Frequency: NR	• Automated function: tailored advice on PA and feedback via email • Communicative function: none • Additional modes: list of local group activities	• Instruction • Action planning • Coping planning • Commitment • Self-regulation • Feedback	• Theory of planned behavior • Precaution adoption process • Integrated model for change • Self-regulation model
Active Plus 65 [46,47]	• Older adults aged ≥65 years with an impairment in PA caused by a noncommunicable chronic disease • PA	• Duration of the intervention: 4 months • Duration of each session: NR • Number of sessions: NR • Frequency: NR	• Automated function: tailored advice on PA via email • Communicative function: none • Additional modes: list of local group activities and email	• Instruction • Problem solving • Action planning • Coping planning • Awareness • Feedback	• I-Change Model • Transtheoretical model • Self-determination theory • Self-regulation theory • Health action process approach
eMind [51,52]	• Community-dwelling older adults aged ≥65 years who presented a subjective memory complaint without dementia • PA and nutrition	• Duration of the intervention: 6 months • Duration of each session: NR • Number of sessions: NR • Frequency: free access	• Automated function: tailored exercise program, nontailored nutritional advice, and website link to a cognitive training • Communicative function: chat with health professionals anytime and chat with a dietician for people at risk of nutritional deficiency • Additional modes: none	• Instruction • Feedback • Self-monitoring with activity tracker	• NR
Healthy Ageing Supported by Internet and Community [38]	• Older adults aged ≥65 years • PA, nutrition, alcohol consumption, and social participation	• Duration of the intervention: 10 weeks • Duration of each session: NR • Number of sessions: NR • Frequency: NR	• Automated function: information on physical (food and drink), social (preventing loneliness), and emotional (eg, self-esteem and resilience) health and videos • Communicative function: chat forum • Additional modes: none	• Instruction and self-monitoring	• NR

Intervention	Population and behavior	Use parameters	Delivery mode	Behavior change technique	Theory
HATICE[c] [12,19,20,48-50]	• Older adults aged ≥65 years with high cardiovascular risk • Smoking, blood pressure, cholesterol, diabetes, weight, PA, and nutrition	• Duration of the intervention: 18 months • Duration of each session: NR • Number of sessions: NR • Frequency: NR	• Automated function: tailored lifestyle and cardiovascular feedback, electronic diary, educational content, and peer-to-peer videos • Communicative function: personal and automated feedback from a coach with the possibility to chat • Additional modes: 12-month phone call and list of local group activities	• Instruction • Goal setting • Self-monitoring • Problem solving • Automated and personal feedback	• Motivational interviewing • Transtheoretical model • Social cognitive theory
Life Project [42]	• Prefrail older adults aged 74 to 91 years • PA	• Duration of the intervention: NR • Duration of each session: NR • Number of sessions: NR • Frequency: NR	• Automated function: healthy lifestyle and PA information, exercise videos, and the possibility to create a tailored program • Communicative function: none • Additional modes: list of local group activities	• Instruction	• Self-determination theory
MyPlan 2.0 [41]	• Older adults aged 65 to 80 years able to walk 100 m without help • PA	• Duration of the intervention: 5 weeks • Duration of each session: NR • Number of sessions: 5 • Frequency: each week and free access	• Automated function: information about PA, quiz about PA and benefits, and tailored feedback • Communicative function: none • Additional modes: email reminders	• Instruction • Computer-tailored feedback • Goal setting • Problem solving • Action planning • Self-monitoring	• Self-regulation theory
Otago [39,40]	• Community-dwelling older adults aged ≥65 years who were not frail • PA	• Duration of the intervention: 8 weeks • Duration of each session: 30 to 40 minutes • Number of sessions: 16 • Frequency: 2 times per week	• Automated function: exercise instruction and plan • Communicative function: possibility to communicate with a coach and peers • Additional modes: possibility to train with peers on the web	• Instruction • Feedback • Self-monitoring • Verbal persuasion	• NR
No name [37]	• Inactive older adults aged ≥65 years • PA	• Duration of the intervention: 2 months • Duration of each session: 5 minutes • Number of sessions: NR • Frequency: every day		• Instruction • Self-monitoring • Feedback • Goal setting • Problem solving	• NR

Intervention	Population and behavior	Use parameters	Delivery mode	Behavior change technique	Theory
			• Automated function: exercise instruction and examples through an embodied conversational agent • Communicative function: none • Additional modes: implementation of the intervention in a clinic waiting room for 12 months		
No name [36]	• Older adults aged ≥70 years with self-reported impaired balance, able to rise from a high chair and stand without support, and not active • PA	• Duration of the intervention: NR • Duration of each session: NR • Number of sessions: NR • Frequency: NR	• Automated function: tailored PA information, exercise video, and diary • Communicative function: feedback from a physiotherapist, peer mentor meeting once a month, phone calls from a researcher after 2 to 3 weeks, and optional phone support • Additional modes: first meeting in group, phone call, and face-to-face meeting	• Instruction • Action planning • Self-monitoring • Feedback from a therapist	• NR

[a]PA: physical activity.

[b]NR: not reported.

[c]HATICE: Healthy Ageing Through Internet Counselling in the Elderly.

What Are the Reported Outcomes of These Interventions?

Outcomes

Of the 6 studies that evaluated the effects of web-based interventions on PA in older adults, 4 (67%) found positive outcomes on PA after the intervention, including increasing weekly minutes of moderate to vigorous PA and greater likelihood of performing self-reported cycling [37,41,45,46]. Other positive effects were also reported on blood pressure, lipid levels, BMI, smoking cessation, self-efficacy [12], and participants' knowledge and skills to adopt a healthy lifestyle [38]. Among the 35% (7/20) of studies that conducted a qualitative evaluation, 5 themes emerged from the thematic analysis, which are detailed in the following sections: tailoring, motivation, support, barriers, and perceptions.

Theme 1: Tailoring

Several studies (4/7, 57%) addressed the concept of tailored web-based interventions. Indeed, older adults mentioned that they appreciated participating in a web-based intervention tailored to their limitations and preferences [20,42]. Some participants mentioned that the exercises proposed in the web-based intervention were too easy and repetitive, not adapted to their environment [51], or of limited value owing to their medical condition [36]. This suggests the need for web-based interventions tailored to older adults' preferences, environments, and conditions.

Theme 2: Motivation

Motivation appeared to be central to behavior change among older adults as most studies (6/7, 86%) addressed it. Participants stated that web-based interventions should help increase their motivation for change [19,51]. Identifying their own motivation is important for older adults to maintain behavior change [36], and the sources of such motivation varied, including personal benefits and health improvement [19,36]. Some participants mentioned that the coach's positive message could help boost their motivation [20,51] and that being motivated helped them continue using the intervention and vice versa [20]. Other participants argued that behavior change, such as being more physically active, was not a goal in itself but rather that they were motivated by other health benefits such as remaining independent as long as possible [42]. For these reasons, it would appear necessary to explore the individual motivations of each older adult to facilitate change.

Theme 3: Support

The theme of support was reported in several studies (5/7, 71%). Older adults mentioned that they need support to achieve their health goals [19] and that the platform could provide continuous support [20], especially as training alone at home requires discipline [42]. Some participants mentioned that they appreciated having discussions with a coach throughout the web-based intervention [19,40]. Some participants also argued that a first meeting with the coach was necessary to develop a relationship of trust and then facilitate change and that the coach played an important role in stimulating the initial use of the web-based intervention and sustaining it [20]. In other words, participants who feel connected with the coach are more likely to keep using the platform and continue pursuing goals for lifestyle changes [20]. In addition, participants in the study by de Souto Barreto et al [51] would have appreciated having more contact with a member of the research team, suggesting that, as older adults, they would have been favorable to having the support of a coach. Conversely, peer interactions were less valued and used by older adults [40].

Theme 4: Barriers

Some barriers were consistently identified in the studies (4/7, 57%) on the use of web-based interventions among older adults. First, older adults mentioned barriers to the web-based interventions, such as a lack of computer skills [19,20] or using an old computer [42]. Difficulties encountered in computer use or limited internet skills could discourage older adults from using a web-based intervention [20]. Some participants also mentioned that they sometimes lacked the discipline required to exercise alone at home [36,42]. Without the support of a coach, older adults feared getting hurt [42], which could be a barrier to behavior change.

Theme 5: Perceptions

Behavior change among older adults seemed to be influenced by their perceptions of their age and the benefits of change. Indeed, older adults who do not perceive a need to improve their lifestyles or who do not prioritize it because of their advanced age are less likely to use a web-based intervention and, therefore, engage in lifestyle changes [20]. By contrast, perceiving that behavior change could lead to health benefits positively influences older adults toward using the intervention [19,20]. However, this theme emerged in only 29% (2/7) of the studies, which is why it may have had less impact than the other themes.

Discussion

Principal Findings

Overview

This scoping review sought to explore the extent of the available literature on web-based interventions as a way to promote healthy lifestyles among people aged ≥65 years. In total, 11 different interventions discussed in 20 published articles were included in this review. Almost all the articles (19/20, 95%) were published in the last 5 years, which indicates growth in the development and evaluation of this type of intervention among older people. This is consistent with the increased use of the web by older adults in recent years [6-8] and the urgent need to deploy cost-effective strategies to facilitate access to health care [13-15].

As found in other studies [22,54], our results show that the studies included predominantly young older adults, with few that took an interest in the “oldest old” such as persons aged ≥85 years. As the literature is so limited on web-based interventions involving people of more advanced age (eg, ≥85 years) and as the components and effects of web-based interventions may differ for this population, further studies are needed across the aging spectrum. This scoping review found that web-based interventions among older adults are mainly focused on increasing PA. This high prevalence could be explained by the fact that older adults are considered the most sedentary age group [55] and that the benefits of PA are considerable for this population [56]. Given that other lifestyle habits such as diet, stress, and alcohol consumption [2] would also be favorable to the health of older adults, more studies should be conducted to evaluate the effects of web-based interventions on these habits in this population.

Components

The web-based interventions included in this review had various components. The interventions were diverse in terms of their use parameters (ie, duration, number of sessions, completion time, and frequency). In almost all the interventions (10/11, 91%), at least one detail regarding the use parameters was omitted, making it difficult to understand the intensity of the interventions offered to older adults. As noted in the studies examining preferences toward web-based interventions, older adults prefer a few 30-minute sessions [57] or shorter 10-minute sessions on a regular basis every 2 or 3 days [57,58]. Among adults, other studies have shown that web-based interventions that are more intensive [24], that allow for longer durations, such as 60-minute sessions or more, and that propose a total number of sessions of >3 [59] are more effective at producing behavior change [24,59]. In this review, because of a lack of detailed information on use parameters, it was difficult to identify any trend in use parameters that were more relevant to supporting change among older adults. Further research is needed to better investigate the optimal use parameters (ie, duration, number of sessions, completion time, and frequency) of web-based interventions for older adults.

In this review, we found that the most used BCTs were instruction, feedback, and self-monitoring, which is similar to the findings of other studies that explored the use of BCTs in web-based interventions [22,60]. However, BCTs were used in combination without explaining why these choices were made and how they were operationalized. For this reason, it was difficult to discern the contribution of each BCT to the results obtained [61] and how they could have led to change [53]. BCTs are the active ingredients in an intervention to effect behavior change. Therefore, it is crucial for authors to be explicit about their choice of BCT combinations to understand how interventions produce their effects [62]. Although some interventions (2/11, 18%) observed that some BCTs such as self-regulation could be effective for adults and not for older adults [63,64], further research is needed to understand which

BCTs are more appropriate to support older adults in their adoption of healthy lifestyles. In particular, further studies are needed to explore which combinations of BCTs could optimize the intervention's impact and how each BCT interacts with the others within an intervention to produce behavior change among older adults [62].

The results of this review show the diverse range of delivery modes used in web-based interventions. Some included an electronic diary (2/11, 18%), quiz (1/11, 9%), or videos (4/11, 36%) as well as supplementary modes such as phone calls (2/11, 18%), face-to-face meetings (2/11, 18%), and email reminders (3/11, 27%). All the interventions (11/11, 100%) provided instructions on how to perform the behavior, which other authors have pointed out as the core of most web-based interventions [65]. Many (5/11, 45%) proposed automated feedback, which would be one of the most effective delivery modes leading to behavior change in adults [26]. Only 9% (1/11) of the interventions included a forum with peers, and it was underused by participants, which is inconsistent with other studies in which adults aged ≥50 years showed high use [66] and appreciation [67]. Few interventions (3/11, 27%) offered a chat with a coach, which is similar to the findings of other studies on web-based interventions among adults [22,59]. In the interventions that did offer a chat with a coach, participants were offered an opportunity to communicate with a coach if needed rather than for constant support. The actual nature, dose, and type of coaching provided by this coach was poorly reported by the studies. However, as pointed out by other authors, the constant support of a coach throughout a web-based intervention could replace the sense of interpersonal connectedness found in in-person interventions [68], which older adults seek [18,69]. A systematic review also found that web-based interventions that include human support are more effective at behavior change among middle-aged and older adults than stand-alone interventions [24]. That being said, although a certain delivery mode could be more appropriate for older adults [27], the literature on this subject is limited. More studies, such as meta-analyses, are needed to identify which delivery modes are more effective at inducing behavior change among older adults. This could guide the design of future interventions. Further studies should also investigate web-based interventions that give older adults the choice to participate in a group forum, as well as different forms of coaching by a professional throughout the web-based interventions. More studies are needed to examine the nature of the role played by the coach throughout a web-based intervention as well as explore the dosing and type of support needed to help older adults adopt healthy lifestyles. For us, it seems clear that this coaching could be provided by a health professional such as a nurse as it is a nurse's role to support people in health promotion and older adults appreciate developing a trusting relationship with a nurse [69].

In this review, few of the interventions (6/11, 55%) were based on a theory. The most common theory reported was the self-regulation theory. This differs from other reviews, in which one mainly finds the social cognitive theory in behavior change interventions among middle-aged [70] and older adults [71]. Among the theory-based interventions, most of the studies (5/6, 83%) did not report how the theory was used to design an intervention that would lead to the desired change. For this reason, it is difficult to draw conclusions regarding the theories and the results obtained. Theories help explain why and how behavior change occurs and provide guidance on the potential determinants to be targeted by the intervention to induce behavior change [62]. In addition, designing interventions based on theories allows us to link the theoretical determinants of behavior change with intervention components [33], know which BCTs to use [62], and ensure that the intervention will lead to behavior change. Indeed, it is well known that theory-based interventions are more effective than non–theory-based interventions [72], and this has also been demonstrated in a population of older adults [71]. Future web-based interventions to promote healthy lifestyles among older adults should be based on theory, and researchers should clearly state how theories guide the development of their interventions. Further studies are needed to compare interventions based on different theories in terms of the effects identified on the lifestyles of older adults.

Outcomes

As reported in previous studies [65,70], we observed a favorable trend in the use of web-based interventions to increase PA among older adults. This review found that web-based interventions can also have positive effects on blood pressure, lipid levels, BMI, smoking cessation, self-efficacy and knowledge, and the skills needed to adopt a healthy lifestyle. This is consistent with research findings on the benefits of web-based interventions [24,25].

As a result of our analysis, 5 themes emerged that appear to be central to web-based lifestyle change interventions among older adults: tailoring, motivation, support, barriers, and perceptions. As has been pointed out by many authors [29,73-75], the results of this review show that motivation is one of the most important factors influencing the lifestyle habits of older adults. As motivation is an intrinsic factor (ie, each person must identify their own), increasing individual motivation among older adults may facilitate behavior change [76]. In this sense, future web-based interventions among older adults should target this determinant as a way to help them adopt healthy lifestyle habits [26]. This review also found that older adults appear to appreciate interventions that include support from a coach, which also supports their motivation for change and engagement with the intervention. These findings are consistent with other studies in which older adults mentioned that support and the development of a relationship of trust are necessary in behavior change interventions [18,29,77]. This finding may inform the development of future web-based interventions intended to promote healthy lifestyles among older adults by including the support of a coach.

In line with the results of other studies [57,78], this review highlighted the fact that older adults would prefer interventions that are tailored to their preferences and conditions. Indeed, it appears that tailored web-based interventions can make older adults more engaged in behavior change [79] and lead to better recall of information [80]. Previous studies have suggested that tailored web-based interventions are more effective at inducing behavior change than generic interventions in a middle-aged adult population [25,26]. For older adults, designing a tailored

web-based intervention appears to be even more important considering the heterogeneity of this population and the various challenges associated with aging, including comorbidities and frailty, which are experienced differently by older adults [27]. Consistent with the findings of other authors [57,79], this review found that older adults may face barriers to using web-based interventions, such as lack of computer skills and difficulties using the technology. For the development of future web-based interventions, it would appear necessary to consider the barriers that older adults face in using technology and find ways to overcome them. Including access to a coach through the web platform for initial and ongoing guidance could help reduce such barriers and, in turn, avoid discouragement among older adults committed to change [79]. In addition, the findings of this review indicate that older adults' lifestyle habits are influenced by their perceptions of change in old age, as reported in other studies [73,75,79]. It would appear necessary to explore older adults' perceptions of change and its benefits in future studies to promote change in this population.

In summary, we believe that the results of this review provide a better understanding of the components of web-based interventions that can lead to behavior change among older adults. In the studies identified, we found an overrepresentation of interventions focused on the PA behavior of older adults and conclude that other studies should be conducted to assess the effects on other lifestyle habits. The results of this review lead us to believe that authors should provide a more in-depth description of their interventions' components, including the use parameters, BCTs, delivery modes, and theories used, to understand what is favorable to the adoption of a healthy lifestyle among other adults, how this is achieved, and how it could have influenced participants in behavior change. In particular, further studies should be carried out to understand how BCTs are used in an intervention, the impact of each of these BCTs, and the influence of the diverse delivery modes used on behavior change among older adults. Future web-based interventions should be based on one or more theories, and authors should indicate how these theories are used in the intervention to induce change. The results of this review suggest that further studies of web-based interventions to promote a healthy lifestyle in older adults should include support from a coach to develop a relationship of trust, seek to increase motivation among older adults, be tailored to older adults' conditions, help them reduce barriers to using technology, and modify their perceptions of effecting change at their age. We propose that future web-based interventions be coconstructed with older adults to better identify their needs and what they seek, particularly with regard to support from a professional.

Limitations

Although this is not the main objective or a necessary step in a scoping review, this review did not evaluate the quality of the studies, which may raise concerns about the rigor of the studies reviewed and affect the generalizability of the results. However, we critically reviewed all the studies. In addition, a language restriction (ie, only studies in English and French) was imposed, and this may have affected the exhaustiveness of the set of articles identified. In this review, we used a broad definition of older adults (ie, aged ≥65 years [2]). These results must be interpreted with caution given that older adults across the aging spectrum age differently and, regardless of their age, their needs may differ according to other characteristics such as comorbidities and frailty. Finally, step 6 of the Levac et al [28] framework (ie, consultation) was not completed as it was not relevant to the objectives of this scoping review. Indeed, this scoping review sought to explore the extent of the available literature on web-based interventions to promote healthy lifestyles among people aged ≥65 years, so consulting older adults would not have provided any insight into our subject. The consultation step may be more relevant in future studies conducted to map the needs of older adults in web-based interventions.

Conclusions

This study identified components and outcomes of web-based interventions to promote healthy lifestyles among older adults. Although a variety of components were found, this scoping review revealed a positive trend in web-based interventions to promote healthy lifestyles, mostly through PA. More research is needed to further develop knowledge in this area, including examining the oldest old, evaluating the effects on various lifestyle habits such as diet and stress, clarifying how theories are integrated into the intervention, and discerning the contributions of each BCT and mode of delivery on the results obtained. Future web-based interventions among older adults should be coconstructed with them to ensure that the interventions are tailored to their conditions, limitations, and preferences; include the needed support of a coach; increase their motivation; help them modify their perceptions of behavior change; and reduce their barriers to using technology. Moreover, this study did not assess the quality of the literature, so the results must be interpreted with caution. With the current aging of the population, the growing use of the internet by older adults in recent years, and the pandemic context, which requires that we review how we provide care, it remains essential to continue developing and evaluating innovative, accessible interventions that will promote the health of older people while meeting the needs of an aging population. The results of this scoping review may inform health professionals and intervention developers about the relevant components and outcomes of web-based interventions in a population of older adults.

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Authors' Contributions

All the authors contributed to the design and development of this scoping review.

Conflicts of Interest

None declared.

Multimedia Appendix 1
Search strategies.
[DOCX File , 23 KB - ijmr_v11i2e37315_app1.docx]

Multimedia Appendix 2
PRISMA-ScR (Preferred Reporting Items for Systematic Reviews and Meta-Analyses extension for Scoping Reviews) checklist.
[DOCX File , 108 KB - ijmr_v11i2e37315_app2.docx]

Multimedia Appendix 3
Characteristics of the studies.
[DOCX File , 26 KB - ijmr_v11i2e37315_app3.docx]

Multimedia Appendix 4
Summary of the behavior change techniques used in the web-based interventions.
[DOCX File , 18 KB - ijmr_v11i2e37315_app4.docx]

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Abbreviations

BCT: behavior change technique
CONSORT-EHEALTH: Consolidated Standards of Reporting Trials of Electronic and Mobile Health Applications and Online Telehealth
PA: physical activity
PRISMA: Preferred Reporting Items for Systematic Reviews and Meta-Analyses
PRISMA-ScR: Preferred Reporting Items for Systematic Reviews and Meta-Analyses extension for Scoping Reviews

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