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From E-Patients to AI Patients: The Tidal Wave Empowering Patients, Redefining Clinical Relationships, and Transforming Care

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Abstract

Artificial intelligence (AI) and large language models offer significant potential to enhance many aspects of daily life. Patients and caregivers are increasingly using AI for their own knowledge and to address personal challenges. The growth of AI has been extraordinary; however, the field is only beginning to explore its intersection with participatory medicine. For many years, the *Journal of Participatory Medicine* has published insights on tech-enabled patient empowerment and strategies to enhance patient-clinician relationships. This theme issue, Patient and Consumer Use of AI for Health, will explore the use of AI for health from the perspective of patients and the public.

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KEYWORDS

artificial intelligence; AI; large language models; LLM; participatory medicine; co-design; coproduction; internet; patients; caregivers; patient engagement; patient empowerment; digital health

Introduction

Artificial intelligence (AI) and large language models (LLMs) offer boundless potential to enhance many aspects of daily life. The promise of AI for health is profound: to discover new treatments, gain efficiencies, and deliver precision medicine—the right intervention to the right person at the right time [1]. Experts are effusive about AI, which can reduce cognitive workload, enhance prevention, and lower costs. Many blunt this enthusiasm with caution, as the field struggles to genuinely address AI ethics, accountability, privacy, and governance [2].

Along with the hope (and hype) of AI within health care, the public is swiftly taking AI into their own hands. Consumers are at the forefront in this era of AI. A survey conducted in January 2025 by Imagining the Digital Future Center found that 52% of US adults used ChatGPT, Gemini, CoPilot, or other LLMs. Among LLM users, half reported personal learning as their goal, and 39% sought information about physical or mental health [3]. Patients burdened with life-changing or rare conditions commonly search for the resources that they need to solve problems. As consumer costs of care keep rising and health care is relentlessly hard to navigate, patients and caregivers are gaining skills and intelligence using LLMs across a breadth of topics. These information seekers go beyond clinical content, using AI for personalized advice to tackle legal, financial, social, and many of life's challenges.

While people may not realize the ubiquity of AI, millions interact with AI daily using assistants such as Siri or Alexa and streaming platforms such as Netflix and Spotify [4]. Launched in November 2022, ChatGPT reached 100 million users in 2 months and hundreds of millions of users by March 2024 [5]. This scorching adoption has been faster than for personal computers and the internet. In 2024, a total of 39.4% of US adults aged 18-64 years reported using generative AI, and 32% used it weekly. In contrast, 20% of the public used the internet 2 years after its launch, and 20% owned a computer after 3 years of availability. While price and ease of use play a role in the difference, the advancement of AI is without historic parallel.

Projections of the health AI market over the next decade are staggering, with estimates of US $27 billion in 2024 climbing to US $613 billion by 2034 [6]. At this early stage, the direct-to-consumer market may mature faster and more readily than inside health care [7]. Yet, current research on AI for health largely focuses on clinician and professional users. It is essential to study how AI can best serve patients while mitigating risks. Although papers on the use of AI by patients and the public are

starting to emerge, we believe this is the first theme issue in a medical journal that is dedicated to the topic.

Rise in AI in Health Care Delivery Settings

Across health care, AI tools vary in their capabilities and stage of adoption (eg, to analyze data or optimize workflows) [8]. LLMs currently evaluate x-rays and images and enhance radiologists' diagnostic accuracy. AI is even in operating rooms, helping surgeons with the use of robotics during procedures. AI-enabled wearable devices gather patient data remotely to inform and augment cardiologists' decision-making. AI is synthesizing vast volumes of data locked in electronic health records, transforming raw data into actionable information. AI is accelerating pharmaceutical development, expediting drug discovery, and reducing the costs of clinical trials [9]. Notably, patient-physician-scientist partnerships are expanding, and using AI for "drug repurposing," or searching existing medications that work for rare diseases, is also accelerating [10].

For patients, the visibility of AI in health care is low but rising. AI scribes are being used to record human conversations during encounters and summarize visits. Automating the documentation of visits may realize a "holy grail" by giving clinicians more time for patients and families. One study found that a year after deploying AI scribes, most physicians had a positive experience. All patients in the study reported that AI had either a positive or neutral impact on the quality of their visit; only 8% of patients felt some level of discomfort [11]. These AI agents remain a work in progress, as AI documentation continues to gain accuracy and completeness.

Health systems are using AI-derived content to respond to patients' emails. Research on AI automated responses suggests that patients find messages to be satisfactory, with many comparable to emails from physicians; moreover, patients rated some responses as more empathetic than human clinician replies [12]. While AI messaging may help, health systems recognize the inherent risks in responding with inaccurate or potentially harmful information. Further, ethical concerns have been raised when patients believe responses are from a human and not a computer, or if they cannot ascertain whether replies are written by AI [13].

AI will remodel the patient experience and affect patient-clinician relationships. AI assistants do not replace the need for human judgment, particularly in cases requiring nuanced decisions. Importantly, patient and public involvement in AI development and refinement are critical to improve value, ensure safety, and engender trust. Further, more attention is warranted on the growth of AI tools that patients and caregivers are using independently for their health [5].

The (R)evolution of Patient and Public Agency and Empowerment

> *The 21st century will be the age of the net empowered medical end user, and the patient-driven online support networks of today will evolve into more robust and capable medical guidance systems that will allow end users to direct and control an ever-growing portion of their own medical care.* [Tom Ferguson, MD, 2002 14]

Ferguson was a family physician and pioneer who advocated for consumer use of the internet, believing that clinicians had much to learn from patients and families. He observed that patients who possessed internet-derived knowledge were more involved in their health and their care—the hallmark of participatory medicine [15]. He presciently wrote about tech-savvy patients who disengage from doctors who do not support patients accessing online information for self-care.

Participatory medicine continues to evolve, albeit sluggishly. For over three decades, the internet has served patients as a powerful tool to access previously unavailable information and connect with peers [16]. This shift in how people manage their health also altered power dynamics at medical visits and led to the term "Dr. Google" [17]. While greater patient control and contribution unfolded, not all clinicians have been comfortable with patients online or serving in a new role as "guide" or "partner" rather than expert authority.

The *Journal of Participatory Medicine* (*JoPM*) has been a pioneer, contributing insights on tech-enabled patient empowerment and enhancing patient-clinician relationships. *JoPM*'s early content was published on the Society of Participatory Medicine website, edited by Charlie Smith, Joe Graedon, and Terry Graedon, from 2009 to 2017. Authors included luminaries such as Esther Dyson, George Lundberg, Jessie Gruman, Kurt Stange, Kate Lorig, "e-patient Dave" DeBronkart, and many others. In 2017, *JoPM* joined JMIR Publications as a peer-reviewed, open access journal to advance the science of participatory care (also referred to as coproduction and co-design). Published papers mirror the 15-year shift in relationships between patients, their health information, and their providers.

Health professionals often overestimate the risks of e-patients (patients and caregivers online) and underestimate their value [18]. Despite the long-standing evidence that a participatory decision-making style leads to greater patient satisfaction and trust in health professionals [19], medical educators and practitioners have yet to fully acknowledge that patients are already active managers of their care, failing to support patients in this role [20]. Yet the evidence is there: e-patients are more prepared, feel more in control of their care, and achieve better outcomes [21].

The value of patient-facing technology continues to soar. Patients can now access all their clinical notes and test results online, mandated by the 21st Century Cures Act. Opening notes ushered in a wealth of research showing benefits of shared data to patients and families [22]. Along with technology empowering patients, health care has adopted a more holistic perspective. This shifted patient inquiry from "What is the matter with you?" to "What matters to you?" This approach robustly assesses social drivers of health and clarifies patient context, allowing care teams to codevelop realistic and achievable care plans.

The democratization of information and near-universal access to the internet have help innumerable patients. Not all health care organizations celebrate such progress, however. Patient portals, a splendid tool for patients, also contribute to clinician's administrative burden. Patient messaging volume has escalated, leading some organizations to charge for e-communication. Real-time access to laboratory, imaging, and pathology tests causes apprehension among clinicians who feel unprepared when patients are first to see results. Some clinicians also believe that patient access to their health information threatens therapeutic relationships and extends the length of visits [23].

AI advancements introduce a range of new challenges. Too much information may overwhelm patients and caregivers and add uncertainty and anxiety when seeking credible and reliable resources, while a lack of information can cause patient anxiety. Lack of internet connectivity or device access excludes patients from benefiting from digital tools [24]. Consequently, there are expectations that AI tools—somewhat paradoxically—will solve the problem of too much information and narrow the digital divide. Then again, AI-derived outputs are knowingly biased since public access to peer-reviewed research is often behind "paywalls" that are restricted to institutional subscribers.

AI Patients and Consumers: It Is Already Here

Often considered "the future," AI is here today and integrated into everyday life. Positioned to facilitate moving patients and families into this new age, AI amplifies earlier e-patient behavior to obtain relevant health information, increase patient control over health and care, enhance health literacy, stimulate coequal contributions in decision-making processes, and enhance relationships with clinicians. Society has moved from e-patients to AI patients.

The public use of AI will grow exponentially. AI assistants will be increasingly used to explore symptoms; help with managing chronic diseases; and offer advice on nutrition, exercise, and more. AI-enabled wearable and smart devices, now used for people to track their activities to make real-time adjustments, will flourish. Those with life-altering diagnoses or rare diseases will use AI as a research assistant and copilot to obtain tailored data to guide treatment planning, especially when traditional forms of care have been exhausted. AI-powered peer support will transform into patient-led knowledge networks, and caregivers will use AI tools to monitor their loved ones while aiming to lower their stress.

As AI augments traditional care, there will be consequences. One example is the surge of low-cost AI chatbots targeting adolescents and young adults to address mood and mental health. Promoted as "personal intelligence" tools, these on-demand chatbots engage users to reflect on their feelings, organize thoughts, and help make decisions. Early research on AI chatbots for anxiety and depression has been mixed. Some studies show reductions in symptoms and perceived loneliness among frequent users [25]. Challenges, however, include emotional attachment and user dependency, lack of professional oversight, harmful messaging, and legal and privacy issues [26].

As health systems use "virtual first" approaches to care, boundaries between patients using AI alone versus AI with clinicians may become blurred. AI accuracy and trustworthiness will require incorporating human intelligence and feedback (human in the loop) to improve its accuracy and earn trust. Still, because patients' needs are often not being met, any tools that can help patients navigate care and solve problems could be valuable.

The Need for Research, Education, and Co-Design

These challenges underscore the need for research to identify both AI benefits and risks, especially among vulnerable populations. Like the e-patient era, the AI patient era may underestimate the significance of people using information to manage their health. Unlike the past, however—where risks to patients online were overestimated—AI stakeholders may underestimate the risks of AI to patients. These tools are powerful yet presently subject to only minimal regulation and governance. AI researchers must study how patients and caregivers use AI and assess how it impacts their lives. AI developments need to be co-designed with patients and ensure that governance includes rigorous regulatory and other guardrails, thereby preventing harm while promoting beneficial use [27]. Reputable organizations provide salient approaches to meaningfully involve patients and the public in research and care delivery, including the Patient-Centered Outcomes Research Institute [28] and the UK Standards for Public Involvement [29]. Critical guidelines are available from the National Academy of Medicine's AI Code of Conduct [30] and The Light Collective's AI Rights for Patients, which outlines seven patient rights critical to the development and deployment of AI in health care [31].

Finally, there is a fundamental educational imperative to equip patients and consumers with the knowledge and skills necessary to critically engage with AI tools for health. Educational offerings should encompass basic concepts and principles of AI and LLMs, effective prompting strategies, and understanding that machine learning systems may generate inaccurate or misleading outputs (ie, "hallucinations"). Learners must be aware of AI's considerable variability in quality, transparency, equity, and reliability. Such instruction is essential to ensure individuals use AI tools responsibly and effectively to support their health and well-being.

Our journal's theme issue, Patient and Consumer Use of AI for Health, begins exploring the use of AI for health from the perspective of patients and the public. The scope of our special issue posits the following:

- What is the patient and caregiver experience using AI tools for health and care?
- How can patients, caregivers, and the public use AI for maximum benefit?
- What are the risks and unintended consequences of AI use by patients, and how can these be mitigated?
- What is the impact of AI derived from health systems and presented to patients?

- How does AI affect patient-clinician relationships or patient–health care relationships?
- How can patient and public involvement be a standard in designing, developing, and deploying AI for health?

The growth of AI has been extraordinary; however, the field is only beginning to explore its intersection with participatory medicine. Health care must expand its "patient-centered" views and embrace the power that AI use affords patients and caregivers, as they are not seeking permission but are already using LLMs. Researchers must investigate consumer use of AI, co-designing studies with patients and caregivers, and determine how to avoid unintended consequences. The innovation community must embrace patient and public involvement throughout the development life cycle. We hope that this work inspires others to contribute to this new era of #PatientsUseAI.

Conflicts of Interest

None declared.

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Abbreviations

AI: artificial intelligence
***JoPM*:** *Journal of Participatory Medicine*
LLM: large language model

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Is This Chatbot Safe and Evidence-Based? A Call for the Critical Evaluation of Generative AI Mental Health Chatbots

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Abstract

The proliferation of artificial intelligence (AI)–based mental health chatbots, such as those on platforms like OpenAI's GPT Store and Character. AI, raises issues of safety, effectiveness, and ethical use; they also raise an opportunity for patients and consumers to ensure AI tools clearly communicate how they meet their needs. While many of these tools claim to offer therapeutic advice, their unregulated status and lack of systematic evaluation create risks for users, particularly vulnerable individuals. This viewpoint article highlights the urgent need for a standardized framework to assess and demonstrate the safety, ethics, and evidence basis of AI chatbots used in mental health contexts. Drawing on clinical expertise, research, co-design experience, and the World Health Organization's guidance, the authors propose key evaluation criteria: adherence to ethical principles, evidence-based responses, conversational skills, safety protocols, and accessibility. Implementation challenges, including setting output criteria without one "right answer," evaluating multiturn conversations, and involving experts for oversight at scale, are explored. The authors advocate for greater consumer engagement in chatbot evaluation to ensure that these tools address users' needs effectively and responsibly, emphasizing the ethical obligation of developers to prioritize safety and a strong base in empirical evidence.

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KEYWORDS

GenAI; mental health; chatbot; ethics; evals

A Call for the Critical Evaluation of Mental Health Chatbots

The internet is flooded with mental health resources, and one of the most common emerging formats is the artificial intelligence (AI) chatbot. A recent Forbes article examines the launch of OpenAI's GPT store, which allows users to post chatbots for ready use by others, and found that many were intended for mental health advisory purposes; another 3 million or so general-purpose chatbots are not intended specifically for mental health purposes but would take on that role if prompted [1]. For example, a quick Google search for "Character.AI" and "therapist" yields a link to a Character.AI bot that says they have "been working in therapy since 1999… [are] a Licensed Clinical Professional Counselor (LCPC)... [and are] trained to provide EMDR treatment in addition to Cognitive Behavioral (CBT) therapies." A small disclaimer at the bottom states, "This is A.I. and not a real person. Treat everything it says as fiction." However, the boundary between reality and fiction can become quite blurry for consumers interacting with AI chatbots, as is illustrated by instances where deaths by suicide have been linked to chatbot usage [2].

This is particularly pertinent for chatbots which use Generative AI (GenAI). Although mental health chatbots have existed for some time, their increasing popularity is in part due to the rise of GenAI. In traditional chatbots, the user's interaction with the bot is typically governed by an explicitly programmed set of rules for choosing between prewritten responses. GenAI chatbots, in contrast, are driven by powerful large language models (LLMs) that produce customized responses to each user message, guided by the instructions written in the "system prompt" provided to the LLM. Generative chatbots provide much greater flexibility at the cost of less predictable behavior.

The legality of such apps, when used for mental health, is questionable, as digital products that make medical claims, such as the ability to treat depression or anxiety, are considered medical devices in many countries. Medical devices are subject to requirements to show evidence of safety and effectiveness, as well as regulatory scrutiny. But the large majority of digital products that make these types of claims are not evaluated by regulatory bodies [3]. Somewhere in between "free for all" and "medical device" is a category of digital products that may provide advice responsibly without claiming they provide treatment. These chatbots can be considered "general mental health support" bots, as opposed to conversational AI chatbots, which have a specific purpose such as triage [4]. Examples include Ada [5], Chai [6], Elomia [7], Mindspa [8], Nuna [9], Serenity [10], Stresscoach [11], Woebot [12], Wysa [13], and

Youper [14,15], as well as newer entrants Ebb (Headspace [16]) and Nova (Unmind [17]). Because these and other similar chatbots do not rise to the level of a medical device, regulatory bodies (eg the US Food and Drug Administration) do not govern the claims made about what the chatbots do. Consumers are therefore left to navigate this landscape without guidance on what makes a chatbot safe and effective. However, there is currently no legal, academic, or industry-agreed standard or method for doing this in a way that enables consumers to be meaningful, active collaborators in their own care.

We argue that companies producing AI mental health products intended for general use should demonstrate, in some systematic and objective way, that the products they provide to consumers are safe and deliver advice that is evidence-based. We argue that doing so is an ethical obligation to consumers, as well as something (quite rightly) expected of digital mental health interventions by both users and providers who recommend digital products. To empower consumers and the public to accurately assess the risks and benefits of using AI for self-care, there needs to be a clear, accessible framework for evidencing how the chatbot addresses the needs and concerns of the individual user. Such a framework will also need to be meaningful and acceptable to potential gatekeepers of access to AI, such as therapists referring patients to AI-based products or employer health benefits providers.

What Criteria Should Generative, General Mental Health Chatbots Be Evaluated On?

Evaluating mental health–related chatbots is a particular challenge due to the sensitive nature of mental health, and the consequences of providing poor-quality responses to potentially vulnerable users discussing sensitive topics. Based on our shared experience in clinical practice, mental health research co-design and/or participatory involvement in research and building AI-powered products, and on the World Health Organization's guidance on Ethics & Governance of Artificial Intelligence for Health (2024) [18], we propose that mental health AI chatbots should adhere to a version of the criteria outlined in Table 1.

Whatever criteria we use and whatever thresholds we set for expected performance of a chatbot, they should have real-world impact and reflect what matters most to users, including perceived relevance and usefulness, privacy and confidentiality [19], and human therapist personal attributes valued by consumers that may be replicable by AI chatbots, such as being respectful, confident, warm, and interested [20,21].

Table . Criteria for evaluating performance of an artificial intelligence–based mental health chatbot.

Criteria	Definition
Be ethical	Responses should benefit users while avoiding harm, be just and fair, promote user autonomy, and allow for transparent, informed understanding of their basis.
Be safe	Clear rules governing a chatbot's behavior when there is a risk of physical or psychological harm to the user or to others must be set and adhered to. These should establish the chatbot's remit, including signposting to external resources and not providing medical diagnosis or treatment or producing any outputs that would constitute use as a regulated medical device.
Be accessible	The chatbot should be accessible to the user, including support for the user's native language where possible and appropriate accommodation for the user's verbal comprehension skills.
Follow the evidence base	Responses should be grounded in the established scientific literature.
Apply core coaching skills	The chatbot should display strong conversational skills and apply conversational techniques including goal identification, alliance building, and empathetic inquiry.

How Could Evaluation Be Implemented?

With the explosion in applications of GenAI, there is greater emphasis placed on "evals," which are systematic approaches to evaluating whether the outputs of the AI system are appropriate for the task at hand before they are rolled out to users [22,23]. Evals will typically consist of a collection of test inputs to the AI system and criteria or scoring rules by which to evaluate the outputs. There are some scenarios where the accuracy of outputs may be evaluated directly, for instance, by comparing against a predefined target or using pattern matching. In other cases, for instance, in applications involving classification, data retrieval, or summarization, outputs can be compared against targets using statistical metrics such as precision and recall.

However, in many applications of GenAI, particularly those involving chatbots, there is no meaningful "right answer" for the chatbot to give. In these cases, we must instead evaluate outputs against a rubric or set of qualitative criteria. Criteria might include formatting features (eg, uses markdown), linguistic style (eg, level of formality), tone of voice (eg, level of warmth), or more abstract features (eg, shows empathy). This approach is used in the reinforcement learning phase of training modern AI LLMs, where models will generate multiple candidate responses to a given question, the preferred response is identified using predefined criteria, and this feedback is used

to adjust the model to make such a response more likely [24,25], but is equally useful in evaluating models after training.

Evaluations against criteria can be performed either by human annotators or by additional AI systems. Expert human annotators can bring deep clinical expertise and nuanced understanding to their evaluations [25,26]. However, this approach is extremely resource-intensive and may suffer from unreliability or inconsistency, particularly when annotating large datasets [27]. An emerging alternative is the "LLM-as-a-judge" approach [28,29], where these evaluations are performed by an LLM. To work reliably, this approach requires an additional process of comparing LLM-generated evaluations against high-quality human evaluations, and modifying the instruction prompt used by the LLM to align and calibrate the human and AI judgements.

Writing criteria against which to evaluate AI-generated responses is a deceptively difficult task, requiring a deep understanding of the domain and the likely behaviours of both the users and the chatbot. It is increasingly recognized that the implicit criteria used by human annotators evolve as they are exposed to a greater variety of data [29]. It is considered best practice [29] to write these criteria iteratively, with expert judges continuously reviewing real user data alongside the previous generation of LLM-judged evals in order to produce criteria that better define how a chatbot should behave.

For chatbots, evals based on single interactions (a message and a response) may fail to capture important dynamics that emerge over multiple turns in a conversation. A promising approach is to use an additional AI system to play the role of the user interacting with the target chatbot in order to simulate multiturn "bot-to-bot" conversations. This approach has its challenges. If we intend to generalize from the chatbot's responses in these simulated conversations to how the chatbot would respond in real interactions with humans, we must ensure that the messages from the simulated user are representative of the range of messages that would be sent by real users. Multiturn conversations can also go down many more diverging paths than single interactions; hence, a large number of simulated conversations under the same conditions may be needed to allow for the variance in outcomes.

The Role of the Consumer

Much research to date has focused on using professional experts, not health care users, to evaluate chatbots. Although inconsistent, research has shown that coproduction of digital mental health interventions can improve their utility [30]. Similar to how there is a need for guidelines around user involvement in intervention development [31,32], we believe that the implementation of a critical evaluation framework for mental health AI chatbots would benefit from health care consumers not only contributing to the evaluation criteria but also being involved in rating chatbot conversations to calibrate the automated testing systems. Our viewpoint builds on previous work that has discussed issues around ensuring AI for consumers is safe, effective, and trustworthy [33,34]. This would ensure that health chatbots are evaluated in line with not only what previous research has demonstrated is important to consumers but also what is currently most relevant, given this technology is emergent. Furthermore, patients have a very different level of fluency with mental health concepts than the average researcher or practitioner, making their input particularly important in the development of mental health AI chatbots. A quote from an anonymous patient (interviewed March 13, 2025) highlights this:

> *I use chatbots that are experts in all kinds of different therapeutic approaches. I get a lot out of them, but I'm also very aware that because I am well-versed in the therapeutic approaches they use, I'm able to ask them for the right things, in the right language. I recognize the concepts they are leveraging and find myself unconsciously staying within the bounds of what therapy is intended to do. I would never trust these chatbots in the hands of the average consumer. There are so many ways to misunderstand meaning or offer the wrong thing if the language of the input is 'wrong'.*

In other words, practitioners and software developers emulating patients are not enough to capture the many ways that a therapeutic chatbot could err—naturalistic patient use will unearth new use cases and reveal new pitfalls. A number of recent papers provide models for taking a participatory approach to designing and testing GenAI tools.

Conclusions

Digital mental health is rife with products that are unhelpful at best and compromise consumer safety at worst. In order to realize the potential of GenAI for mental health, it is recognized that all stakeholders need to be involved in its development and regulation [34]. We have argued for the importance of evaluating GenAI mental health chatbots, even in a nonregulated context, objectively, with a common set of criteria that can provide guidance for consumers and practitioners on which products are safe and evidence-based. We provide some suggestions to start and highlight some of the key challenges to implementing those suggestions. By involving consumers in the evaluation process, and addressing their needs during development, the true promise of GenAI can be realized for all health care users. At the same time that we push for more rigorous evaluation and regulation of GenAI-based digital mental health products, we must also keep in mind the urgent need for such products, and the potential cost of hindering progress. A patient cited in the Medicines & Healthcare products Regulatory Agency (MHRA) research report on digital mental health technology says, "I think apps are likely to be safer than the range of side effects present in many meds" [35]. For some patients, digital mental health products may be appealing in a way that other forms of treatment are not, such that they will not seek in-person care if digital options are not available. Another patient in the MHRA report notes, "People may find it easier to write how they are feeling rather than struggling to find the words or sentences" [35]. Further, as the earlier anonymous patient highlighted to us, "The alternative [to using GenAI therapy] for me is to receive nothing, and that's the norm. The majority of patients receive no care at all." So, even as we work to keep digital products safe and ensure their effectiveness, we must also be

mindful that the need for these solutions is high, and the risk of not making digital solutions available may be higher than the risks of offering them.

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Authors' Contributions

Data curation and assimilation—AP
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Conflicts of Interest

All authors were employed by Unmind Ltd at the time this viewpoint was written, and MM, ME, RPD, ET, and PM own share options at Unmind Ltd. Unmind Ltd is the creator of Nova, one of the GenAI chatbot products discussed in this article.

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Abbreviations

AI: artificial intelligence
GenAI: generative artificial intelligence
LLM: large language model
MHRA: Medicines & Healthcare products Regulatory Agency

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From Internet to Artificial Intelligence (AI) Bots: Symbiotic Evolutions of Digital Technologies and e-Patients

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Abstract

Abstract: This paper will view the rise of the e-patient, who is "equipped, enabled, empowered, and engaged" through the lens of the evolution of successive digital technology innovations, each building on its predecessors, creating new tools for patient empowerment. We begin with the dawn of the web and the proliferation of health websites and discuss the use of digital communication tools. We then discuss the adoption of electronic health records, which enabled the rise of patient portals. This digitization of health data, along with the rapid adoption of mobile internet access and the proliferation of health-related smartphone apps, in turn, provided a platform for patients to coproduce health care by contributing their own health data to their self-care and health care. The exchange of health information between patients and providers has also been facilitated by telehealth or telemedicine technology, which enables direct care delivery. The use of social networks in health, in use since the early days of the web, has expanded since COVID-19, when public health authorities worldwide, as well as patients, sought the use of social media channels to get connected and share information. Most recently, artificial intelligence and large language models have emerged with yet untapped potential to provide patients with the information that could improve their understanding of their conditions and treatment options. We conclude that innovations in digital health technology have symbiotically evolved with the ascendance of the e-patient, enabling improved communication, collaboration, and coordination between patients and clinicians and forging a health care system that is safer and more responsive to patient needs.

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KEYWORDS

e-patient; participatory medicine; digital health technologies; artificial intelligence in health care; patient-generated health data; electronic health records; patient portals; telemedicine or telehealth; social networking in health; smartphones and health apps; internet and health care; health care innovation; digital communication tools; self-monitoring devices; health care cost transparency; chronic disease management; OpenNotes; 21st Century Cures Act; social media in health care; consumer health informatics; data sharing; wearable electronic devices

Introduction: The Rise of the e-Patient

Until the later half of the 20th century, the concept of an empowered, engaged patient did not exist. Physicians were viewed as experts who, based on their medical education, were supposed to understand every issue or concern a patient presented. The patient was expected to comply and follow their doctor's orders passively. Dr Tom Ferguson, physician, author, educator, and innovator, had a different view, possibly inspired by his involvement in the patient self-care movement that started in the 1970s.

In his sentinel white paper, "e-Patients: How they can help us heal health care," completed posthumously by the e-Patient Scholars Working Group in 2007, the term e-patient is defined [1]:

> *e-Patients represent the new breed of informed health consumers who go online to seek information on their own ailments and to find better health information and services for others. They work collaboratively with their doctors and within the system to resolve health issues.*

The e-Patient Scholars Working Group fostered the movement of participatory medicine, in which patients, using digital health tools, become active drivers of their health, leveraging newly developed and available digital health technologies that have changed medicine forever.

The rise of digital health technologies has fueled the emergence of the e-patient. First, the World Wide Web, followed by the adoption of electronic health records (EHRs), patient portals, and connected self-monitoring instruments that enable patient-generated health data (PGHD) and facilitate patient involvement in their own care have successively empowered patients. In addition, technologies such as smartphones, telehealth, and social networking, and finally, recent innovations that include various iterations of artificial intelligence (AI), have fostered engagement of both patients and clinicians in a way that has changed how health care operates. Pressure from patients who want to manage their own health, participate in their health decisions, communicate and collaborate with their health care providers, and push back against a health care system that does not meet their needs has led to the creation of digital technologies—with their attendant questions about safety and privacy—that have evolved to meet these needs. The rise of the e-patient and these digital technologies has shaped a new dynamic in health that has indelibly changed the face of health care and "enhanc[ed] the capacity of [patients] to make purposive choices and to transform those choices into desired actions and outcomes" [2]. We will look at 9 important innovations in recent decades and identify specifically how they have empowered patients to better pursue their health goals (Table 1).

Table . Technologies and their impact on e-patients.

Technology	e-Patient impact
World Wide Web	• Web-based health information • Medical literature search
Email	• Patient-patient communication • Patient-clinician communication
Social networking	• Emotional support • Sharing disease-specific information • Sharing treatment and outcome data
Electronic health records	• Enhanced safety • Increased confidence in care
Patient portals	• Direct access to medical records • Communication with the clinical team • Convenience transactions (appointments, prescriptions, referrals, and financial) • Health information
Smartphones	• Ubiquitous access to health information, portals, and social networks • Health apps • Health monitoring
Patient-generated health data	• Insights into lifestyle and impact on health conditions • Greater participation in care
Telemedicine	• Improved access to professional care • Access to lifestyle medicine providers • "Digital primary care"
Artificial intelligence	• Greater understanding of medical records • Enhance comprehension of medical literature • Assist with triage and diagnosis • Discuss treatment options • Aid to communication • Gain new insights from self-monitoring data combined with medical record

The Internet and the World Wide Web

Overview

The internet is a global network of servers and networks originally conceived and developed to meet the demand for automated information-sharing between scientists in universities and institutes throughout the world [3]. The protocols that enabled the evolution of the World Wide Web were created by Berners-Lee et al [4]. By the mid-1990s, the proliferation of websites and the technologies for publishing on the web had democratized access to information and communication on the internet. Over the last 3 decades, there has been significant innovation in the use of the web as a platform for accessing enormous multimedia information resources and enabling many of the technologies described in this paper. The widespread adoption of these technologies has been facilitated by the

development of broadband internet access, Wi-Fi, wireless internet access, and powerful and highly portable mobile technologies.

A recent Pew Research Center survey of 5733 US adults, published in January 2024, reported that nearly 95% of US adults are using the internet; 80% say they subscribe to high-speed internet (broadband) at home. The study determined that a large proportion of American people are connected to the world of digital information while "on the go" via their smartphones and other mobile devices. From these numbers, it is apparent that the internet is a staple of the 21st-century lifestyle and an important way that patients remain empowered and armed with the information and tools they need to make medical decisions [5].

Impact of the Web on Patient Empowerment

The advent of the web has greatly facilitated patient access to health information, once largely the domain of health care professionals. A proliferation of sites provided medical information to patients, with still-running WebMD [6], which debuted in 1996, one of the earliest examples. As website technology matured, these sites offered increasing interactivity to patients to better address their questions and concerns. Interestingly, patient use of web-based information has often been opposed by the medical establishment [7], leading to conflict in patient-physician interactions. Another important example is enabling patients to search medical journals. The world's medical literature is cataloged by the National Library of Medicine (NLM) and, beginning in 1879, a comprehensive bibliography was published on paper as Index Medicus [8]. Medical librarians and appropriately trained physicians could query this index on the NLM's computers through MEDLINE [9] beginning in 1971. In 1986, the Grateful Med app eased access for health care professionals [10], but the advent of the web enabled the NLM to create PubMed [11], which made it easy for anyone (including patients and nonprofessional caregivers) to search the world's biomedical literature to help diagnose and manage their medical conditions.

Email

Overview

Email, asynchronous computer-based communication technology, was created in the 1970s, and its use proliferated with the dawn of the web in the 1990s. In 1998, Kane and Sands [12] first promoted the broad use of email between patients and physicians and offered guidelines for its appropriate use. Prior to the use of email, only synchronous communication in the office or over the phone was used in health care interactions.

Common uses of patient-provider email are many and include advice regarding new or recurrent medical conditions, including recommendations on the best site of care (home vs clinic vs urgent care vs emergency department), which may include photos or other media as needed; response to quick questions that should not involve an office visit; sharing data such as blood pressure and blood sugar; and follow-up on the effectiveness or side effects of medications.

Because of the need for patient privacy, which is not inherent in email, patient portals, offering secure messaging, gained widespread use in the 2010s. Many of these messages today are triaged by nursing staff before being sent to physicians.

Impact of Email on Patient Empowerment

AIDS activists used email for information sharing and organizing in the 1980s. Patient-physician email broke down communication barriers imposed by phone-based triage and "telephone tag" and permitted a greater frequency of brief connections, thereby potentially enhancing relationships. Because it is asynchronous, it removes the time pressure of the office visit, affording patients the ability to take the time to craft their questions and more time to absorb their physicians' responses [13].

Social Networking

Overview

Although many think of social networking as a recent phenomenon, early social networks, such as USENET, FIDONET, and The WELL, date to the 1980s and enabled mainly asynchronous communication on a variety of topics. The advent of the web and faster connection speeds enabled the immersive social networking experience to which we have become accustomed. These platforms permit peer-to-peer information-sharing and support.

Impact of Social Networks on Patient Empowerment

e-Patients do not rely on medical professionals' views alone. Not surprisingly, in the 1980s, they began actively engaging with peers to share information and support through health groups on USENET, FIDONET, and The WELL. These became popular for AIDS activists to share information and support [14,15]. Peer-support communities proliferated in the early days of the web. For example, in 1995, the Association of Cancer Online Resources began to offer cancer-specific support for patients with cancer and their caregivers, ultimately offering communities for more than 200 different cancers with 115,000 messages exchanged each day [16]. Frydman (personal communication, 2025), the founder of the Association of Cancer Online Resources, estimates that the site helped over half a million people. Over the subsequent years, web-based health communities proliferated and were a primary source of information during the COVID-19 pandemic. Many web-based peer-support networks bring together patients who are living with illnesses and health care professionals who may be interested in these conditions.

There are web-based communities for different cancers, neurologic diseases, autoimmune diseases, mental health disorders, and many other conditions. These communities provide emotional support, peer coaching, and medical advice. The advice gathered from these communities has been reported to be life-saving [17]. Like other forms of web-based information, individuals in communities may provide incorrect advice. Studies show that communities will usually self-correct erroneous information [18].

While these and their successors were generally platforms for peers to share emotional and care advice, in 2004, PatientsLikeMe created a web-based community health data platform that also encouraged patient-driven research collaboration to test therapies and share actual outcome data [19]. The network has over 800,000 members who are dealing with more than 2900 conditions, including amyotrophic lateral sclerosis, multiple sclerosis, and epilepsy [20]. As the technology has improved, web-based support communities have added synchronous tools like chat and video, and in some cases, have facilitated patient meet-ups in real life [21].

Electronic Health Records

Overview

Digital health records got off to a slow start when they were introduced in the United States starting in the 1980s. It was not until 2004, when President George Bush set the goal that every American would have an EHR within 10 years, supported with funding for demonstration projects and the development of common standards that digital health records became ubiquitous [22]. The passage of the Health Information Technology for Economic and Clinical Health Act, enacted under Title XIII of the American Recovery and Reinvestment Act of 2009, helped to foster the growth of the EHR. In 2008, only 17% of health care providers had electronic medical records, but by 2021, 9 in 10 US office-based physicians had adopted EHRs [23].

Impact of EHRs on Patient Empowerment

Even before the advent of patient portals, the adoption of EHRs may have led to greater patient confidence in the safety of their care and the persistence of their health data and reduced frustration when they see the availability of their health records to all their physicians. However, the greater impact was yet to come when patient-facing apps were added to their physicians' EHRs in the form of patient portals.

Patient Portals

Overview

EHRs were adopted to improve the quality and safety of patient care, but they also permitted patients access to their health information through connected patient portals. Patient portals are secure websites that provide access to EHR information (including sharing access with caregivers), communication with the health care team, and convenience transactions such as tools for booking appointments, requesting prescriptions, and paying medical bills. Through these portals, patients can view substantial parts of their medical records—including office notes, thanks to the advocacy of organizations like OpenNotes [24]—pulling back the curtain on health care decision-making and permitting them to manage and monitor their health issues and collaborate with their physicians to resolve health problems.

Impact of Portals on Patient Empowerment

Patient portals have had a major impact on patients' ability to engage in their health care. For one, portals have facilitated secure asynchronous communication between patients and health care professionals, reducing barriers to communication and sometimes obviating the need for a medical appointment. It has also been a useful mechanism for patients to provide updates on their conditions, such as sharing blood pressure measurements or responses to medications. Messaging has become so popular among patients, especially since the COVID-19 pandemic, that it has been cited as a contributor to physician burnout [25].

While streamlining transactions, such as requesting prescription renewals and making appointments, has further made it easier for patients to interact with their physicians' offices, arguably the most important impact of patient portals has been to enable patients to see their own health information. Initially, this was only problems, medications, and test results, but patients wanted more, and activists and advocacy organizations (including the Society for Participatory Medicine) pushed the Obama administration to require that patients have full access to their records.

The 21st Century Cures Act (Cures Act) [26], signed into law on December 13, 2016, was designed to help accelerate medical product development and bring innovations and advances to patients who need them faster and more efficiently. The Cures Act legislation makes patient access easier and digitally unrestricted by mandating that providers give them access to data from their medical records so they can make better choices regarding their care and experience transparency regarding costs and health care outcomes.

However, just viewing information is not enough. e-Patients want to download their data and use it in novel ways. Dedicated technology and patient activists worked together to develop the capabilities of Fast Healthcare Interoperability Resources, a data exchange standard, to support this functionality, and the Cures Act requires providers to offer an application programming interface to EHRs to permit patients to download their records, usually through apps [27]. Each of these improvements enhanced the patient's ability to know what is going on with their health, which is the cornerstone of empowerment.

The Smartphone

Overview

Modern smartphones combine a full suite of mobile tools for patients and clinicians in one compact device that has a large memory, fast processing speeds, wireless internet access (both through the mobile networks and Wi-Fi), a high-quality camera, an accelerometer, GPS, Bluetooth for connectivity to devices, near-field communication, and, of course, a phone. They provide the ability to manage personal information, streaming music, videos, and games, 24/7 access to social media, text messaging, and real-time language translation. The number of tasks that can be accomplished with this platform is almost infinitely expandable through access to app stores. The average person uses 9 mobile apps daily, 30 apps per month [28].

A Pew Research study in 2023 [5] found that 90% of adults reported they owned a smartphone, and 4 in 10 individuals polled reported being on the web "almost" constantly. The study found that smartphones are used across income levels, but those

in households earning US $100,000 or more annually are far more likely than those earning less than US $30,000 per year to use a smartphone (98% vs 79%). Education level and age also played a factor in the ownership of smartphones. Those individuals with a higher education generally had a smartphone. People older than 65 years of age were reported to be about 20% less likely to have a smartphone than those younger than 50 years.

Impact of Smartphones on Patient Empowerment

Smartphones provide patients with ubiquitous access to health information, including their health records, participation in social networks, connection with their health care team, health plan, and pharmacy, as well as access to apps that allow them to track their activity, food intake, blood pressure, glucose, sleep, and weight. Combined with connected wearable devices like smartwatches, available apps can also track heart rate and rhythm, oxygen saturation, and cardiovascular fitness. Being better informed about their health status and better equipped to take timely action empower patients to better manage their health between visits. App stores host more than 350,000 health care–related apps available globally, and new health apps are constantly being developed.

Patient-Generated Health Data

Overview

According to the RAND Corporation, nearly 60% of adult American people have at least 1 chronic disease—including diabetes, cardiovascular diseases, such as irregular heart rhythm or hypertension, or lung problems such as asthma or chronic obstructive pulmonary disease, cancer, arthritis, and kidney disease—and 42% have more than 1 [29]. These chronic conditions account for hundreds of billions of dollars in health care spending every year in the United States alone. Their estimates suggest that nearly 150 million American people are living with at least 1 chronic condition; around 100 million of them have more than 1. Nearly 30 million are living, day in and day out, with 5 chronic conditions or more.

In a 2019 study of 4159 individuals from the Health Information National Trend Survey [30], about 30% were using a wearable device. The use of wearable devices was more common among those with chronic conditions. This study found that 49% of those with a usual source of care had shared data with their provider. This behavior was more common in those with chronic conditions. Both adoption and data sharing have likely risen in the ensuing years.

Since patients only spend a small fraction of their lives in formal medical care, PGHD have increasing potential to help patients with self-care and improve the health care of patients with many chronic conditions. In their 2014 paper on the topic, Sands and Wald concluded [31]:

> *Patient-generated health information, enabled by data transparency and consumer engagement, is not a panacea, but can help address information gaps in important areas, leverage untapped patient experience, and offer information that will improve self-management, provider-directed, and joint decisions made by patients and providers together and facilitate more frequent contacts with patients for better management of chronic conditions.*

Impact of PGHD on Patient Empowerment

Home blood pressure cuffs have been in use since the 1970s, and glucometers have been used widely since the 1990s. Both technologies have enabled patients to contribute data to their care and self-care, improving their self-awareness and enriching the data available to their clinicians.

Although electronic biometric self-tracking dates back to the 1970s, the availability of a new generation of wearable devices caught the attention of Kelly and Wolf [32] at *Wired Magazine*, who proposed the “quantified self” movement as a means to self-knowledge in 2007 [32]. Internet-connected wearable devices such as the Fitbit (2008) prompted increasing consumer demand [33], which led to ongoing innovation, and ultimately the incorporation of multifunction self-tracking into wearable devices in the form of a watch [34] and even a ring [35]. e-Patients have been able to leverage successive generations of self-tracking technologies for their self-care and to share this information with their physicians, while companies have developed apps to facilitate structured data sharing.

In another vein, patients with type 1 diabetes, dissatisfied with the state of siloed diabetes technology and unified by the hashtag #WeAreNotWaiting, developed a do-it-yourself closed-loop system in 2014 that integrates data from continuous glucose monitors with their insulin pumps to better manage their diabetes [36]. Commercial entities later developed their own systems based on that e-patient innovation.

Telemedicine or Telehealth

Overview

The convergence of the internet, high-speed telecommunications, video technology, and the availability of patients’ digital health records make it possible for real-time video visits between a clinician and a patient to occur over a remote network on a computer screen or smartphone. Telemedicine consultations can be augmented with PGHD to address the difficulty of telemedicine physical examinations. With PGHD and a patient history, the examining physician will have baseline information. This is a viable option for patients in need of medical assistance, and although the physical examination is quite limited, there are guidelines that physicians can use to do physical examinations via telemedicine [37].

For many years, telemedicine struggled with slow adoption, partly due to a lack of payment for services rendered remotely and partly due to the lack of infrastructure to conduct such video calls. The COVID-19 pandemic prompted payers to change their payment policies to encourage telemedicine encounters; telemedicine use increased from 11% to over 60% in a very short time [38]. After the pandemic, reimbursement for telehealth remains in place, as it has been remarkably popular. As health care has become more digitized, physicians across specialties are integrating telemedicine into their practices. A remaining obstacle is that almost all state medical boards

continue to prohibit care of patients within that state by physicians not licensed in that state [39].

Impact of Telemedicine on Patient Empowerment

Patients have been the beneficiaries of the wider use of telemedicine, and patient demand for remote care has mirrored workers' demand for remote work. This has resulted in greater technological innovation, as it has spawned a rising number of businesses, and business models focused on meeting the rising demand for remote care. For example, the need for mental health care has far exceeded the availability of local therapists, so numerous companies are providing "telemental health" services. Numerous companies are providing direct-to-consumer remote care for "lifestyle" health needs, such as sexual health, hair growth, and weight management. Finally, the shortage of primary care physicians has prompted the development of "digital primary care," which was pioneered in Sweden [40] and is being promoted in the United States as an alternative to traditional primary care.

Artificial Intelligence

Overview

A few years ago, physicians made medical decisions based on the knowledge they accumulated during their training and subsequent experience. Today, the rapid development of AI is slowly changing that. Machine learning can process vast amounts of information to identify hidden patterns and replicate clinical thought processes. AI and machine learning are increasingly used in fields such as pathology, radiology, and gastroenterology [41,42]. The advent of chatbots, such as ChatGPT, Gemini, and Claude, built on large language models, has profoundly changed how we search for and interact with information, including health information.

More importantly, for patients, though, the availability to consumers (patients) of generative AI has produced an explosion in patient access to advanced clinical information. In the words of Dave deBronkart, as quoted in the *New York Times* [43]: "Google gives you access to information. A.I. gives access to clinical thought."

Impact of AI on Patient Empowerment

AI chatbots have been a boon for patients (as well as health care professionals), allowing them to better understand their health conditions, not only by answering questions but also by helping them understand their medical records [44-46]. These tools have enabled patients to diagnose conditions when their physicians have been unable to do so, underscoring the empowering nature of having access to clinical reasoning [47]. Leveraging AI, patients can combine large quantities of self-tracking data and data from their medical records to gain new insights into their health [48], leading to proposals for responsible governance [49]. The future uses of these technologies will continue to expand, pushed by technology-savvy e-patients.

Conclusions

We have witnessed exponential advancements in communication and information technology followed by their rapid adoption. e-Patients use these technologies to learn about, get support for, obtain care for, and manage their health and illnesses. e-Patients, many of whom are impatient and frustrated with the status quo, will spur technological innovation, sometimes even developing technologies themselves.

We are at the precipice of dramatic transformations in health care made possible by the expanding capabilities and availability of AI, machine learning, communication, and self-monitoring technologies. This revolution is timely, as we confront an aging population, a proliferation of chronic diseases, and a shortage of health care professionals.

We must be considerate about introducing any technology, but AI presents unique ethical challenges. Concerns regarding patient safety, quality, and data privacy and security, along with the stability of different care models that prioritize equity and inclusion at an affordable cost, are all crucial questions that currently lack satisfactory answers. We anticipate that as digital health technologies continue to evolve, e-patients will continue to leverage these technologies to facilitate self-care and improvements in their health care experiences, which will, in turn, spur the evolution of the next generation of digital health technologies.

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Conflicts of Interest

None declared.

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Abbreviations

AI: artificial intelligence
EHR: electronic health record
NLM: National Library of Medicine
PGHD: patient-generated health data

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Seek and Ye Shall Not Find (Yet): Searching Clinical Trial Registries for Trials Designed With Patients—A Call to Action

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Abstract

Clinical trial registries were designed to help patients search for potentially suitable clinical trials. When our family faced another serious cancer diagnosis, we searched multiple international clinical trial registries. Despite increasing evidence that trials designed *with* patients can be better for trial participants (eg, they can have more relevant outcome measures and fewer burdens), it is currently impossible to search registries for these specific types of trials. In this Patient Perspective article, we make the first "call to action" for clinical trial registries to include (1) a filter that allows for efficient searching for clinical trials designed with patients and (2) structured information, in plain language, on how patients were involved. We propose how these two innovations could help reduce barriers to clinical trial participation. We also highlight how new regulatory and ethical guidelines are encouraging patient involvement in trial design, and we identify the benefits to many of doing so. Given the pressing need to improve clinical trial participation, we respectfully call on the clinical trial community to respond to our call to action and consider our proposed action plan. Ideally, when patients want to search for clinical trials designed with patients for patients, we should be able to find them. A plain language summary for this publication is available in the supplementary material for this paper.

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KEYWORDS

patient and public involvement; clinical trial; clinical trial registry; diversity, equity, and inclusion; patient author; caregiver author; patient partner; GRIPP2; plain language summary

When a serious cancer diagnosis struck our family—again—we searched clinical trial registries for trials designed *with* patients. Given the increasing evidence for the value of patient involvement in trial design, if we were going to consider a trial, we wanted to know if and how patients had been involved. Today, this search is impossible. In the future, we hope it can be routine. In this Patient Perspectives article, we provide the first published "call to action" for clinical trial registries to include (1) a filter that allows for efficient searching for clinical trials designed with patients and (2) structured information, in plain language, on how patients were involved. We propose that addressing these two gaps could accelerate clinical trials by enhancing clinical trial participation. We have included a plain language summary of this article in Multimedia Appendix 1.

Within our family, we have managed clinical trials, participated in clinical trials, and faced cancer diagnoses where our care has been directly enhanced by clinical trials. In our current situation, we already know we will be relying on evidence generated from forthcoming clinical trials. From these professional and personal experiences, we fundamentally understand that patient participation in cancer clinical trials advances cancer treatment [1,2]. However, for decades, most (92% - 98%) patients with cancer have not participated in clinical trials [1,2]. New ways to boost clinical trial participation are needed.

Importantly, when it comes to proposing potential solutions, we recognize that both nonpatient and patient barriers to trial participation must be taken into account. Notably, the main barriers occur well before a clinical trial is even offered to a patient [1]. That is, patients are not the main cause of low participation rates. The upstream nonpatient barriers can be structural (eg, access to a trial), clinical (eg, eligibility criteria) or doctor related (eg, offering a clinical trial) [1]. Indeed, when clinical trials are offered to patients with cancer, many (55%) agree to participate [1]. If and when a clinical trial offer is finally made to a patient, the patient may decline participation because of concerns related to treatment, trust, and the burden of participating [1]. In this traditional model, patients have not had an active and participatory role in finding clinical trials and in considering whether to participate. This traditional model can

and should change. Our proposed innovations to clinical trial registries could positively disrupt this traditional model and help reduce both nonpatient and patient barriers.

In terms of nonpatient barriers, patients would not have to wait for clinical trials to "trickle down" to them through structural, clinical, and doctor-related barriers. Patients could have enhanced agency to find potentially suitable clinical trials designed with patients. They could find these trials more quickly, easily, cost-effectively, and independently via their own search of a clinical trial registry. For patients, self-searching for these trials, using a filter that matters to them, would be a new form of self-care. After all, it is patients who bear the greatest burden in a clinical trial. After patients found potentially suitable trials designed with patients, they could then work in partnership with their doctor to consider—from the medical and the patient perspective—whether to participate. Both perspectives can affect participation success (eg, recruitment and retention). As clinical trial registries were explicitly developed to allow patients to search for trials and as approximately half of registry users are patients [3], our call to action would help registries meet their original goals. Further, as anyone with access to the internet could search clinical trial registries, our proposal may also help break down diversity, equity, and inclusion barriers to clinical trial participation.

In terms of patient participation barriers, concerns about a trial may be reduced if potential participants knew that patients had been involved in trial design. Increasing evidence indicates that the "lived experience" from patient advisors can translate into a better "trial experience" for patient participants. For example, trials designed with patient input may be more clinically relevant, faster, less costly, and reduce the trial burden for participants [4-9]. Within our family, we have participated in patient advisory boards and have seen first-hand how patient input can enhance trial design. A protocol can go from good to great with patient input. If patients could access information on how patients had (or had not) been involved in a trial, we believe that this could affect their trust and interest in that trial.

Our call to action for a search filter and information on patient involvement in trial design aligns well with broader changes driving more involvement of patients in clinical research. For the first time, the Declaration of Helsinki, an internationally accepted and highly influential guideline on research ethics, now calls for researchers to involve patients meaningfully in trial design [10]. The ICH GCP (International Council for Harmonisation - Good Clinical Practice Guideline), issued by international regulators and adhered to by industry and nonindustry research sponsors, have recently been updated, with the new version explicitly calling for sponsors to involve patients in trial design [11]. Under the new European Clinical Trials Regulation, sponsors must also describe if and how patients were involved in trial design [12]. Importantly for both trial design and trial reporting, the new 2025 SPIRIT (Standard Protocol Items: Recommendations for Interventional Trials) [13] and CONSORT (Consolidated Standards of Reporting Trials) [14] guidelines now include specific items for reporting patient involvement in clinical trial protocols and publications.

If our call to action is taken up, patient involvement information in structured, plain language included in the clinical trial registry could build on the precedent set by *The BMJ* in 2014 [4]. To promote transparency and to avoid a tokenistic tickbox approach, *The BMJ* requires authors to include a patient and public involvement statement, which describes how patients were involved in the reported research. If the researchers did not involve patients, they must disclose that in their statement. As the patient and public involvement statement is included in the publication, readers (including patients) can readily identify if and how patients were involved. With more patients authoring publications [15], involving patients in trial design would make it more straightforward for these patient experts to meet authorship criteria. Further, transparency about early patient involvement would also facilitate research into the "patient advisor" to "patient author" journey. Given *The BMJ*'s intent to re-energize the Patients Included charter for conferences [16], we also encourage discussion as to whether the charter could extend to patients included in trial design. The earlier that patients and other stakeholders know about patient involvement in research, the better.

Without regulatory requirements and enforcement, a proposed change in clinical trial registry practices is unlikely to succeed unless key stakeholders see value in doing so. Our investigations have shown that the widely used registry ClinicalTrials.gov does not allow patients to search for clinical trials designed *with* patients; nor do other major registries managed by not-for-profit (0/18, 0%; Table 1) or for-profit (0/10, 0%; Table 2) organizations.

Table . Primary clinical trial registries in the World Health Organization registry network lack a search function for finding clinical trials designed *with* patients.[a]

World Health Organization: primary registries[b]	
Registry	Filter for patient involvement in trial design
1. Australian New Zealand Clinical Trials Registry	N
2. Brazilian Clinical Trials Registry	N
3. Chinese Clinical Trial Registry	N
4. Clinical Research Information Service (Republic of Korea)	N
5. Clinical Trials Information System (European Union)	N
6. Clinical Trials Registry - India	N
7. Cuban Public Registry of Clinical Trials	N
8. EU Clinical Trials Register	N
9. German Clinical Trials Register	N
10. Iranian Registry of Clinical Trials	N
11. ISRCTN (United Kingdom)	N
12. International Traditional Medicine Clinical Trial Registry	N
13. Japan Registry of Clinical Trials	N
14. Lebanese Clinical Trials Registry	N
15. Thai Clinical Trials Registry	N
16. Pan African Clinical Trial Registry	N
17. Peruvian Clinical Trial Registry	Site unavailable
18. Sri Lanka Clinical Trials Registry	N

[a]Registries were searched April 27 and 30, 2025.

[b]The World Health Organization lists 18 primary registries that meet its specific criteria; these registries also meet the requirements from the International Committee of Medical Journal editors [17].

Table . Clinical trial registries managed by major international pharmaceutical companies lack a search function for finding clinical trials designed *with* patients.[a]

Global pharmaceutical companies: clinical trial registries[b]		
Company	Company clinical trial registry	Filter for patient involvement in trial design
1. Merck & Co	Y	N
2. Johnson & Johnson	Y	N
3. Roche	Y	N
4. AstraZeneca	Y	N
5. Abbvie	Y	N
6. Bristol Myers Squibb	Y	N
7. Eli Lilly	Y	N
8. Pfizer	Y	N
9. Novartis	Y	N
10. Sanofi	Y	N

[a]Registries were searched April 27 and 30, 2025.

[b]Clinical trial registries managed by the top 10 global pharmaceutical companies (based on research and development expenditure in 2023) [18].

We recognize that resources would be needed to add a patient involvement search field to a registry and, ideally, to automate (eg, via human-in-the-loop artificial intelligence) the upload of patient involvement information from a protocol into a clinical trial registry. However, we anticipate that the benefits of these changes could outweigh the anticipated costs. For example,

these changes might be paid for from the major financial benefits gained from increasing recruitment and retention, accelerating trial start-up and completion, and reducing protocol amendments and associated operational costs [5-8]. Additional benefits, across multiple stakeholders, could include the following:

- Acting as a catalyst for advancing truly patient-focused and patient-vetted research
- Providing the clinical trial community (including patients, researchers, sponsors, and ethics committees) with a free, fast, and transparent way to see how patients have been involved in trial design
- Enhancing the power and agency of patients to find and assess potentially suitable clinical trials, particularly for patients underserved by the current clinical trial enterprise
- Encouraging sponsors to use this tangible, transparent, and timely way to demonstrate how they have engaged patients as clinical trial advisors and how they have strived to enhance the clinical trial experience for participants
- Providing sponsors with a new and justifiable way to gain credit for their commitment to involve patients as research partners and to enhance their reputation among patients, the media, investors, and other communities
- Demonstrating to researchers and sponsors how they can leverage patient involvement content multiple times beyond registries (eg, patient involvement statements in protocols, grant applications, ethics submissions, publications, corporate annual reports, regulatory submissions, and reimbursement applications)
- Providing journal editors, reviewers, and readers with source information on patient involvement that can be validated and verified against protocols and publications
- Facilitating new ways to conduct research, undertake benchmarking, and identify best practices for patient involvement in trial design (eg, across trial type, phase, disease, country, or year)

As a family facing another serious cancer diagnosis, we are deeply grateful to all the patients, researchers, and sponsors who have and are enhancing cancer treatment through clinical trials. We respectfully call upon the clinical trial community, in its broadest sense, to consider the merits of enhancing clinical trial registries to enable patients to (1) search for clinical trials designed with patients and (2) find information on how patients were involved. From initial discussions within our family and, subsequently, with international thought leaders from patient advocacy, academia, publishing, and industry sectors, it appears our call to action has merit. We are now exploring how to move from a call to action to an action plan. While any action plan will require input from a broad stakeholder group, we propose that the following steps may help progress this initiative:

1. Share this open-access publication widely among the clinical trial community to build awareness of the call to action
2. Establish a small core team (eg, 3 - 5 people representing different stakeholders, including patients) to help secure resources and develop a project plan, with short-, medium-, and long-term goals. Ideally, this core team would align itself with organizations already focused on patient partnerships and enhancing clinical trial design, trust, transparency, accessibility, and infrastructure (eg, the World Health Organization's International Clinical Trials Registry Platform) [19]
3. Conduct stakeholder consultations with key representatives from clinical trial registry owners and clinical trial registry users, as well as experts in other core areas (eg, database architecture, compliance and security, artificial intelligence, user design, and plain language)
4. Conduct a "sprint" project (ie, time-boxed, iterative) to co-create proposed standards for a "designed with patients" filter and plain language–structured descriptors of patient involvement in trial design
5. Present results from the sprint to registry owners and identify registry owners (ideally, from not-for-profit and for-profit sectors) willing to pilot-test a prototype
6. Evaluate the results from the pilot tests against predefined criteria for success
7. Present and publish results from the pilot tests
8. If successful, advocate for broader implementation across international registries

We recognize that many steps will need to be taken to respond to our call to action, but this publication is a tangible first step. As our family was reflecting on how easy it is to use filters to search for and access information that can affect our lifestyles (such as cars, hotels, and flights), we pondered when it will be just as easy to search for and access information that can literally affect our lifespans. Because, when it comes to patient involvement in clinical trial design, we sincerely hope that one day our family can say to other desperate families, "Seek and ye *shall* find."

Acknowledgments

We are grateful to the patient advocates, researchers, journal editors and publishers, and funders whose feedback encouraged us to publish this "call to action" to improve clinical trial registries. We give special thanks to Trishna Bharadia, Liz Clark, Jan Geissler, Liz Salmi, Avishek Pal, and Beverely Yamamoto for their helpful insights. We also appreciate interest from PALADIN (Patient Advocacy Leaders And Drug Development Industry Network) in this initiative.

Conflicts of Interest

We are advocates for greater patient involvement in medicine development.

Multimedia Appendix 1

Plain language summary (visual abstract).
[PNG File, 95 KB - jopm_v17i1e72015_app1.png]

Checklist 1
Guidance for Reporting Involvement of Patients and the Public 2 (GRIPP2) checklist.
[PDF File, 184 KB - jopm_v17i1e72015_app2.pdf]

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Abbreviations

CONSORT: Consolidated Standards of Reporting Trials
ICH GCP: International Council for Harmonisation - Good Clinical Practice Guideline
SPIRIT: Standard Protocol Items: Recommendations for Interventional Trials

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Correction: Consumer Data Is Key to Artificial Intelligence Value: Welcome to the Health Care Future

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Abstract

(J Particip Med 2025;17:e82984) doi:10.2196/82984

In "Consumer Data is Key to Artificial Intelligence Value: Welcome to the Health Care Future" (J Particip Med 2025;17:e68261), five corrections were noted.

First, the author's name was corrected from "James C" to read as "James P Cummings."

Second, the author's affiliation was changed to "Participatory Health, 20 Grasmere Ave, Fairfield, CT, 06824, United States, 1 (212) 280-1600".

Third, in the "Forever on Call" section, a repetition of "comprehensive" was removed.

Fourth, in the "Where to Start?" section, this sentence:

> *The Diamond Blackfan Anemia Registry (DBAR) [41, established in 1993 by Dr. Jeffery Lipton...*

Was changed to read as follows:

> *The Diamond Blackfan Anemia Registry (DBAR) [41], established in 1993 by Dr. Jeffrey Lipton...*

Finally, under the second paragraph of the Lone Custodian section, a repetition of the following was removed: "different providers over their lifetime."

The correction will appear in the online version of the paper on the JMIR Publications website, together with the publication of this correction notice. Because this was made after submission to PubMed, PubMed Central, and other full-text repositories, the corrected article has also been resubmitted to those repositories.

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The Effectiveness of Adaptations for Online Remote Public Deliberation Across Three Continents: Mixed Methods Study

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Abstract

Background: Public deliberation is a qualitative research method that has successfully been used to solicit laypeople's perspectives on health ethics topics, but it remains unclear whether this traditionally in-person method can be translated to the online context. The MindKind Study conducted public deliberation sessions to gauge the concerns and aspirations of young people in India, South Africa, and the United Kingdom with regard to a prospective mental health databank. This paper details our adaptations to and evaluation of the public deliberation method in an online context, especially in the presence of a digital divide.

Objective: The purpose of this study was to assess the quality of online public deliberation and share emerging learnings in a remote, disseminated qualitative research context.

Methods: We convened 2-hour structured deliberation sessions over an online video conferencing platform (Zoom). We provided participants with multimedia informational materials describing different ways to manage mental health data. We analyzed the quality of online public deliberation in variable resource settings on the basis of (1) equal participation, (2) respect for the opinions of others, (3) adoption of a societal perspective, and (4) reasoned justification of ideas. To assess the depth of comprehension of the informational materials, we used qualitative data that pertained directly to the materials provided.

Results: The sessions were broadly of high quality. Some sessions were affected by an unstable internet connection and subsequent multimodal participation, complicating our ability to perform a quality assessment. English-speaking participants displayed a deep understanding of complex informational materials. We found that participants were particularly sensitive to linguistic and semiotic choices in the informational materials. A more fundamental barrier to understanding was encountered by participants who used materials translated from English.

Conclusions: Although online public deliberation may have quality outcomes similar to those of in-person public deliberation, researchers who use remote methods should plan for technological and linguistic barriers when working with a multinational population. Our recommendations to researchers include budgetary planning, logistical considerations, and ensuring participants' psychological safety.

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KEYWORDS

young people; qualitative research; public deliberation; deliberative democracy; data governance; online; remote; MindKind Study; digital divide; mental health data

Introduction

Public deliberation is a community engagement method stemming from (and at times used synonymously with) the political theory of deliberative democracy [1]. Public deliberation, through purposeful provision of information, aims to generate "a discussion that is informed, value-based, and transformative" [2]. Public deliberation engages participants in iterative dialog around complex ethical issues [1]. Public deliberation is used in the biomedical space in contexts such as biobanking [3], genomic research [4], and childhood vaccinations [5], and it differs from focus groups in that intentional information and facilitation are provided to participants to produce dialog, leading to consensus or well-reasoned policy positions [6]. Public deliberation has been traditionally conducted in person, and online public deliberation is an emerging adaptation of this method, which was inspired in earnest by the COVID-19 pandemic [7,8]. Given the novelty of this adaptation, particularly for a high-interaction methodology, such as public deliberation, open questions remain regarding how to engage with participants across the digital divide and how to remotely provide comprehensible information. Furthermore, additional approaches may be needed to assess the quality of deliberation when adapted for a remote audience [7], especially given the concerns of deliberative practitioners that the online environment may lend itself to more uncivil discourse, leading to low-quality engagement [9].

The MindKind Study was a mixed methods international collaboration to investigate the feasibility of a global databank to derive mental health insights [10]. The MindKind Study included a quantitative assessment that recruited participants to collect their mental health data via a mobile app and a qualitative public deliberation assessment that was conducted in concert at sites in India, South Africa, and the United Kingdom. Given the use of public deliberation in biological databanks [1,11] and young people's rights online [12], we saw this methodology as an appropriate vehicle to educate young adult participants (aged 16 - 24 years in the United Kingdom and 18 - 24 years in India and South Africa) about data governance and solicit their preferences. In light of the COVID-19 pandemic, we rapidly transformed a method usually held in event spaces over the course of 1 or multiple days [13] into an online, synchronous deliberation coupled with asynchronous dissemination of multimedia informational materials.

In this paper, we discuss the adaptations that the MindKind Consortium made to the public deliberation method in order to inform participants and conduct deliberative sessions online. We also demonstrate our efforts to evaluate the effectiveness of these adaptations, including obtaining evidence of informational material comprehension and assessing the quality of deliberative sessions [14].

Methods

Ethical Considerations

The MindKind Study was approved by relevant institutional review boards and ethics boards in the United States (WIRB #20212067), United Kingdom (University of Cambridge - Department of Psychology Research Ethics Committee: Ref. PRE.2021.031; University of Oxford: Ref. R73366/RE00), South Africa (Walter Sisulu University: #029/2021; Department of Higher Education and Training), and India (India Law Society: #ILS/242/2021), as well as by the Health Ministry Screening Committee in India. Potential participants were directed to the enrollment website [15], where they could access the website-based informed consent. The informed consent detailed the privacy and confidentiality procedures for the project, which included anonymous participation and disclosures of the use of the data for research purposes. South African participants were provided with data/airtime, a system to access the internet, to enable their participation.

Study Design

We recruited young people aged between the minimum age for consent to research as an adult (16 years in the United Kingdom, and 18 years in India and South Africa) and 24 years. We selected these countries for the full study [10] in order to explore the impact of variable high-, medium-, and low-income settings on study results. We held public deliberation sessions in 2 rounds. The first round included participants of a shared nationality, and the second included multinational participants. This design was chosen to build participant confidence in a more familiar setting prior to placing participants of mixed nationalities together.

The topic of deliberation was young people's preferences for the management and sharing of mental health data (broadly termed "data governance"). Consistent with other online public deliberation studies that have reduced the total deliberation time to avoid "Zoom fatigue" [7], discussion sessions were limited to 2 hours each. In another adaptation from a traditional in-person deliberative model that includes a facilitator, who guides the discussion, and an expert researcher, who serves as a content expert [13], facilitators in this study were trained to answer content-based questions. We combined these 2 roles to ease scheduling constraints and allow for just-in-time sessions, consistent with the participation patterns of young people.

As the provision of informational materials is a key component of public deliberation, the creation of these materials was an intentional and multiphasic process. We iteratively developed informative materials that could be downloaded, rather than live-streamed, by participants in low-bandwidth settings. We adapted a traditional PowerPoint presentation format to the digital environment by interspersing animations and other visual tools to maintain engagement. The basis for these materials was prior work [16] on models of data governance that maximized

openness to researchers of a prospective global mental health databank. We solicited feedback from a panel of researchers and technologists, distilling each model of data governance into a description of its function, a use case featuring its application, and a set of advantages and disadvantages of its use.

We then undertook a process of plain language adaptation. In addition to ensuring that language was at an eighth-grade reading level or lower, we renamed the technical terminology for each model to an animal that exhibited the characteristics of the model. For instance, a distributed autonomous community model was termed the *ant model*, representing how a community is capable of major advances when community members work together. During the plain language adaptation process, we consulted with youth panels to ensure that language was accessible and that animal representations were culturally relevant. Each animal and its model equivalent are provided in Figure 1. For Indian participants, informational materials were translated into Hindi, Marathi, and Tamil.

The resultant informational materials included a 2-module video series with narration by a study team member on each of the India, South Africa, and UK teams. All informational materials are available in an open-access repository [17]. Additionally, inspired by a project at the Open Data Institute [18], we developed an interactive concept map [19] to offer participants a more tactile way to engage with these materials.

An exit survey, hosted on Qualtrics [20], was offered to all participants at the conclusion of the session. The questions were adapted from the study by De Vries et al [14], with the aim of measuring the quality of the remote deliberative sessions. We analyzed four metrics of quality: (1) equal participation, (2) respect for the opinions of others, (3) adoption of a societal perspective, and (4) reasoned justification of ideas. Our exit survey also contained an open response question (“Please use this space to share any additional thoughts.”). We analyzed these data using content analysis [21].

Figure 1. Data governance models described to participants and their animal representations.

Results

Overview

In total, 143 people aged 16‐24 years participated in the public deliberation study (46 from India, 52 from South Africa, and 45 from the United Kingdom), and 61 of these attended multinational sessions. The qualitative results of the full study are detailed elsewhere [10]. Insights on the process of public deliberation in an online, variable resource context are presented below. We developed four types of insights with regard to remote public deliberation: (1) influences of the medium on participation, (2) evidence of informational material comprehension, (3) participant sensitivity to semiotic and linguistic choices, and (4) assessment of quality.

Influences of the Medium on Participation

Participants used a range of communication modalities within the session, including audio/video participation, writing in the online video conference chat, virtual hand raising, and using the "thumbs up" function and other emoji reactions. At the South African site, participants also added comments over WhatsApp when they experienced a loss of internet connection, and the strength of the participants' connections often varied throughout the length of the session. Participation was hampered by technical and connectivity barriers at all 3 sites, but most profoundly at the South African site. All 8 in-country sessions in South Africa were affected by participant connectivity, and 2 of these were affected by the loss of facilitator connectivity as well. Participants' sound quality was frequently compromised by background noise, connection deterioration, or mistakes with the "mute" function. At times, participants who joined the online video conference did not respond to multiple requests by the facilitator for comment, perhaps engaging in other activities instead. As participation was voluntary, participants' attendance at the session was sufficient to provide a gift card (India and the United Kingdom) or data package (South Africa) incentive, which may have influenced why some participants chose to multitask.

Conversely, the advantage of remote data collection was the ability to safely conduct deliberative sessions in a pandemic context. In our sample, there were participants with clinical vulnerability to COVID-19 and participants who were caretakers for others who may have been excluded from in-person sessions. Facilitators also noted the utility of working from home when sessions were conducted outside regular working hours. The remote approach enabled us to reach participants in geographically distinct locations, both within a given country and in multinational sessions. Participants shared positive reflections on the opportunity to talk to people from other countries. In a multinational session that was live translated for participants of different linguistic groups, a participant shared the following at the end of the session:

> *[It] felt very nice, that is we got to do something new and that we are attending the international meeting for the first time. We had a problem with English [.] but still, the opinion of all of us turned out to be similar, and it felt very nice to have a meeting with you. I feel that we are like a family. Thank you.* [Multinational session 2; translated to English]

Indeed, while the session was logistically challenging to plan and execute, it was well-received by participants and provided unique insights for the research team.

Evidence of Informational Material Comprehension

We found strong fidelity across participants in relation to the informational materials. Our qualitative results indicated that these materials were, in general, widely consumed, widely understood, and accurately reiterated by participants. Participants made direct references to viewing the informational materials:

> *I think, for me, [the option of having a] government [take on the cost of data management] is a "maybe" because if government pays for something, then they have the right to betray us, like in the first module, I saw the government of a certain country betrayed them and shared their information….* [South Africa session 3; Participant A]

> *Funny thing is, she just said it the way I was planning to say because watching those videos. Simply says everything.* [South Africa session 3; Participant B]

The participants in this exchange recalled an example used in the first video module of TraceTogether, a COVID-19 tracking app created by the Singapore Government that generated controversy when the government shared some location information with the Singapore police force, despite publicly claiming that they would not do so [22]. Participants demonstrated not only a recollection of the details of this example but also an application to their own context, considering whether such an event could occur in South Africa.

Participants exhibited a command of the complex details of data governance models presented to them:

> *I chose the octopus model as my favorite one. I mainly liked the controls over the sharing of the data in the sense that, with the example one that was in the video, showing that people were…able to access a base level of data just online, so anyone have that access, but for specific research access, it was more involved with what they wanted to do with it…I guess the main issue with that model, though, is the fact that because it is so decentralized and it might be hard to know what you're going to need to provide when you're trying to access that data, because, say, if it's all from different groups, they might all have different requirements.* [UK session 1]

This quote referencing a federated query data governance model and the example of Beacon Network [23], a search platform for genetic variants, demonstrates a sophisticated recollection of informational material details. This participant not only accurately described the way in which Beacon Network functions but also went on to appraise this system ("I guess the main issue"), indicating how the participant is applying their learnings.

Participants, at times, may have made mistakes in their recall of informational materials but retained understanding of their core messages:

> *[W]hen we're talking about research, I am constantly thinking about the example that owl model had.... [W]hen we give access to everyone, somewhere, what the results of these kinds of researches will be, will also be accessible by everyone, and then how people, you know, take this information and what they do with it, and how they present it later, will then be to their discretion. And when the general public sees that information, they'll believe it, irrespective of whether that person has the skills to even, you know, work on that data in the first place or not.* [India session 4]

The participant directly referenced the *owl* model, which was the animal term for a model-to-data governance scheme, wherein researchers submit computational models that are run on a private dataset. The example used in relation to this model was the National COVID Cohort Collaborative's research on the predictors of COVID-19 infection [24]. Because creating computational models requires sophisticated programming skills, it is not quite accurate that "everyone" has the ability to engage with the electronic health record data in this use case. It may be that the participant is referring to a more democratizing data governance model, such as a distributed autonomous community model (what we called the *ant* model), which does enable collective data ownership and use by citizen scientists [25]. Regardless, this quote demonstrates how even participant recollections with putative errors are still usable to qualitative researchers. This participant articulated a concern that if unqualified people in the "general public" have access to mental health data, they could use this information at "their discretion," potentially nefariously. Ultimately, speaking mistakes were of little consequence because the facts upon which participants made value judgments were well understood.

Participant Sensitivity to Semiotic and Linguistic Choices

Despite the strong overall understanding of participants, we want to share some specific findings that demonstrate participants' awareness and sensitivity to choices made in informational material development. Prior to data collection, we tested an image that was to form the basis of our interactive concept map with youth panelists (Figure 2).

Although the animal images (ant, kangaroo, owl, and octopus) are specific touchpoints on a webpage that users can select to learn about a given governance model further, the background scenery (water and landmasses) was designed to be insignificant. However, youth panelists thought that the positioning of the animal touchpoints communicated the similarity and dissimilarity of animal models to one another. Panelists gathered that the *ant* and *kangaroo models* were uniquely similar because they shared a landmass, although this was merely a design choice. This finding indicated to the research team both the utility of testing informational materials prior to deploying them and the possibility for participants to glean information from unintentional semiotic signifiers in the materials.

Figure 2. Original draft of the interactive concept map image.

During data collection, we also observed participants' sensitivity to particular linguistic choices. The cornerstone of our informative materials was a set of data governance choices presented in a 7-question data governance typology [10], which was the product of extensive iteration and plain language adaptation. In response to the question *Who controls the data?*, participants were offered the option of *community hires a manager*, which refers to a community of participants, users, or researchers using a data steward to manage a database. While a data steward can be a single individual, it is more often a group of individuals working for an organization. However, this language (*community hires manager*) was frequently understood by participants to indicate a single individual managing a database. As such, participants indicated a fear of undue concentration of power in such a manager:

> *I don't think you can ever trust one person, especially with global data. It'll put too much pressure on them...also, it's just one person,...they don't have the same views as everyone else who also wants to be able to control the data or know what's happening with the data.* [Multinational session 1]

> *I really don't like the idea of a manager because there are bad eggs everywhere and you don't want to give one person that amount of power.* [UK session 4]

Accordingly, even in light of extensive testing of this typology, there were still unknown signifiers in the language we used that could influence participant preferences.

Assessment of Quality

We obtained 159 exit survey responses (40 participants who marked their country as India, 38 who marked South Africa, 52 who marked the United Kingdom, and 29 who marked multinational). Each survey response does not represent a unique individual (there were 143 in this study) because, following

multinational sessions, wherein all participants were sourced from earlier in-country sessions, participants were directed to the same survey. Despite our efforts to distinguish the in-country responses from the multinational responses by asking participants to select *multinational* as their country, many participants in multinational sessions still selected their home country, making it difficult to disentangle in-country session responses from multinational session responses.

Equal Participation

While De Vries et al [14] measured the volume of text contributed by each participant, the multimodal ways in which participants contributed to our study make this a challenging metric to replicate. Coupled with participants who joined late, left early, or experienced technical difficulties, we did not feel that the volume of text was a meaningful measurement in our case. Instead, we are reporting our facilitator training strategy for ensuring equal participation. Facilitators were instructed to solicit the opinions of quieter participants and to seek approximately equal participation of the 3 countries in multinational sessions. Facilitators directly solicited participants with statements like "I would be interested to hear [name]'s thoughts on this" or "Does anyone from South Africa have an opinion to share?" Another effective strategy was assigning a number to each participant and making a request like "Let's hear from the even numbers" when conversation became stilted. Despite our best efforts, it was challenging to obtain true equal participation in this context.

Respect for the Opinions of Others

Our metric for the item is adapted directly from the study by De Vries et al [14]. It asked "Do you feel your opinions were respected by your group?" (response on a scale ranging from 1 [not at all] to 10 [very much]). The average score in the study by De Vries et al [14] was 9.4 (SD 1.0). Our score was similar at 9.6 (SD 1.0; median 10, range 1-10; n=150) (Multimedia Appendix 1). We also replicated the next question from the study by De Vries et al [14] on the same scale: "Do you feel that the process that led to your group's responses was fair?" Again, the results were similar. De Vries et al [14] found a mean score of 9.7 (SD 0.7) [14], and we found a mean score of 9.5 (SD 1.0; median 10, range 5-10; n=143) (Multimedia Appendix 2).

Adoption of a Societal Perspective

We adapted the inquiries in the study by De Vries et al [14] for the metric. De Vries et al [14] inquired at different time points whether participants would allow a surrogate to decide to enroll them in a gene transfer study (54% affirmative immediately following the study) and whether participants would use surrogate consent to enroll a loved one in a gene transfer study (41% affirmative immediately following the study). We asked two adapted questions at a single time point immediately following the study: (1) If a global mental health databank was created according to the specifications your group chose today, would you contribute data about yourself? (2) If a global mental health databank was created according to the specifications your group chose today, would you recommend that your community contribute data about themselves? The "yes" response rates for questions 1 and 2 were 91% and 93%, respectively.

Notably, our "yes" response rates are considerably higher than those in the study by De Vries et al [14], which might be attributable to the relative clinical invasiveness of a gene transfer study as compared to an informational databank study.

Reasoned Justification of Ideas

Participants shared richly reasoned arguments for why various data governance schemas were or were not acceptable to them. Sessions were not without "Because I said so" justifications, as defined by De Vries et al [14], but facilitators were trained to ask follow-up questions, as exhibited by this exchange:

> *Participant: [in response to the question Who controls the data?] Okay. So I would say no one [controlling the data] is acceptable.*
>
> *Facilitator: Could you elaborate on why?*
>
> *Participant: I say no one is acceptable because if you meet the requirements in whatever process you have to undergo, then it means you simply qualified [.] and the information should only be given or not given. It should be accessible to people with the necessary qualifications to access the information.* [South Africa session 8]

There are methodological reasons why a participant may not initially share a fully reasoned response, such as the limited time for discussion and the awareness of consensus-building as a goal. As demonstrated by the open-text responses below, wherein participants reflected on the value of hearing from others, participants warmly received the discussion aspect of the session, suggesting the richness of the interpersonal communication displayed.

In response to the open-text question, respondents shared broadly complimentary comments on the research process. Some shared recommendations to improve the participant experience of data collection:

> *Make a document that the group can communally edit (ie google slides)* [UK session participant]

On the other hand, some reflected on the utility of a mental health databank in general:

> *Data about mental health and mental health related studies should be accessible to students and s researchers [sic] just for the purpose of understanding the community better, providing them better help and doing better by the people.* [Indian session participant]

Many commented on the value of the discussion experience itself:

> *I felt really heard and that everyone had the opportunity to speak and share their thoughts. I feel like it is so important for people to be involved in these conversations. The call was really interesting too and the hosts ensured the atmosphere was welcoming.* [UK session participant]

> *[A]s an individual coming from a country that is vastly different from those within the meeting, there were many commonalities that we were able to decide on during the session. [S]ome topics did require more of a discussion and debate, while others were collectively decided.* [Multinational session participant]

As demonstrated in the quotes above, among participants who shared an open-text response, their comments reflected engagement and willingness to continue the conversation.

Discussion

Principal Findings

The qualitative arm of the MindKind Study offers an example of remote, online public deliberation with participants in varied geographies. Other deliberative studies have provided video-based informational materials to participants [26], including young people [27], with similar success. Our research team may have benefited from an approach we adopted during the development of informational materials by trying to optimize project tools for the online environment (eg, by using animations, an interactive concept map, and emoji reactions on video conferencing platforms) rather than trying to mirror the in-person experience more closely. However, this undertaking was not without limitations.

Participation was hampered by barriers due to time zones, technology access, and language challenges. Multinational sessions, for instance, were only conducted within a limited time window to allow participation from 3 distinct time zones. As such, participants who were unable to connect during this period due to school or work commitments could not join the study. Indeed, as articulated by Bulling et al [28] in an overview of deliberation models involving young people: “Many youth schedules are tighter and more inflexible than those of the decision-makers who hope to involve them.”

We chose to limit the deliberative session time to 2 hours, which is consistent with other online public deliberation studies, but we did not ask participants to return for multiple weeks of ongoing meetings in the way that other remote deliberation studies requested [7]. At most, participants engaged in 4 hours of deliberative sessions in total if they attended both an in-country and a multinational session. While online public deliberation studies in high-resource countries have been able to obtain a high retention rate across several deliberative sessions (such as 91% across 5 sessions in Canada [29]), we struggled to retain many South African and some Indian participants across just a 2-hour timeframe due to variable connectivity.

Given that a traditional in-person deliberative study is performed over a multiday period [13], there are substantive questions of whether online deliberation, especially in low-resource contexts, truly approximates in-person data collection. The online environment may not lend itself to the collective, focused experience achieved in an in-person setting [8]. Furthermore, young people lacking a device connected to the internet were unable to join the study, and participants with a weak network connection may have experienced less meaningful interactions than others. While we did not provide device loans to participants as other deliberative researchers have [8], we provided data packages to participants in South Africa to counter the high costs of data for connectivity, which we found to be highly influential. However, when the network infrastructure itself poses barriers to connectivity, such as ongoing rolling blackouts in South Africa, there may be little that researchers can do to account for this effect.

Public deliberation practitioners have also expressed concern about the balance of power in online deliberation, potentially leading to degraded quality of conversations and even perversion of results [9,30]. We were particularly concerned about this effect across postcolonial contexts, which is why we implemented in-country deliberation prior to multinational deliberation. While the results of our assessment of quality [14] are promising, we acknowledge that this is an imperfect tool for our context, especially in light of the digital divide, which may have a heightening effect on social inequality [30]. We encouraged facilitators to practice awareness of social dynamics on deliberative quality, but an assessment tool that is better suited to an online, variable resource setting would be beneficial.

Some concepts in the informative materials were particularly challenging to explain, especially without an in-depth dialog with participants, as is customary in an in-person research setting where participants can direct questions to expert presenters [13]. Similar to the findings of Lemke et al [3] with regard to educating participants on the concept of a “biobank,” this study also exposed participants to terminology and concepts that were novel to them. The explanation of the concept of a synthetic dataset [31], which we termed a *recreated dataset*, was persistently challenging for both participants and facilitators. This had been evident since the testing phase of the materials, and we attempted several analogies and representations with youth panelists, which were not well-received. Participants often expressed concerns that a recreated dataset would not accurately capture the underlying data, which is a legitimate concern in the research literature [32].

A more fundamental shortcoming of these materials was related to their accessibility to non-English speakers who spoke 1 of 2 regional languages in India or one or more of a mix of Indigenous South African languages. While site teams in India, South Africa, and the United Kingdom perceived high levels of understanding among their English-speaking participants (mixed first- and second-language English speakers), the materials were not as successful among non-English–speaking participants. Facilitators in India noticed substantive differences in the nature of clarifying questions between English-speaking and non-English–speaking participants, with the former asking questions about sophisticated research processes and the latter asking more fundamental questions about concepts around data and research. Facilitators needed to make rather unrelated analogies that were relevant to participants’ everyday lives to bridge the understanding gap.

There are a few potential reasons for this discrepancy. The original copy of the informational materials was written in English, and the materials were based on research concepts largely published and discussed in English. As such, multilingual

Indian researchers found these materials to be challenging to translate into regional languages because either equivalent terms did not exist or such terms were not in everyday use to be comprehensible to young people. Moreover, the materials were translated into a more formal register of a given regional language, which the participants found difficult to understand, considering the novelty of the concepts. Additionally, the non-English–speaking participants may have had lower levels of exposure to technology and research in general. Although we tested materials for plain language readability, the concepts presented were still very sophisticated and perhaps better understood by participants with some exposure to research studies, research data, and related technologies. In future studies, it may be preferable to first develop materials in the target language and subsequently translate them to English [33]. Finding language representations, analogies, stories, and semiotic representations that bridge the understanding gap without compromising the integrity of the message is an ongoing challenge for public deliberation researchers seeking to communicate about complex concepts.

Recommendations

In the context of multinational online remote public deliberation using multimedia informational materials, we present a set of recommendations based on our experience. First, researchers may need to make structural adjustments to their project timelines and budgets to account for remote data collection. Despite the relatively lesser time commitment of a video conference compared with an in-person event, the recruitment of participants and development of informational materials for remote public deliberation are arguably more labor-intensive. Furthermore, researchers should include data reimbursement or data package provisions in their budgets, especially for participants in regions with low internet penetration levels. At the South African site, we found that upfront data package provision was a necessary precondition for most participants to join the study. Correspondingly, researchers should ensure that their teams have sufficient provisions in place to account for a team member losing internet connection during a session.

Researchers working with multinational participants should also take into account participants' comfort and psychological safety in these settings. In our multinational deliberative sessions, we arranged for 1 research team member from each site to be present, and we developed a language use guide of terminology that could help participants sensitively communicate with peers having different nationalities, language backgrounds, and mental health experiences.

Finally, we were unable to use an online learning management system due to time and capacity constraints. Such platforms may enable researchers to organize materials at a single location, confirm participants' viewing of materials, and break videos into smaller segments. We encourage researchers to consider and budget for such platforms. Additionally, we recommend that researchers co-develop these materials with representatives from the participant population and make the language as accessible as possible.

Conclusion

Online remote public deliberation is a useful adaptation of a traditionally in-person research approach, which can enable safe and meaningful multinational participation. However, researchers who use remote methods must attend to technological and linguistic barriers, especially when translating informational materials from their original language.

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Authors' Contributions

Conceptualization: MD
Formal analysis: CM
Investigation: CM
Methodology: CM, MD
Project administration: CM, MD
Writing – original draft: CM
Writing – review & editing: MD, EB, EAB, AMB, EC, BF, AM-K, JK, SL, HM, LN, SR, HS, RS, SKS, SS, CS, YT, JV, PYC, M Fazel, TF, M Freeman, SP, ZZ

Conflicts of Interest

TF consults with Place2Be, a third-sector organization providing mental health support to children, parents, and staff in schools, and is the vice chair of the Association of Child and Adolescent Mental Health. The other authors declare no conflicts of interest.

Multimedia Appendix 1
Score distribution for the question “Do you feel your opinions were respected by your group?” (response on a scale from 1 [not at all] to 10 [very much]).
[PNG File, 96 KB - jopm_v17i1e59697_app1.png]

Multimedia Appendix 2
Score distribution for the question “Do you feel that the process that led to your group’s responses was fair?” (response on a scale from 1 [not at all] to 10 [very much]).
[PNG File, 96 KB - jopm_v17i1e59697_app2.png]

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Exploring Patient and Caregiver Perceptions of the Facilitators and Barriers to Patient Engagement in Research: Participatory Qualitative Study

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Abstract

Background: Patient engagement in research is the meaningful and active involvement of patient and caregiver partners (ie, patients and their family or friends) in research priority-setting, conduct, and governance. With the proper support, patient and caregiver partners can inform every stage of the research cycle, but common barriers often prevent their full engagement.

Objective: This participatory qualitative study aimed to answer the question: What are the facilitators and barriers to patient engagement experienced by patient and caregiver partners in a Canadian research context?

Methods: Participants were N=13 patient and caregiver partners (median age 62 y, IQR 58-69 y; 11/13, 85% women; 13/13, 100% White) from 4 provinces who completed 60 - 90-minute semistructured videoconferencing interviews. The interviews were transcribed verbatim. A researcher and a patient partner reviewed the transcripts and curated a dataset of 90 participant quotations representing facilitators and barriers to patient engagement. This dataset was co-analyzed using participatory theme elicitation alongside 7 patient and caregiver partners with diverse identities who were not among the participants we interviewed and, therefore, contributed novel perspectives.

Results: We generated four themes depicting factors that facilitate meaningful patient engagement alongside barriers that arise when these factors are not in place: (1) Co-defining roles and expectations; (2) demonstrating the value and impact of engagement; (3) psychological safety; and (4) community outreach, training, and education. We then discuss how barriers to enacting these 4 factors can be mitigated and provide a practical checklist of considerations for both researchers and patient and caregiver partners for engaging together throughout the research cycle.

Conclusions: Research teams conducting patient and caregiver engagement activities should draw from our findings to mitigate barriers and facilitate meaningful engagement experiences.

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KEYWORDS

participatory research; patient-oriented research; public and patient engagement; patient partnership; co-analysis

Introduction

Patients and their care partners (family or friends) offer unique insights into the health care system, making them key contributors to health research. By collaborating with researchers, patient and caregiver partners ensure that research addresses the needs and priorities of patients and their families, ultimately improving the health care system. In Canada, this is known as patient engagement—the meaningful and active engagement of patients and their care partners as co-researchers throughout the research cycle, ideally beginning at the grant-writing stage [1]. This concept may be referred to as patient and public involvement [2] or consumer involvement [3].

Individuals who share their lived or living experiences to inform a health research project may be given various titles depending on their role or identity, such as patient, caregiver, family member, or person with lived experience. These titles may also reflect their level of involvement, including terms like collaborator or partner. In this study, the terms “patient partner” and “caregiver partner” refer to individuals with experience

navigating health or the health care system, either directly or as a caregiver.

Engaging patient and caregiver partners can occur at any stage of and throughout the research cycle, from planning to knowledge mobilization [1]. The benefits of patient engagement range from improving recruitment [4] to personal gains for researchers (eg, increased confidence) and patient or caregiver partners (eg, community building) [5]. Given these advantages, major research funders now often require patient and caregiver engagement in funding calls [1]. However, some researchers still face challenges with engagement, such as a lack of time, funding, training, or institutional support [6-8]. These barriers can lead to tokenistic involvement and dissatisfaction among patient and caregiver partners [9].

To improve their practice, researchers can learn from studies on the barriers and facilitators to patient engagement, including perspectives from researchers [8], patient and caregiver partners [9], and combined viewpoints [10]. However, only a few studies have captured the perspectives of patient and caregiver partners by involving them on the research team [5,7,9], and more co-led studies on patient and caregiver engagement are needed. In addition, most studies are from the United Kingdom, with fewer focusing on the Canadian context. As engagement practices vary by country, more research in Canada is needed.

This qualitative study, which was co-designed, co-led, and co-authored by patient and caregiver partners, examines the barriers and facilitators to patient engagement in Canada. Our primary research question is: What are the key barriers and facilitators to patient engagement experienced by patient and caregiver partners, and how do these impact their perceptions of engagement?

Methods

Research Team

This study was led by AMC, an early career patient-oriented researcher with expertise in patient engagement, and SMK, a PhD student who was the patient engagement liaison and oversaw all engagement activities. Both researchers identified as women. A total of 8 individuals with previous experience of research partnering (ie, LB, AC, AD-K, DE, NK, MK, AM, and LS) were engaged throughout the study. We refer to this group as patient-caregiver partners, but they identified with a variety of terms to describe their research involvement, as shown in Multimedia Appendix 1. We specifically chose the term “patient-caregiver” because the individuals we partnered with had experience as both patients and caregivers. Within their range of experience, 4 of our research partners primarily identified themselves as patient partners, while the other 4 identified equally with the patient and caregiver partner role.

Collectively, the 8 patient-caregiver partners had between 1.5 and 32 years of experience in research partnering and resided across 5 provinces in Eastern and Central Canada. A total of 4 patient-caregiver partners lived in urban areas and 4 lived in semiurban or rural areas. A total of 6 patient-caregiver partners identified as women, 1 as a transgender woman, and 1 as a man. Collectively, the patient-caregiver partners had a wealth of experience in research partnering across health care domains, including basic science, cancer, chronic pain, pediatric disability, mental health, patient safety, health care provider education, and health care policy. Their contributions included informing clinical trials, knowledge synthesis and mobilization, reviewing research grants, co-developing educational modules, co-chairing committees, and shaping national and provincial health initiatives. The patient-caregiver partners’ past research experiences, diverse backgrounds, linguistic perspectives, and direct experiences with health care informed our research findings.

Philosophical Approach

This research is informed by critical realism, a philosophical approach that acknowledges an independent reality while emphasizing the need to explore underlying mechanisms that shape observable experiences [11]. Within this critical realist approach, our stratified realist ontology supports the idea that engaging patient and caregiver partners in research helps bring researchers closer to understanding the truth of their experiences. Our constructivist epistemology also acknowledges that experiences vary between individuals [11]. Therefore, incorporating diverse patient and caregiver partner perspectives through interviews and participatory analysis should help us capture the complex factors that shape their experiences.

Participants and Data Collection

This research is part of a larger 3-part project exploring the current and preferred future states of patient engagement in research in Canada [12-14]. Participants (N=13) were patient and caregiver partners with previous experience engaging in research funded by the Canadian Institutes of Health Research through the Strategy for Patient Oriented-Research [1] who completed a cross-sectional survey assessing the activities and impacts of patient engagement [12]. These individuals subsequently agreed to participate in a qualitative interview about their engagement experiences [13]. Details of participant recruitment are described elsewhere [13]. After providing written informed consent, all participants completed a 60 - to 90-minute semistructured interview via videoconferencing. Each interview was co-facilitated in English by an academic researcher (AMC) and a patient partner (Mr. Roger Stoddard). Interviews were audio-recorded, transcribed verbatim, and all identifying information was removed from the transcripts to protect participants’ privacy. Participants member-checked summaries of the interview data using a participatory process in which they refined the data and informed future directions for the analysis [15].

Ethical Considerations

All members of the research team (including patient-caregiver partners) completed research ethics training, privacy training, and signed oaths of confidentiality before engaging in research activities. The data was deidentified to protect participants’ privacy, and their names were replaced with confidential participant numbers. Both patient-caregiver partners and research participants provided written informed consent to ensure they understood and were comfortable with their respective roles in the study. The University of Manitoba Health

Research Ethics Board approved our work with patient-caregiver partners (Protocol HS26450; H2024:142). In addition, the University of Manitoba Human Ethics Board approved the study from which we collected our qualitative data (Protocol E2019:082; HS23180). All patient-caregiver partners were compensated at a rate of CAD $25 (approximately US $18) per hour. Research participants were compensated with CAD $75 (approximately US $54) in total.

Patient Engagement in This Study

This research was conceptualized and driven by patient and caregiver partner collaboration. The larger qualitative study from which we drew our data was initiated by a patient partner (Mr. Roger Stoddard) in collaboration with the senior author (AMC). Examining barriers and facilitators to patient engagement was identified as a priority by patient and caregiver partner participants who member-checked the qualitative data [15]. In this study, 8 patient-caregiver partners were engaged at the levels of "consult," "collaborate," and "empower" [16] throughout each stage of the research process, as described in the following sections and Figure 1. We report our patient engagement activities using the Guidance for Reporting Involvement of Patients and the Public, Version 2 (GRIPP2) checklist [17] (see Checklist 1) and qualitative research process using the Consolidated criteria for Reporting Qualitative research (COREQ) checklist [18] (see Checklist 2).

Figure 1. Patient-caregiver partner engagement throughout the research process.

Patient-Caregiver Partner Recruitment

Patient-caregiver partners were recruited through social media and email newsletter advertisements. An additional patient-caregiver partner (LS), who had participated in the larger qualitative study, was directly recruited to assist with dataset curation (in addition to article preparation) due to her familiarity with the interview data. Before the project began, SMK engaged all patient-caregiver partners in an introductory and icebreaker meeting where they co-created a "Terms of Reference" document (also known as a "team charter") outlining the project's aims, proposed team member roles, and how the group would foster mutual respect, co-building, support, and inclusion [19]. Specific actions we took to promote these values included having 5 - 10 minute informal check-ins at the start of each meeting, accommodating all schedules by offering 2 options for each meeting (1 on a weekday and 1 on a weekend), sharing written materials at least 5 days before meetings, sending frequent reminders, discussing compensation and reimbursement openly, and setting guidelines for respectful communication. All patient-caregiver partners waived the option to remain anonymous so they could be recognized as co-authors.

Analysis: Participatory Theme Elicitation

In collaboration with our patient-caregiver partners, we analyzed data from the larger qualitative study using participatory theme elicitation (PTE) [20]. The 5 steps of PTE are described below:

PTE Step 1: Dataset Selection

In PTE step 1, a subset of data from the 13 interview transcripts was curated for analysis. SMK consulted with patient-caregiver partner LS across three 2-hour videoconferencing meetings to complete this step. Quotations were excluded from the analysis if they could not be understood as standalone statements, lacked relevance to the research question, were repetitive, or came from frequently quoted participants when less vocal participants expressed similar ideas. In total, n=94 quotations were selected for analysis. These quotations were then reviewed by the 7 patient-caregiver partners (LB, AC, AD-K, DE, NK, MK, and AM) who would collaborate on the data analysis. These patient-caregiver partners removed 4 quotations from the dataset due to their lack of relevance or clarity and expanded 17 quotations to include more context. A final sample of n=90 quotations was subjected to the PTE analysis.

PTE Steps 2 and 3: Capacity Building and Open Sorting

In PTE step 2, SMK trained the patient-caregiver partners to perform step 3 of PTE, open sorting, using a practice data sorting activity. In PTE step 3, the 7 patient-caregiver partners and SMK independently sorted the quotations in the dataset into groups they found conceptually similar, using any criteria they found meaningful [20]. All data sorting was conducted using Miro whiteboards, a web-based collaboration platform used in past PTE research [21]. Each team member completed this step over a 4-hour period following the instructions in Multimedia Appendix 2.

PTE Step 4: Data Grouping

In PTE step 4, all group members' individual open sorting decisions were recorded in a spreadsheet (see Multimedia Appendix 3). A network analysis was used to generate a consensus of the independent card-sorting decisions made during PTE step 3 [20]. The analysis produced 4 clusters of quotations, representing candidate themes that emerged from the sorting process. These clusters were visualized using the network diagram shown in Multimedia Appendix 4. In this diagram, each quotation was represented by a colored node. The node color, spatial distance between nodes, and the lines connecting them indicated how frequently different quotations were sorted together by patient-caregiver partners. This step helped ensure all research team members contributed equally to initial theme generation [20].

PTE Step 5: Data Analysis and Interpretation

In PTE step 5, SMK and the 7 patient-caregiver partners collaborated over six weekly 2-hour meetings to refine the candidate themes from PTE step 4, creating a final set of themes that addressed the research question [20]. To support this process and group discussion, a Miro Whiteboard was created containing all 90 quotations, color-coded according to the network diagram's clusters (see Multimedia Appendix 5). Each meeting followed a structured approach: SMK began by reading aloud all quotations within a cluster and prompting patient-caregiver partners to share their initial impressions. Then, using the "tag" function in Miro, patient-caregiver partners collaboratively tagged each quotation with descriptive words to highlight recurring ideas that could inform themes or subthemes, allowing them to build on each other's insights. During this process, patient-caregiver partners could also move quotations from their original cluster to a different cluster or create new clusters if needed. Once all quotations were tagged and patient-caregiver partners were satisfied with the quotation groupings, they named each theme and subtheme.

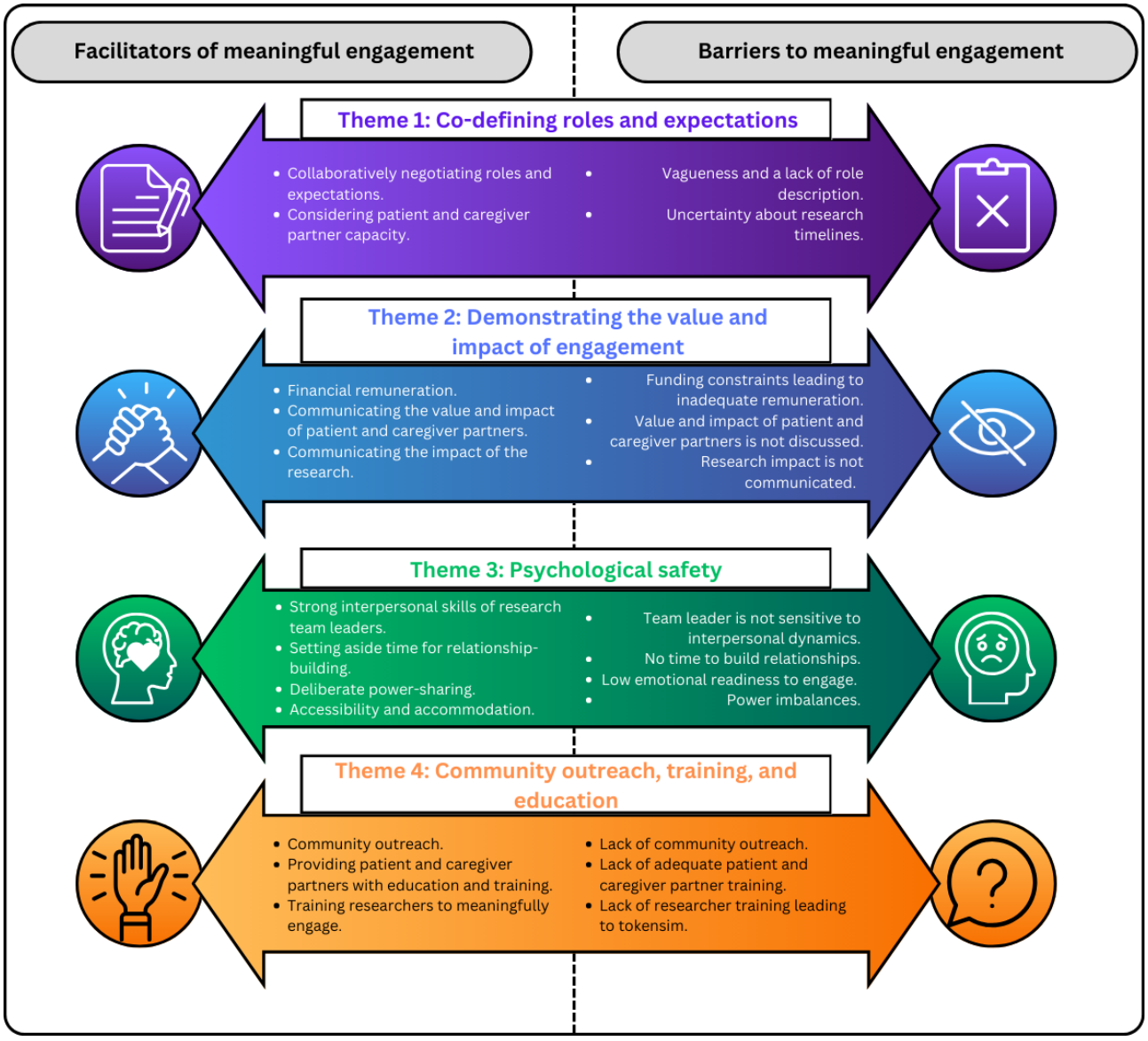
Results

Overview of Results

The qualitative dataset used in the present analysis contained data from N=13 participants who identified as patient (9/13; 69%) or caregiver (4/13; 31%) partners. Participants had a median age of 62 years (IQR 58-69 y), 11/13 (85%) identified as female, and 2/13 (15%) identified as male. All participants identified as White, and a majority had completed a master's degree as their highest level of education (8/13, 62%). Participants were located in 4 Canadian provinces: Ontario (7/13, 54%), Alberta (3/13, 23%), British Columbia (2/13, 15%), and Québec (1/13, 7%). The collaboration with patient-caregiver partners who co-conducted this research added additional perspectives from the provinces of Saskatchewan, Manitoba, Ontario, Québec, and Prince Edward Island.

In collaboration with patient-caregiver partners, 4 themes were generated depicting factors that facilitate meaningful patient engagement alongside barriers that arise when these factors are not in place: (1) Co-defining roles and expectations; (2) demonstrating the value and impact of engagement; (3) psychological safety; and (4) community outreach, training, and education (see Figure 2). Within these themes, 14 subthemes are discussed.

Figure 2. Summary of thematic results.



Theme 1: Co-Defining Roles and Expectations

The first theme highlights how patient engagement is facilitated when roles and expectations are established collaboratively. Within this theme, 3 subthemes are explored: (A) the necessity of co-defining roles and expectations, (B) the value of discussing the capacity of patient and caregiver partners, and (C) instances where roles and expectations were not clearly defined.

Subtheme A: "It Has to Be a Discussion and a Negotiation"—The Need to Co-Define Roles and Expectations

Defining the role of patient and caregiver partners should involve a collaborative negotiation. By working together with researchers to clarify roles and expectations at the research outset, patient and caregiver partners can better contribute their lived or living experiences and professional expertise (if applicable) to the research process. As Participant 4 described, this approach ensures that the skills and interests of a patient and caregiver partners align well with the research activities. It also provides them with the opportunity to decline roles that are not a good fit:

> *I think [patient engagement] has to be a deliberate matching of the skills, interests, and aptitudes of that [patient or caregiver] partner with the purpose that you're drawing them in at the particular stage of research.* [Participant 4]

Flexibility in defining roles is also key. Researchers should have a vision for their engagement but remain open to patient and caregiver partners' input. Communication and trust are fostered when patient and caregiver partners can collaboratively negotiate their roles. To achieve clear role expectations, participants recommended co-developing a "team charter" or "terms of reference"—a document outlining the goals, scope, and expectations within a research project. This process can help patient and caregiver partners understand where they fit within the research and encourages researchers to explore new ways of engaging with them. It can also be helpful to appoint one research team member as the "patient engagement liaison" who

oversees all engagement activities and addresses questions or concerns from patient and caregiver partners.

Subtheme B: "You Want to Do Your Part, but It Can Take Its Toll"—Considering Patient and Caregiver Partner Capacity

Patient and caregiver partners often balance research engagement with employment, personal health responsibilities, caregiving duties, or simultaneous engagement in other studies. When defining roles, it is crucial to work with patient and caregiver partners and consider the extent they wish to be engaged in a study. For example, some may hesitate to decline opportunities due to their passion for research and advocacy, even when they are at capacity. Relatedly, less experienced patient and caregiver partners may worry that declining one research opportunity will result in fewer offers in the future, leading to situations of overwork:

> *Being able to say "no" to doing more and more is a challenge. Because you want to help, and you want to push the science, and the collaboration between patients and researchers and clinicians working together more in the future. You want to do your part, but it can take its toll also in terms of pain and fatigue.* [Participant 5]

On the opposite end of the spectrum, some patient and caregiver partners may want to expand their role but are not given opportunities to do so because researchers fear overburdening them or underestimate their capacity to take on more research tasks. Researchers can support patient and caregiver partners by providing clear information about time commitments, responsibilities, and opportunities to get involved, ensuring they can tailor their role to suit their capacities and interests. Since capacity can change over time, all members of the research team should be open to rediscussing and adjusting their roles as needed.

Subtheme C: "Vagueness and Lack of Role Description"—When Roles and Expectations Are Not Clearly Defined

When roles and expectations are not established collaboratively, barriers to engagement may arise. As noted by Participant 13, a lack of clear, co-defined roles can make patient and caregiver partners feel like tokenistic members of the research team who are kept at arm's length from the project.

> *We [were] given the task, which was very vague, 'tell us how patients should be involved?' But it seemed like none of our suggestions were going anywhere… We started with about half a dozen [patient and caregiver partners] and we're down to two… I assume it had something to do with the vagueness and the lack of a role description.* [Participant 13]

Uncertainty around research timelines also creates engagement challenges. Patient and caregiver partners may not anticipate how long research projects take due to ethics reviews, publication processes, and other delays. Regular timeline updates and ongoing education about research stages help patient and caregiver partners stay informed. When these updates are absent, partners may feel disconnected from their roles or struggle to balance their other commitments.

Theme 2: Demonstrating the Value and Impact of Engagement

The second theme highlights how understanding the value and impact of one's role enhances patient engagement. Within this theme, we discuss 2 subthemes: (A) monetary compensation and (B) communicating the impact of patient and caregiver partners as well as the broader impact of the research. The third subtheme explores (C) how a lack of clarity regarding the value of their role can negatively affect patient and caregiver partners.

Subtheme A: "Patient Expertise Is Expertise, and It Should Be Compensated and Acknowledged in Its Own Right"—The Importance of Financial Remuneration

Patient and caregiver partners often join research projects with an altruistic desire to improve health research. However, altruism does not equate to volunteerism, and compensating patient and caregiver partners through financial remuneration or other ways of showing appreciation (eg, donations, training opportunities) is an important facilitator of engagement. Compensation validates partners' lived or living expertise and acknowledges the greater mental and emotional burden they may carry as team members who share their experiences to inform the research. In addition, monetary compensation can make research engagement more financially feasible for some patient and caregiver partners and can encourage engagement from a broader range of groups. Despite its importance, some participants, like Participant 3, found discussing compensation challenging, creating a barrier to engagement:

> *I think what helps me the least is the inability to talk about compensation, to talk about expectations… But the amount of work you put in. It should be compensated, and it should be budgeted for, and it should be talked about. We aren't there yet to talk about it… I'm learning to, but it's one of the hardest things.* [Participant 3]

Transparent and proactive conversations about compensation allow patient and caregiver partners to make informed decisions about their engagement. Open discussions about compensation also reflect good communication practices, demonstrating respect and value for patient and caregiver partners and affirming that it is reasonable for them to anticipate compensation.

Subtheme B: "It Feels Good to Be Involved, but There Has to Be More Than That"—Communicating Impact

Researchers can also demonstrate the value of patient engagement by clearly communicating the impact of patient and caregiver partners' contributions. This can be done by gathering their feedback, incorporating it into decision-making, and showing how it influenced the project. Participant 4 highlighted the importance of seeing a response to input:

> *Having an impact means there's a response to the input that I provide. Maybe it's a change in how a sentence is worded, maybe it's adding a couple of questions to a questionnaire, maybe it's changing*

> *some of the layout and the content in an infographic... And if there's no response, an explanation for why there's no response.* [Participant 4]

When patient and caregiver partners understand the impact of their contributions, they take more pride in their work and may gain greater confidence in their ability to contribute to future projects, especially those who may have initially doubted their role.

Furthermore, when the outcomes of a research project are personally significant to patient and caregiver partners (eg, related to their own or their loved one's health), they will likely be invested in sharing the results with the world. Researchers can reinforce the value of patient and caregiver partners by engaging them in knowledge translation activities, co-authoring publications, or explaining how research findings might influence future work. Participant 10 emphasized the importance of tangible impact:

> *I've been doing this for many years… I don't want to be doing this for nothing… I don't want to [partner] if I don't see that there's really an impact. I mean it makes me feel good, it feels good to be involved, but beyond that, there has to be more than that.* [Participant 10]

Subtheme C: "I Don't See That Impact"—When Patient and Caregiver Partner Value is Not Demonstrated

Barriers to engagement arise when researchers fail to communicate impact, leading patient and caregiver partners to feel undervalued, tokenized, or disconnected. Participant 3 expressed frustration about not knowing how their contributions influenced the project:

> *I mean, I certainly had an impact on the project because [the researchers] got their funding, [the study] got published. So that was an impact for them, but it was not an impact for me. And I see the need to go so much further in the project, and yet I've never been involved since then.* [Participant 3]

Frustration can also arise from mismatched expectations about research timelines and anticipated outcomes. Research-to-practice translation often takes years, which can be discouraging for patient and caregiver partners seeking immediate impact. Researchers must communicate the intended impacts and timelines of their research to patient and caregiver partners. For example, while some studies aim to inform practice or policy, others are designed to build an evidence base and guide future research. By sharing this information at the outset, researchers can ensure patient and caregiver partners' expectations for research timelines and outcomes are realistic within the project's scope.

Theme 3: Psychological Safety

The third theme describes an essential facilitator of patient engagement in research—psychological safety. Psychological safety occurs when members of a team are comfortable and eager to share their ideas, ask questions, and challenge others without fear of being dismissed, ignored, judged, or humiliated [22]. We describe 4 subthemes capturing aspects of the team environment that support psychological safety, including (A) interpersonal skills of team leaders, (B) setting aside time for relationship building, (C) deliberate power-sharing, and (D) physical accessibility. Finally, a fifth subtheme (E) discusses the barriers to a psychologically safe team environment.

Subtheme A: "The Principal Investigator Sets the Tone"—Interpersonal Skills of Team Leaders

The interpersonal skills of the principal investigator (PI) are crucial for fostering psychological safety within the team and building reciprocal relationships with patient and caregiver partners. Participants reported positive engagement experiences when their PI demonstrated kindness, warmth, and acceptance. These interpersonal skills set the tone for the entire team and reinforced the value of the patient and caregiver partner role. For example, Participant 10 reflected:

> *The environment was inclusive from day one and I will credit that to the principal investigator. It was obvious there was a lot of value to what the [patient and caregiver] partners were going to say, and her team just follows that lead…[The PI] sets the tone with all of the people who are working with them.* [Participant 10]

Participants also appreciated when the PI created opportunities for patient and caregiver partners to connect with other researchers and clinicians. This approach helped the patient and caregiver partners to feel more integrated into the broader research and clinical community. While some PIs may naturally possess these relational skills, others may need time and practice to develop them. PIs can consider completing training in leadership and team dynamics or seeking mentorship from other researchers who have successfully facilitated strong teams with patient and caregiver partners. In addition, establishing a team charter or terms of reference can help ensure all members understand the expectations for respectful interactions.

Subtheme B: "You Have to Establish a Trusting Relationship Slowly"— Setting Aside Time for Relationship Building

A key component of psychological safety is building trusting relationships. Research teams that dedicated time to informal, friendly discussions were more successful in building trust with patient and caregiver partners. These discussions could take place during brief check-ins at the start of meetings or while sharing meals afterward. Informal settings allowed the research team to connect, learn about each other, and collaborate more effectively. As Participant 5 explained:

> *I think our collaborations strengthened between the investigator and myself the more we got to know each other, and it wasn't necessarily in a very formal setting… it's been those informal chats and her getting to know me and vice versa.* [Participant 5]

Trust is essential for authentic patient engagement, where disagreements are addressed openly and constructively with a sense of curiosity. Respectful discussions foster trust and camaraderie, making it easier to handle challenging conversations. While in-person discussions can enhance trust among team members, they are not always feasible, especially

for those in different geographic areas. Alternative methods for building relationships in web-based team settings include organizing one-on-one introductory meetings with the PI or engagement liaison, creating email or messaging groups, dedicating time for check-ins at the beginning of each meeting, or arranging informal coffee calls for team members to get to know each other better.

Subtheme C: "Here We Are as People; We're Going to Work Together"— Deliberate Power-Sharing

Power-sharing practices are another essential element for promoting psychological safety. Effective research teams encouraged all members to leave their degrees and titles at the door and approach meetings with an open mind. This collective approach made patient and caregiver partners feel respected and valued. As Participant 9 explained:

> *It was the processes that [the researchers] used in regard to bringing the group together and connecting with them that were a big part of the respect. It wasn't language that was top-down language. It was the 'we' language versus the 'I will' language. And if they had to make decisions at times they would share them. It was transparent.* [Participant 9]

Power-sharing also involved directly asking patient and caregiver partners for feedback and providing space for quieter voices to contribute. Participant 11 noted, "Every time we meet, [the PI] will say, 'I'd like to hear from our [patient and caregiver] partners now." This practice ensured that patient and caregiver partners were regarded as essential contributors, not just names on a paper. It also created a collaborative, respectful environment where new ideas could be shared. Participant 3 emphasized, "When you feel that you're listened to, you feel that it's a safer place to speak because it will be accepted."

Finally, this discussion of power-sharing requires a caveat concerning the word empowerment. For some, this term can be problematic, as it suggests that researchers hold all the power to be shared with patient and caregiver partners. Instead, we believe that researchers should aim to create environments where all team members (both researchers and patient or caregiver partners) can leverage their internal strengths and resources to benefit the research.

Subtheme D: "My Patient Experience May Provide Barriers to Participating"—Physical Accessibility

Psychological safety also requires addressing physical accessibility and inclusion. Patient and caregiver partners felt included, respected, and accepted when engagement opportunities were accessible, and accommodations were offered. As Participant 1 shared, "Understanding, from the medical point of view, the restrictions in how and how much people can participate" is crucial. Without accommodations, patient and caregiver partners experienced frustration or feelings of exclusion. Teams that supported patient and caregiver partners' participation by offering flexible options for meetings, whether in-person, via videoconferencing, or hybrid, made it easier for partners to engage. Providing sufficient time to complete tasks and scheduling work around patient and caregiver partners' other responsibilities also made their involvement more manageable. In addition, when researchers provided support for technical aspects of the patient or caregiver partner role (eg, completing grant application paperwork) and offered multiple avenues for giving feedback (such as written or verbal options), patient and caregiver partners were better able to complete their tasks and contribute meaningfully.

Subtheme E: "There Are Some Unique Challenges to Making That What You Call a Safe Place"—Barriers to Psychological Safety

Despite efforts to promote psychological safety, factors such as low emotional readiness or power imbalances can detract from it. First, participants reflected that if patient and caregiver partners are not emotionally ready to share their lived or living experiences, they may experience negative mental health consequences from their role. Participants emphasized that emotional readiness varies among individuals and can change over time. Our findings suggest that patient and caregiver partners may find it beneficial to consider their emotional readiness when determining if a research project is a good fit for them. In addition, researchers should ensure that mental health resources are available for any team member who may need them.

Power imbalances can also affect psychological safety, especially when a single patient or caregiver partner is involved in a research team. This can lead to isolation and difficulty asking for clarification or sharing one's perspective. Participant 4 shared, "Many times, I'm the only lay person on the research team… and the language that is used is intimidating." For patient and caregiver partners, having other non-researcher voices in the room can help balance these dynamics. Finally, patient and caregiver partners may face challenges when working alongside clinicians who are also part of the research team. This concern is especially relevant when a community of clinicians and patients or caregivers is small, and it is more common for partners to be on the same research team as their own health care providers, as Participant 10 noted:

> *You're at [the] table now and the doctor who treats your child is there. With that power imbalance are you going to be able to speak up? There's a lot to consider in those kinds of situations.* [Participant 10]

To address this, researchers should offer opportunities for patient and caregiver partners to contribute anonymously or in separate meetings from clinicians (in addition to full team meetings) to ensure they can provide open and honest feedback about their experiences.

Theme 4: Community Outreach, Training, and Education

The final theme emphasizes the crucial role of community outreach, training, and education in facilitating patient engagement. Within this theme, three subthemes explore: (A) the importance of community outreach for raising awareness about patient engagement, (B) how training opportunities can support the meaningful engagement of patient and caregiver partners, and (C) how education can help researchers facilitate better engagement.

Subtheme A: "We Need to Make People Aware That They Can Be Involved in Research"—The Importance of Community Outreach

Community outreach is vital for ensuring patient engagement is inclusive and reflective of diverse experiences. Many health issues are linked to social determinants, and without broad representation, research risks overlooking valuable perspectives. Participants in our study observed that most patient and caregiver partners came from a narrow demographic, with limited outreach to underrepresented groups. Participant 4 noted:

> *It's a high education cohort. It's a high-income cohort. So, a lot of voices from the general public are probably being filtered out in that environment… Do I think [patient engagement] is inclusive at the moment, I would say no.* [Participant 4]

Typical recruitment methods, such as social media or advertising within established patient and caregiver partner networks, often do not reach individuals outside of the existing patient engagement community. To recruit more diverse patient and caregiver partners or individuals who have not engaged in research before, researchers may need to expand their recruitment toolkit. For example, it is important to use culturally relevant recruitment approaches, collaborate with community leaders, and meet people in familiar environments (eg, libraries and community centers) to build trust and foster strong relationships. When one person from a community engages, they can encourage others to join, thus strengthening community ties to research. As Participant 4 emphasized:

> *There has to be more of that dedicated outreach that involves both clinicians and existing [patient or caregiver] partners... It has to be planned. It has to be deliberate.* [Participant 4]

Subtheme B: "Support Patient and Caregiver Partners in Building Their Research Capacity"—Training Opportunities Contribute to Meaningful Engagement.

Providing training to patient and caregiver partners is a critical strategy for supporting equitable and effective collaboration in research. Although not all partners will require or seek out training, offering such opportunities can help clarify research terminology and expectations, while enhancing partners' confidence in engaging within research environments. Training may be particularly valuable for first-time patient and caregiver partners or for those entering a new area of research. In the absence of these supports, patient and caregiver partners may encounter barriers that constrain their ability to contribute at their desired capacity or may feel restricted in the scope of their role despite wishing to be more actively involved. As emphasized by Participant 8, adequate preparation is a key foundation for meaningful engagement:

> *I like being prepared and I like having as much information as I can. So personally, I would have benefited from formal training… maybe some more information about what it looks like to be a [patient or caregiver] partner in terms of communication skills and stuff.* [Participant 8]

Some patient and caregiver partners may also find it helpful to gain familiarity with specific aspects of research, such as ethical review procedures or the publication process. Without this context, changes to the research protocol or delays in progress and publication may become sources of frustration. Training can therefore enhance transparency in decision-making and research workflows by clarifying which aspects of the project are open to patient and caregiver partner influence and which are determined by institutional oversight.

Subtheme C: "It Has to Start With Awareness and Education"—Educating Researchers for Better Engagement.

Meaningful engagement with patient and caregiver partners requires specific knowledge and skills, yet many researchers have limited formal training in this area. Without such preparation, engagement efforts may unintentionally become tokenistic. Education offers a way forward by highlighting the value of lived and living experience and by providing practical guidance on how to collaborate respectfully with patient and caregiver partners. While hands-on experience is a valuable learning opportunity, a strong theoretical foundation is also necessary to understand the importance of patient engagement and how it can be effectively implemented. Introducing these concepts early in researchers' careers, for example, within undergraduate research methods courses and continuing throughout graduate training, can help cultivate a culture where meaningful patient engagement is the norm. As Participant 11 stated:

> *I think that we need to engage researchers and let them know that getting us involved is going to enhance their research... continuous education of medical researchers, or anybody who's involved in healthcare research to understand the importance of involving [patient and caregiver] partners right from the beginning.* [Participant 11]

Participants also highlighted the need for more detailed examples of successful patient and caregiver engagement across diverse fields in the published literature. Sharing engagement protocols and reflecting on how engagement shaped research processes and outcomes can contribute to a broader community of practice. Ultimately, education can reinforce that research engagement is grounded in principles of equity and respect for lived and living expertise, rather than being approached as a procedural formality.

Evaluation of the Engagement Process

The 7 patient-caregiver partners who engaged in the data analysis and co-wrote the results were asked to evaluate the engagement process after the midpoint and end of the study. Evaluations were conducted qualitatively through a 30-minute group discussion and quantitatively using a survey (the Public and Patient Engagement Evaluation Tool [23] at both of these points. All 7 patient-caregiver partners engaged in the group discussions, 6 of the 7 responded to the first survey, and 5 of the 7 responded to the second survey. Overall, 100% of comments suggested the patient-caregiver partners had a positive and meaningful engagement experience. Suggestions for

improvement centered around more flexible compensation options (which in this study were constrained by institutional procedures) as well as more relationship-building between the weekday and weekend meeting groups. The qualitative and survey responses from each time point are summarized in Multimedia Appendix 6.

Discussion

Principal Findings

This study examined the barriers and facilitators to patient engagement experienced by patient and caregiver partners in the Canadian context. In collaboration with patient-caregiver partners who co-analyzed the data and co-wrote the manuscript, four themes were generated: (1) co-defining roles and expectations; (2) demonstrating the value and impact of engagement; (3) psychological safety; and (4) community outreach, training, and education. These themes align with and provide new insights into existing literature as described below.

Co-Defining Roles and Expectations

Consistent with our findings, past research highlights patient and caregiver partners' desire for clarity on team roles, research timeframes, and outcomes [24,25]. However, some researchers may assume patients and caregivers do not wish to be involved in certain tasks or are unsure of how to engage them [26], leading to feelings of exclusion and team tensions [27]. Furthermore, when roles are not clearly defined, patient and caregiver partners have reported feeling overwhelmed by the unpredictable time demands of research [7]. To address these issues, researchers should aim to engage patients and caregivers early in the research process and co-define engagement opportunities throughout the study [7]. As an example of this, Jackson and colleagues [28] appointed a research fellow to oversee all patient engagement activities in their research institute, ensuring patient and caregiver partners were not "overburdened or overlooked" (p.3).

Demonstrating the Value and Impact of Engagement

Financial remuneration (ie, compensation for time and reimbursement for expenses incurred) is one way to acknowledge patient and caregiver partners' contributions, symbolizing the value of their lived or living expertise [9] and removing financial barriers to engagement [5]. However, we recognize that remuneration is not always possible due to funding constraints or patient and caregiver partner preferences [6]. In these situations, it is important to work with patient and caregiver partners to identify nonmonetary forms of compensation that are suitable for them (eg, education or skill training, conference attendance, or donations) [29] or to provide remuneration retrospectively after funding is acquired. We also found that compensation alone is insufficient to demonstrate patient and caregiver partners' value; showing their impact on the research is also essential. Simple strategies, such as using "track changes" in written work, documenting contributions in meetings, and maintaining consistent communication, can demonstrate patient and caregiver partners' influence on the research.

Our findings and past research both suggest that patient and caregiver partners feel their role is valuable when they understand how research can impact the "real world" (eg, changing future research, policy, or practice) [13]. However, researchers do not always communicate research goals effectively, and some cease communication after a study concludes, leaving patient and caregiver partners uncertain about the project's impact or success [30]. To address these issues, researchers should engage patient and caregiver partners in knowledge dissemination efforts, such as co-authoring publications [27] and translating findings into accessible formats beyond academic journals [5]. Importantly, co-authorship must be a meaningful, collaborative process, ensuring patient and caregiver partners are fully informed of their role and given opportunities to contribute [31].

Psychological Safety

Psychologically safe work environments are spaces where research team members feel free to bring their whole selves to work, share ideas, and make mistakes without fear of isolation or exclusion [32]. Effective team relationships, empowerment, and inclusion are important components of psychological safety [32]. Co-writing a team charter or terms of reference at the outset of engagement can help define what a psychologically safe work environment means for the whole team [5,7].

Related research on patient engagement supports our finding that a study's PI must possess strong relational skills (such as communication, open-mindedness, empathy, and friendliness) to foster meaningful relationships with patient and caregiver partners [10,14]. Dedicating time to relationship-building through "check-in" meetings [7] and group activities [5] can support psychological safety. Monitoring patient and caregiver partners' experiences through surveys or group discussions can also help address psychological safety concerns as they arise. Power-sharing is another important consideration, as patient and caregiver partners feel encouraged to bring their full selves to a research project when they can contribute their strengths [30] and receive peer support [7]. Researchers must be mindful of group power dynamics; good facilitation practices may involve dedicating specific meetings to gathering feedback from patient and caregiver partners [5] in addition to ensuring that quieter individuals are not overshadowed by more outspoken group members [27]. Finally, when research activities are accessible and accommodating, patient and caregiver partners feel welcomed, valued, and able to engage to their full desired capacity. Researchers should proactively engage in discussions about accessibility, rather than waiting for their research partners to make requests [33]. Patient and caregiver partners' need for accommodations may also change over time, so accessibility should be an ongoing conversation.

Community Outreach, Training, and Education

Training and education were key facilitators of patient engagement in this study. Past research shows that patient and caregiver partners want opportunities to be involved in the entire research process and are more willing to take on new roles, such as data analysis, when training is available [24,26]. Researchers can also benefit from training to effectively engage with patient and caregiver partners [14,24,34]. Skills such as communication,

integrating patient input [5,26], following engagement guidelines [25], and distinguishing patient engagement from qualitative research [28] can all be honed through training. Multimedia Appendix 7 lists select educational resources identified by the patient-caregiver partners on our authorship team that can support meaningful patient and caregiver engagement in research.

Related literature also notes several barriers to inclusive engagement that require more than education and training to address. These barriers include a lack of community outreach from researchers [24,28], communities' mistrust of researchers [5], and recruitment strategies that rely only on university or patient and caregiver networks [27]. These barriers may be particularly salient for individuals and communities who have experienced systemic oppression, stigmatization, or historical harms within the health care system and health research. Examples include people with lived experience of substance use or mental health conditions, newcomers to Canada, people experiencing homelessness, and First Nations, Inuit, and Métis Peoples [35]. This underscores the importance of not only supporting researchers as they learn to engage in ways that are respectful, trauma-informed, and culturally safe, but also practicing reflexivity to recognize one's own social location in relation to the research. Equally important is ensuring that individuals and communities are supported in self-determining their own research directions, priorities, and outcomes [35]. To increase diversity, researchers can provide translation services [7], partner with community leaders or advocates to build trust and guide respectful interactions, intentionally form relationships with underrepresented communities, ensure research priorities are community-driven [36,37], support the development of new patient and caregiver partner groups [6], and create tools to help connect patient and caregiver partners with researchers [25].

Practical Implications

Throughout the results and discussion, we offer practical recommendations to support the facilitators and address the barriers of patient engagement. To consolidate these recommendations, we have developed an actionable checklist for patient engagement, organized by stages of the research cycle (see Multimedia Appendix 8). This checklist serves as a tool for researchers when planning engagement activities and can also help patient and caregiver partners identify supports they can advocate for in their role.

Strengths and Limitations

This study was conceptualized, co-led, and co-authored by a diverse group of experienced Canadian patient-caregiver partners who were integrated within all aspects of the research process from data collection to qualitative analysis and manuscript writing. As detailed in our engagement evaluation (see Multimedia Appendix 6), several factors contributed to our strong engagement process in this study. These included the co-development of a team charter at the research outset to clarify roles, expectations, and needs; offering flexible meeting times by scheduling both weekday and weekend options; setting aside time for relationship building at the start of each meeting; and providing meeting materials well in advance, along with regular reminders from the patient engagement liaison. These efforts contributed to a respectful and supportive working environment that prioritized relationship-building and accessibility.

Despite these strengths, we encountered several challenges. For example, there was limited flexibility in how patient-caregiver partners could be compensated within our institution. This process created administrative burdens and discomfort for some, particularly around the need to submit Social Insurance Numbers and navigate tax documentation. Another challenge was the unintended division of the patient-caregiver partner team into 2 separate groups based on meeting availability, which limited opportunities for the full group to build collective relationships. Future projects could benefit from scheduling full-group meetings at the beginning, midpoint, and end of the project to foster stronger cross-group cohesion.

Conclusion

We examined key barriers and facilitators to patient engagement in the Canadian context from the perspectives of experienced patient and caregiver partners. In collaboration with seven patient-caregiver partners, we generated four themes: (1) co-defining roles and expectations, (2) demonstrating the value and impact of engagement, (3) psychological safety, and (4) community outreach, training, and education. When these qualities of engagement were present, meaningful patient engagement was facilitated. When they were absent, barriers to engagement and tokenism arose. To promote the facilitators of engagement and mitigate the barriers, we consolidated our findings into an engagement checklist that is supported by our research findings, the experiences of the patient-caregiver partners on this team, and the patient engagement literature. Researchers, patient partners, and caregiver partners should consider the items in our checklist when planning for their next research partnership endeavor.

Acknowledgments

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Data Availability

The datasets used or analyzed during this study are available from the corresponding author upon reasonable request.

Authors' Contributions

Conceptualization: AMC (equal), RS (equal)
Data curation: SMK (equal), LS (equal)
Formal analysis: SMK (lead), LB (equal), AC (equal), AD-K (equal), DE (equal), NK (equal), MK (equal), AM (equal)
Funding acquisition: AMC
Methodology: SMK
Project administration: SMK
Supervision: AMC
Visualization: SMK (lead), LB (equal), AC (equal), ADK (equal), DE (equal), NK (equal), MK (equal), AM (equal), LS (equal)
Writing – original draft: SMK (lead), LB (equal), AC (equal), ADK (equal), DE (equal), NK (equal), MK (equal), AM (equal)
Writing – review and editing: AMC (lead), LS

Conflicts of Interest

None declared.

Multimedia Appendix 1
Word cloud depicting the titles patient-caregiver partners in this study identified with.
[PNG File, 519 KB - jopm_v17i1e79538_app1.png]

Multimedia Appendix 2
Open sorting instructions for participatory theme elicitation.
[DOCX File, 23 KB - jopm_v17i1e79538_app2.docx]

Multimedia Appendix 3
Data file used in participatory theme elicitation step 4 to conduct the network analysis.
[DOCX File, 58 KB - jopm_v17i1e79538_app3.docx]

Multimedia Appendix 4
Network diagram of participant quotations generated in step 4 of participatory theme elicitation.
[DOCX File, 202 KB - jopm_v17i1e79538_app4.docx]

Multimedia Appendix 5
Image depicting the Miro whiteboard used to conduct data analysis and interpretation in participatory theme elicitation step 5.
[DOCX File, 189 KB - jopm_v17i1e79538_app5.docx]

Multimedia Appendix 6
Patient-caregiver partner evaluations of their engagement in this study.
[DOCX File, 30 KB - jopm_v17i1e79538_app6.docx]

Multimedia Appendix 7
Select patient engagement resources identified by the patient-caregiver partners on our research team.
[DOCX File, 30 KB - jopm_v17i1e79538_app7.docx]

Multimedia Appendix 8
Select considerations when engaging patient-caregiver partners in research studies.
[PDF File, 149 KB - jopm_v17i1e79538_app8.pdf]

Checklist 1
GRIPP2 reporting checklist–short form.

[DOCX File, 20 KB - jopm_v17i1e79538_app9.docx]

Checklist 2
COREQ 32-item checklist.
[DOCX File, 25 KB - jopm_v17i1e79538_app10.docx]

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Abbreviations

PI: principal investigator
PTE: participatory theme elicitation

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Empowering Patients and Caregivers to Use Artificial Intelligence and Computer Vision for Wound Monitoring: Nonrandomized, Single-Arm Feasibility Study

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Abstract

Background: Chronic wounds affect 1%-2% of the global population, and pose significant health and quality-of-life challenges for patients and caregivers. Advances in artificial intelligence (AI) and computer vision (CV) technologies present new opportunities for enhancing wound care, particularly through remote monitoring and patient engagement. A digital wound care solution (DWCS) that facilitates wound tracking using AI was redesigned as a patient-facing mobile app to empower patients and caregivers to actively participate in wound monitoring and management.

Objective: This study aims to evaluate the feasibility, usability, and preliminary clinical outcomes of the Patient Connect app (Swift Medical Inc) in enabling patients and caregivers to remotely capture and share wound data with health care providers.

Methods: A feasibility study was conducted at 2 outpatient clinics in Canada between May 2020 and February 2021. A total of 28 patients with chronic wounds were recruited and trained to use the Patient Connect app for wound imaging and secure data sharing with their care teams. Wound images and data were analyzed using AI models integrated into the app. Clinicians reviewed the data to inform treatment decisions during follow-up visits or remotely. Key metrics included app usage frequency, patient engagement, and wound closure rates.

Results: Participants captured a median of 13 wound images per wound, with images submitted every 8 days on average. The study cohort included patients with diabetic ulcers, venous ulcers, pressure injuries, and postsurgical wounds. A median wound closure surface area closure of 80% (range 15-100) was achieved across all patients, demonstrating the app's clinical potential. Feedback from patients and clinicians highlighted during the feasibility testing support insight into the app's usability, data security features, and ability to enhance remote monitoring that need to be explored in further qualitative research.

Conclusions: The Patient Connect app effectively engaged patients and caregivers in chronic wound care, demonstrating feasibility and promising clinical outcomes. By enabling secure, remote wound monitoring through AI technology, the app has the potential to improve patient adherence, enhance care accessibility, and optimize clinical workflows. Future studies should focus on evaluating its scalability, cost-effectiveness, and broader applicability in diverse health care settings.

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KEYWORDS

artificial intelligence; AI; computer vision; wound care; patient engagement; mobile phone; diabetic foot ulcer

Introduction

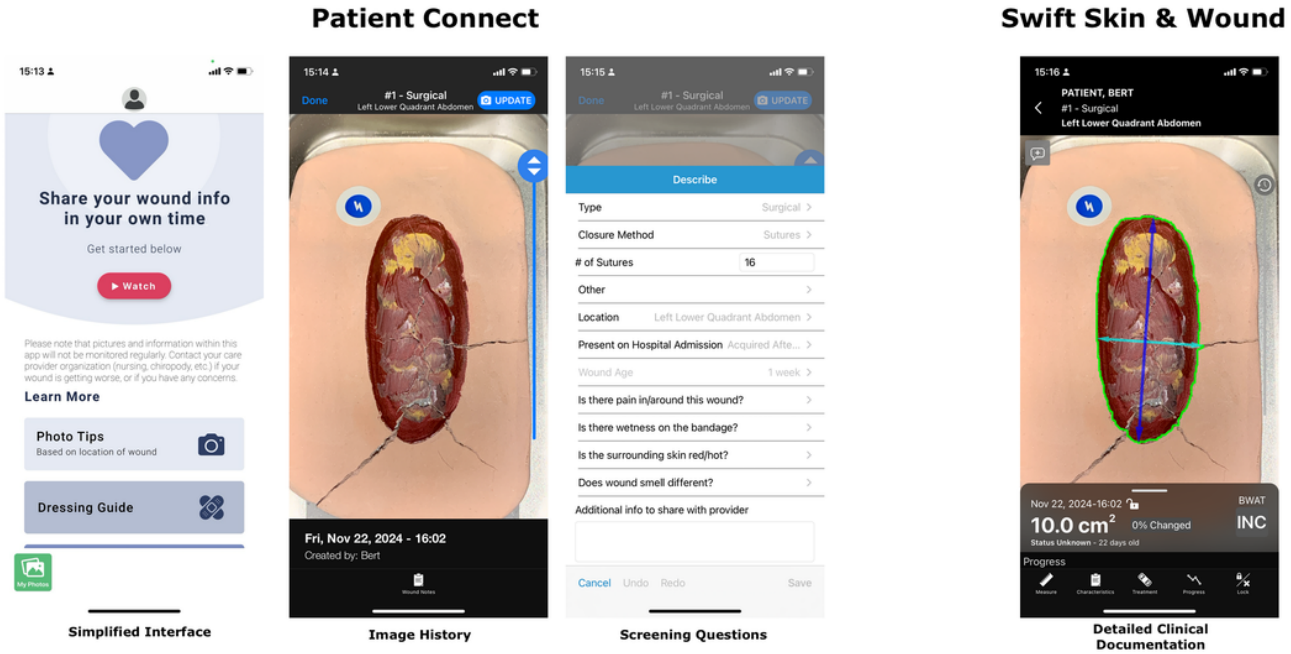
Chronic wounds are commonly defined as wounds that fail to heal within 4 - 12 weeks through normal, timely, and orderly stages [1]. These wounds pose a major public health challenge, with 1% - 2% of the global population estimated to experience a chronic wound during their lifetimes [2]. Diabetic ulcers (DUs), venous ulcers (VUs), and pressure injuries (PIs) are especially prevalent, making up over 90% of all chronic wounds [3] and often require significant wound care management and resources. However, due to their low rate of complete healing, chronic wounds have major impacts on both the health and quality of life of patients and their families, leading to significant issues, such as severe and prolonged pain, loss of function and mobility, amputation, mental health deterioration, social isolation and embarrassment, financial burden, and chronic morbidity or death [4]. Recently, there has been a significant transformation in health care delivery, focusing on remote access through telemedicine that leverages the widespread availability of smartphones and their apps. Technologies that facilitate telemedicine and ensure continuity of care for chronic wound patients are urgently needed, as high risk of wound-related complications exist for those without access to consistent follow-ups [5].

The rise of AI has shown great promise, particularly in the field of wound care. These technologies provide health care professionals with novel tools that contribute towards many improvements in treatment efficiency and efficacy, including early detection, risk factor analysis, prediction, diagnosis, intelligent treatment, outcome prediction, and prognostic evaluation [6]. In addition, AI-powered tools have been shown to empower patients to take control of their own health and well-being. For instance, AI tools can provide patients with information regarding their conditions and treatment options, thereby enabling them to make informed decisions while also strengthening patient-health care provider relationships through trust-building [7]. Computer vision (CV) is a particular form of AI that extracts information from digital images or videos in order to recognize content from visual data [8]. These technologies are especially promising in the field of wound care, as they can help classify wound severity, provide accurate predictions of wound healing, and track changes in wounds over time through image analysis [9,10]. CV technologies have previously been shown to provide significant time savings during wound assessments [11], decrease costs and days needed for wound healing [12], and improve data capture reproducibility and accuracy [13]. Notably, patients have also been found to exhibit positive perceptions toward the use of wound photography in their treatment journeys by helping them track their wound progress or increasing their involvement within their own care [14].

Swift Medical Skin & Wound (hereafter referred to as digital wound care solution [DWCS]) developed a mobile app and dashboard, specifically designed to accurately and reliably measure and document wound characteristics. The system, which is already available and is a privacy-compliant (Health Insurance Portability and Accountability Act and Personal Health Information Protection Act), Health Canada registered and FDA Class I medical device, uses CV technology to automatically focus and calculate wound dimensions from images acquired by the mobile device's camera, allowing users to obtain precise and consistent measurements. These capabilities have been demonstrated to reduce the time needed to assess the wounds of patients in a more accurate manner [11,15]. In addition, to viewing a wound's image series over time, additional information such as healing-associated metrics, wound-bed information, anatomical location, and patient identifiers are captured. While the app has provided doctors and wound-care specialists with a powerful assessment solution and a dashboard to remotely monitor and collaborate for an effective wound management strategy, in order to fully realize the system's potential, patients themselves will need to be able to acquire and securely share images and other relevant information with their care providers. By actively engaging patients in their own wound care journeys through a patient-centric application, individuals may feel empowered to be more active in the treatment process.

Understanding the importance of innovative technologies in improving health outcomes for chronic wound patients, the DWCS have recently developed a stream-lined, patient-facing version of the AI-powered application called Patient Connect (Swift Medical Inc). Patient Connect is designed for easy use by patients or their care providers using their own personal smartphones, ensuring a more patient-centric approach to wound management (see Figure 1). The user interface (UI) was designed with differences in technology and clinical literary in mind. The DWCS has detailed clinical documentation fields an advanced reporting included. The patient user experience is simplified and provides educational content to support image capture and wound care best practices. The Patient Connect interface had language changes to be grade 3 literacy level accessible. Educational materials including instructional videos and simply language guides for basic wound dressings were included within the app to attempt to improve engagement. The patient image history shows only images and access to information the patient submitted in the documents section, which includes basic screening questions for signs of infection and a free text (see Figure 1; third image from the right). The clinician app has standardized documentation for wound assessment, treatment, and progress to be documented (see Figure 1; first image from the left).

Figure 1. A simulated wound is used to illustrate the difference between the patient-facing mobile app and the clinician mobile apps.



Patients are authorized directly by their health care provider and can only access their own records through their personal device. This requires a 2-step verification via email or a mobile phone number and their date of birth. Like the standard version of the app, it automatically focuses and calculates wound dimensions from the images acquired. Images and other measurements are not stored on the phone camera roll of the patient's personal devices, instead they are encrypted within the app and securely transmitted to health care providers on the same secure, web-based servers from the DWCS. The patient's health care provider can access the patient's generated images and patient-reported data using their app or the web dashboard; thereby, enabling the remote monitoring of wound progression.

The objective of this report is to present results of a feasibility study of early adopters of our patient-centric AI-powered wound assessment technology to image their wound to be included in their medical record and for self-monitoring, within 2 outpatient clinics in a university-affiliated hospital and a community hospital to determine overall feasibility, usability, and preliminary outcomes of the Patient Connect app.

Methods

Overview

A nonrandomized, single arm-feasibility study was conducted between May 2020 and February 2021. A nurse practitioner at Scarborough Health Network and 2 physicians at Montreal Jewish General Hospital were the primary clinicians engaged in the project, and both had previous experience using AI-enabled wound care documentation in clinical practice. Standardized training was provided on enrolling patients, enabling access, and reviewing patient-submitted wound images and information in the clinician application and dashboard. Training materials were provided to support patient onboarding to use the service. This included multimedia content (videos on how to download and access the app) that was shared via SMS text messages when the patient was enrolled and content embedded within the app (eg, how to capture wound images). Paper hand out material including instructions were also provided (see sample in Multimedia Appendix 1). Clinicians had access to review images submitted through the dashboard on a weekly basis and during follow-up visits.

A purposive sampling technique was used to recruit patients or caregivers from the Montreal Jewish General Hospital and the Rouge Valley Scarborough Hospital for early testing of the Patient Connect app. A sample size between 20 and 30 participants was determined based on feasibility study design considerations. According to established feasibility study guidelines, sample sizes of 30 or fewer participants may be appropriate for qualitative feasibility studies [16]. This sample size allowed for evaluating the usability, engagement, and feasibility of the intervention while balancing recruitment and resource constraints. Patients were the primary focus for the inclusion criteria, with patient caregivers acting as an inclusion alternative if the patient consented. Inclusion criteria to the cohort were (1) patients' attending staff were already a user of the DWCS, (2) the patient or a close relative possessed and was familiar with a smartphone device, and (3) the patient had a stable wound, as assessed by their health care provider. Caregivers were considered as an inclusion alternate if the patient consented. Caregivers were suitable alternatives if the wound was in an area that was difficult to image (eg, sacrum and back) or the patient had limitations that made them unable to use the app (eg, mobility and technology literacy). Exclusion criteria were Android phone users as the Patient Connect app currently only runs on iOS devices. In addition, the study excluded patients who did not consent and who did not approve their caregiver to act as an alternate, since, for these patients, caregiver participation was essential for independent app usage. No changes were made to the study methods after the commencement of the study, including eligibility criteria and assessment measurements. All prespecified metrics and inclusion criteria remained unchanged throughout the study period.

Enrolled participants were encouraged to use the app when their dressing was being changed by themselves, by caregivers, or y bother health care professionals outside of the participating organizations (eg, home health). A 2 case series displaying the measurement and progress tracking of patient-captured and caregiver-captured wound images on the Patient Connect app are shown in Figures 2 and 3, respectively. Due to the variation in wound-changing protocols and the feasibility design, there was no set requirement for imaging completion by the patients per week. However, patients were encouraged to take at least one picture during each wound-changed session. The clinicians collected additional feedback during follow-up appointments. User experience, facilitators, and barriers were documented and shared with the project manager and software development team to support quality improvement and ensure app performance and stability.

Usability metrics were collected to assess feedback on the engagement, consistency, and effectiveness of the tool. These include the frequency app use (ie, the number of wound images uploaded per patient), submission intervals, completion rates of imaging sessions, and tracking adherence rates concerning continued use during the study period. The mean was used to report on continuous or normally distributed variables, and median was used for data with outliers or skewed distribution (eg, wound size and number of images) to minimize influence of extreme values (see Table 1). The app has embedded monitoring software (Mixpanel) for debugging that enabled logging of successful logins, progress through the imaging workflow and deidentified summaries were available to the research team to see counts and frequency of image submission. These features are common practice in mobile and cloud based-software development to identify software issues and iteratively improve user workflows.

In addition, qualitative feedback was collected about ease of use, technical difficulties, general user experience, satisfaction with the tool that was collected during follow-up visits, as well as barriers like light, clarity of images, and comfort level using the app alone. The degree of clinician engagement was assessed by tracking the frequency of image review, using the AI-assisted assessments into treatment decisions, and feedback on patient-submitted data.

The patients were followed until the closure of their wounds or February 2021, whichever occurred first. Wound closure was defined as a wound measurement of 0 $cm^{2.}$ All data included in this report was obtained from the solution's deidentified servers, allowing for data retrieval while maintaining the confidentiality of patients' personal information.

Figure 2. A case series of a postoperative wound. First image on the left was captured by the clinician. Then the patient was taught to capture images and a second image the same day was documented. The 2 images on the right half show follow up monitoring submitted by the patient as the wound closed.

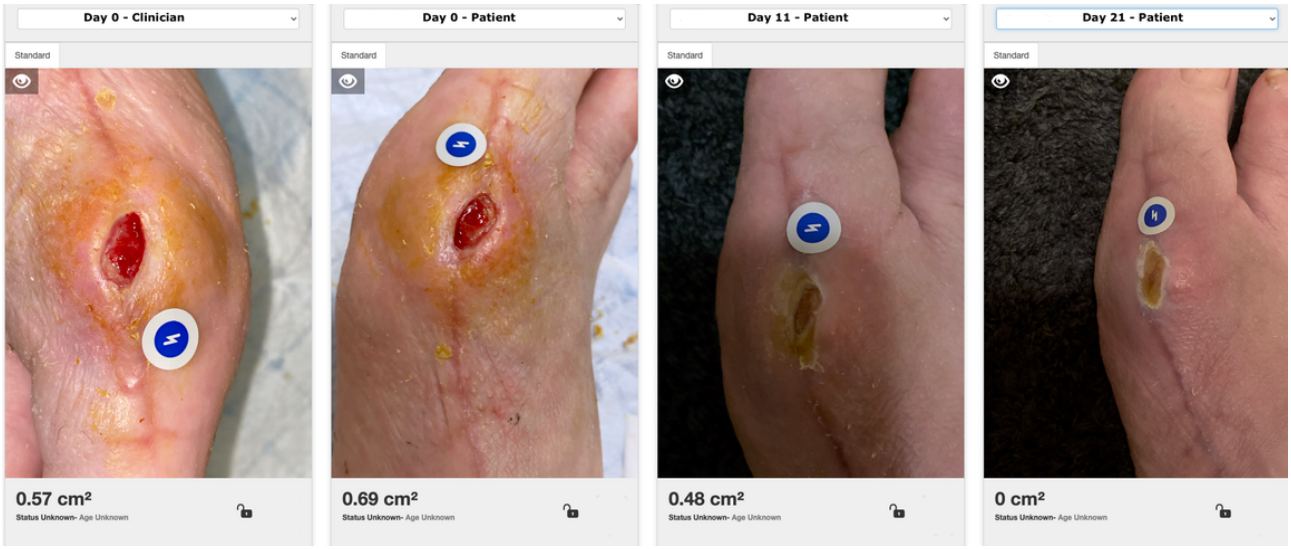


Figure 3. A case series of a hard-to-heal wound on the sacrum imaged by a caregiver during the patient journey. Images have adequate lightening, focus, color correction, and artificial intelligence (AI)-based measurement is shown to the clinician monitoring the wound remotely.

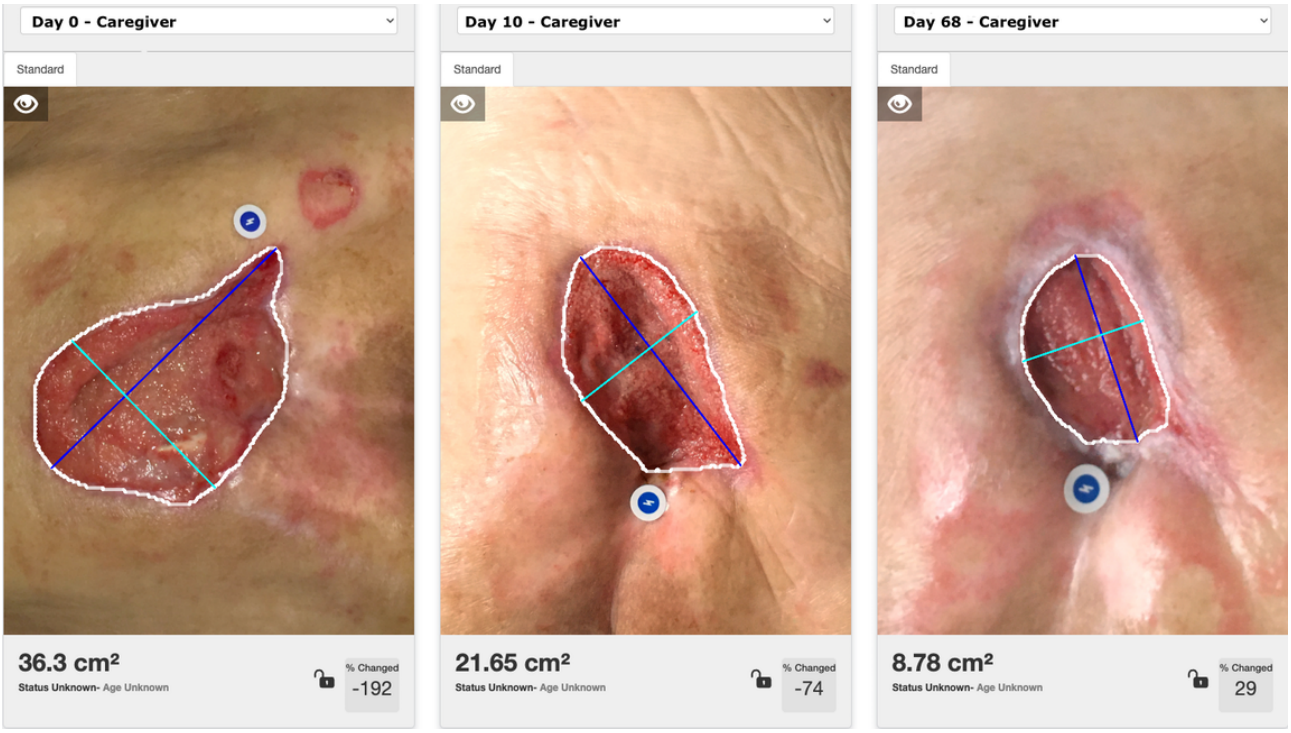


Table . Patient characteristics. Data are presented as mean (SD), median (range), or proportions.

Variable	Results (N=28)
Age (years), mean (SD)	66.4 (18.5)
Gender, n(%)	
Female	14 (52)
Male	13 (48)
Type of lesion, n (%)	
Diabetic ulcer	14 (52)
Venous ulcer	7 (26)
Pressure ulcer	4 (15)
Postsurgical	2 (7)
Initial wound size (cm^2), median (range)	3.71 (0.48-27.91)
Follow up time (months), median (range)	3 (1-9)
Number of images submitted, median (range)	13 (4-45)
Average time between images (days), median (range)	8 (3-14)
Percentage of wound closure achieved (%), median (range)	80 (15-100)

Ethical Considerations

The study received multisite ethics approval provided by the Scarborough Health Network Research Ethics Board (SUR-21 - 007). Patient or substitute decision-makers provided consent and had the ability to withdraw at any time. Data from subjects that withdrew would be excluded from analysis and their data would not be used for secondary analysis without their consent.

Results

Patient Characteristics

A total of 28 patients adopted the Patient Connect App as early users. The cohort included patients with varied wound types, including diabetic foot ulcer (DFU), venous leg ulcer (VLU), PI, and surgical wounds. The characteristics of the wounds are presented on Table 1.

Approximately half of the patients were diabetics with plantar ulcers (52%, n=14). There was a balanced gender mix in this

study, with 52% (n=14) of patients reporting as males and 48% (n=13) as females. The sample population had a range of wound sizes from 0.48 cm^2 to 27.91 cm^2 and a median size of 3.71cm^2 (6.17 cm^2). Wound measurement was captured from photographs using AI models, so wounds outside of the photograph (ie, circumferential) had limitations to their data. This suggested that single-surface wounds were optimal for patient and caregiver imaging and automated AI analysis of the wound. Wound imaging was found to be ideally suited for patients with images on a single surface. However, it was possible to upload multiple images if wounds were circumferential.

The median follow-up was 3 months, with a median of 13 images aquired by the patient or caregiver per wound. Images were captured on average every 8 days. Interestingly, despite a general infrequency of in-person follow-up visits, the median wound closure rate recorded in the app was 80% (IQR 15% - 100%). No adverse events or unintended harms were reported among participants.

Projected Cost Savings

The Patient Connect app enables remote monitoring of the wounds and reduces the need for in-person visits and related costs. With patients documenting a median of 13 images per wound over 3 months, this assessment could replace several visits to the clinic. Assuming that each time a picture is submitted, 1 trip is saved, that could mean there is the possibility of eliminating up to 13 trips per patient, representing savings anywhere between US $140 and US $281 in travel costs per patient (with an average travel cost of US $10.82 per visit) [17,18]. As for the sample of this study consisting of 28 patients, this would mean US $3931 to US $7862 in total travel savings over the three months. Savings could amount to US $140,000-$281,000 with 1000 users in a year.

In addition, fewer trips would equate to fewer hours lost at work for both patients and caregivers. Assuming 2 hours off work per visit at an average hourly wage of $36.64 CAD , with 13 visits avoided, a direct saving of $595 per missed trip or $16,674 could be achieved for the study cohort. A scale of 1000 users would mean savings of $595,000/year in workforce productivity.

User Experience and Quality Improvement Insights

Patient feedback on Patient Connect was useful in determining usability, engagement in wound care, and areas for improvement. Many participants noted that remote wound image capture and sharing opened their eyes to changes in the wound that made them more active in the wound care process and compliant with treatment. Some patients reported that taking pictures regularly helped monitor their healing and increase their motivation to adhere to wound care protocols such as the frequency of dressing changes, hygiene practices, and alleviating pressure techniques.

Although Patient Connect appeared useful in many aspects, several issues came to light. Literacy and accessibility problems were felt, particularly among older adults or other patients unfamiliar with smartphone apps, who sometimes required caregiver assistance to capture and submit images of their wounds. Patients had difficulty taking clear pictures if the wounds were in hard-to-reach areas (eg, sacrum, back, or heels) and tended to submit images erratically. Lighting posed challenges since some patients had difficulty ensuring adequate exposure for accurate AI analysis. While many people found the app helpful, some users experienced fatigue with engagement and became less consistent in taking images, especially if slow healing of the wound was involved. A few participants expressed common data privacy concerns about sharing images digitally, while continued education on encryption and security protocols was offered to help provide reassurance.

Discussion

Principal Findings

In this report, we demonstrate that the Patient Connect's regular use by a group of selected patients allowed the remote monitoring of their wounds, successfully capturing medical-grade images that were subsequently used by clinicians for treatment decisions. This capability is not only crucial for maintaining continuity of care but also for enhancing patient engagement and treatment adherence, as evidenced by the increase in image sharing and self-monitoring behavior. The app facilitated the collection and analysis of data, which was instrumental in improving patient behavior and health outcomes by providing real-time feedback and enabling timely communication through wound status updates with health care professionals.

Patients using the Patient Connect app exhibited a high frequency of engagement with the AI software, submitting an average of 13 pictures, or 1 image every 8 days to clinicians throughout the duration of their wound care. In addition, a median wound closure rate of 80% (IQR 15-100) was observed across all patients and wound types. These findings suggest that the use of the Patient Connect app for participants may have supported engagement with monitoring wound healing, which may have influenced better healing outcomes across the diverse wound types. It is recognized, however, that factors such as standard wound care practices, clinical interventions, and individual patient conditions may have influenced the results. Clinical decisions within wound care may be delayed without adequate history. Patients in the study enabled a better record of the wound's response or lack of response to treatment that may support more timeline adjustments in care, which could be better understood through future research.

Interestingly, our results align with findings from other smartphone-based AI treatment platforms. For instance, Labovitz et al [19] demonstrated that, among patients with recently diagnosed ischemic strokes receiving anticoagulants, real-time monitoring via a smartphone-based AI app led to significantly improved medication adherence. This intervention resulted in a 50% increase in adherence rates compared to the standard care control group, as measured by plasma drug concentration levels.

Our findings also align with previously published results demonstrating the potential of the patient-centered digital wound care technology for remote wound monitoring. For example, a case study by Kong et al [20] highlighted the successful

application of the DWCS technology in the management of a male patient with type 1 diabetes and multiple comorbidities, including chronic kidney disease and a previous toe amputation. Initially managed for osteomyelitis of a chronic foot ulcer via text and email, the patient transitioned to using the DWCS Patient Connect app for monitoring and management between June 2020 and January 2021. Over 7 months, the patient submitted 39 wound images—a nearly 20-fold increase in the sharing of wound-related data compared with the situation before using the app—enabling the tracking of accurate measurements of 2 additional wounds. The app fostered patient engagement through weekly assessments, promoting self-examination, and preventive behaviors such as infection and trauma monitoring and off-loading of wound pressure through orthotics. Remote follow-ups reduced health care visits, alleviating patient anxiety by minimizing direct contact and enhancing physicians' confidence to deliver effective care remotely. Streamlined workflows and the use of images captured during dressing changes further saved time and costs, demonstrating the app's potential to optimize wound management and expand care capacity. The patient also found the app "educational and empowering," highlighting the ability of patient-centred technology to improve patient sentiment and better engage individuals with their wound care treatments.

In Kong and colleagues' case study [20], the assessed patient expressed concerns about sharing wound images via standard messaging platforms, highlighting a common issue with smartphone-based remote care strategies: the security of patient data [21]. Before transitioning to the app, the patient, despite having direct access to their physician, felt that sending images could impose on the physician's time. In addition, the patient was uncomfortable with the idea that the images would be transmitted through standard messaging and stored on the physician's smartphone, raising privacy and data security concerns. In contrast, by storing images captured using the app on secure cloud-based servers, this reduced the patient's anxiety toward sharing images and facilitated the physician's ability to rapidly and securely receive images.

While the sample size is small, this pilot study provides promising results regarding the use of the Patient Connect app. Our findings demonstrate that the app can be effectively used across various types of wounds and health care settings. It has been used in hospital departments, such as the Division of Infectious Diseases at the Jewish General Hospital, as well as in ambulatory settings, including ostomy care and pressure ulcer prevention at Centenary Hospital, Scarborough Health Network, and Ontario Health at Home. No adverse outcomes or wound complications were recorded with the use of the Patient Connect app during the study period. No significant privacy or security issues arose as well as the app followed all regulatory protocols regarding data protection. However, a few participants, usually elderly patients, may have highlighted the need to use assistance in taking pictures of wounds for difficult to reach or seen areas such as the sacrum or back. Lighting conditions also had an effect on the quality of the images, which indicated the need for further instruction or caregiver assistance in cases where optimal image capture was crucial.

Future studies are needed to rigorously evaluate the time savings associated with the use of the app, such as reductions in days lost due to unplanned hospital admissions or the average number of missed workdays. In addition, research should investigate whether incorporating the app as part of a remote wound care strategy can deliver care that is comparable to or even superior to standard in-person appointments by measuring median days to heal and wound complication rates. Beyond clinical outcomes, the app's potential to reduce patient costs related to travel, time off work, and other logistical burdens associated with frequent health care visits highlights its value in remote care settings. As this study had a 3-month follow-up period, which may not fully capture the healing trajectory or wound recurrence for some wound types, an extended follow-up duration is recommended in future studies. Such insights will be critical in validating the app's role in enhancing accessibility, efficiency, and cost-effectiveness in wound care. In addition, we are currently exploring the potential use cases of our technology for postsurgical sites, aiming to evaluate the effectiveness and feasibility of patient-centered wound images to detect infection. Understanding the potential use cases of generative AI for patient support may also be a worthwhile avenue for further exploration, for example, summarizing the AI analysis of the images captured by patients and providing information on the next steps (eg, clinician follow-up or continued self-management). AI and CV technology may offer patients and caregivers meaningful tools that empower them to understand better their condition, treatment options, and progress addressing gaps that chronic wounds face due to falling outside of a medical specialty. Furthermore, this study explained and discussed the development of the Patient Connect app for feasible remote wound monitoring. Swift Medical further introduced advanced AI-enhanced features such as AutoDepth and SmartTissue to deal with any challenges surrounding the monitoring of complex wounds. For example, AutoDepth identifies wound edges, calculates dimensions, and pinpoints the deepest area of the wound in real-time. SmartTissue is capable of quantifying tissue types, namely, epithelial, granulation, slough, and eschar—irrespective of the skin tone (Gupta et al [22]). These innovations enhance precision, introduce automation, and facilitate clinical decision-making. Future studies should examine the effect of the innovations on patient engagement, complex wound assessment, and treatment outcomes.

Limitations

This study was limited to a targeted patient group of 28 individuals across two hospitals, which may restrict the generalizability of our findings. In addition, while images were collected from a variety of wound types, further research is needed to evaluate the applicability of the technology for complex versus simple wounds and location of wounds. For example, situations may exist where caregiver support would be necessary like for wounds in inaccessible locations. However, differences in patient and caregiver technical proficiency with smartphones and apps were not standardized or controlled for as potential confounding factors. Furthermore, understanding the relationship between the technological capability and the app's use, engagement level, and clinical outcome would

provide valuable insight. Future studies could help inform the creation of training programs to increase adoption and usability in various patient and caregiver populations. In addition, the study only included patients using iOS devices, potentially excluding the experience from a broader population who use Android or other platforms. Future research should evaluate the feasibility and usability, as well as the clinical advantages, of an Android-compatible version. Furthermore, cross-platform studies comparing user experiences and engagement between iOS and Android users might give insight into possible differences in adoption, functionality, and effectiveness for remote wound monitoring.

Due to the nature of this as a feasibility study, the absence of a control group limits the ability to infer causality from the Patient Connect app to wound healing outcomes. However, feasibility studies are still important as they inform and guide the design of future large-scale trials. The findings from this study, where an observed median wound closure rate was 80% (IQR 15%-100%), offer preliminary insights into potential benefits. Such data could facilitate a sample size estimation in a randomized controlled trial to be run in the future. Sample size calculation suggests that 81 per group (162 total) would be required to have a power of 80% to detect a statistically significant difference between wound healing outcomes in the intervention and standard care without it done with a level of significance of 5% (α=.05), assuming a healing rate of 60% with standard care without intervention. These findings should be further investigated to understand their validity, as well as some other broader clinical and economic implications.

Conclusion

AI-powered medical tools exhibit tremendous potential in their ability to promote treatment optimization, patient satisfaction, treatment adherence, and overall health outcomes. Our pilot study found numerous clinical benefits using the novel patient-centered, CV-powered mobile app for chronic wound assessment. Similarly, the regular image capture by patients enabled physicians to conduct real-time wound assessments, thereby increasing patient adherence to management plans, as evidenced by an 80% wound closure rate within the participating sample. Considering the potential for technologies like the Patient Connect app to positively impact patient behavior and involvement within their own health care treatment journeys by collecting data that benefits their own self-awareness and clinical decision-making, future research should be conducted to understand the clinical, operational, and financial outcomes impacted by patient self-monitoring of wounds and chronic wounds. Factors that would help the widespread adoption of this innovation include more evidence-based research from larger patient populations to demonstrate the app's effectiveness and benefits in helping deliver remote care, continued user-interface improvements, further maturation of the AI wound assessment technology, patient education on the use of apps and general improvements in specific populations (eg, the elderly) familiarity with technology, and access to high-speed internet, especially for rural populations.

Conflicts of Interest

Patient Connect is a software product of Swift Medical Inc. RDJF, SCW, and HTM are current employees of Swift Medical, and JLRG is a former employee of Swift Medical Inc. None declared by the other authors.

Multimedia Appendix 1
Patient Connect instructions for patient or care giver support in adoption of AI-powered wound self-monitoring solution.
[PDF File, 561 KB - jopm_v17i1e69470_app1.pdf]

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Abbreviations

AI: artificial intelligence
CV: computer vision
DFU: diabetic foot ulcer
DU: diabetic ulcer
DWCS: digital wound care solution
PI: pressure injury
UI: user interface
VLU: venous leg ulcer
VU: venous ulcer

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Original Paper

Developing a Health Education Program for the Prevention and Control of Infectious Diseases Culturally Adapted to Ethnic and Rural Communities: Co-Design Study Using Participatory Audiovisual Methods

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Abstract

Background: Infectious diseases disproportionately affect rural and ethnic communities in Colombia, where structural inequalities such as limited access to health care, poor sanitation, and scarce health education worsen their effects. Education is essential for preventing and controlling infectious diseases, fostering awareness of healthy behaviors, and empowering communities with the knowledge and skills to manage their health. Participatory and co-design methods strengthen educational programs by ensuring cultural relevance, enhancing knowledge retention, and promoting sustainable community interventions.

Objective: This study aims to describe the co-design process and evaluate the capacity building of an education program for the prevention and control of infectious diseases using participatory audiovisual methods culturally adapted to ethnic communities and rural contexts in Colombia.

Methods: A qualitative case study approach was used. 15 community leaders contributed to the program's design, implementation, and evaluation. Nominal groups and a participatory social diagnosis identified key topics, while theoretical-practical sessions with visual methods guided the cocreation of workshops and audiovisual materials. Evaluation combined qualitative analysis of participants' perceptions and quantitative assessment of knowledge acquisition. Qualitative data were coded through content analysis, while multiple-choice questionnaires (initial and final) categorized knowledge acquisition into 3 levels (low, medium, and high), with percentage distributions used for comparative analysis.

Results: The co-design process resulted in 12 theoretical and practical workshops in infectious diseases and 3 audiovisual products: an animation about malaria, a comic book about cutaneous leishmaniasis, and a puppet show about tuberculosis. The quantitative evaluation applied to the 15 participants revealed substantial improvements, with the proportion that achieved excellent scores in pedagogy increasing from 40% (6/15) to 93% (14/15), in leadership from 13% (2/15) to 27% (4/15). In terms of health knowledge, excellent scores increased from 40% for leishmaniasis, 60% for malaria, and 13% for tuberculosis, reaching 80% for all three diseases. The qualitative evaluation showed positive results in terms of the participants' perceptions of both the methodology and the co-design process outcomes.

Conclusions: The co-design process was driven by 3 key factors: (1) active community participation at every stage; (2) knowledge exchange between multidisciplinary technical expertise and practical local knowledge; and (3) the use of innovative, culturally adapted pedagogical tools tailored to the rural context and population. This co-design process proved to be an effective method for meaningful capacity building among populations experiencing vulnerability in complex settings, and has the potential to contribute significantly to the improvement of infectious disease prevention and control.

(J Particip Med 2025;17:e65116) doi:10.2196/65116

KEYWORDS

co-design of health interventions; participatory audiovisual methods; cultural adaptation; infectious diseases; health education program; ethnic communities

Introduction

Background

Infectious diseases represent a public health challenge worldwide, particularly in low- and middle-income countries where their impact is most severe [1]. Participatory education is key in preventing and controlling infectious diseases because it enhances knowledge, raises awareness, and empowers communities [2]. Co-design, understood as a collaborative approach where various stakeholders, including community members, contribute to the development of interventions tailored to local contexts, also plays a crucial role in health strategies by improving health care access, reducing costs, and promoting local ownership [3-5].

This study was conducted in Pueblo Rico, a municipality in the department of Risaralda, Colombia, situated in a vast rainforest area endemic to tropical diseases [6]. Despite ongoing efforts by health institutions, infectious diseases remain a significant public health challenge in Pueblo Rico [1]. In 2022, the number of malaria cases surged to 1971; tuberculosis cases reached their highest level in 15 years, with 24 cases and an incidence rate of 113.5 per 100,000 inhabitants; and the number of cases of cutaneous leishmaniasis rose to 48 [7].

The populations mainly affected by infectious diseases are those living in rural areas, of whom 31% are Indigenous people from the Embera community, and 15.1% are people of Afro-Colombian descent [8]. All face a multidimensional poverty index of 82% [8], which heightens their risk for infectious diseases. Factors related to poverty, such as inadequate water management, poor sanitation, and overcrowding, significantly contribute to the disease burden in these areas [9]. Furthermore, the enduring impact of the armed conflict has left 5699 affected individuals in Pueblo Rico, including Embera communities recognized as eligible for collective reparations [10]. In previous studies, we have identified significant barriers to health care accessibility, limited facilities, and administrative issues within the Colombian health system [11]. In addition, low schooling levels, communication challenges, cultural conflicts between traditional and western medicine, and community mistrust of health personnel hinder effective health literacy and health-related behaviors of Embera populations [12].

We considered the characteristics of the rural population when culturally adapting the participatory audiovisual methods used in this study. Cultural adaptation refers to modifying or developing interventions to better align with the sociocultural characteristics and needs of a target population, in this case, ensuring comprehensive health education and promoting behavioral change to improve uptake, acceptance, and ultimately health outcomes [12,13]. Techniques such as dramatizations, drawings, photographs, and videos not only capture participants' knowledge, experiences, and perspectives but also transcend language and literacy barriers, simplifying complex health concepts such as infectious disease transmission and prevention [14].

By fostering discussion and community involvement in content creation, participatory methods enhance engagement, ownership, and practical application of knowledge, making them particularly valuable in rural and ethnic communities with limited formal education and structural barriers [14]. The World Health Organization has promoted participatory approaches such as ENGAGE-TB, which emphasizes the importance of community involvement and participatory methods to enhance the reach and sustainability of tuberculosis services [6].

Objectives

This study aims to describe the co-design process and evaluate the capacity building of an education program for the prevention and control of infectious diseases using participatory audiovisual methods culturally adapted to ethnic communities and rural contexts in Colombia.

Methods

Study Design

This paper presents the second phase of an implementation research project designed to enhance the prevention and control of malaria, tuberculosis, and leishmaniasis in Pueblo Rico through culturally adapted interventions. The first phase involved a participatory social diagnosis to identify barriers and facilitators to disease prevention and control. The second phase, explored in this paper, focuses on the co-design of a health education program, encompassing the training process and the cocreation of workshops and audiovisual materials (Table 1). The third and final phase will involve the program's implementation.

A qualitative case study methodology was used for its exploratory and explanatory potential in open systems where context cannot be controlled [14,15]. Case studies are widely used in social innovation research to assess the effectiveness of social and cultural strategies [16].

Table 1. Co-design process.

Variables	Description	Program details
Training	• Content • Community work (leadership and pedagogy) • Infectious diseases (malaria, leishmaniasis, and tuberculosis)	• Sessions: 19 • Duration: 160 h • Month and year: September 2023
Workshop cocreation	• Result: 12 theoretical-practical workshops • 4 for malaria • 4 for leishmaniasis • 4 for tuberculosis	• Sessions: 20 • Duration: 120 h • Month and year: October 2023
Audiovisual material cocreation	• Result: 3 audiovisual products, each consisting of 4 episodes • Stop-motion animation about malaria • Comic book about leishmaniasis • Puppet show about tuberculosis	• Sessions: 20 • Duration: 120 h • Month and year: November 2023

Participants

The co-design process involved 15 community leaders hired by the project to contribute to the design, implementation, and evaluation of the program. Participants were selected through convenience sampling, with support from social organizations and local authorities. Eligibility criteria included being aged >18 years; residing in Pueblo Rico for at least 10 years; speaking Spanish; being literate; and having experience, interest, or knowledge in health.

Data Collection

For the training plan, workshops, and cocreated audiovisual materials, technical consultations with experts in malaria, leishmaniasis, and tuberculosis were conducted using nominal group exercises to identify key workshop topics. Simultaneously, a participatory social diagnosis was carried out to identify unhealthy practices, knowledge gaps, and negative attitudes, shaping the workshop objectives. Both techniques were led by the research team, after which an ethnoeducator developed the pedagogical design for the cocreation sessions.

The cocreation of workshops and audiovisual materials occurred through theoretical-practical sessions using participatory audiovisual methods. This process was made possible by the collaboration of multiple stakeholders: the research team, which guided content and methodology; the community leaders, who designed the workshops and contributed to audiovisual creation; and the audiovisual production team, which provided technical support. A total of 40 six-hour sessions were conducted (20 for workshop design and 20 for audiovisual production).

The evaluation focused on community leaders' perspectives to understand their experiences and learning during cocreation. Qualitative data were collected through 2 focus groups, each lasting approximately two-and-a-half hours and conducted by the first author (MMB-G). The first focus group took place at the end of the training phase, after participants were introduced to theoretical concepts, while the second was held at the conclusion of the co-design process, emphasizing practical application. Both assessments examined perception, pedagogy, learning, skills, and critical thinking (Multimedia Appendix 1).

In addition, a quantitative evaluation of knowledge acquisition was conducted at the beginning and end of the co-design process by the research team. Individual initial and final assessments measured theoretical knowledge through 6 multiple-choice questions with images to aid comprehension, along with 2 open-ended questions for further exploration. The final evaluation also included a group exercise to assess participants' acquired competencies and their ability to apply theoretical knowledge in practice. For the 3 infectious diseases under study, the evaluation covered disease overview, transmission cycles, diagnosis and treatment, and preventive behaviors. Leadership assessment focused on negotiation skills, teamwork, and communication, while pedagogy evaluation considered learning objectives, content structuring, practical application, and assessment criteria.

Coding and Analysis

Focus groups were audio recorded, transcribed verbatim, and coded using ATLAS.ti software (Lumivero, LLC) by the second author (LSZ). Content analysis was conducted by MMB-G, considering both the learning process and participants' perceptions of methodology. Quantitative data from multiple-choice questionnaires were manually coded, with scores weighted on a 5-point scale for individual evaluations. Final individual and group evaluation scores were averaged. Open-ended responses were scored based on their alignment with the correct answer. Evaluation data were categorized into 3 performance levels (low, medium, and high), with percentage values assigned to each. A comparative analysis was then performed to assess changes in knowledge by comparing the percentage distribution of scores from the initial and final evaluations.

Ethical Considerations

The research was approved by the research ethics committee of Centro Internacional de Entrenamiento e Investigaciones Médicas (International Center for Training and Medical Research; 1272). To conduct this study, written informed consent was obtained from all participants involved. They are preserved in the physical and digital records of the project, which are for the exclusive use of the research team.

Results

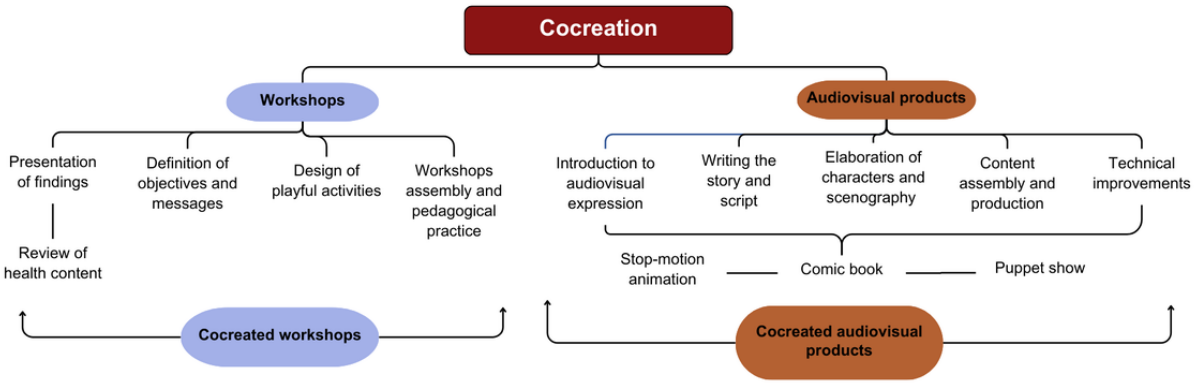
Participants

Of the 15 participants, 9 (60%) were Indigenous people from the Embera community, and 6 (40%) were people of Afro-Colombian descent; moreover, 11 (73%) were women, and 4 (27%) were men. The participants were aged between 19 and 50 years. Of the 15 participants, 4 (27%) were nursing assistants, 4 (27%) were education technicians, 3 (20%) were high school graduates, 3 (20%) studied public health, and 1 (7%) was a psychologist.

The Cocreation Process

The cocreation process yielded 2 main outcomes (Figure 1). The first was the development of 12 workshops co-designed with the community leaders, with 4 workshops dedicated to each of the 3 diseases under study: leishmaniasis, malaria, and tuberculosis. Each workshop focused on a general theme: awareness and motivation, promotion of preventive practices, promotion of early diagnosis and timely treatment, and mitigation of risk factors. The community leaders were divided into 4 subteams, each responsible for designing 1 workshop for each disease.

Figure 1. The cocreation process.



The methodology for designing each workshop included 4 main steps. The first was preparation, which involved the presentation of the findings of the participatory diagnosis by the social research team, highlighting the strengths and weaknesses of the community regarding disease-related knowledge and behaviors. Basic information regarding the diseases was then reviewed with a health expert. In the second step, the social research and pedagogy teams collaborated with the community leaders to define a clear objective and message for each workshop. In the third step, playful activities for the workshops were designed by community leaders with the support of the social research and pedagogy teams: one to promote reflection, one to demonstrate learning, and one to promote action. Finally, in the fourth step, the community leaders reviewed and assembled the workshops they had designed and conducted a pedagogical practice where they shared the complete workshop with their peers.

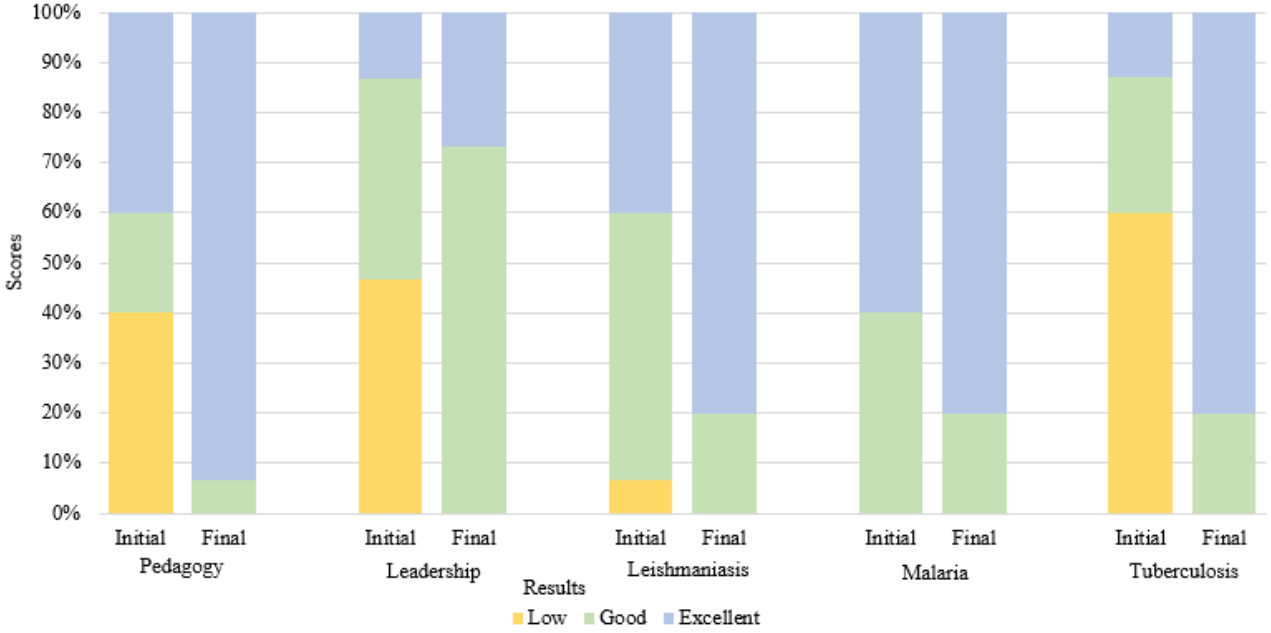
The second main outcome of the cocreation process was the creation of 3 audiovisual products (refer to Multimedia Appendices 2-4): an animation about malaria [17], a comic book about leishmaniasis [18], and a puppet show about tuberculosis [19]. Each audiovisual product consisted of 4 episodes. The cocreation process involved the community leaders, audiovisual producers, the social research team, and a health expert who helped define themes and content. This process included 5 steps. The first step was an introduction to audiovisual expression, which included exercises such as dance to engage the creative side of the community leaders, as well as basic training in artistic techniques. The second step was defining the story and script, incorporating key and precise knowledge about the diseases under study. Next came the elaboration of characters, scenography, and other elements through drawing, painting, and other crafts. The fourth step involved assembly for the puppet show and recording for the animation. Finally, the audiovisual producers made technical adjustments and improvements to the products cocreated with the community leaders.

Once the audiovisual products were incorporated into the workshops, the final outcome was 12 workshops, each with five sections: (1) introduction of the workshop facilitators and main theme and a playful activity to determine preexisting knowledge about the theme; (2) content presentation, featuring 1 episode of the cocreated audiovisual material to explain the theme of the workshop and a presentation by the community leaders to elaborate on the theme; (3) a playful activity to practice what was learned; (4) a motivational activity to promote application in participants' day-to-day lives; and (5) an evaluation of what participants learned and their perceptions of the workshop.

Quantitative Evaluation

The quantitative evaluation (Figure 2) yielded positive outcomes for knowledge acquisition and significant improvement in leadership and pedagogy. In the initial evaluation, of the 15 participants, 7 (47%) demonstrated low leadership performance, and 6 (40%) showed low pedagogical performance; however, by the final evaluation, no participant scored low in either domain. For leadership, the proportion of participants with good results increased from 40% (6/15) to 73% (11/15), and the proportion of those with excellent results increased from 13% (2/15) to 27% (4/15). For pedagogy, the majority of the participants made substantial progress, with 93% (14/15) attaining excellent scores in the final evaluation.

Figure 2. Quantitative evaluation results.



Concerning health knowledge, specifically regarding leishmaniasis, the proportion of participants achieving excellent scores doubled, increasing from 40% (6/15) in the initial evaluation to 80% (12/15) in the final evaluation. Moreover, the elimination of low scores in the final evaluation represented notable progress. For malaria, participants already performed well in the initial evaluation, with no low scores and 60% (9/15) achieving excellent scores. By the final evaluation, the proportion with excellent scores increased to 12 (80%), reflecting a positive results. In contrast to malaria, tuberculosis presented the poorest initial scores, with 60% (9/15) of the participants attaining low scores and only 13% (2/15) achieving excellent scores. However, tuberculosis demonstrated the most significant improvement, with low scores being completely eliminated by the final evaluation. The proportion of participants with excellent scores surged to 80% (12/15), showcasing a substantial increase.

Qualitative Evaluation

In the qualitative evaluation, one of the sections discussed participants' perceptions of the methodology (Textbox 1), which were positive overall.

Textbox 1. Results from the coding process of the qualitative evaluation, summarizing participants' perceptions of the methodology.

Learning facilitators

- Clarity and precision (low concentration)
- Use of playful activities (low concentration)
- Use of humor (low concentration)
- Exchange of experiences (low concentration)

Cultural exchange

- Cultural practices (high concentration)
- Knowledge (medium concentration)
- Exchange (medium concentration)

Evaluation

- Innovative methodology (low concentration)
- Challenges (low concentration)

Participants emphasized pedagogical strategies that served as learning facilitators**.** These included the use of playful activities and humor in addressing pedagogy topics, as well as clarity, precision, and constant reiteration when discussing health-related topics. In addition, drawing on community health work experiences in similar contexts from different parts of the world as inspirational examples was recognized as a valuable strategy to motivate participants. Both Embera and Afro-Colombian participants emphasized the value of having a mixed group with members of both communities because through the cultural exchange, they learned about each other's cultural practices, and it allowed the Embera participants to develop new language

skills. Finally, the community leaders discussed the evaluation, noting that performing group evaluations allowed each participant to contribute what they knew and that including traditional elements from their culture in the evaluation was a novel approach. However, they also identified challenges in terms of time management and understanding the evaluations:

> *We spent time together with the Afros today, we had fun, if we didn't understand a word, we learned from them. I didn't know too many words, but with them we learned a little bit, now I understand more.* [Embera participant; focus group; November 2023]

The second section of the qualitative evaluation (Table 2) centered on the learning process, assessing participants' performance in 6 focus areas (the 3 diseases under study and the domains of leadership, pedagogy, and audiovisual creation). For the diseases, the initial evaluation revealed new learning identified by participants, which increased by the final evaluation. This improvement was evidenced in the greater quantity, specificity, and detail of the responses and topics mentioned.

Table 2. Results from the coding process of the qualitative evaluation, summarizing participants' perceptions of learning related to the focus areas (diseases and domains).

Focus areas	Initial evaluation	Final evaluation
Diseases		
Leishmaniasis	• Vector characteristics[a] • Transmission cycle[a]	• Prevention strategies[a] • Vector characteristics[a] • Treatment adherence[a] • Timely diagnosis[a] • Types of leishmaniasis[a] • Importance of balanced diet[a]
Malaria	• Treatment[b] • Prevention strategies[a] • Transmission cycle[a] • Vector characteristics[a]	• Timely diagnosis[a] • Treatment adherence[a] • Importance of going to the physician[a] • Prevention strategies[a] • No self-medication[a] • Importance of balanced diet[a]
Tuberculosis	• Prevention strategies[a] • Symptoms[a] • Treatment[a]	• Symptoms[b] • Transmission[a] • Prevention strategies[a] • Timely diagnosis[a] • Importance of balanced diet[a]
Domains		
Leadership	• Characteristics of a leader[b] • Experiences of world leaders[a] • Difficulties of dealing with a new subject[a]	• Public speaking[c] • Characteristics of a leader[a]
Pedagogy	• Methodologies adequate for the context[a] • Learn by teaching[a] • Crafting objectives[a] • Planninga	• Crafting objectives[b] • Writing messages[a] • Importance of planning[a] • Describing activities step by step[a]
Audiovisual creation	• Development of the product[b] • Usefulness[a]	• Audiovisual techniques[c] • Crafts[c] • Usefulness[b] • Technology[a]

[a]Low concentration.

[b]Medium concentration.

[c]High concentration.

Concerning leishmaniasis, the initial evaluation showed that participants primarily learned about vector characteristics and the transmission cycle. In the final evaluation, there was a notable improvement, with the participants demonstrating knowledge not only about vector characteristics but also about prevention strategies, the importance of treatment adherence and timely diagnosis, the types of leishmaniasis, and the importance of a balanced diet. An example of the knowledge acquired about leishmaniasis is illustrated in the following quote:

> *When they get the medicines, they should have the entire treatment applied and not interrupt the application, because if they interrupt it, the parasite is not going to die and then they are going to get more lesions in other places.* [Afro-Colombian participant; focus group; November 2023]

In the case of malaria, the initial evaluation had the highest number of responses and topics mentioned, covering vector characteristics, prevention strategies, transmission cycle, and treatment. However, as with the other diseases, there was an increase in the specificity of the responses in the final evaluation, with participants additionally mentioning timely diagnosis, treatment adherence, the importance of seeking medical attention and not self-medicating, and the importance of a balanced diet. A participant stated as follows:

> *In malaria, it is important to finish the treatment so that the bug that enters our body dies, it's completely eradicated, because if we take the first four, five days, we feel relieved, and we abandon the treatment, then the disease will get worse.* [Afro-Colombian participant; focus group; November 2023]

Regarding tuberculosis, in the initial evaluation, participants mainly mentioned learning about prevention strategies, symptoms, and treatment. There was an improvement in the final evaluation, in which they reiterated learning about prevention strategies and symptoms while adding learning about transmission, timely diagnosis, and the importance of a balanced diet:

> *[A] mother always waits for 15 days when children have the flu, "oh, it's a normal flu," but you don't know if it is tuberculosis, so go to the hospital in time to find out if it is tuberculosis, you have to go to the hospital.* [Embera participant; focus group; November 2023]

With regard to the domain of leadership, in the initial evaluation, participants noted their acquisition of theoretical knowledge, such as the characteristics of a leader, as well as insight into the experiences of renowned world leaders. At the same time, they recognized that it was a difficult subject because it was new to them. However, in the final evaluation, participants highlighted the development of practical public speaking skills:

> *For my part, I participated for two months and I improved a lot, talking in public during the presentations I have done to give the messages...for my part, that improved everything, my shyness, at the beginning I was very shy, but little by little I improved, I stopped being shy.* [Embera participant; focus group; November 2023]

Regarding the pedagogy domain, in the initial evaluation, participants highlighted learning about the importance of using the appropriate methodology to reach their communities, including the use of audiovisual tools and playful activities. However, they encountered difficulties in grasping more practical aspects, such as planning and crafting objectives for the workshops. These challenges persisted in the final evaluation; for instance, they mentioned the challenges in describing activities step by step. Nonetheless, they recognized the importance of planning to better address community needs, establishing clear objectives to guide workshops, and creating clear messages without using technical terms to facilitate the community's comprehension of the topics:

> *It's just like a necklace [talking about planning], the necklace when you are crafting it is the same.... I have always made necklaces and when you don't start well, then it gets tangled up and that's how it ends, it stays tangled up and it doesn't look good.* [Embera participant; focus group; November 2023]

The last domain evaluated was audiovisual creation. In the initial evaluation, participants had only engaged in the creation of basic audiovisual products during the workshops. Despite their limited experience, they expressed their enjoyment in developing this type of product, particularly highlighting TikTok videos and radio dramas, with a participant noting the usefulness of audiovisual products for community education.

By contrast, in the final evaluation, they emphasized the value they found in learning to create diverse types of audiovisual products, especially animations. However, they reported facing several challenges during the creation process, such as experiencing frustration with the time-consuming nature of stop motion or the physical demands of assembling a puppet show. These challenges, common when working with artistic or physical skills, did not hinder the process. Instead, they were acknowledged and mitigated by balancing activities during implementation.

Another aspect participants emphasized was the enjoyment they found in crafting visual elements for the audiovisual products, such as creating drawings for comics and crafting puppets for shows. They also noted improvement in their artistic skills. Furthermore, they found the use of apps to be an interesting aspect of the process; however, they encountered technological barriers. Regarding the utility of the products, participants emphasized their potential to amplify the impact of the workshops by reaching more people due to their participatory nature, which facilitates engagement and learning, as expressed by a participant:

> *Yes, the comics would be good for coloring. It would be good because they are going to be entertained and they are going to gain knowledge about the mosquito, the dog....* [Afro-Colombian participant; focus group; November 2023]

Discussion

Principal Findings

The co-design process showed that participatory methods, knowledge exchange, and culturally adapted tools enhanced ownership, engagement, and knowledge acquisition, leading to significant improvements and positive feedback.

Key Factors of Co-Design Useful for Replication

Throughout the development and evaluation of this co-design process, 3 key factors were identified as useful for replication in future studies, based on both the research team's experience and the results obtained from the qualitative evaluation, including participants' perceptions of the methodology, learning facilitators, cultural exchange, and evaluation. The first factor was the participatory approach used throughout the process (diagnosis, design, and implementation). As evidenced in other studies [20], this approach empowers participants to develop a sense of joint ownership over the project, helps to build trust between the participants and the research team, and facilitates the integration of research into practice [21]. In this study, applying the participatory approach at every stage led to participants seeing their contributions reflected in the strategies and co-designed audiovisual products, giving them a stake in the project's success and facilitating the next phase, which involves implementing these strategies with the community at large.

The second factor was the knowledge exchange process involving multiple stakeholders: community leaders, who contributed expertise based on their lived experience; social researchers, who brought expert knowledge of community work and pedagogy; a health expert, who contributed expertise on infectious diseases; and audiovisual producers, who provided technical knowledge on audiovisual production. In line with the literature [22], to ensure the success of the co-design process, the researchers acted as facilitators who promoted capacity building and provided tools and methodological structures [23] to support the community leaders in creating workshops and audiovisual products. This process acknowledged the different levels of interest, creativity, and skills among the community leaders. The knowledge exchange process enabled researchers to understand the actual conditions experienced by the community and learn how to make interventions feasible, while also equipping the community leaders with tools to act within their own context. Diversity among participants, in terms of ethnicity, gender, educational level, and health knowledge, and the inclusion of representatives of health workers as well as community members who are beneficiaries of health interventions, played an important role. Within the research team, interdisciplinarity was key.

The third and final factor was the use of innovative, culturally adapted pedagogical tools. Throughout the co-design process, creative strategies such as the use of digital and audiovisual tools, case studies set in similar contexts, and games and playful activities were involved in the facilitation of knowledge acquisition. To be effective, these strategies required adaptation to better respond to the context and cultural characteristics of the population, and they were tied to attempts to integrate the cultural traditions of the communities involved into the co-design process, which enhanced their acceptability among the participants.

Capacity Building for Ownership

The Design Council of the United Kingdom defines "co-design" as "the meaningful involvement of end users in the design process" [24]. In this study, co-design with end users helped develop the skills and knowledge necessary for achieving ownership of interventions aimed at improving community health conditions. One of the most important accomplishments of this cocreation process was building capacity within the community and promoting meaningful learning through a theoretical-practical methodology that enabled effective training and helped overcome barriers related to low schooling levels and communication. The co-design process evaluated in this study involved training in health topics and skills for community work, as well as the cocreation of workshops and audiovisual products. The quantitative evaluation showed positive results regarding knowledge acquisition by the community leaders, and the qualitative evaluation demonstrated positive perceptions of the methodology and the learning outcomes. Consistent with previous studies [25], the involvement of the community leaders in creating audiovisual materials, as well as the use of traditional games and playful activities, facilitated the presentation and explanation of complex information, the improvement of comprehension and recall, and the promotion of engagement and skill development. These benefits were recognized by the community leaders in their qualitative evaluations, and the positive outcomes were also reflected in the quantitative results.

Contribution to Health Outcomes

Community participation was recognized in the Declaration of Alma-Ata as essential for primary health care [26], and diverse studies have shown its contribution to the prevention and control of infectious diseases. The co-design process can be understood as participative, enabling better understanding of context and background, while scientific knowledge enhances and supports the design of evidence-based solutions to improve health conditions in communities experiencing vulnerability that are affected by infectious diseases [27].

In this study, the cultural adaptation of content was crucial to better respond to participants' literacy levels, communication barriers, and identified skills. As shown in previous studies [28,29], culturally adapting health education to respond to such population characteristics improves its effectiveness. In this case, the cultural adaptation involved presenting clear and precise information, constantly repeating information, incorporating playful activities and audiovisual materials, and using examples of community health workers in similar contexts. Participants evaluated these strategies positively in the qualitative assessment, and the quantitative results showed marked improvement in knowledge acquisition across the 6 focus areas (diseases and domains) addressed.

Furthermore, the participation of the community leaders in the creation process allowed the audiovisual products to be better adapted to the context and population characteristics because their preferences could be incorporated from the outset in a

more meaningful way than if they had been involved in the adaptation only after the initial products had been already created, an approach that is also in line with findings from other studies [28]. As a result of the cocreation process, the audiovisual products conveyed clear messages using simple language and familiar images; incorporated colloquialisms and idioms; featured Embera and Afro-Colombian characters; and reflected community settings and cultural practices, including traditional medicine.

Limitations

As a case study, this research prioritized depth over representation; accordingly, a purposive sample was selected. In future studies, the development of other case studies will be useful for comparing and generalizing the findings of this study.

Conclusions

The co-design process was driven by three key factors: (1) active community participation at every stage; (2) knowledge exchange between multidisciplinary technical expertise and practical local knowledge; and (3) the use of innovative, culturally adapted pedagogical tools tailored to the rural context and population. This co-design process proved to be an effective method for meaningful capacity building among populations experiencing vulnerability in complex settings and has the potential to contribute significantly to the improvement of infectious disease prevention and control.

Acknowledgments

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Conflicts of Interest

None declared.

Multimedia Appendix 1
Focus groups guide.
[DOCX File , 17 KB - jopm_v17i1e65116_app1.docx]

Multimedia Appendix 2
Co-designed audiovisual product (a comic book) about cutaneous leishmaniasis.
[MP4 File (MP4 Video), 6324 KB - jopm_v17i1e65116_app2.mp4]

Multimedia Appendix 3
Co-designed audiovisual product (a puppet show) about tuberculosis.
[MP4 File (MP4 Video), 51488 KB - jopm_v17i1e65116_app3.mp4]

Multimedia Appendix 4
Co-designed audiovisual product (an animation) about malaria.
[MP4 File (MP4 Video), 18246 KB - jopm_v17i1e65116_app4.mp4]

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Development of a Cocreated Decision Aid for Patients With Depression—Combining Data-Driven Prediction With Patients' and Clinicians' Needs and Perspectives: Mixed Methods Study

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Abstract

Background: Major depressive disorders significantly impact the lives of individuals, with varied treatment responses necessitating personalized approaches. Shared decision-making (SDM) enhances patient-centered care by involving patients in treatment choices. To date, instruments facilitating SDM in depression treatment are limited, particularly those that incorporate personalized information alongside general patient data and in cocreation with patients.

Objective: This study outlines the development of an instrument designed to provide patients with depression and their clinicians with (1) systematic information in a digital report regarding symptoms, medical history, situational factors, and potentially successful treatment strategies and (2) objective treatment information to guide decision-making.

Methods: The study was co-led by researchers and patient representatives, ensuring that all decisions regarding the development of the instrument were made collaboratively. Data collection, analyses, and tool development occurred between 2017 and 2021 using a mixed methods approach. Qualitative research provided insight into the needs and preferences of end users. A scoping review summarized the available literature on identified predictors of treatment response. K-means cluster analysis was applied to suggest potentially successful treatment options based on the outcomes of similar patients in the past. These data were integrated into a digital report. Patient advocacy groups developed treatment option grids to provide objective information on evidence-based treatment options.

Results: The Instrument for shared decision-making in depression (I-SHARED) was developed, incorporating individual characteristics and preferences. Qualitative analysis and the scoping review identified 4 categories of predictors of treatment response. The cluster analysis revealed 5 distinct clusters based on symptoms, functioning, and age. The cocreated I-SHARED report combined all findings and was integrated into an existing electronic health record system, ready for piloting, along with the treatment option grids.

Conclusions: The collaboratively developed I-SHARED tool, which facilitates informed and patient-centered treatment decisions, marks a significant advancement in personalized treatment and SDM for patients with major depressive disorders.

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KEYWORDS

shared decision-making; clinical decision support; decision support; mental health; mental illness; mental disorder; depression; depressed; major depressive disorder; depressive disorder; precision medicine; precision care; personalized medicine; personalized care; individualized medicine; individualized care; data-driven

Introduction

Major depressive disorder (MDD) is a prevalent disorder that significantly impacts various aspects of life, including in the community and at home, school, and work, affecting millions of individuals globally. Despite the availability of several evidence-based treatments, such as antidepressant medication and psychotherapy [1,2], treatment responses vary significantly among patients [3]. This variability underscores the need for personalized treatment approaches to improve individual patient outcomes. One promising strategy to enhance treatment response is to predict which treatment options a patient is most likely to respond to [4], thereby reducing the trial-and-error process often associated with finding the right therapy [5]. Patients' preferences play a crucial role in treatment outcomes, with research indicating that positive expectations regarding treatment prior to its start can enhance recovery [6].

Recently, patient empowerment has accelerated the implementation of shared decision-making (SDM). SDM is an approach where patients and clinicians make decisions together, using the best available evidence regarding screening, treatment, or management options [7]. SDM enables patient-centered choices [8,9] and is effective in achieving treatment agreement [10]. However, determining the most appropriate treatment for each patient remains challenging. SDM requires accessible information for patients and clinicians about evidence-based treatment options, including their benefits and harms [7,11-13]. In clinical practice, decision aids and feedback from routine outcome monitoring (ROM) can be valuable sources of information during the SDM process to make informed choices [14,15].

Decision aids are known to increase guideline adherence, enhance access to measurement-based care strategies, and provide personalized treatment options tailored to each patient's characteristics and circumstances [16,17]. They also offer several additional advantages, such as increasing patients' knowledge, improving the accuracy of risk perception, and aligning care choices with patients' values [18]. Furthermore, decision aids reduce decisional conflict, decrease passive decision-making, and positively impact patient-clinician communication [19].

In psychiatry, ROM data are gathered systematically to monitor a patient's progress during therapy [20]. Using feedback from ROM data may increase patient engagement in treatment [21] and positively impact treatment effectiveness, efficiency, and collaborative practice [22].

Questions arise concerning what to include in a decision aid for depression. While many biological tests, clinical observations, and patient-reported outcome measures have been found to be predictive of different MDD treatment responses, no single established measure or test has sufficient prognostic accuracy to optimally guide treatment selection [23]. A promising avenue to enhance treatment response is to facilitate informed SDM before starting treatment [24,25]. This may be achieved by identifying potentially successful treatment options and tailoring them to a patient's clinical characteristics and preferences, initiating discussions to find the preferred option.

Existing computerized decision support (CDS) tools for patients with MDD have been developed to serve various purposes, such as facilitating screening [26], targeting specific populations (eg youth depression [27] and pregnant women with MDD [28]), supporting treatment allocation [29-31], improving treatment adherence [32], facilitating the implementation of evidence-based care [33,34], and supporting decision-making regarding pharmacological treatment [8,35-37]. Despite previous efforts, a practical CDS tool that incorporates personalized treatment recommendations based on intake information and outcome monitoring data for use in the specialized mental health care setting has, to our knowledge, not yet been developed for patients with MDD.

Therefore, this study aimed to develop an instrument for SDM in MDD through cocreation with patient representatives and in collaboration with end users (both clinicians and patients) and data scientists. The proposed "Instrument for Shared Decision-Making in Depression (I-SHARED)" CDS tool aims to provide patients and clinicians with (1) thorough, systematic information regarding symptoms, medical history, contextual factors, and potentially worthwhile treatment strategies in a digital report (patient summary) and (2) objective information regarding treatment options to guide depression treatment decisions. This study is imperative to address the variability in treatment response among patients with MDD and to enhance treatment effectiveness through personalized approaches and SDM. By developing the I-SHARED tool, the study aims to improve patient outcomes, satisfaction, and engagement in treatment. This paper reports on the development of the I-SHARED tool for use in specialized mental health care.

Methods

Setting

In the Northern Netherlands, a unique collaboration has been established between several specialized mental health care organizations and academic researchers [38]. This collaboration includes active client participation through client representatives and facilitates treatment innovation via applied research. Within these organizations, ROM data and health care usage data are collected prior to and during treatment. The Improving Mental Health care using Personalized treatment based on analyses of Routine data for Optimal Value and Effectiveness (IMPROVE) consortium, which includes patient representatives, researchers, a health insurer, and specialized mental health care organizations [39], created a unique joint data infrastructure called the RoQua Management Information System (RQ-MIS). This system was developed in compliance with applicable laws and regulations, including the General Data Protection Regulation (GDPR) [40]. Section A in Multimedia Appendix 1 describes the structure of data linkage via a trusted third party.

General Procedures

The study team was co-led by 2 researchers (KK and FJ) and 2 patient representatives (DM and Paul Ulrich). Regular meetings were organized, and all major decisions regarding development and research were made collaboratively between researchers and patient representatives. The development of I-SHARED followed a mixed methods approach, comprising four phases:

(1) qualitative research to understand end users' needs, preferences, and perspectives; (2) a scoping review to identify potential predictors of treatment response; (3) the development of the I-SHARED report, which includes a patient summary of collected intake and outcome monitoring data, and the prediction of potentially successful treatment options by comparing an individual with similar patients who received treatment in the past; and (4) the development of treatment-option grids for use in clinical practice to guide the SDM process. In phase 3, routinely measured variables were identified for inclusion in the I-SHARED report, and a prediction model and graphical interface for the report were developed. The goal was to create a tool that could function independently of any specific electronic medical record system.

Mental health care usage data, ROM data, and patient characteristics were accessed via the RQ-MIS data infrastructure. Data were obtained from 2 IMPROVE-partners: the University Center of Psychiatry (UCP) and GGZ Drenthe Mental Health Institute [41]. Information regarding diagnoses, treatment types (recorded for billing purposes and registered administratively by clinicians), start and end dates of treatment, and the number and duration of treatment sessions was retrieved. The resulting dataset is referred to as the I-SHARED data.

I-SHARED Development

Phase 1: Stakeholder Involvement Through Qualitative Research

In total, 3 focus group interviews were conducted with 11 patients with (a history of) depression, and 7 semistructured interviews were conducted with clinicians from 5 different mental health care organizations. The aim was to identify gaps in clinical practice, relevant components of a decision aid, preferences regarding treatment outcomes, and preferences for the user interface of the decision aid. All interviews were audio-recorded, transcribed verbatim, and analyzed using thematic content analysis [42,43]. Data collection occurred between November 2016 and June 2017 until data saturation was reached.

All interview transcripts were coded using the software package ATLAS.ti version 8.0.40.0 (ATLAS.ti Scientific Software Development GmbH). Transcripts of the focus group interviews and the semistructured interviews were first coded separately, and each perspective was compared. More details regarding the qualitative research, including recruitment, participant characteristics, data collection, and analyses, are reported elsewhere [44]. This analysis resulted in a list of proposals and preferences regarding the design and relevant input for the I-SHARED report and possible treatment outcomes.

Phase 2: Scoping Review

A scoping review was conducted to summarize previously identified predictors of treatment response in patients with MDD. The search was performed in September 2018 using PubMed and was restricted to papers in English. Search terms included "depression" or "depressive disorder*" in combination with "prediction," "predictors," "determinants," "moderators," "mediators," "factors," and "treatment outcome," "remission," and "response." The scoping review identified predictors of treatment response, which were then compared with the preferences in phase 1.

Phase 3: I-SHARED Report Development

Cluster Model for Personalized Treatment Options

The I-SHARED dataset was used to develop a data-driven prediction algorithm to guide depression treatment decisions. To be included in the dataset, patients had to have a primary diagnosis of MDD (N=17,788). The dataset comprised routinely collected intake and outcome data, as well as mental health care usage data. Intake data included sociodemographic characteristics and medical and mental health information (for a complete list, see Section B in Multimedia Appendix 1). Treatment response was assessed using changes in Outcome Questionnaire-45 (OQ-45) scores during treatment [45,46]. We included individuals with at least 2 OQ-45 scores, at least 90 and at most 365 days apart during treatment. In cases with more than two measurements, the last score within 365 days was used (see Section C in Multimedia Appendix 1). Prediction modeling was based on validated Dutch OQ-45 cutoff scores to assess a clinically relevant decrease in symptoms between two measurements (reliable change index: a decrease of at least 14 points in total score) [45,47].

The health care usage data distinguished 10 types of treatment: psychotherapy, (cognitive) behavioral therapy, interpersonal therapy, family therapy, pharmacotherapy, art, dance, and movement therapies, psychomotor therapy, hospitalization, day treatment program, and a category of remaining treatments. The psychotherapy group contained treatments using techniques from various methods, in contrast to an exclusive approach such as cognitive behavioral therapy. The remaining treatment group comprised treatments that were used too infrequently to be included as a specific treatment category, such as physical therapy (eg, transcranial magnetic stimulation), physiotherapy (individual or group), and specific procedures (eg, outpatient methadone, forensic psychiatric supervision, and interpreter or sign specialist). Dummy variables were created for each patient and type of treatment to indicate if it was received between 2 OQ-45 assessments (yes or no).

In total, N=2478 patient records were suitable for the cluster analysis (see Section C in Multimedia Appendix 1 for the steps of patient selection). Table 1 presents the characteristics of this group, including the percentage of patients who showed recovery between baseline and follow-up assessment. The median duration between the first and second OQ-45 assessments was 268.5 (IQR 123) days, influenced by the choice to use the last OQ-45 score in cases with more than 2 measurements and the 90 - to 365-day period. Information on age and sex was available for all individuals, while data on other questionnaires or sociodemographic information were often incomplete.

Table . Patient characteristics of the data used for model development.

Characteristic	Value
Number of patients	2478
Significant Recovery rate (–Δ OQ-45[a] >=14), n (%)	1256 (50.7)
Male, n (%)	1011 (40.8)
Baseline OQ-45 total score, mean (SD)	86.7 (23.5)
Improvement (OQ-45) points, mean (SD)	–16.5 (25.5)
Time between 2 OQ-45 measurements (days), mean (SD)	253 (79)
Type of treatment received, n (%)	
Psychotherapy	182 (7.3)
(Cognitive) behavioral therapy	570 (23)
Interpersonal therapy	203 (8.2)
Systemic therapy	124 (5.0)
Pharmacotherapy	1149 (46)
Art, dance, and movement therapies	554 (22)
Psychomotor therapy	746 (30)
Hospitalization	361 (15)
Day treatment program	92 (3.7)
Remaining treatments	920 (37)

[a]OQ-45: Outcome Questionnaire-45.

To inform new patients about treatment options that previously benefitted patients with similar characteristics, a cluster model was estimated in the I-SHARED dataset. Clusters were based on the 3 subscales of the OQ-45 (Symptom Distress, Interpersonal Relations, and Social Role) and age. The k-means algorithm was used for the cluster model [48]. Initially, more complex models, such as extreme gradient boosting, incorporating a range of variables, were evaluated in a prediction model. However, k-means clustering was ultimately preferred due to its lower complexity and ease of interpretation for both patients and practitioners when discussing various treatment options. Z-score normalization was first applied to the data to ensure that each subscale was equally weighted in the algorithm. To determine the optimal number of clusters, we deployed 4 techniques. First, we used an elbow plot to determine the total within-cluster sum of squared error given various cluster sizes (k). Second, we used the average silhouette width to determine the distance between clusters. Third, we used principal component analysis to evaluate the overlap between clusters [49]. Finally, we estimated the stability of clusters for each k using 100 iterations. Based on these performance measures, k was chosen to ensure a good fit, large distances between clusters, minimal overlap, and high stability. Statistical analyses were performed using RStudio IDE (version 1.4.1103) running R (version 4.0.3).

Sensitivity Analyses

Sensitivity analyses were performed to investigate whether different patient selection criteria would result in larger sample sizes and different distributions of treatment data. In Section F in Multimedia Appendix 1 the sample was compared with (1) a sample where the first OQ-45 measurement was within 30 days of intake instead of the main analysis in which the first OQ-45 measurement available was selected and (2) a sample where the time window of the second OQ-45 measurement was at least 60 days instead of 90 days.

Development of the Graphical Interface of the I-SHARED Report

Based on the outcomes of phase 1 and phase 2, items were selected for inclusion in the I-SHARED report if they were either (1) routinely captured in the data or (2) required a minimal additional administrative effort to include.

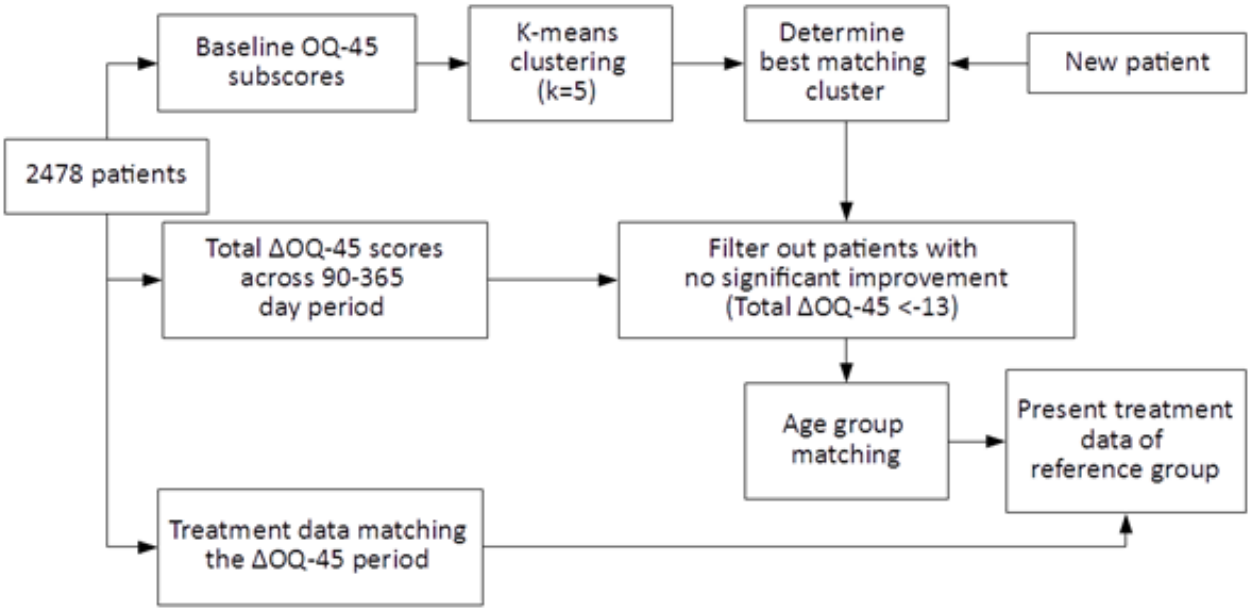
Visual feedback, including ROM results and other patient characteristics, was automatically generated for patients and clinicians from a series of applications. A generic application was built to combine the outcomes of the k-means cluster model with the generated visualizations and supporting text into a single document.

For the k-means clustering model, we implemented an OpenCPU (version 2.0.8) R-based service. Based on the answers to a series of questionnaires and the pretrained cluster model, this service can return the treatments of the reference group. To generate the visualizations in the I-SHARED report, we implemented a visualization service using the Data Driven Documents library (D3, version v5.4.0), accessed via a NodeJS web service (version 10.16.0).

The collected intake data of the individual patients were used to identify the most similar cluster. From this cluster, patients with clinically relevant improvements on OQ-45 and from similar age categories were identified to form a reference group. The age categories were <34 years old, 34-49 years old, and

>50 years of age. Treatments used by patients in the reference group were extracted. Figure 1 depicts the general functioning of the algorithm. The I-SHARED report then presented the percentage of patients from the reference group who received each type of treatment. Finally, the treatment data were graphically presented in the I-SHARED report.

Figure 1. The clustering model for the presentation of treatment data of patients with a clinically relevant improvement on the OQ-45 (Outcome Questionnaire-45) total score.



Following the construction of a draft version of the I-SHARED report, we conducted an additional focus group interview with 7 patients to assess the comprehensibility and added value of the visualizations in the I-SHARED report. Their feedback was used to adapt the visualizations in the final I-SHARED report, including a second treatment overview based on the cluster model. This overview now selects patients with a clinically relevant deterioration (significant increase of ≥14 points) as an alternative reference group from the relevant cluster.

Phase 4: Treatment Option Grids

Treatment option grids were developed to meet the needs of patients with MDD in accordance with the findings from the focus group interviews. These grids were developed by MIND, a Dutch umbrella organization uniting various patient organizations involved in mental health. MIND advocates for mental health patients and their families on several important issues (eg, patient rights and quality of care), in collaboration with the Dutch Patient Association for people affected by depression (in Dutch: Depressie Vereniging). The treatment option grids reflected the evidence-based treatments advised by the national clinical guidelines for depressive disorders [50].

MIND first selected the topics and corresponding interventions relevant to patients with MDD throughout their patient journey (self-management, first-step interventions, psychotherapy, and pharmacotherapy). Second, relevant texts from the clinical guidelines were extracted on the topics. Third, new text snippets were developed to match the needs of patients with MDD. Fourth, concepts were tested by Experts by Experience from the patient association to ensure that the texts were suitable for patients. The fifth and final step included a review with the chair of the guideline development group to ensure that the new text still conformed to the clinical guidelines. After development, these option grids were field-tested along with the I-SHARED report.

Ethical Considerations

The Medical Ethics Review Board of the University Medical Center Groningen, in accordance with the Dutch Medical Research on Human Subjects Law (in Dutch: Wet Medisch-Wetenschappelijk onderzoek met mensen,WMO), exempted the current research from full review. This waiver was granted because the study did not infringe on the physical and psychological integrity of the participants (Reference number 2017/116). Research was conducted in compliance with GDPR and Dutch privacy regulations. All participants in the qualitative study provided informed consent to participate in focus groups and individual semistructured interviews. Participants were compensated one time €25 (US $29) for the time spent in focus groups. Participants consented to the audiotaping of interviews and their use for scientific research after anonymization. Separate informed consent was obtained for the use of ROM data, or patients were given the opportunity to opt out of the use of their anonymized data in the research database. Data were anonymized and linked without personal identifiers through a trusted third party.

Results

Results From Qualitative Research

Identification of Gaps in Clinical Practice

Patients reported that a decision aid for depression could help provide a comprehensive overview of all available treatment options, including those not offered by their mental health care provider. According to patients, a decision aid that provides objective treatment advice tailored to their situation and supports

SDM could help reduce clinicians' tendency to compartmentalize.

Clinicians reported that a decision aid should ideally provide an overview of important contextual factors in addition to an overview of treatment options. It might confirm the type of treatment considered and suggest treatment options not initially thought of. They expected the decision aid to facilitate SDM, with patients being more involved and able to express their treatment preferences. Clinicians also anticipated that a data-driven decision aid could help identify profiles or clusters of patients that respond well to specific treatments, which might subsequently advance research as new data are collected and used to improve the algorithm's performance.

Relevant Components of the Decision Aid

All components that patients and clinicians found relevant for inclusion in the decision aid are listed in Table 2. The final column displays components included in either the I-SHARED report or the treatment option grids. Some components were added for inclusion in future routine questionnaires (eg the Individual Recovery Outcomes Counter, Medication Adherence Rating Scale, and Mental Health Continuum-Short Form). The preferences of patients and clinicians regarding outcomes and the interface are included in the last two rows of Table 2. Along with functioning and symptom relief, the achievement of personal goals was also considered relevant by both patients and clinicians.

Table . Relevant components of the decision aid, including preferences regarding outcomes and interface.

Component	Relevant according to patients	Relevant according to clinicians	Captured in I-SHARED[a]
Depressive symptoms	✓	✓	✓
Physical complaints	✓		✓
Psychiatric comorbidities	✓	✓	✓
Personal characteristics			
Intelligence level	✓		
Coping mechanisms	✓		
Personality	✓	✓	
Physical activities	✓	✓	✓
Hobbies	✓		
Age	✓	✓	✓
Gender		✓	✓
Life events	✓		
Cause of the depression	✓	✓	
Family history of psychiatric disorders and treatment	✓	✓	✓
Contextual factors			
Patients' own strengths and possibilities	✓		✓
Personal situation	✓		✓
Social network	✓		✓
Financial situation		✓	
Housing/relationship issues		✓	
Patient's environment		✓	✓
Therapeutic alliance	✓		
Depression severity		✓	✓
Blood levels if applicable		✓	
Sexual complaints		✓	
Preferences regarding treatment outcomes for use in the decision aid			
Decrease of depressive symptoms	✓	✓	✓
Personal and social functioning	✓	✓	✓
Achievement of personal treatment goals	✓	✓	
Increase in quality of life		✓	✓
Chance of remission/recovery		✓	✓
Time to recurrence		✓	
Preferences regarding the interface			
Positively formulated outcomes	✓		✓
Expected outcomes of the treatment options, or overview of potentially successful treatment options	✓	✓	✓
Tailored to the individual patient	✓	✓	✓
Basic information regarding content of the treatment, goals of treatment, side effects of treatment, and treatment duration	✓		✓
A print-out or digital by email	✓	✓	✓
Discussion with the clinician/patient	✓	✓	✓

Component	Relevant according to patients	Relevant according to clinicians	Captured in I-SHARED[a]
A distinction in gender and age categories when the results of the outcomes of the decision aid are displayed		✓	✓
Preferably, the expected outcomes in the data-driven analyses that take into account previous episodes, comorbidities, long-term outcomes, and the expected duration of the episode		✓	
Easy to interpret by visualizations		✓	✓

[a]I-SHARED: Instrument for Shared Decision-Making in Depression.

Results of the Scoping Review

We identified 31 studies on potential predictors of treatment response in patients with depression. An overview of the studies can be found in Section D in Multimedia Appendix 1. The potential predictors were classified into four categories: (1) personal characteristics, (2) current clinical factors, (3) factors related to treatment history, and (4) biological and genetic factors. Table 3 shows the identified predictors and indicates whether they were present in current routine data and captured in I-SHARED. Predictors related to biological and genetic factors, intelligence level, income, a range of comorbidities, certain personality traits, and coping strategies were not collected routinely and therefore could not be considered for the current version of the I-SHARED report.

Table . Potential predictors of treatment response in patients with depression.

Predictors	Captured in I-SHARED[a]	Added to I-SHARED for future data collection and analysis
Personal characteristics		
Income		
Education	✓	
Marital status	✓	
Having social support		✓
Living situation	✓	
Ethnicity	✓	
(Older) age	✓	
Intelligence		
Unemployment	✓	
Current clinical factors		
Presence of psychiatric comorbidities: anxiety, bipolarity, personality disorder, and substance use disorder	✓[b]	
Current suicidal risk	✓	
Melancholic features/symptoms		
Traits: low reward dependence, low cooperativeness, high neuroticism, low extraversion, low openness, and low conscientiousness		
Depression/symptom severity	✓	
Duration of index episode	✓	
Use of medical services	✓	
Increased levels of daily hassles		
Perceived logicalness of therapy/less positive outcome expectancies/preference for treatment type		
Type of treatment	✓	
Early symptomatic improvement		
Having any significant medical comorbidity at baseline/ somatic symptoms/physical illnesses	✓	
Global functioning/executive dysfunction	✓	
Life satisfaction		✓
Self-esteem		
Psychotic features		
Increased levels of avoidance in dealing with problems		
Increased levels of dysfunctional attitudes		
Decreased levels of positive coping strategies		
Factors related to treatment history		
Nonresponse to the first antidepressant received or history of medication failure	✓	
Early onset of first depressive episode or age at onset	✓	
(High) number of previous episodes or recurrences	✓	

Predictors	Captured in I-SHARED[a]	Added to I-SHARED for future data collection and analysis
Lack of full remission after previous episode or more residual depressive symptomatology and psychopathology		
Higher number of hospitalizations		
Higher dosage of antidepressants	✓	
Having experienced a greater number of recent life events		
Childhood maltreatment		
Previous treatment or therapies for depression	✓	
Biological and genetic factors		
GABA[c] levels in occipital and anterior cingulate cortices		
5-HT1A[d] C1019 polymorphism GG genotype+A allele of BDNF[e] G196A (Val66Met) polymorphism		
NTRK2[f] gene polymorphisms (T-Thaplotype)		
Functional polymorphism of GRIN2B[g]		
BDNF levels at baseline		
TNF-α[h] levels at baseline		

[a]I-SHARED: Instrument for Shared Decision-Making in Depression.

[b]Some psychiatric comorbidities are captured.

[c]GABA: gamma-aminobutyric acid.

[d]5-HT1A: 5-hydroxytryptamine receptor subtype 1A.

[e]BDNF: brain-derived neurotrophic factor.

[f]NTRK2: neurotrophic receptor tyrosine kinase 2.

[g]GRIN2B: Glutamate Receptor, Ionotropic, N-Methyl-D-Aspartate, Subunit 2B.

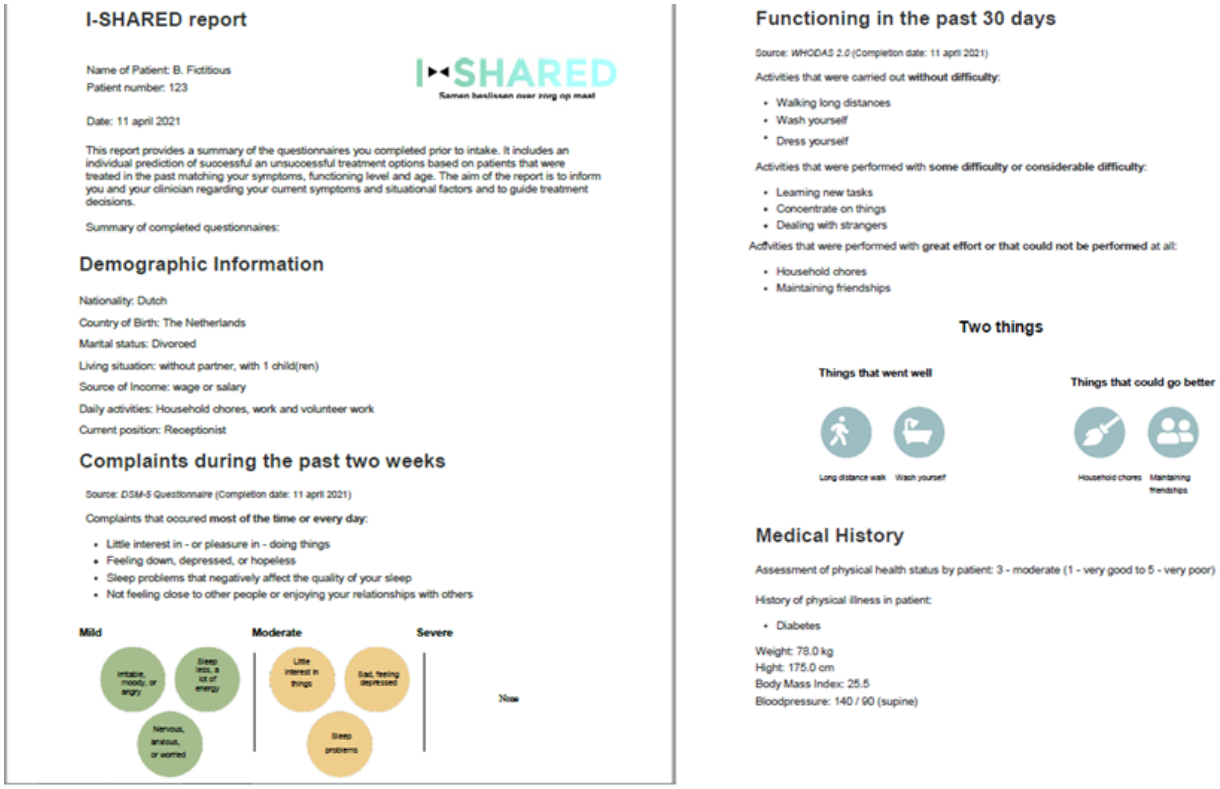
[h]TNF-α: Tumor necrosis factor alpha.

Results From the I-SHARED Report

Graphical Interface of the I-SHARED Report

A snapshot of the I-SHARED report is shown in Figure 2. Note that the original I-SHARED report was developed for national use and is therefore in Dutch. In Figure 2 data of a hypothetical patient was entered, and the report was translated into English for illustration purposes. The entire report can be printed or made available to the patient as a PDF file. Patients and clinicians discuss the content of the I-SHARED report prior to jointly deciding which treatment to initiate. The data infrastructure is designed to allow continuous improvement of the algorithm and expansion of the number of predictors in the future.

Figure 2. A snapshot of the graphical interface of the Instrument for shared decision-making in depression report.



Cluster Modeling

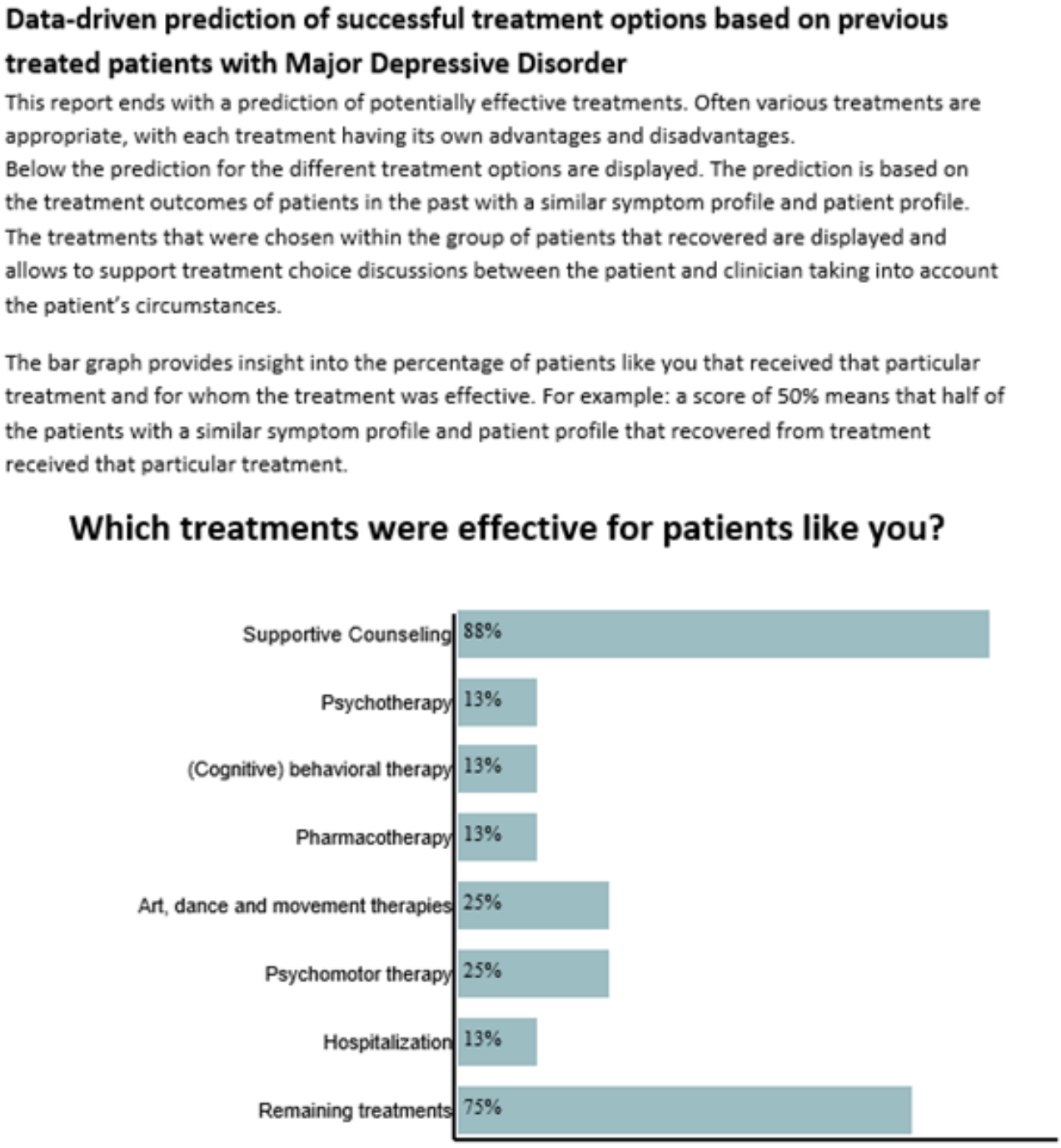
A total of 5 clusters showed the best performance, with cluster sizes ranging from 321 to 642 patients. Table 4 displays the cluster centers of the different subscales of the OQ-45. Further increasing the number of clusters did not substantially decrease the total within sum of squares errors, while the stability of clusters considerably deteriorated. Also, cluster overlap increased with the number of clusters. See Section E in Multimedia Appendix 1 for an overview of the clustered data points after applying principal component analysis. An example of the data of the clustering model as presented to the patient is shown in Figure 3. In Figure 3 data of a hypothetical patient was entered, and the information was translated into English for illustration purposes.

Table . The values of the cluster centers for the Outcome Questionnaire-45 scores subscales after reverting the z-score normalization.

Cluster	OQ-45[a] symptom distress	OQ-45 interpersonal relations	OQ-45 social role
1	70.81	24.88	21.10
2	47.38	13.36	12.00
3	58.96	17.71	18.44
4	29.12	8.35	7.75
5	62.83	21.80	12.08
Overall mean (SD)	54.93 (15.27)	17.06 (6.55)	14.71 (5.39)

[a]OQ-45: Outcome Questionnaire-45 scores.

Figure 3. Illustration of the clustering algorithm in the I-SHARED (Instrument for Shared Decision-Making in Depression) report.



Sensitivity Analyses

In the sensitivity analyses, we obtained a smaller sample when selecting a first OQ-45 measurement around the time of intake (−30/+30 d). However, the distribution of treatments after intake was comparable. When the time window of the second OQ-45 measurement was at least 60 days, instead of 90 days, the sample size increased by 144 participants. Recovery rates, percentage of males, mean baseline OQ-45 score, and mean improvement during treatment were similar to the results obtained with a time window of 90 - 365 days. For more details regarding the sensitivity analyses, see Section F in Multimedia Appendix 1.

Treatment Option Grids

Four treatment option grids were developed for patients with MDD: (1) self-management interventions, (2) short-term treatments, (3) treatment with psychotherapy and vocational therapy, and (4) treatment with pharmacotherapy. The treatment option grids provide an overview of the available evidence-based treatment options and describe when a particular treatment is used, its content, aims and side effects, and what to expect from the treatment. The treatment option grids resulted in a toolkit titled "Shared decision-making for depression - Appropriate care and support" and became publicly accessible on the Dutch national standards of mental health care website in 2021 [51].

The Clinical Decision Support Tool I-SHARED

The I-SHARED report, comprising the patient's summary data and cluster-based treatment selection information, combined with the treatment option grids, resulted in the Clinical Decision Support Tool I-SHARED [41]. The tool was piloted by 2 specialized mental health care providers (results forthcoming). Clinicians were trained on how to use the personalized patient report and the treatment option grids in discussions with patients about treatment choices. This training aimed to ensure that both clinicians and patients are better informed regarding important patient and disease characteristics and potentially successful treatment options.

Discussion

Principal Results and Comparison With Prior Work

Using co-design and cocreation, the I-SHARED decision support tool for patients with depression was developed. I-SHARED consists of personal information summarized in a patient report, including an overview of potentially successful and unsuccessful treatment options based on reference groups, and more general information in treatment option grids. I-SHARED potentially facilitates SDM by providing patients with relevant and objective information regarding treatment options. Also, patients and health care professionals are informed about which treatments would best suit a particular patient, based on historical routine outcome data and patient (treatment) preferences.

Previous research has identified a range of patient needs to enhance SDM, including a summary of treatment options, information about potential side effects, costs and effectiveness of treatment options, examples of previous patient experiences related to the patient's disease and treatment, discussions with their clinician, access to printed information, patient preferences and values, and information from health care professionals and health associations [11-13,52]. Several conditions need to be met to ensure that SDM becomes part of mainstream clinical practice, such as readily available evidence-based information about treatment options, guidance on weighing the pros and cons of treatment options, and a supportive clinical culture that facilitates patient engagement [7]. In our study, we began with focus group discussions to identify patient needs prior to the development of the I-SHARED tool. The needs identified by participants mostly corresponded with those identified in the studies mentioned above. Thus, most of these components were incorporated into I-SHARED or its usage, such as a supportive culture to facilitate patient-clinician discussions.

Several clinical decision support tools have been developed over the years [8,34-36]. Small study sample size hampered the predictive value of most tools regarding treatment response [23]. To address this problem, large prospective observational studies and comprehensive batteries of self-report and clinical predictors are recommended [23]. I-SHARED is based on readily available, low-cost self-report and clinical predictors data. It incorporates personalized treatment recommendations based on intake and outcome monitoring data used in the specialized mental health care setting. Several self-report questionnaires were added to I-SHARED, based on the outcomes of our qualitative research and the scoping review, to routinely capture relevant data not yet available.

In the current clustering algorithm, we used the 3 subscales of the first OQ-45 measurement. The main reason not to include other available questionnaires was lack of patients with complete data. The same was true for sociodemographic data, including living situation and education level. This is a common issue in real-world patient data. Inclusion of these variables would therefore also hinder implementation in practice. Another limiting factor was the fact that the use of less commonly measured variables would result in a model that is not easily implementable across institutions. Furthermore, results might have been influenced by the training population. To facilitate implementation across other institutions, additional training data from these institutions could be incorporated first to reduce bias within the new population. Besides, for accurate clustering, it was important to balance the number of predictors included with the number of patients available in the dataset. In future versions of the algorithm, when more patients are included in the dataset and data from additional predictors become available, we can refine predictions by adding predictors and matching filters to the clustering model.

The sensitivity analyses demonstrated that the distribution of treatments was very comparable for all options compared. Although a time window of 60 - 365 days to select the second OQ-45 questionnaire resulted in a larger sample size (144 more patients), we chose the time window of 90 - 365 days. This decision was made because, first, the median number of days between 2 measurements was 269 (9 mo), and second, a longer window was more likely to capture the treatment effect for psychotherapies and pharmacotherapies.

Strengths and Limitations

A major strength of our study is the optimal use of routinely collected data prior to and during treatment in the Dutch mental health care system. The OQ-45 questionnaire was selected due to its widespread application in adult mental health care in the Netherlands and its suitability for a diverse population, thereby facilitating the potential for increased future usage of the algorithm. Although this data collection was initially set up to improve treatment monitoring, the provision of feedback on the outcomes of the questionnaires to patients is far from self-evident. By incorporating the data into the I-SHARED tool, patients and health care professionals are provided with relevant feedback for treatment selection and monitoring purposes in an accessible way. Second, the outcomes of the clustering process allowed us to inform patients and professionals about potentially successful treatment options based on historical data of treated patients with similar characteristics who had recovered after treatment. Third, the cocreation of I-SHARED by patients, patient organizations, health care professionals, and researchers resulted in a technically sound instrument appreciated by the end users. It explicitly incorporated values and preferences of both patients and professionals. By decreasing information asymmetry, both the I-SHARED report and the treatment option grids enable the patient to start a conversation with the clinician on an equal footing. In this way, I-SHARED facilitates SDM between the patient and the clinician. Patients can express their

treatment preferences, and at the same time, I-SHARED provides clinicians with insight into patient-specific issues, shifting toward patient-centered care.

Our study nevertheless has several limitations. First, it was not possible to incorporate all relevant items revealed by the end users, the scoping review, and data analyses into I-SHARED. Items related to biological or genetic factors or items unknown or not recorded were omitted (eg, cause of depression and therapeutic alliance). Increasing the number of questionnaires has the disadvantage of increasing the administrative burden for patients, and some items do not lend themselves to routine monitoring and may be expensive to measure. Predictors were evaluated on overall response to treatment and not matched for the different treatment types. In addition, predictors derived from the scoping review were not weighted in importance or predictive power since we used these predictors in a cluster analysis and not in a prediction model.

Second, the use of self-report and clinical predictor data allows large sample sizes. However, after data linkage and patient selection, sample size was still moderate. This reflects mainly a lack of complete data regarding the type of treatment and outcomes during follow-up. A flexible design will allow for future updates once more complete data becomes available. Possibly, the availability of tools such as I-SHARED that allow actual use of routine data in clinical practice will enhance data completeness in the future.

Third, treatment data were derived from the treatments that were registered by clinicians for billing purposes and consequently were not always as accurate as desired. For instance, the number of unspecified follow-up contacts was relatively high. Occasionally, the registered treatment may not fully cover the precise content of the treatment received, and overlap in treatments might be possible. For example, when pharmacotherapy is registered, additional nonregistered counseling may have taken place during consultation. However, based on information about the professionals involved, a specific treatment type could be derived for most follow-up contacts. In addition, the “remaining treatments” group should ideally be disaggregated, especially for the specific group of patients that might benefit from it. The lack of specificity in this group of treatments might limit patient confidence and the decisional clarity needed for meaningful engagement.

Finally, from the patients’ feedback, we learned that those with a current depressive episode sometimes feel overwhelmed by the amount of information provided in I-SHARED. Health care professionals thus have a role in selecting the applicable treatment option grids and guiding patients through the I-SHARED report, but SDM still requires an active patient role.

Further Research and Implications for Clinical Practice

I-SHARED focused on enhancing SDM and personalizing treatment; however, further research should investigate whether I-SHARED leads to more effective treatment allocation, improved knowledge, and decreased decisional conflict in patients with depression. Although the latter is likely to be reduced through decision aids in general, the effect on patient (mental) health and treatment effect should be further investigated [53]. In addition, we would like to expand I-SHARED by investigating the prediction of and recommendations for the type of pharmacotherapy, examining both effects and tolerability. Also, we aim to incorporate personal treatment goal formulation and monitoring into the I-SHARED report, which was not feasible in the current system.

During the pilot tests, we observed that the I-SHARED report can be used and generated for any mental disorder; however, the cluster analysis only applies to patients with depression. In its current version, the I-SHARED tool applies to patients with depression as the primary area of concern. Before the I-SHARED report can be used in other patient groups, the cluster analyses should be adapted to patients with other diagnoses, and all relevant treatment options for these diagnoses should be included.

The I-SHARED tool can deal with more recent treatment advancements and can be updated accordingly; the only requirement is that mental health care organizations must register treatment types and monitor outcomes. To date, the I-SHARED report has been implemented in several mental health care organizations and is currently being revised due to changes in questionnaire usage. When new funding becomes available, the algorithm can be updated and improved. The treatment option grids are included as a tool in the Dutch Care Standard for Depressive Disorders and are freely available on the web to inform patients regarding available and suitable treatments based on their personal preferences and goals [51]. The treatment option grids are structurally included in the cycle of revision of the Dutch Care Standard for Depressive Disorders.

I-SHARED is intended for joint use and requires training of health care professionals to use it in daily clinical practice. To this end, we developed training materials and eLearning modules. In addition, we observed that I-SHARED (and SDM in general) requires an active role from patients, who thus also need to be trained to take control during the SDM process. More information regarding I-SHARED and training materials can be found on the I-SHARED website [54].

Conclusions

The development of the I-SHARED tool represents a significant advancement in personalized treatment and SDM for patients with MDD. By providing systematic and comprehensive information regarding symptoms, medical history, contextual factors, and treatment options, I-SHARED facilitates informed and patient-centered treatment decisions. Despite limitations, such as sample size and data completeness, the tool’s cocreation with patient representatives and collaboration with clinicians and data scientists ensures its relevance and usability in clinical practice. Future research should focus on expanding the generalizability of the tool to further enhance its usefulness in clinical practice and support impact on treatment outcomes and patient satisfaction. In addition, the effectiveness of the tool should be studied in experimental settings with a control group.

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Authors' Contributions

KK, TF, FJ, EV, KW, DC, and RS were involved in the conceptualization and methodology of the study. KK, EV, MB, and FB performed data curation. MB, KW, EV, KK, and FJ conducted the formal analysis. TF, FJ, RS, and EV were responsible for funding acquisition. KK, DM, EV, and FJ carried out the investigation. TF and KK led project administration. MB and FJ were involved in software development. KK, EV, MB, FB, and DM contributed to validation. KK, FJ, TF, MB, and FB were involved in writing the original draft.

Conflicts of Interest

None declared.

Multimedia Appendix 1
Further details of the data: variables, data infrastructure and linkage, patient selection, studies of the scoping review, and cluster and sensitivity analysis
[DOCX File, 228 KB - jopm_v17i1e67170_app1.docx]

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Abbreviations

CDS: computerized decision support
GDPR: General Data Protection Regulation
I-SHARED: Instrument for Shared Decision-Making in Depression
IMPROVE: Improving Mental Health care using Personalized treatment based on analyses of Routine data for Optimal Value and Effectiveness
MDD: major depressive disorder
OQ-45: Outcome Questionnaire-45
ROM: routine outcome monitoring
RQ-MIS: RoQua Management Information System
SDM: shared decision-making
UCP: University Center of Psychiatry

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Proof of Concept for a Digital Framework to Support a Shared Agenda at Surgical Ward Rounds: Participatory Design Study

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Abstract

Background: Surgical ward rounds (SWRs) are often unstructured and deprioritized compared to traditional surgical tasks, leading to limited interdisciplinary collaboration, unprepared patients, and low family attendance.

Objective: This study aims to co-design and develop a digital framework to facilitate a shared agenda for SWRs, ensuring all core participants can attend and participate effectively.

Methods: Participatory design (PD) methodologies were used, using user-engaging activities within an iterative process. A multidisciplinary team, including patients, relatives, health care providers, technology designers, and researchers, collaborated in workshops and testing to translate user needs into prototypes of technologies consisting of the digital framework.

Results: A logistics system was developed for nurses to prebook the SWRs in designated time slots, enabling them to prepare relevant data and partake in the dialogue with patients. In addition, a mobile health (mHealth) app displayed the schedule for patients and relatives, helping them to participate and prepare questions in advance. Multiple iterations ensured that the digital framework met user needs and was feasible for clinical practice.

Conclusions: Our findings underscore the importance of collaboration between users and technology designers in developing digital health technologies. Engaging the users helped identify technical and organizational constraints that needed to be addressed to integrate the digital framework into clinical settings.

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KEYWORDS

surgical ward rounds; structured interprofessional bedside rounds; digital technologies; logistics system; patient participation; family involvement; mobile health app

Introduction

Background

Surgical ward rounds (SWRs) are crucial for the communication between patients, their families, surgeons, and the care team, providing opportunities for high-quality, collaborative, and person-centered care planning [1,2]. Nevertheless, research demonstrates that SWRs are often unstructured and deprioritized compared to other surgical tasks, compromising interdisciplinary collaboration, patient and family involvement, and patient safety [3-6]. Due to the senior surgeons' numerous competing commitments, junior doctors often lead the SWRs with minimal learning opportunities and supervision, affecting round quality, efficiency, and structure [7,8]. The unpredictable nature of the SWRs results in the bedside nurses being unprepared and limits their access to attend. Consequently, it hampers their ability to properly contribute with relevant patient information and follow-up [9-13]. Accordingly, patients and their relatives experience the SWRs as disruptive, short, and with a narrow medical focus, making it difficult for them to participate actively. Patients are often unprepared for the SWRs and can

not distinguish between the many health care providers attending the room [14]. Consequently, they are not always aware of the SWRs taking place [15-19]. Due to the lack of planning, the relatives seldom have the chance to attend. As a result, they feel uninvolved and lack information [20,21]. Altogether, existing research indicates that the timing and agenda for the SWRs are primarily set by the doctors, making nurses, patients, and relatives merely passive recipients of treatment decisions and care plans. A central part of person-centered health care communication is identifying issues the patient wishes to address, thereby negotiating a shared agenda for the encounter. Furthermore, a mutual plan of action should be negotiated by involving the patients and relatives in decision-making [22,23]. For this to happen, the participants must be well prepared and given the opportunity to partake. However, the existing organizational structure in the surgical wards seems to hinder the chances of initiating a truly person-centered dialogue. Several studies indicate that implementing a structured approach by informing patients of the timing of the SWRs enhances their readiness for participation and facilitates family attendance. Furthermore, prioritizing a dedicated time for SWRs would enable nurses to schedule their day more effectively, ensuring they are prepared and can attend [15,16,21,24,25]. Building on this previous knowledge, our study explores how such structured approaches can be adapted and implemented within the specific organizational context of SWRs. Digital technologies have been suggested to support nurses, patients, and relatives to partake in ward rounds, eg, by notifying nurses and patients via electronic devices [26-30], mobile health (mHealth) apps [31-33], and video communication with relatives [34-38]. Patients and health care providers recognize the benefits of these digital technologies [14]. However, existing solutions are fragmented, typically targeting only a single participant group, and their adoption is limited by user reluctance, as well as technical and organizational barriers [26-28,31,33,37]. To unlock their full potential, digital technologies must be integrated into more innovative, user-centered designs that align with the needs of key participants and the clinical settings in which they are intended to be used [32]. A suitable method for developing digital technologies that meets the needs of both patients, relatives, and health care providers is participatory design (PD). Central to PD is mutual learning, aiming to balance the power between users and technology designers through knowledge sharing. Researchers and designers require a deep understanding of the needs, clinical context, and experiences of the users, while users benefit from the technological knowledge of the designers. This collaborative and democratic approach empowers users to influence the design of digital technologies affecting their lives [39].

Objective

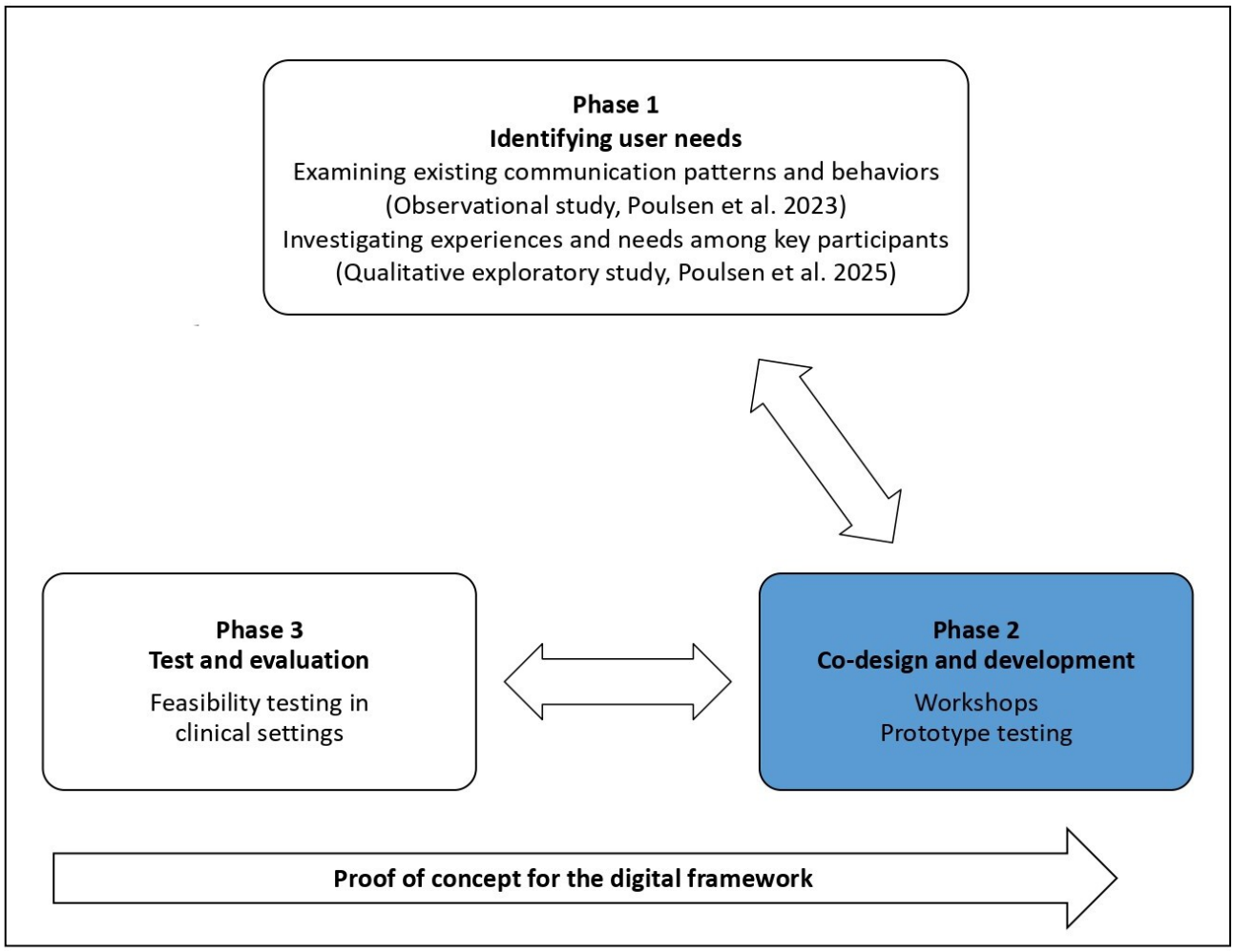
This study aims to co-design and develop a unified digital framework to ensure that all core participants can actively engage in and contribute to the agenda and decisions made at SWRs. We define a digital framework as a structured system that supports communication and collaboration among health care providers, patients, and relatives, with intentional coordination of both human and technical components.

Methods

Study Design

In health research, PD studies typically adopt an iterative, phase-driven approach, beginning with identifying user needs, followed by prototype design and development, and concluding with pilot testing and evaluation [40,41]. In Phase 1, we have investigated existing communication patterns and behaviors during SWRs as well as experiences and needs among key participants. The results are reported in previous studies [14,20] and informed the planning of this study. In this study (Phase 2), we co-designed and developed the digital framework through workshops and prototype testing with various key stakeholders to address the needs identified in Phase 1. In Phase 3, the organizational requirements of the digital framework were tested for feasibility in clinical settings. These results further informed the design process. All phases were conducted iteratively throughout the PD study (see Figure 1). Literature studies were conducted continuously to broaden our understanding of the emerging findings. This paper presents and critically discusses the findings from Phase 2, which serves as a proof of concept for the digital framework.

Figure 1. The 3 phases of the digital framework design and development [14,20].



Ethical Considerations

PD research respects the fundamental human right to actively influence the design of digital technologies, elevating users from mere informants to recognized and integral participants in the co-design process [41]. To achieve this, a trustworthy and collaborative relationship among users, researchers, and technology designers must be established, providing users with the power to partake in decisions. Hence, all choices made by the design team and researchers were guided by user feedback through various user-engaging activities. Each user must willingly participate in such activities, working as themselves, with themselves, and for the task and project at hand [39]. All participants provided written informed consent and were informed that they could withdraw from the user activities at any time without consequences. The study was approved by the Danish Data Protection Agency (Journal 20/60035), and personal data were stored in compliance with the European General Data Protection Regulation (GDPR). To protect participants' privacy and maintain confidentiality, data material was anonymized. The study was reviewed by the Regional Committees on Health Research Ethics of Southern Denmark and deemed exempt from the Danish Committee Act (case S-20252000 - 37). Participants did not receive any compensation for their participation in the study.

Setting and Participants

The setting was a surgical ward at Lillebaelt University Hospital, which provides treatment and care for acutely admitted adult patients primarily suffering from benign gastrointestinal disorders. The hospital is located in Southern Denmark, serving approximately 300,000 residents. The workshop participants included doctors, caretakers, patients, relatives, and a support team with skills in health care communication and quality, IT systems, information technology, and PD research. The health care providers were purposively selected to represent differences in gender, roles, seniority, and experience level in the surgical ward. Patients and relatives were enrolled during interviews conducted in the first phase of the study. Thus, in this study, these were former patients discharged within 1 to 2 months. In prototype testing, all eligible inpatients, relatives, and health care providers present were asked to participate. The inclusion criteria targeted acutely admitted Danish-speaking patients and their relatives who were ages 18 years or older. Individuals diagnosed with dementia, delirium, or other conditions leading to disorientation were excluded. Totally, 12 doctors were recruited, of whom 7 were highly experienced senior surgeons and 5 were junior doctors with low experience. The caretakers were either registered nurses or nurse assistants; some had special functions, for example, as specialist nurses, coordinating nurses, or head nurses. In total, 16 caretakers were recruited. A total of 13 patients and 9 relatives were recruited, and the

support team consisted of 8 individuals. Altogether, 58 participants were enrolled in this second phase of the PD study (see Table 1).

Table . Characteristics of participants and their attendance in workshops and tests throughout the participatory design process.

Participants (n=58)	Characteristics		Overview of attendance, n				
	Males, n (%)	Experience[a]/age range	Creative workshop	Future workshop	Mock-up workshop	Laboratory testing	User testing
Doctors (n=12)	7 (58)	<0.5-20	5	5	2	0	9
Senior surgeons (n=7)	5 (71)	0.5-20	2	2	1	0	6
Junior doctors (n=5)	2 (40)	<0.5	3	3	1	0	3
Caretakers (n=16)	2 (13)	<0.5-21	4	4	1	0	13
Specialist nurses (n=2)	0 (0)	3-21	2	2	1	0	1
Work environment nurse (n=1)	1 (100)	2	1	1	0	0	0
General nurses (n=6)	0 (0)	<0.5-12	1	1	0	0	5
Coordinating nurses (n=2)	0 (0)	2-3	0	0	0	0	2
Head nurses (n=2)	0 (0)	<0.5-5	0	0	0	0	2
Nurse assistants (n=3)	1 (33)	1-11	0	0	0	0	3
Patients (n=13)	7 (54)	31-84	4	2	0	0	9
Discharged patients (n=4)	2 (50)	68-82	4	2	0	0	0
Inpatients (n=9)	5 (56)	31-84	N/A[b]	N/A	N/A	0	9
Relatives (n=9)	3 (33)	31-93	4	2	0	0	5
Partners (n=6)	2 (33)	59-93	3	2	0	0	3
Adult children (n=2)	1 (50)	39-50	1	0	0	0	1
Friend (n=1)	0 (0)	31	N/A	N/A	N/A	0	1
Support team (n=8)	2 (25)	0.5-15	4	6	4	5	5
Communications consultant (n=1)	0 (0)	5	0	1	0	0	1
Quality coordinator (n=1)	0 (0)	10	1	1	0	0	1
Technology designer (n=1)	1 (100)	14	0	0	1	1	0
IT-coordinators (n=2)	0 (0)	0.5-9.5	1	2	1	2	1
Robot technologist (n=1)	1 (100)	4.5	N/A	N/A	N/A	1	1
Researchers (n=2)	0 (0)	1.5-15	2	2	2	1	1

[a]Years of experience in the surgical ward/years of experience in current role.

[b]Not applicable.

Data Collection

Data were collected through a series of workshops and prototype testing conducted between October 2021 and January 2023: (1) creative workshop generating ideas for the digital framework, (2) future workshop developing requirements needed to fulfill user needs, (3) mock-up workshop discussing initial design concepts, (4) laboratory testing of functionalities and user-flows of the initial prototypes, and (5) user testing of high-fidelity prototypes in clinical settings. The first 2 workshops were facilitated by 2 innovation consultants specialized in co-operative design processes, drawing on the concept of Future workshops developed by Jungk and Müllert [42]. These workshops were structured into distinct phases (critique, vision, and implementation) to collectively critique the current system and develop proposals for a more desirable future. The workshops were held in a conference room at the hospital and each lasted 4 hours. Data consisted of written post-it notes from participants, field notes taken by HP and JC, photographs, and audio-recorded transcripts. HP and the IT coordinators facilitated the mock-up workshop and the prototype testing. The mock-up workshop lasted 3 hours, while the laboratory and user testing spanned 46 hours over nine days. These activities were held in IT environments and real-life settings, respectively. Feedback reports with adjustments needed to ensure usability, along with photographs and screen prints, served as data for this part of the study. The user activities followed the PD approach, iterating through the steps: plan, act, observe, and reflect [40,41]. After each workshop or test, the researchers shared insights and perspectives as part of the initial analysis. Thus, each activity was planned based on reflections from the previous one, using detailed scripts outlining the various steps and responsibilities.

Creative Workshop

The creative workshop focused on generating ideas for the digital framework based on user needs. A total of 21 team members participated in this workshop (see Table 1). The workshop comprised both a critique and a vision phase. In the critique phase, the participants were presented with the critical findings from Phase 1, allowing them to comment or contribute with new perspectives. In the vision phase, participants were divided into 4 groups and encouraged to list user needs and ideas to address them for each step of the SWR process: (1) during preparation, (2) in the patient room, and (3) when following up. A total of 2 groups entailed nurses and doctors, respectively, and 2 entailed a mix of patients and relatives. The support team was assigned to various groups, supporting the discussions, observing, and listening to the ideas and concepts being generated. Participants were encouraged to be creative and to record their thoughts, ideas, and visions without considering organizational or economic constraints. Each group recorded their needs and ideas on post-its and arranged them on posters illustrating the 3 steps of the SWR process. Posters were subsequently presented and discussed in a plenary session. After the workshop, the researchers and innovation consultants summarized the user needs and ideas into a Service Blueprint, visualizing the user journey of the SWRs.

Future Workshop

The future workshop comprised the implementation phase, which aimed to develop feasible concepts based on the ideas generated in the creative workshop. A total of 19 team members participated in this workshop (see Table 1), which began with qualifying the Service Blueprint. The participants were divided into similar groups as in the creative workshop. First, the groups were asked to write supplementary comments or immediate ideas on post-its and place them on the Service Blueprint. Subsequently, each group was tasked with developing precise and realistic descriptions of requirements for selected ideas from the Service Blueprint. The final part was exclusively dedicated to the health care providers, who focused on developing a detailed organizational framework necessary for implementing the proposed technologies into clinical practice. Based on the workshop, product requirement specifications were developed by the research team, outlining prioritized requirements for the digital framework as specified by the users. The requirements specification process hinged on the idea that the users understood what the digital technologies should do and why, while the technology designers had the technical expertise to determine how to make it work. Thus, the requirements specifications were handed to an IT company for further processing. The specifications were not static and were constantly revised and refined through iterative processes and collaborations between users, researchers, and technology designers in the upcoming user activities.

Mock-Up Workshop

Using the product requirements specifications as a starting point, 2 doctors, a specialist nurse, and 4 support team members participated in a mock-up workshop conducted at the IT company (see Table 1). During the workshop, participants created low-fidelity prototypes of the digital framework using simple, nondigital representations such as drawings and wireframes. The technology designers introduced various ideas for different design concepts through whiteboard sketches. This approach allowed the participants to explore multiple design directions through rapid and intuitive iterations before proceeding to more detailed design elements. From these sketches, initial wireframes of the digital framework were developed to agree on the basic structure and functionalities of the IT systems needed. The wireframes entailed visual representations of the basic idea of the digital framework. Following the workshop, the technology designers and IT coordinators created mock-up versions of the digital framework, which were handed to the health care providers and researchers for feedback and corrections. From these low-fidelity prototypes, a revised requirements document, and a specifications document describing detailed component requirements for the various subsystems of the digital framework were developed.

Laboratory Testing

Based on the revised requirements documents, the IT-coordinators and technology designers developed high-fidelity prototypes of the IT systems. These prototypes were laboratory-tested by 5 members of the support team (see Table 1). In a test setup at the IT department, the prototypes' performance, functionality, and security were tested in a

controlled environment simulating real-life conditions without affecting live systems. The functionality of every single component was tested to verify whether the prototypes met the requirements and functioned correctly under various circumstances. Different usage scenarios were exposed to ensure the software handled the expected demands. Furthermore, compatibility was tested to ensure the software worked correctly across different devices (iOS, Android, and web). Feedback on requirements that were fulfilled or neglected was sent to the technology designers and IT coordinators to be refined or changed.

User Testing

A total of 41 participants, including 22 health care providers, 14 patients and relatives, and 5 support team members, conducted user testing through simulated interactions with the revised high-fidelity prototypes (see Table 1). These versions closely resembled the look, feel, and functionality of the final products, and realistic data were used to replicate their actual use. Participants alternately tested the prototypes in a simulation room within the surgical ward. If patients could not move to the simulation room, the test setup was moved to their rooms. Each participant focused on testing the functionalities relevant to them while the researchers simulated the roles of the other participants. The purpose of the user tests was to ensure that the high-fidelity prototypes met user expectations and achieved precise adaptation in clinical practice, as well as to validate design decisions, visual aesthetics, and interactive elements. Detailed feedback on user experiences and interactions was sent to the technology designers and IT-coordinators for final revisions before releasing the advanced prototypes. Table 2 visualizes the various user-engaging activities and their outputs during the PD process.

Table . User-engaging activities and their outputs during the participatory design process.

User-engaging activities	Outputs (from user needs to advanced prototypes)
Workshops	
Creative workshop	Service Blueprint
Future workshop	Product requirements specifications
Mock-up workshop	Low-fidelity prototypes
Test setup	
Laboratory testing	Advanced prototypes
User testing	High-fidelity prototypes

Data Analysis

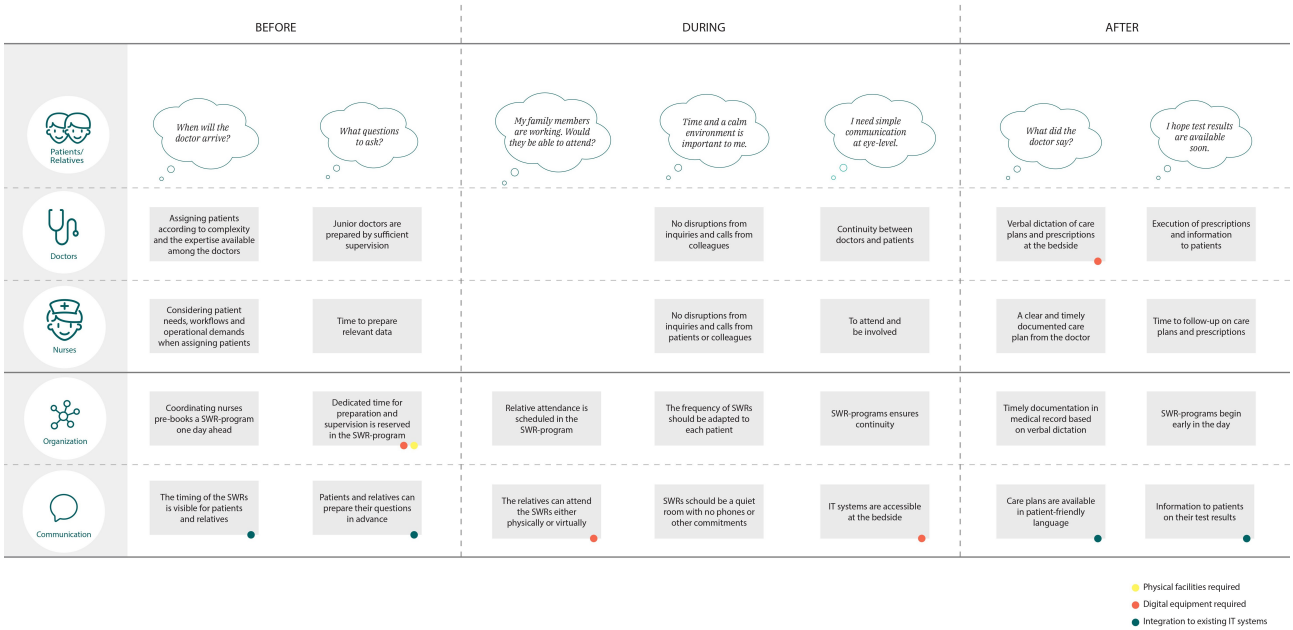
Notes, transcribed material, and feedback gathered from each user activity were analyzed, inspired by systematic text condensation, to get an overview of each activity's dominating themes, ideas, and feedback [43]. The analysis followed a 4-step process, beginning with a thorough reading of the text material while identifying preliminary themes (Step 1). Next, meaningful units from each data source were extracted (Step 2), organized into subcategories (Step 3), and grouped into broader overall categories (Step 4) [43]. Analysis matrices with direct quotes and post-it notes from participants, along with excerpts from the product requirements specifications, are provided in supplementary files to enhance the credibility and confirmability of the findings and design decisions.

Results

Service Blueprint

As a result of the creative workshop, the Service Blueprint (see Figure 2) mapped the structure and key elements of the SWR process, highlighting user needs and supporting processes. This provided an understanding of the relationships between the various steps of the SWR process, including the front-stage actions, back-stage processes, and IT systems needed to fulfill user needs. The Service Blueprint was vertically divided into three columns representing each step of the SWR process. Horizontally, the user needs of each group of participants were listed in the upper half section. In the lower half section, the back-stage organizational processes and front-stage communicative actions suggested to address user needs were listed. Dots represented demands for the physical facilities, digital equipment, and IT systems needed.

Figure 2. Service Blueprint visualizing dominating user needs across the surgical ward round (SWR) process (upper half) and suggested ideas to address them (lower half).



Dominating needs of patients and relatives were to be informed well in advance about the timing of the SWRs, allowing them to attend and prepare relevant questions. The doctors requested a more deliberate distribution of patients, considering the condition of patients and the expertise of the doctors. If the patient case were complex, junior doctors needed to be prepared through supervision from seniors. Nurses sought to have a say in the order of patients, considering patient needs, their workflows, and the operational demands of the ward when assigning patients. Furthermore, they required adequate time to prepare relevant patient data. Doctors emphasized that the nurses had the best overview of patients to properly distribute them and suggested that they should be responsible for planning a SWR-program. The nurses agreed but emphasized that the distribution process should not be too time-consuming for the individual nurse. Thus, it was decided that the coordinating nurses should be overall responsible for prebooking the SWRs a day ahead (see Multimedia Appendix 1). An important theme for patients and relatives during the SWRs was to have sufficient time in a calm environment to have an attentive conversation with health care providers communicating at eye-level. The health care providers wanted to minimize disruptions from inquiries and calls from other patients or colleagues during the SWRs by planning a dedicated time for the conversation. In addition, senior doctors suggested that the frequency of SWRs should be tailored to each patient and emphasized that continuity, achieved by conducting rounds on consecutive days with the same doctor, would lead to more efficient and attentive SWRs. Patients and relatives agreed that SWRs should be conducted only on days with a clear agenda. Furthermore, the participants agreed that IT systems should be available at the bedside to access relevant information and data. Patients and relatives highlighted that they appreciated when the health care providers visually displayed information from the electronic medical record on the computer screen, for example, test results, x-rays, or scans. Nurses emphasized that prescriptions and care plans should be handed directly to the care team at the bedside and be timely recorded in the medical record to ensure optimal follow-up. The doctors preferred to dictate their prescriptions verbally at the bedside to automatically integrate these into the electronic medical record, but needed updated systems and equipment to do that efficiently. Patients had difficulties remembering the information from SWRs. Thus, they requested access to verbal or written summaries of the care plans.

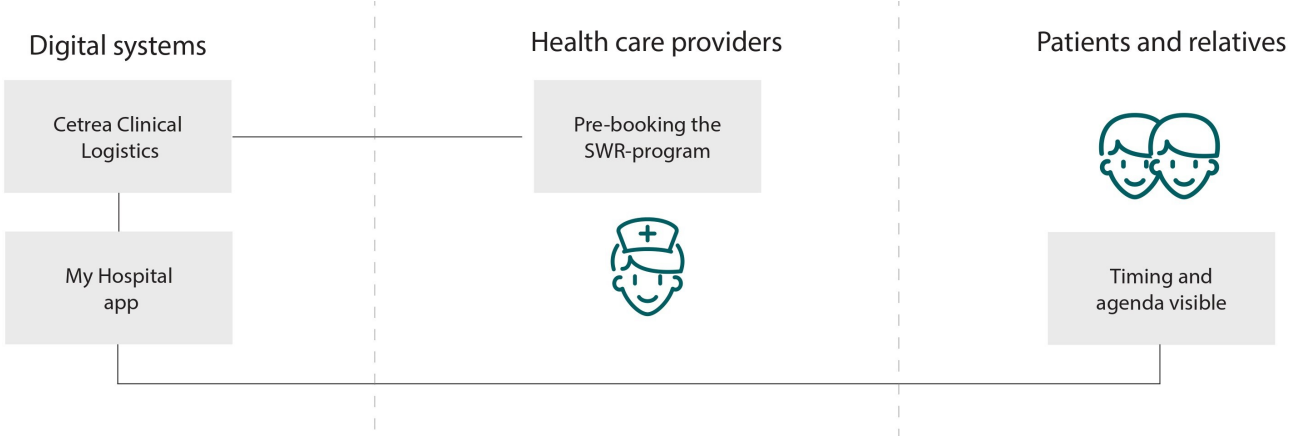
Product Requirements Specifications

The product requirements specifications entailed the bottom lines of the Service Blueprint encompassing back-stage organizational processes and front-stage communicative actions to address user needs. These were expanded into more detailed requirement components, and the participants prioritized each from 1 to 3. The first priorities were “must-haves,” representing essential requirements. The second priorities were “should-haves,” representing requirements to be met if possible. The third priorities were “nice-to-haves,” representing nonessential requirements that were not critical to the core concept of the digital framework. Must-haves were a booking system to prebook the SWR-program, allowing the nurses to prioritize patients appropriately. Furthermore, the timing and names of the attending doctor and nurse should be visible to the patients and relatives. If possible, the timing should be presented as time slots with a defined start and end time. In addition, it was considered helpful, although not essential, if patients and relatives could access the agenda for the SWRs to prepare themselves by noting questions for the doctors. Furthermore, photo presentations of the health care providers were considered a nice-to-have feature (see Multimedia Appendix 1). Since computers-on-wheels with voice recorders were already available for health care providers to use at the bedside, and patients had access to their electronic medical records online to revisit care plans, developing new technologies to support communication during and after the SWRs was not a top priority. However, patients requested a more patient-friendly language in the electronic medical record.

Low-Fidelity Prototypes

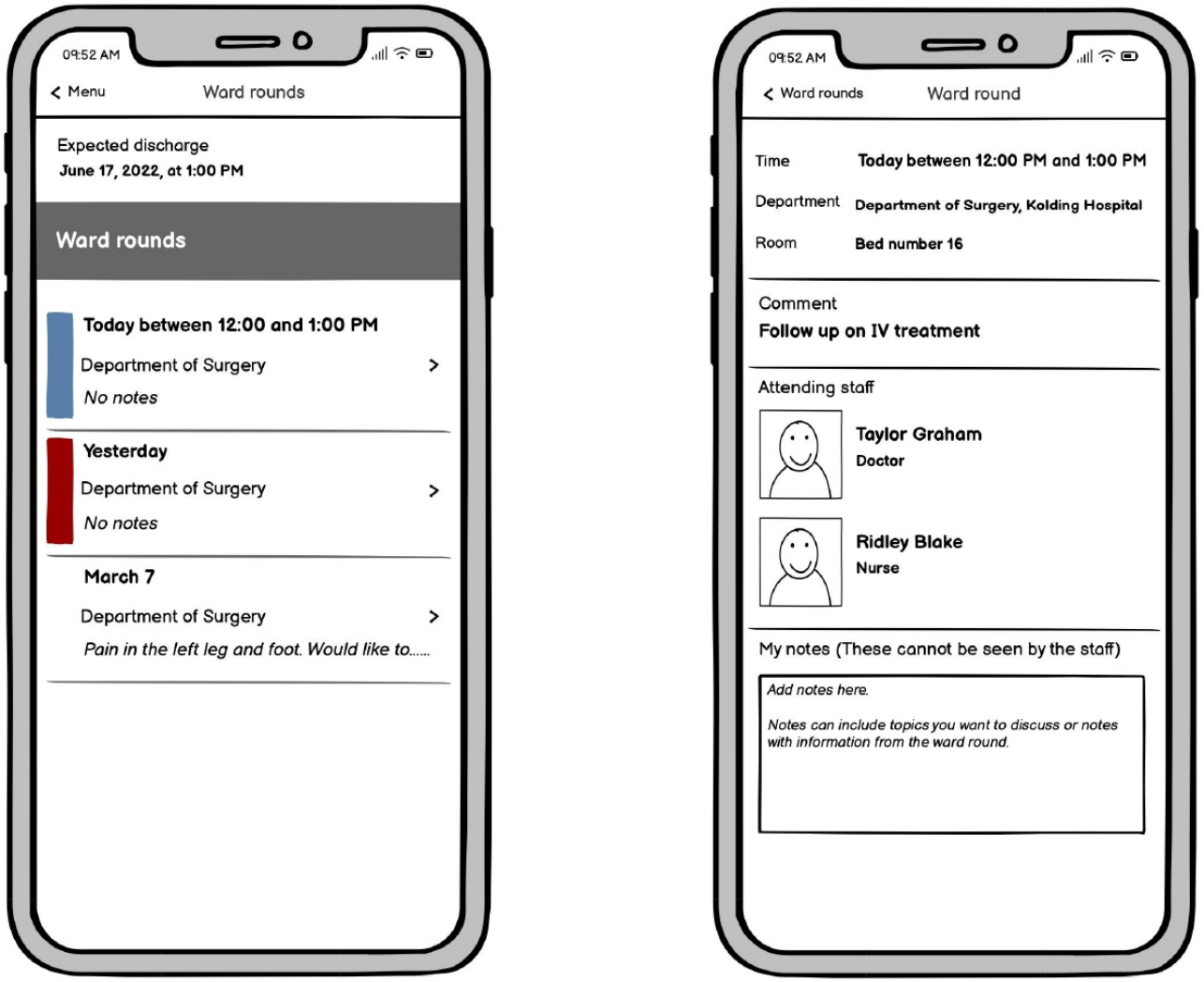
The health care providers emphasized that automation and integration to existing IT systems were of utmost importance to ensure implementation of the digital framework. Thus, the initial wireframes entailed 2 central and integrated IT systems at the hospital (see Figure 3): (1) a logistics system used by the health care providers and (2) an mHealth app for patients and relatives. The health care providers suggested that the SWR-program should be developed as part of the existing IT system, Cetrea Clinical Logistics, which is the leading patient flow management solution in Denmark. The system was already in use at the department, providing an overview of central activities in the patient journey. To inform the patients and relatives of the SWR schedule, participants suggested that a module should be developed as part of the existing mHealth app My Hospital, used by patients across the Region of Southern Denmark. My Hospital was already integrated with the electronic medical record. However, to make data from Cetrea Clinical Logistics visible for patients, the technology designers proposed a software robot to enable automatic data transfer.

Figure 3. Wireframes of the basic idea of the IT systems to be part of the digital framework. SWR: surgical ward round.



The IT coordinators created the SWR-program in Cetrea Clinical Logistics, enabling the nurses to prebook the SWRs in time slots. To enhance interdisciplinary collaboration, names and diagnoses of patients, pictures, and telephone numbers of attending doctors and nurses, and the nurse agenda for the round appeared in the program. To make the timing and agenda visible to patients and relatives, the technology designers developed a mock-up version of the app module in My Hospital. A list of prebooked SWRs appeared in the first screen frame, along with the expected discharge date (see Figure 4A). To accommodate difficulties among patients in recognizing the SWR team, names and pictures of the participating doctor and nurse were provided in the second screen frame. In addition, a note section to prepare questions for the doctors was added (see Figure 4B). Using My Hospital as an IT platform enabled relatives to get access if the patient provided consent, and video communication was available.

Figure 4. Mock-up version of the app module for patients and relatives.



(A) (B)

High-Fidelity Prototypes

Implementing the SWR-program required massive organizational changes. Thus, the logistics system was feasibility tested in clinical practice before proceeding (part of Phase 3). Using the SWR-program in clinical practice revealed a need for flexibility in time slots to be able to adhere to the appointments scheduled for visiting patients and the different workflows of senior and junior doctors. Thus, various widths of time slots and dedicated time for preparation, supervision, and follow-up were developed on individual SWR tracks. As senior doctors had multiple commitments and often prepared to visit 2 to 3 patients in a row, their time slots were set to 2 hours as the standard. Junior doctors generally prepared for one patient at a time. Thus, their time slots were set to 1 hour.

An emergency track was established for newly arrived or critically ill patients or patients who did not require a specific appointment. This track had no fixed time slots. Instead, the nurses prioritized the patients in order 1, 2, and 3 based on specific criteria. Ideally, a senior and junior doctor should manage this track collaboratively, freeing the doctors from the time-scheduled tracks from this commitment. To ensure attentive conversations and optimal use of time, it was decided that the health care providers should jointly agree with their patients on the timing of their next appointment at the end of each SWR. Nurses emphasized that the SWR-program should end at least an hour before shift change to ensure optimal follow-up. Once the SWR-program were fully developed in Cetrea Clinical Logistics, the robot technologist coded the data and shared it with the technology designers. Based on the available data, they developed a high-fidelity prototype of the app module. Laboratory testing led to multiple adjustments to ensure an interactive representation that appeared meaningful for patients and relatives. This version entailed the functionalities already agreed on in the mock-up version but featured realistic user experiences, making it suitable for user testing.

Advanced Prototypes

In the user testing, the caretakers requested that the SWR timing should be visible on their care lists along with other essential information about each patient. This functionality was added in Cetrea Clinical Logistics. Some health care providers reacted to their full names being displayed for patients in the mHealth app. However, from a patient's perspective, knowing the names

of the health care providers was desirable. Thus, surnames were removed, while first names remained. Some participants suggested that patients should be able to share their questions with the health care providers through the app. However, opinions on this were mixed. Some patients would like the health care providers to be prepared for their questions, while others preferred to keep their written questions private. Some doctors, especially the junior ones, would appreciate the chance to prepare for questions in advance, whereas others worried that they might not be able to fulfill the expectation of preparing for the questions beforehand. Some relatives expressed a wish to receive written responses to their questions in the app, especially if they were not able to attend the SWR. As only 1-way communication was technically possible in the high-fidelity prototype, transferring data from the app to the health care providers was not feasible. Thus, the preparation of questions remained a private matter. Some patients, particularly the elderly and frail, had limited digital health literacy and required assistance from caregivers to use the mHealth app. To address this, simple user manuals were developed, and iPads were made available for patients who wanted to use the app but did not have a device. If patients were still unable or unwilling to use the app, the users suggested that the information should be provided in an analogue format on whiteboards at the bedside. Due to ongoing adjustments of the SWR-program during the day, the health care providers noticed a risk of spamming patients with incorrect bookings if the software robot operated continuously. Participants agreed that the highest priority was to avoid confusing patients with frequent changes. Therefore, they decided that the robot should be activated at scheduled times: at 2:30 PM, once the SWR-program for the next day was planned, and at 9:00 AM, when the doctors and nurses had entered their names into the program. Yet, this decision did not allow electronic notifications to be sent to patients about potential delays in the SWR-program, which was a major concern for the health care providers. To align expectations with the patients and relatives, they were informed that time slots were estimated and delays might occur, which they fully accepted. Yet, nurses reiterated the need for improved adherence to the time slots, especially among the senior doctors. Senior doctors expressed a desire to know when relatives attended the SWRs, allowing them to be even more mindful of time slots in those cases. To support this, it was agreed that nurses should note in the SWR-program whenever relatives were present (see Multimedia Appendix 1). Furthermore, a steering committee, comprising 2 specialist doctors, the department management, and a clinical nurse specialist, was appointed overall responsible for potential further adjustments of the SWR-program during the forthcoming implementation process. Ultimately, advanced prototypes of the logistics system and the mHealth app were released (see Figure 5). These, along with the electronic medical record, constituted the digital framework developed through the PD process (see Figure 6).

Figure 5. Screenshots of the advanced prototype of the mobile health app (Danish version).

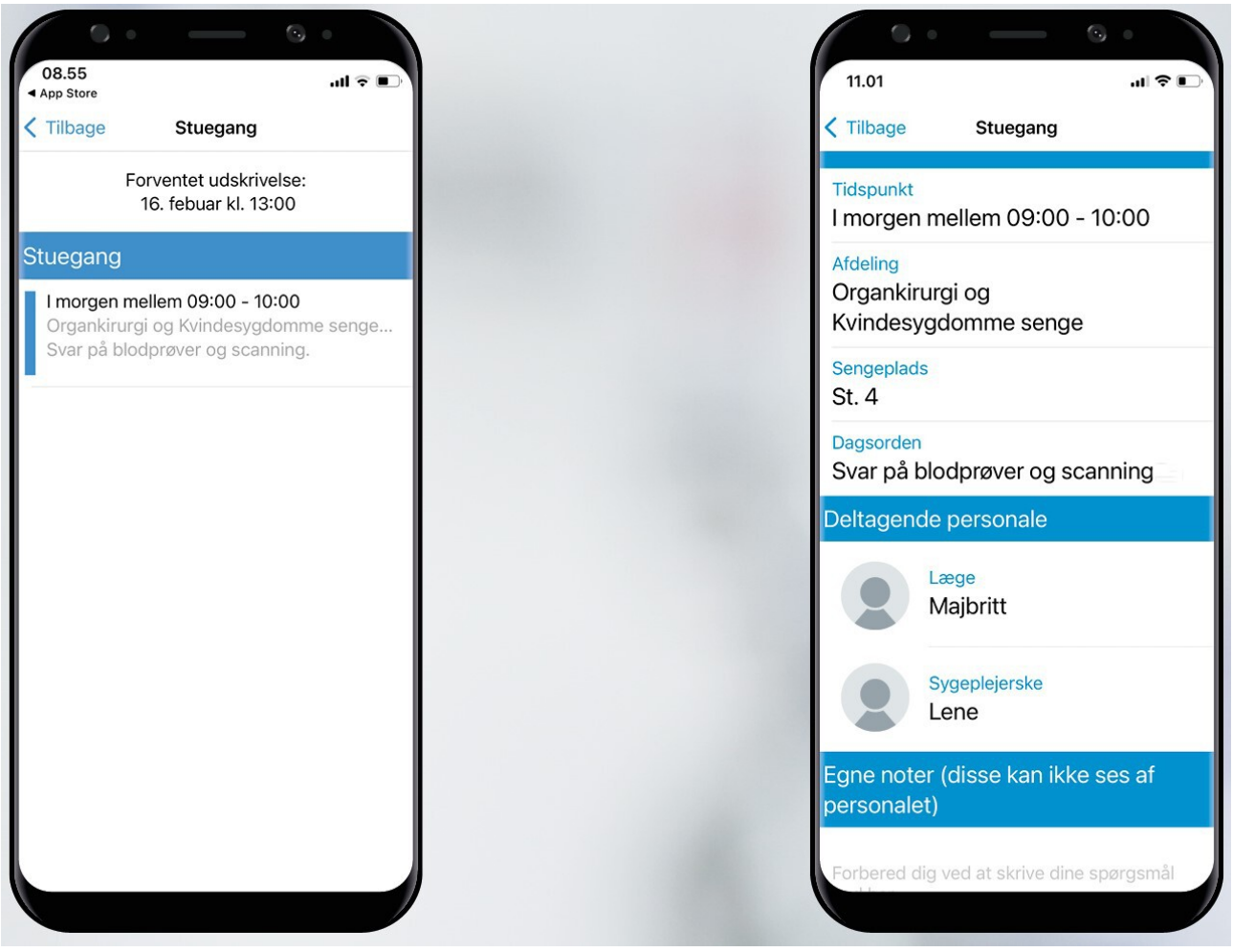
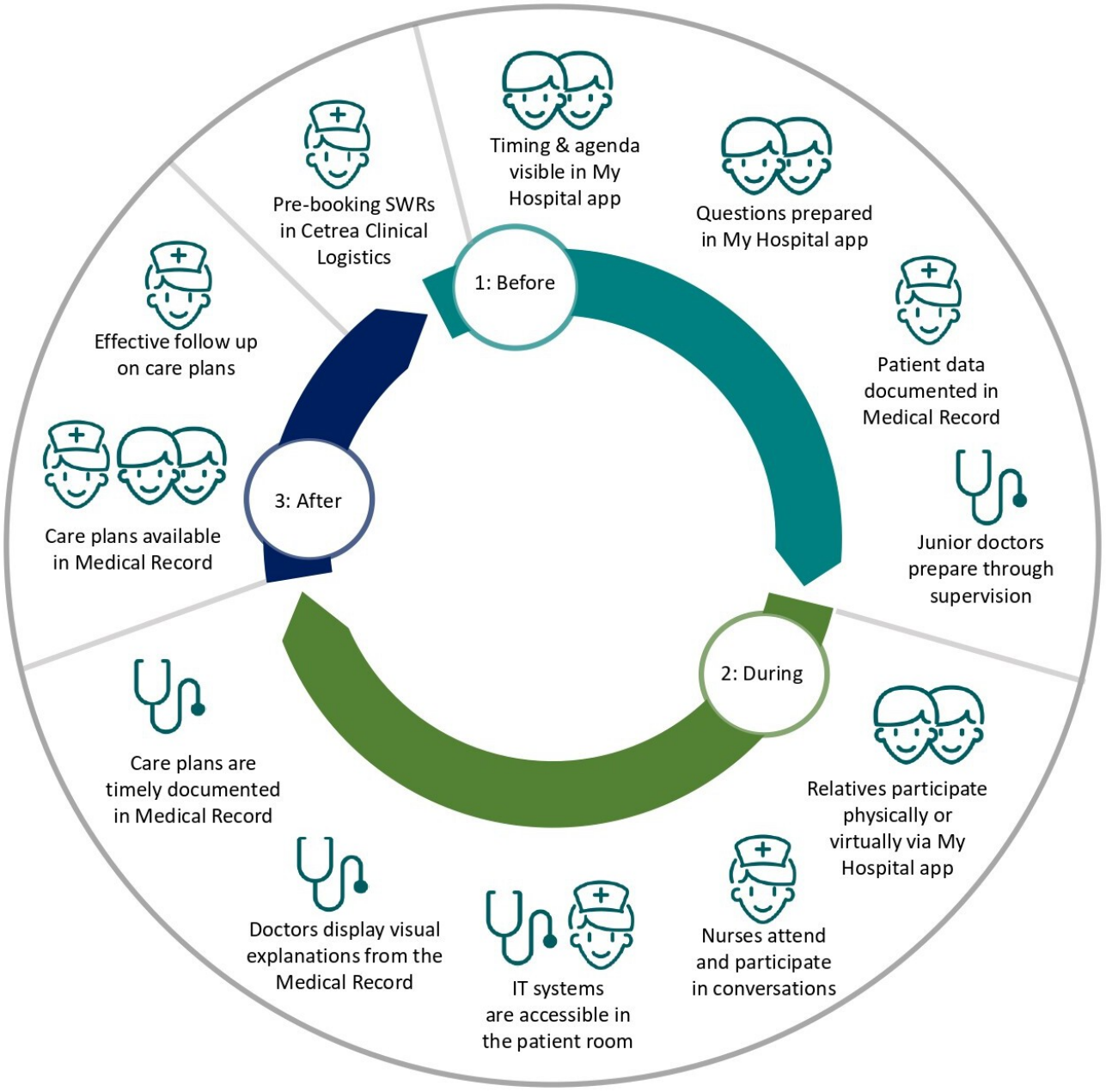


Figure 6. Digital framework to support a shared agenda at surgical ward rounds.



Discussion

Principal Findings

Using PD, we collaboratively designed, refined, and tested a unified and context-sensitive digital framework to support a shared agenda at SWRs. The highest priority of the users was to improve the processes leading up to the SWRs, and they emphasized that the presence and readiness of all core participants was essential for initiating a person-centered dialogue. To facilitate this, a logistics system was developed, enabling the coordinating nurses to prebook SWRs a day ahead and allowing patients and their relatives to access the schedule through an mHealth app. The design of the digital framework was guided by the assumption that increased transparency around the timing and content of SWRs, combined with the opportunity for patients and families to submit questions in advance, could enhance their sense of preparedness and support more active engagement during the round. Although the framework primarily targets logistics, it represents an initial step toward reshaping the nature of ward round conversations from being predominantly doctor-led to being more collaborative and person-centered. Workshops and prototype testing played a crucial role in developing the digital framework, enabling ongoing refinement in close collaboration with users until an acceptable and contextually appropriate solution was achieved. Thus, our study, like many others [44], underscores the significance of the active collaboration between technology designers and users as a key to developing innovative digital technologies that can be successfully integrated into the health care system. More specifically, our study demonstrates how PD can be used to navigate technical and organizational constraints that might otherwise hinder implementation.

Comparison With Previous Work

Providing the participants with a solid foundation for preparation adheres to the core principles of initiating a person-centered dialogue. According to the Calgary-Cambridge guide for evidence-based health care communication, a key aspect of initiating the encounter is to confirm the issues to be discussed and to screen for additional questions, thereby negotiating a shared agenda for the encounter [22,23]. This process ensures that both the agendas of the health care providers and those of the patients and relatives are incorporated into the dialogue. The digital framework aims to support this, by facilitating patients and relatives to prepare themselves by documenting their questions in the mHealth app beforehand. Correspondently, Walton et al [45] suggest that preparing patients for what to expect and providing them with the round schedule might facilitate their inclusion in conversations and lead to more person-centered communication. Furthermore, in video-consulted rounds with relatives [38], patients describe the benefit of having a fixed time, allowing them to prepare in advance.

At our hospital, basic communication behaviors are taught through communication skills training based on the Calgary-Cambridge guide. This training has shown positive effects on the health care providers' self-efficacy and communication behavior, fostering a more person-centered approach [46,47]. Nevertheless, our study emphasizes the importance of considering the organizational frameworks that shape the encounters, particularly in the wards where key participants may be absent or unprepared to engage in the dialogue. Several studies [34-38] suggest that enabling video communication can offer family members flexible alternatives to participate and enhance their involvement in patient care. However, most family members perceive video calls as a supplementary option and prefer in-person communication, especially when conversations include serious messages [35,36]. Furthermore, time, culture, and change of work routines have been found to be the primary barriers to implementing video communication [37]. The digital framework developed in this study supports the organizational changes necessary to coordinate family participation at SWRs, with video communication as an option when physical presence is not feasible.

Another essential yet often overlooked behavior of health care providers is to begin the encounter by greeting the patient and introducing themselves and their roles [22,23]. The mHealth app supports this by providing names and pictures of the attending doctor and nurse for patients and relatives to recognize the SWR team. Similarly, other studies [31,33] have reported high satisfaction levels and perceived usefulness of apps delivering patient information, along with pictures, names, and role descriptions of care team members. Vawdrey et al [33] noted that patients regarded care team information as one of the most beneficial features. In addition, O'Leary et al [31] found that providing this information significantly increased the percentage of patients recognizing their attending doctor. Nevertheless, these apps proved not to affect patient activation.

Investigating interdisciplinary collaboration, Walton et al [48] emphasized that having the right individuals present at the right time, along with a clear understanding of each person's roles and responsibilities, is essential for effective teamwork. In addition, several studies [26-28] indicate that advance notifications of round schedules increases nurse attendance, fosters cultural change, and may ultimately improve patient outcomes, including greater satisfaction, improved care coordination, and slight reductions in length-of-stay. The digital framework, developed in our study, went even further and gave the nurses the power to influence the SWR schedule. This represents a significant shift from the traditional round culture, in which the doctors solely dictated the timing and agenda for the SWRs. The nurse agenda was clearly outlined in the SWR-program to be integrated into the discussions, as recommended in the Calgary-Cambridge guide [22,23]. Correspondently, Truelove et al [29] identified that nursing-centered round schedules and including nursing input at the beginning of encounters were critical factors for improving nurse attendance. Furthermore, the nurse agenda was visible for patients and relatives in the mHealth app. Accordingly, Vestergaard et al [36] suggest that predefining the topic of rounds might help family members to attend to important messages. However, future versions of the mHealth app should consider allowing patients and relatives to influence the round schedule and share their questions with health care providers in advance. Similarly, Ratelle et al [49] suggest that encouraging patients to inform health care providers about their goals, concerns, and questions might prepare doctors to address these issues and consider psychosocial factors extending beyond the hospital stay.

Although the process leading up to the SWRs was the primary focus area of the digital framework, the users emphasized several essential aspects to consider during and after the SWRs. These include minimizing interruptions, communicating at eye level, providing tailored explanations and illustrations, and clarifying care plans and next steps. Each of these practices are central aspects of evidence-based health care communication [22,23] and the digital framework support them in various ways. Scheduling the SWRs might reduce interruptions and foster more attentive dialogues. Furthermore, bringing IT systems to the bedside allows health care providers to access visual illustrations and information from the electronic medical record, dictate mutually acceptable care plans at the bedside, and collaboratively schedule the next SWR. The use of mobile devices such as tablets or computers-on-wheels for information sharing and patient engagement during rounds has been investigated in several other studies [50-52]. Crowson et al [52] found that the use of mobile tablets significantly shortened the round duration and increased time spent with patients. This suggests that mobile devices can effectively reduce time-consuming activities, such as leaving the bedside to look up medical queries and ease documentation practice. However, the extent to which doctors use these mobile devices varies significantly [50,51]. Future studies should investigate acceptable and time-efficient approaches, such as ambient artificial intelligence [53], to enhance bedside rounding documentation to foster more attentive conversations, provide patient-engaging information, and optimize follow-up care.

Engaging the health care providers in developing and testing the back-stage organizational processes of the digital framework proved vital for ensuring feasibility and minimizing the risk of resistance to use the IT systems. By addressing user needs from the outset, our study demonstrates how digital systems can be tailored to meet the expectations of all user groups, including health care providers, patients, and their families. Actively involving the users not only kept our focus on user needs but also revealed how integrations to existing IT systems as well as the clinical workflows of the health care providers needed to be addressed to successfully integrate the digital framework into clinical settings. Correspondently, Esdar et al [32] revealed that the adoption of mobile IT solutions was associated with close user participation and organizational cultures of innovation. Similarly, Andersen et al [54] highlighted that for mHealth prototypes to be successful, it was crucial to align or reconcile the concerns of patients and relatives with those of the health care providers, ensuring that both perspectives are considered and addressed. Failure to do so may lead to reluctance to use the prototypes. The user-engaging activities conducted in this study enabled us to develop a feasible solution for all stakeholders. In this way, our study refines current understandings of how structured SWRs should be designed to meet the demands of real-world clinical environments. Flexibility proved essential, allowing the digital framework to be adapted to the clinical context of the study. These findings provide valuable insights for the development of future collaborative digital solutions in health care, emphasizing the need for continuous engagement with key stakeholders and the flexibility to accommodate diverse needs.

Limitations

In PD studies, the user-engaging activities typically involve all key stakeholders throughout the process [40]. In our study however, it was not possible for patients and relatives to attend the mock-up workshop at the IT company, and only 3 health care providers participated in this activity. To ensure their voices were genuinely heard, a large group of health care providers, patients, and relatives (n=36) took part in the user testing, offering invaluable feedback on the final design.

As recommended in PD, the researchers should remain flexible and open to various user suggestions [40]. While we strived to maintain this approach, limitations in resources meant we could not address every user request. Future studies should explore ways to integrate more interactive elements into the digital framework, as suggested in the user testing. The study was conducted at a single clinical site, which may limit transferability of the findings. However, the PD process was informed by insights from previous research, which helped integrate the perspectives and needs of a diverse patient population and a wide range of experienced health care providers. While certain aspects of the framework, such as the focus on logistics, patient and family engagement, as well as the use of digital technologies to facilitate collaboration, are likely to be applicable in other acute and surgical health care settings, some elements, such as specific workflows and institutional norms at our study site, may be more context-dependent. Further research in different health care settings is essential to assess transferability of the digital framework and refine its applicability across various contexts. Furthermore, as the study is currently at the proof-of-concept stage, the digital framework requires further validation and testing to establish its effectiveness in achieving real-world quality improvement outcomes. Although the digital framework was developed to support the preparation of patients and families for SWRs, its actual impact on enhancing their readiness and participation was not evaluated in this study. Additional research is needed to assess how the digital framework influences patient and family preparedness, as well as their engagement in SWRs.

Conclusions

The PD process led to the development of a unified digital framework to support person-centered communication at SWRs, including a logistics system for nurses to prebook SWRs in designated time slots, making the schedule visible to patients and relatives via an mHealth app. Engaging key participants in the design and development helped uncover technical and organizational constraints that must be addressed to successfully integrate the digital framework into clinical contexts, while preserving its value for patients and their families. In conclusion, our study offers important insights by demonstrating how PD can be used to adapt digital technologies, ensuring they are both user-centered and context-sensitive. The next step of the research aims to pilot-test the digital framework in clinical settings and explore whether it fulfills its purpose of securing broader participation in SWRs.

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Data Availability

The datasets generated or analyzed during this study are not publicly available due to the inclusion of sensitive and confidential information, but are available from the corresponding author on reasonable request.

Authors' Contributions

HP contributed to conceptualization, methodology, investigation, formal analysis, and writing – original draft. JC contributed to conceptualization, methodology, investigation, and writing – review & editing. JA contributed to conceptualization, and writing – review & editing. P-EK contributed to conceptualization and writing – review & editing. MW contributed to conceptualization, writing – review & editing, and supervision.

Conflicts of Interest

None declared.

Multimedia Appendix 1
Data material from workshops and user-engaging activities.
[DOCX File, 21 KB - jopm_v17i1e69679_app1.docx]

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Abbreviations

GDPR: General Data Protection Regulation
mHealth: mobile health
PD: participatory design
SWR: surgical ward round

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A Training Program to Support Patient Engagement in Primary Health Care Research: Co-Design, Implementation, and Evaluation Study

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Abstract

Background: Patient engagement in research represents an evolution in how new knowledge is being created. Individuals and teams seeking to conduct research in this way want to learn how to best approach this aspect. Specialized training is required to ensure that these individuals and groups have the knowledge and skills to engage with and accomplish these goals. We developed a training program, called Patient-Oriented Research Training & Learning - Primary Health Care (PORTL-PHC), to address this need.

Objective: The objective of this paper was to describe key learning needs and knowledge gaps regarding patient-oriented research in primary health care, as well as the design, implementation, and evaluation of the PORTL-PHC program.

Methods: First, we completed a needs assessment to determine the learning needs of the program's target groups (including patient partners, policy makers, health care practitioners, and researchers). Second, building on the results of the needs assessment, the development and implementation of the program followed a series of iterative steps, including user testing of the program's content and format. Third, we conducted an evaluation with two components: (1) program registrants were asked to respond to questions as they progressed through the training content that explored what aspects of the content users found the most useful, suggestions for improvement, and any difficulties navigating the learning platform; and (2) program registrants were administered a questionnaire in three waves (January 2020, July 2020, and September 2021) 6 months after they had completed the program, that asked them to rate their gains in different areas of knowledge and skills regarding patient-oriented research on a 5-point Likert scale.

Results: There were 205 learners who participated in the program from January 2018 to January 2022. The target audience was reached with registrants from all groups; the majority of learners were from Canada (194/205, 95%). A total of 6 main areas of knowledge needs were identified from the needs assessment, and the program was iteratively developed and refined to address these needs and our learning objectives. Suggestions for improvement received from the first component of the evaluation were used to enhance and refine the program. Of the 88 learners who had completed the program at the time of the evaluation questionnaire administration, 28 responded to our request to complete an evaluation. The results indicate that PORTL-PHC increased knowledge of patient-oriented PHC research (overall mean score of 4.36, SD .56). Learners gained skills and knowledge in identifying patient priorities in PHC (mean 4.27, SD .63), understanding the methods of patient engagement (mean 4.32, SD .65), and skills for engagement in patient-oriented research (mean 4.41, SD .50). The majority of respondents (23/28, 82%) indicated that they intended to use the information from the PORTL-PHC training program in the future.

Conclusions: Through the PORTL-PHC program, we are training a new cadre of interested individuals who are committed to patient engagement in research to improve the provision of primary health care, and thus, patient outcomes.

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KEYWORDS

patient engagement; patient-oriented research; patient and public involvement; primary health care research; primary care research; capacity-building; training; course evaluation; co-design

Introduction

Background

Patient engagement in research, which has been defined as "The active, meaningful, and collaborative interaction between patients and researchers across all stages of the research process, where research decision making is guided by patients' contributions as partners, recognizing their specific experiences, values, and expertise" [1], represents an evolution in how new knowledge is being created. This approach respects the fact that patients and the broader public ultimately fund research and thus should be part of its creation and evaluation [2]. As this approach to research has become more widespread, patient partners and researchers have reflected on their experiences [3,4], the impacts of approaching research in this way have been described [5,6], and models and frameworks to guide this work have emerged [7].

Organizations such as the Patient-Centered Outcomes Research Institute [8] in the United States, and the Centre for Engagement and Dissemination at the National Institute for Health and Care Research in the United Kingdom [9], have supported and promoted this work. In 2011, the Canadian Institutes of Health Research (CIHR) launched the Strategy for Patient-Oriented Research (SPOR) [10] and supported SUPPORT Units across Canada to enact the SPOR strategy. The SPOR Patient Engagement Framework states that "Patient-oriented research refers to a continuum of research that engages patients as partners, focuses on patient-identified priorities and improves patient outcomes. This research, conducted by multidisciplinary teams in partnership with relevant stakeholders, aims to apply the knowledge generated to improve healthcare systems and practices" [10]. The goal of SPOR was to engage patients, caregivers, and families as partners in the research to make sure that health research focused on priorities of patients. CIHR developed the SPOR initiative to help transform the role of patients in the research process and to change the way research was being conducted in Canada [10,11]. As a result, there are many patient-oriented health research initiatives that exist [12,13], including the Passerelle program, which is the main hub for patient-oriented research training and capacity building in Canada [14]. Other developments include new patient-led initiatives such as the PxP For Patients, By Patients [15], and centres such as the Patient Expertise in Research Collaboration—Primary Health Care [16]. Please note that, in this paper, we use both the terms patient engagement in research and patient-oriented research.

Individuals and teams (including patient partners, policy makers, health care practitioners, and researchers) seeking to conduct and use patient-oriented research want to learn how to best approach this work. They want to ensure that patients' voices are heard, make sure that the research produced is relevant to patients, and ultimately to improve the health of patients [17]. Specialized training is required to ensure that these individuals and groups have the knowledge and skills to engage with and accomplish these goals [2]. Beginning in 2014, the Ontario SPOR SUPPORT Unit (OSSU) funded a suite of training and capacity building initiatives to respond to this need for specialized training in patient-oriented research [18-21]. In addition, the OSSU publishes a compendium of patient-oriented research capacity building programs and resources across Ontario, reflecting the evolving and expanding nature of these initiatives [22].

Members of our team are active in developing and delivering research training initiatives focused in the primary health care setting. Therefore, we knew that (1) it was important to provide specialized training so that individuals would know how to engage with and conduct patient-oriented research; and (2) that this training should focus on the primary health care setting and its patients, to best match the perspectives and learning needs of patients, practitioners, policy makers and researchers in this setting, which includes services provided by primary care practitioners. Recognized as the "foundation of the health care system" [23], primary care is characterized by essential attributes known as the 4Cs—"first contact, comprehensiveness, coordination, and continuity" [23,24]. The scope of primary care in terms of the health care system is large—most of the care provided in health care systems in terms of monthly contacts for example occurs in primary care [25]. Therefore, we developed a training program to address the unique needs of learners in the primary health care setting [26]. The program was funded by the OSSU as part of its original suite of capacity building initiatives. The training program is called Patient-Oriented Research Training & Learning-Primary Health Care (PORTL-PHC) and is hosted on The University of Western Ontario's (UWO) Learning Management Platform called OWL. The goal of PORTL-PHC was to build capacity among patients, health care providers, policy makers or managers, researchers and trainees to conduct and use patient-oriented primary health care research. This work was conducted in two main phases, which involved (1) the collection of foundational information about learning needs and gaps in knowledge regarding primary health care patient-oriented research; and (2) the design, delivery, and evaluation of the program.

This paper reports on the key learning needs and knowledge gaps that were identified, as well as the design, implementation, and evaluation of the PORTL-PHC program.

Principles Underpinning the Creation and Design of PORTL-PHC

The overarching principles that underpinned the creation of the program were to ensure that co-design and co-building processes were used from the start of the original program proposal to the final development and delivery of the program; the training program would meet the needs of multiple interested groups, the perspectives of potential end-users were incorporated throughout the process, and the content would reflect the primary health care research context.

In keeping with these principles, we struck an Advisory Committee with representatives from four groups (patients, primary health care practitioners, policy makers, and researchers). The committee provided input, feedback, and guidance for the main activities of the program, including curriculum design, content and delivery, engagement strategies and recruitment, and evaluation, as well as identifying appropriate resources to support the project over the short and long term.

The project team closely followed the overarching principles throughout the program development process. Representing the patient perspective, co-authors (LB and LM) were engaged at the beginning stage of the proposal development for the project and were an integral part of the development and user testing of the program. LB and LM supported the creation of the program by: (1) attending all PORTL-PHC team meetings, (2) identifying new materials for the program, (3) contributing to logic model and evaluation design, (4) reviewing materials, (5) testing the program, and (6) making connections to promote the program within their own networks. They engaged a significant number of patients, caregivers, and citizens to provide input at the needs assessment stage of the project. An additional patient partner was a member of the Advisory Committee.

Methods

Learning Needs and Knowledge Gaps: Data Collection and Analysis

To ensure that the program addressed existing knowledge gaps regarding patient-oriented research, we completed a needs assessment in 2 main steps to determine the learning needs of the targeted groups. First, we conducted a review of relevant documents regarding the learning needs of these groups, including reports prepared for the OSSU's MasterClass on Patient-Oriented Research [27], and the Canadian Institutes of Health Research's Evaluation of the Strategy for Patient-Oriented Research [28]. A total of 2 study authors (ALT and RVH) collated this information and categorized it into broad thematic areas.

Second, we conducted an informal survey to explore learning needs for participating in, conducting, or using patient-oriented primary health care research. We developed a short questionnaire based on a brief review of literature and the document review described above. The questionnaire was designed to elicit responses regarding interest in participating in patient-oriented research, what type of knowledge and learning individuals were looking for in a training program, what topics were most important to address, and whether they had ever participated in patient-oriented research previously. Research team members and members of the Advisory Committee iteratively reviewed the questionnaire to improve clarity and to adjust the content. The questionnaire was administered through Qualtrics, which is an survey software program [29]. Qualtrics was used for the remainder of the data collection activities described in this methods section. Networks and programs relevant to primary health care and patient-oriented research across Ontario, Canada were asked to distribute the questionnaire to their members. Descriptive statistics were calculated to summarize the quantitative data. A total of 2 study authors (ALT and RVH) reviewed and summarized responses to the open-ended questionnaire elements.

PORTL-PHC Program Design

Building on the results of the needs assessment, the development and implementation of the program followed a series of iterative steps. First, we developed educational objectives that served as a guide for the content of the program. Second, using the information gathered in the learning needs assessment, we developed the structure and content of the program. The overall design was guided by adult learning principles [30] using tested pedagogic and andragogic approaches for both content and process. Approaches include research skills development [31], explicit knowledge [32], tacit knowledge [32], collaborative co-created learning [32], critical reflection [33], educating for capability [34], and building a community of scholars. Building on Knowles' [30] "self-concept" principle, we set out to design the program to allow the learner to individualize their experience by exploring the content in a way that would be most helpful to them and pertinent to their immediate needs. Third, the content and structure of the program were configured for self-directed learning within the learning platform. Aspects of the visual display, site navigation, and structure were created and refined, and then, the content was added. Fourth, after the initial version of the training program was developed, we conducted a series of steps in user testing and program refinement. PORTL-PHC Advisory Committee members reviewed and tested the program; their feedback on the appearance, structure, and content of the modules and the overall design was incorporated into a revised version of PORTL-PHC. Partner organizations of the PORTL-PHC program including the Patient Expertise in Research Collaboration (PERC), the Centre for Rural and Northern Health Research (CRaNHR) and Innovations Strengthening Primary Healthcare through Research–Primary Health Care (INSPIRE-PHC) were then asked to provide names of potential program user testers associated with their organizations. These user testers—5 patients, 2 researchers, 1 policy maker, and 1 research trainee—were asked to complete the program, provide feedback on the content, and assess the site's functionality, the appearance of the program, the design, and the clarity of the instructions. The input received was used to revise the appearance, content, and design of the PORTL-PHC training modules and website.

PORTL-PHC Program Recruitment and Promotion

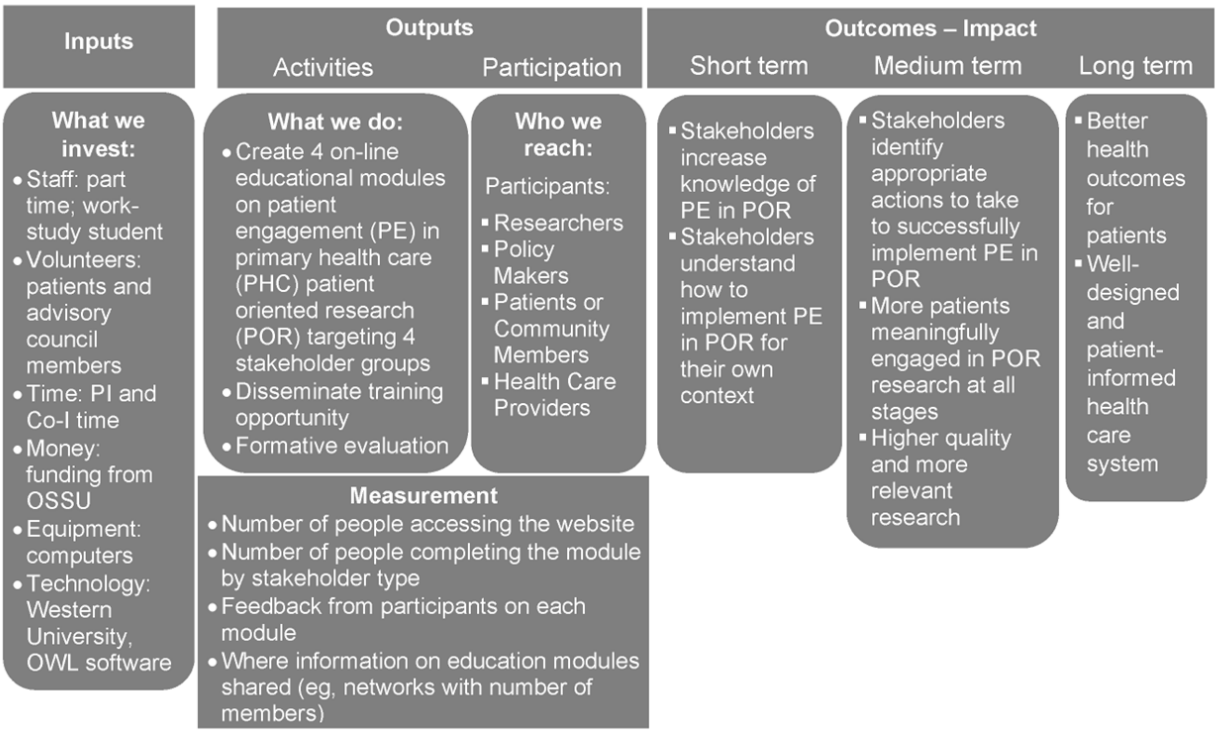
A variety of methods were used to promote the program including information circulated to: the OSSU; SUPPORT Units and Primary and Integrated Health Care Innovations Networks (PIHCINs) in each province across the country; OSSU Member Centers including INSPIRE-PHC and CRaNHR; Patient Expertise in Research Collaboration (PERC); Transdisciplinary Understanding and Training on Research—Primary Health Care (TUTOR-PHC) alumni network; patient networks such as the Patient Advisory Network (PAN); mailing lists of these connected networks, newsletters such as in the Department of Family Medicine at Western University and on social media via X (formerly known as Twitter). We also promoted the program, and shared early findings about its implementation

and uptake, by making presentations about PORTL-PHC at primary health care Research Conferences such as the North American Primary Care Research Group Annual Meeting [35] and the Trillium Primary Health Care Research Day [36,37], as well as advertising with bookmarks and brochures available to conference attendees.

PORTL-PHC Program Evaluation

The overall evaluation of the program was informed by Kirkpatrick's 4-level training evaluation model [38] and guided by a logic model developed for this purpose (see Figure 1); we measured outputs and assessed short-term impacts in this phase of the project. Data collection for evaluation purposes occurred in four ways. First, learners were asked to provide their group and location upon registration. Second, we administered a questionnaire to new learners in the program, requesting information about their experience participating in or using patient-oriented research, how they identified the training program, and their affiliation with any patient-oriented research organizations. Third, learners were asked to complete a series of questions at the end of each module that explored what aspects of the module users found the most useful, suggestions for improvement, and any difficulties navigating the learning platform; this information was collected through a questionnaire embedded at the end of each module. Finally, we conducted a survey of learners in three waves (January 2020, July 2020, and September 2021) 6 months after they completed the program to ascertain if the learning objectives for the training program were met. One follow-up reminder was sent to learners who had not completed the evaluation questionnaire. We also collected information on where the learners were located, and category of learner (ie, administrative staff [eg, project coordinator, research assistant]), patient or caregiver, student or trainee, primary health care researcher, health care practitioner, and policymaker or manager. We calculated descriptive statistics to summarize these data.

Figure 1. Program logic model. Co-I, co-investigator; OSSU, Ontario SPOR SUPPORT Unit; OWL, Western University's online learning management system; PI, principal investigator; UWO, The University of Western Ontario.



Ethical Considerations

For the survey component of the needs assessment (described in the "Learning Needs and Knowledge Gaps: Data Collection and Analysis" section above), participants reviewed a letter of information before consenting to participate. No personal identifiers were collected and no compensation was offered for participation. This project was approved by the UWO Health Sciences Research Ethics Board (109621). Additional activities (described in the "Program Evaluation" section above) are program evaluation activities and therefore would be considered exempt from human ethics review in accordance with Article 2.5 of the Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans, which states that "Quality assurance and quality improvement studies, program evaluation activities, and performance reviews, or testing within normal educational requirements when used exclusively for assessment, management or improvement purposes, do not constitute research for the purposes of this Policy, and do not fall within the scope of REB review" [39].

Results

In this section, we present the results of the steps undertaken in our needs assessment (see "Learning Needs and Knowledge Gaps: Results" section), followed by the results of our program design process (see "PORTL-PHC Program Design: Results" section), and finally, the process and outcome results of the

PORTL-PHC program evaluation (see "PORTL-PHC Program Evaluation: Process and Outcome Results" section).

Learning Needs and Knowledge Gaps: Results

In the first step of our needs assessment, overall themes emerged from the document review we conducted regarding learning needs and knowledge gaps for patient-oriented-research, as well as those that related to specific groups; Textbox 1 shows these themes.

Textbox 1. Document review results

Overall themes included a need for:

- Basics of patient-oriented research, definitions, frameworks, and methods.
- Concrete information or steps regarding conducting patient-oriented research, tools, skills development, and understanding enablers and barriers.
- Information regarding ethics and patient-oriented research.
- Examples of patient-oriented research and "learning by doing" exercises and simulations.
- Clear articulation of roles of members of the research team, for example, co-building.

Groups and their themes:

Patients:

- Ensuring patient perspectives are included and valued.
- Need for technical research knowledge—curriculum vitae, ethics, report writing, and granting processes.
- Issues in conflicting priorities among different groups and organizations.
- How to engage in patient-oriented research?
- Role on research teams—need for clarity, participation at the right time.
- Knowledge regarding existing research and how it can be applied.

Practitioners:

- Assessing patient needs or balancing priorities.
- Need for resources (funding and literature).
- Identifying and engaging patients and partnerships.

Policy makers:

- Access to relevant information.
- Culture change required regarding value of patient engagement.
- Need for resources to support patient-oriented research and capacity for patient engagement.
- Tension regarding the need for representative evidence versus qualitative information.
- Time and resources.

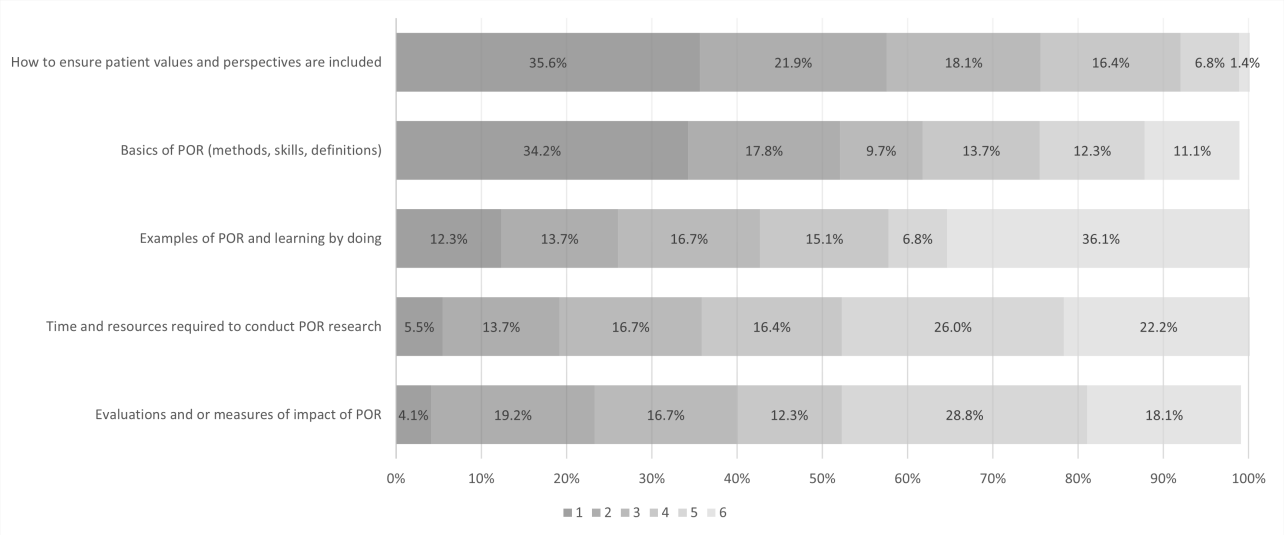
Researchers:

- Finding or accessing patient members.
- Understanding the best way to include patients in research and the right type of involvement for each project.
- How to elicit, incorporate, or balance patient priorities and preferences?
- How to handle language and terminology differences?
- Understanding and demonstrating the value of patient engagement in research.
- Need for evaluation and outcome measures to assess patient engagement and its impact.
- What are the long-term strategies and vision for patient-oriented research?

For the second step of the needs assessment, 75 individuals responded to the PORTL-PHC learning needs assessment questionnaire. Most respondents were primary health care researchers (31/75, 41%) or patients (17/75, 23%), followed by students or trainees (9/75, 12%), clinicians (6/75, 8%), with the remainder being caregivers, other, or policy makers or managers (12/75, 16%). The majority of respondents (66/75, 88%) expressed interest in participating in a patient-oriented research training program, with just over half (39/75, 52%) having ever participated in, or previously used, patient-oriented research.

Of the 73 respondents who answered questions about topic preferences, the basics of patient-oriented research and ensuring the inclusion of patient values and perspectives were consistently the highest ranked topics for inclusion in a patient-oriented research training program, while other topics such as roles on research teams, time and resources required to conduct patient-oriented research, and evaluating the impact of patient-oriented research were of lower priority (see Figure 2).

Figure 2. Ranking of topics for inclusion in a patient-oriented research (POR) training program (N=73). Participants were asked to rank the listed topic from 1 to 6, with 1 being most important.



In total, 6 main areas of knowledge needs were identified through a synthesis of the open-ended survey questions. Respondents were seeking information about the "basics" of patient-oriented research, such as how to recruit patients. They wanted an understanding of the roles that patients take on in research, and how to ensure that patient values and perspectives were included. Information regarding the time and resources required to conduct patient-oriented research was important. Respondents were seeking examples of patient-oriented research, best practices, and lessons learned. Finally, they wanted to know how to evaluate their patient-oriented research work and understand its impact.

PORTL-PHC Program Design: Results

The results of our program design steps included the development of five cross-cutting educational objectives of the PORTL-PHC program, which are as follows: (1) to develop an understanding of the experiences of primary health care patients; (2) to gain knowledge of approaches to identifying patient priorities in primary health care; (3) to understand methods of how to engage and be engaged in patient-oriented research, and how to listen to patient voices; (4) to develop knowledge and skills in conducting and participating in patient-oriented research, in using patient-oriented research, and in an outlook that supports effective patient engagement; and (5) to actively apply patient-oriented research skills and knowledge in the learners' own context. A total of five learning modules, described in Table 1, were created to address these educational objectives. The design and delivery methods for each module include seven common components (see Table 2).

Table . Overview of Patient-Oriented Research Training & Learning—Primary Health Care (PORTL-PHC) program: module objectives and description.

Module	Educational objectives addressed	Description
Module 1A and 1B	• First, to develop an understanding of the experiences of primary health care patients. • Second, to gain knowledge of approaches to identifying patient priorities in primary health care.	Patient priorities and patient engagement in primary health care research: • Module 1A focuses on learning what the "big picture" issues are for primary health care patients. It provides information to all interested groups about what is important to primary health care patients in terms of their needs and priorities. • Module 1 B provides information about how to identify patient priorities for primary health care research. This module discusses some of the methods for involving patients in identifying priorities for research and provides some real-world examples.
Module 2	• Third, to understand methods of how to engage and be engaged in patient-oriented research, and how to listen to patient voices.	Methods and examples of patient engagement in primary health care research: • Module 2 focuses on approaches to engage patients in research. Methods which go along with each level of patient engagement are illustrated though examples of real-world studies. Relevant content addresses how to listen to patient voices throughout each of the levels or stages of patient engagement in research.
Module 3	• Fourth, to develop knowledge and skills in conducting and participating in patient-oriented research, in using patient-oriented research, and in an outlook that supports effective patient engagement.	Skills development in patient engagement and patient-oriented research: • Module 3 focuses on the knowledge, skills, and outlook needed to participate in patient-oriented research, to conduct patient-oriented research, or to use this type of research. The module aims to identify gaps in knowledge, skills, and outlook for learners. After identifying these gaps, learners are directed to seek out the necessary resources and examples presented in the program modules to address these gaps.
Module 4	• Fifth, to actively apply patient-oriented research skills and knowledge in the learners' own context.	Applying patient-oriented research in the learner's own context: • Module 4 focuses on applying the learnings from Modules 1 through 3 to the learner's own perspective as a patient, or work as a researcher, policy-maker, or health care practitioner. Based on each learner's perspective, this module focuses on real-world application of ways to be involved in patient-engaged research, opportunities and challenges, and means to evaluate these projects.

Table . Overview of Patient-Oriented Research Training & Learning—Primary Health Care (PORTL-PHC) program: the 7 common components of the delivery methods and designs of each module.

Component	Description
Introduction	An overview of the topic, explanation of how to use the training, why the training was created, and what learners could expect from the training.
Content	Slides, video (including patient perspectives), and text were used to deliver relevant content. Using different types of media allowed learners with different learning styles (visual, auditory, and kinesthetic) to maximize their learning experience.
Existing resources	Links to existing resources for all sections of the modules.
Examples	Experiences of team or advisory group members and actual POR[a] work were used as examples.
Exercises	Dynamic exercises that include built in questions leading to different content for different learner groups.
Self-reflection	Self-reflection questions or short quizzes based on content.
Feedback	Feedback opportunities via evaluation questions.

[a]POR: patient-oriented research.

Thus, for each module, learners were able to review pertinent content regarding primary health care patient-oriented research, work through a series of examples and exercises, engage in self-reflection, and provide feedback. This feedback was reviewed with a view to further enhancing the program. Within an e-learning environment, the program guides the learner and provides ample resources while allowing them to "discover" much of the information and incorporate it as needed [40]. This is a self-directed program, where learners can move through the modules at their own pace, according to their schedules. Each learner is registered individually to the learning platform and has unlimited access to the program's content.

The final version of the program was created and launched via OWL (UWO's Online Learning Management System) in December 2018. Ongoing support for the OWL platform through UWO allows the PORTL-PHC program to be sustained over time. A comprehensive review of the program's content and resources was conducted in 2023; updated materials and links to new resources were added to the program site.

PORTL-PHC Program Evaluation: Process and Outcome Results

There were 205 learners who participated in the program from January 2018 to January 2022 (see Table 3). The target audience was reached with registrants from all target groups; the majority of learners were from Canada (194/205, 95%). Of the 133 registrants who responded to a question about their patient-oriented research experience, more than half (68/133, 51%) had participated in or used this type of research. Responses to questions posed at the end of each module about the aspects of the module that were most useful, suggestions for improvement, and any challenges in navigating the website indicate that that the content and delivery platform was well-received by learners. Suggestions for improvement were used to enhance and refine the program.

Table . Profile of Patient-Oriented Research Training & Learning—Primary Health Care (PORTL-PHC) program learners (N=205).

Characteristics	Values, n (%)
Country of Residence	
Canada	194 (94.6)
United States	6 (2.9)
Other (Australia, Japan, Pakistan, and Qatar)	5 (2.4)
Learner category	
Administrative staff (eg, Project coordinator, research assistant)	59 (28.8)
Patient or caregiver	40 (19.5)
Student or trainee	36 (17.6)
Primary health care researcher	29 (14.1)
Health care practitioner	28 (13.7)
Policymaker or manager	13 (6.3)

We conducted an evaluation survey in 2020-21 with learners who fulfilled two criteria: (1) they had completed the PORTL-PHC program; and (2) they had completed the program at least 6 months before the survey time period. This meant

there were a total of 88 learners eligible to participate. On administration of the evaluation questionnaire, 34 individuals began to complete the questionnaire, and 28 individuals finished (32% response rate; see Table S1 in Multimedia Appendix 1). The vast majority of the respondents were from Canada; two-thirds of the group was made up of researchers and administrators with the remainder a mix of clinicians, trainees, and patients or caregivers. Respondents indicated that the PORTL-PHC training program had increased their knowledge of patient-oriented primary health care research (overall mean score of 4.36, SD .56, five response options from strongly disagree to strongly agree were scored 1 through 5). Learners gained skills and knowledge in areas such as identifying patient priorities in primary health care (mean 4.27, SD .63), understanding the methods of patient engagement (mean 4.32, SD .65), and skills for engagement in patient-oriented research (mean 4.41, SD .50). The majority of respondents (23/28, 82%) indicated that they intended to use the information from the PORTL-PHC training program in the future. Respondents were also asked several open-ended questions about how the PORTL-PHC training program helped shaped their research goals and to explain how knowledge gained from the program was used to shape and design their research initiatives. Respondents indicated that they applied the learnings from the program in a variety of ways, such as using the training to develop their own research methods, to conducting peer reviews, and to critique patient engagement in research projects. Respondents noted that the program provided clarification about what was involved in patient-oriented research and gave the learners confidence in joining research teams or implement patient-oriented research-related activities.

Discussion

Principal Findings

In building the PORTL-PHC program, we used an iterative and collaborative process to ensure that our principles of co-design and co-development that supported the creation and delivery of the program were upheld. These principles included having patient partners, practitioners, policy makers, and researchers involved from the start of the program development to its final delivery, designing a program to meet the needs of multiple groups, capturing and addressing the perspectives of end users, and ensuring that the content of the program was highly relevant to the primary health care context. The experience of co-designing and developing the PORTL-PHC program further heightened our shared awareness of the value of end-users shaping the program to meet their needs. Iteratively seeking input on the program allowed us to capture feedback provided by all interested groups, including patients, and refine the program accordingly. This resulted in a highly relevant program that has been successfully taken up by learners in Canada and internationally. We plan to apply this model of assessing needs, co-design, and iterative refinement in our future research and educational program development initiatives.

The main areas of knowledge needs identified in our needs assessment process included basic knowledge of methods and skills in patient-oriented research, understanding patients' roles in research, ensuring patient values and perspectives were included, understanding the time and resources required to conduct patient-oriented research, having exemplars of research and best practices, and how to evaluate or measure the impact of patient-oriented research. These areas of knowledge needs formed the basis of the program's content. Following an iterative design process, we developed cross-cutting educational objectives for the program and created 5 learning modules to address these objectives. The PORTL-PHC program includes modules that lead the learner through a series of topics regarding patient experiences in primary health care, identifying patient priorities in primary health care, methods of how to engage and be engaged in patient-oriented research, development of knowledge and skills around patient engagement in research, and how to apply the knowledge gained in the learner's own context. Responses to questions posed to each learner about the module content and format were used to enhance the overall program. Evaluation results indicate that the program met its educational objectives, with learners indicating that they had increased their knowledge and skills in patient-oriented research, and that they would use the information from the program in their future work. The results also suggest that the program was responsive to user needs, reached the target audience, and heightened the awareness and knowledge of multiple groups including patients, policy makers, practitioners, and researchers.

As patient and community engagement in research continues to grow and mature, it will be increasingly important to have a suite of options available for interested individuals to participate in training to enhance their knowledge and skills in co-creating patient-oriented research. The possibility of coordinated offerings of such training programs as outlined by Chudyk et al [41] represents an ideal to strive toward. Initiatives such as Canada's Passerelle Program are important developments that support this aim; the Passerelle program is a national training entity and a central pan-Canadian hub that brings together networks and programs to support capacity development in patient-oriented research [14]. PORTL-PHC is actively collaborating with Passerelle around the shared goal of providing enhanced patient-oriented research training in Canada. PORTL-PHC is a sustainable program that is designed to facilitate capacity building and strengthen efforts to engage patients as partners in primary health care research. By providing primary health care specific exercises, examples and resources, we addressed the needs of our learners by attending to the unique context within which primary health care research occurs. Part of the success of the program lies in the foundational work conducted to understand the knowledge needs of our learners, the engagement of the target audiences in our design process, and the testing and subsequent refinement of the program with interested individuals and groups. Our training program was developed at a stage when patient engagement in research was earlier in its emergence, yet there is an ongoing demand for the PORTL-PHC program itself, and an overall need for this type of training to carry on [2]. Although guidance regarding patient-engagement in research continues to emerge [42], the PORTL-PHC program responds to a specific need by delivering training tailored to the primary health care setting; addressing a gap in current educational offerings focused on engaging patients in research.

Strengths and Limitations

Several strengths of the PORTL-PHC program include: (1) the extent of the engagement with patients and other partners in its development, (2) the responsiveness to the findings of our needs assessment in creating the program's content, and (3) the iterative nature of user testing and development of the program. The evaluation results indicate that the PORTL-PHC program is achieving its objectives and attracting its target audience. The self-directed nature of the program allows us to sustain the program's delivery and the openly accessible learning platform means that we can provide the program to all who are interested [43]. Several limitations must be noted, and include: (1) the fact that the evaluation results are based on self-reported data from approximately a third of participants, (2) there is an overrepresentation of primary health researchers and an underrepresentation of health care practitioners and policy makers in the evaluation survey respondent group, (3) the program is offered in OWL and therefore assumes access to a computer and internet connectivity, and (4) and that the program is currently only offered in English.

Conclusions

Through the PORTL-PHC program, we are training a new cadre of interested individuals who are committed to patient engagement in research to improve the provision of primary health care, and thus, patient outcomes. In particular, primary health care researchers and health care practitioners are able to partner with patients in a meaningful way in their research, and patients and policy makers are better prepared for participation in primary health care research.

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Authors' Contributions

Conceptualization- ALT (lead), LB (equal), LM (equal), RVH (supporting), SR (equal) Data curation – RVH (lead)Formal analysis – ALT (lead), EL (equal), RVH (equal)Funding acquisition – ALT (lead), SR (supporting)Investigation – ALT (lead), RVH (equal)Methodology – ALT (lead), LB (supporting) LM (supporting), SR (supporting)Project administration – RVH (lead), ALT (supporting)Resources – RVHSupervision – ALTVisualization – ALT (lead), EL (supporting), RVH (supporting)Writing – original draft – ALT (lead), LM (supporting), RVH (supporting)Writing – review & editing – ALT (lead), LB (supporting), LM (supporting), EL (supporting), RVH (supporting), S. Regan (supporting)

Conflicts of Interest

None declared.

Multimedia Appendix 1
Patient-Oriented Research Training & Learning—Primary Health Care (PORTL-PHC) evaluation questionnaire responses (n=28).
[DOCX File, 16 KB - jopm_v17i1e65485_app1.docx]

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Abbreviations

CIHR: Canadian Institutes of Health Research
CRaNHR: Centre for Rural and Northern Health Research
INSPIRE-PHC: Innovations Strengthening Primary Healthcare through Research
NIHR: National Institute for Health and Care Research
OSSU: Ontario SPOR SUPPORT Unit
OWL: Western University's online learning management system
PAN: Patient Advisory Network
PERC: Patient Expertise in Research Collaboration
PHC: primary health care
PIHCINs: Primary and Integrated Health Care Innovations Networks
PORTL-PHC: Patient-Oriented Research Training & Learning - Primary Health Care
SPOR: Strategy for Patient-Oriented Research
TUTOR-PHC: Transdisciplinary Understanding and Training on Research—Primary Health Care
UWO: The University of Western Ontario

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Experiences and Needs of Core Participants in Surgical Ward Rounds: Qualitative Exploratory Study

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Abstract

Background: Surgical ward rounds (SWRs) are typically led by doctors, with limited involvement from key participants, including patients, family members, and bedside nurses. Despite the potential benefits of a more collaborative and person-centered approach, efforts to engage these stakeholders remain rare.

Objective: This qualitative exploratory study aims to examine the experiences and needs of doctors, nurses, patients, and their relatives during SWRs as part of a participatory design process.

Methods: Data were collected through ethnographic field studies, focus groups with the health care providers, patients, and relatives, and dyadic interviews conducted as part of home visits to patients and their partners after discharge. Field notes and interview data were analyzed using systematic text condensation.

Results: Lack of organization, traditional roles, and cultural norms compromised the quality, efficiency, and user experience of SWRs in multiple ways. SWRs were routine-driven, treatment-focused, and received lower priority than surgical tasks. Unpredictability resulted in unprepared participants and limited access for nurses, patients, and relatives to partake.

Conclusions: The study identified a gap between the organizational and cultural frameworks governing the SWRs and the experiences and needs of key participants. Digital technologies were perceived as a potential solution to address some of these challenges.

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KEYWORDS

surgical ward rounds; interdisciplinary rounds; patient participation; family involvement; digital technologies

Introduction

A ward round is a complex hospital activity with multiple purposes and diversity in function, participants, and attendance within different hospital settings [1]. Despite its importance and global implementation, there appears to be no universally agreed-upon definition or shared understanding of a ward round [2-4]. In a literature review, Walton et al [2] identified 8 classifications, ranging from traditional rounds led by junior doctors presenting patient cases to the seniors, to interdisciplinary rounds involving health care providers from different disciplines. The primary purposes of these rounds include patient-care planning and teaching activities. Hence, ward rounds play a crucial role in ensuring person-centered care, patient safety, and high-level education [4-6]. Medical ward rounds typically involve a wide range of health care providers, including nurses and allied health care providers. Bedside interdisciplinary rounds in medical settings have been extensively investigated, showing several positive effects, such as improved interprofessional teamwork, quality of care, efficiency, and patient safety. They also promote holistic care by incorporating input from various disciplines, providing a comprehensive understanding of the patient's conditions and

needs [7-12]. In contrast, doctors are most likely to attend and lead surgical ward rounds (SWRs) with limited involvement from other health care providers, patients, or relatives [2,13]. Logistic challenges, lack of time, and persistent traditional hierarchies may present barriers to bedside interdisciplinary rounds in surgical departments, and in some cases, contribute to the exclusion of bedside nurses [3]. A systematic review by He et al [14] identified interventions to improve SWRs, most of which involved checklists to enhance documentation and patient safety. While these checklists have demonstrated significant improvements in documentation compliance, staff understanding, and patient satisfaction, they are primarily aimed at reducing prescribing errors and critical mistakes in postoperative care, similar to practices used to improve operating room processes [5]. However, research on broader clinical and organizational frameworks to support collaborative and holistic SWRs is scarce.

Furthermore, a recent scoping review examining the use of bedside whiteboards found improvements in some aspects of patient communication in 6 of the 13 studies identified [15]. Nevertheless, the integration of these whiteboards has been insufficient to ensure significantly higher levels of patient and family participation in the SWRs [16]. As holistic and person-centered care becomes more evident in modern health care, frameworks that ensure a shared agenda during SWRs, where all relevant parties can contribute and be involved, are essential [17-19]. However, limited descriptions of the perceptions and expectations of core participants present a significant gap in understanding their roles, attitudes, and collaboration. Thus, this study aimed to investigate the experiences and needs of doctors, nurses, patients, and their relatives during SWRs.

Methods

Study Design

The study represents the first phase of a participatory design process, in which ethnographic methods, involving detailed observation and analysis of current practices and needs, are central [20,21]. To gain in-depth knowledge of key participants' lived experiences and needs during SWRs, we conducted a qualitative exploratory study. Data were collected through ethnographic field studies, focus groups, and dyadic interviews conducted during home visits to patients and their partners after discharge.

The health care providers, patients, and relatives who participated in this study were also invited to serve as ambassadors in the next phase of the participatory design process, aiming to co-develop digital technologies that support a shared agenda at SWRs. Digital technologies refer to electronic systems or devices that facilitate communication, information sharing, or automation [22].

Ethical Considerations

In accordance with the Helsinki Declaration, all participants received both written and oral information about the study's purpose and provided informed consent. Participation was voluntary, and participants were informed they could withdraw at any time without consequence. The study was reviewed by the Regional Committees on Health Research Ethics of Southern Denmark, who determined that the project falls outside the scope of the Danish Committee Act's definition of a reportable health science research project (S-20252000 - 37) [23]. However, the study was approved by the Danish Data Protection Agency (Journal No. 20/60035), and data were stored in OPEN Analyse in compliance with the European General Data Protection Regulation [24]. Data were anonymized to ensure privacy and confidentiality. No compensation was provided to participants for their involvement in the study.

Setting

The study was conducted at the Department of Surgery, Lillebaelt University Hospital, Denmark, from August 2021 to October 2021. The department had 26 beds and primarily treated acutely admitted adult patients with various gastrointestinal conditions, including ileus, gallstones, and pancreatitis. The length of patient admissions varied from a few days to several months for long-term stays. In 2017, Patient Care Boards (PCBs) were introduced to empower patients and their relatives to participate more actively during SWRs. Questions from the patients and an agreed-upon plan, including the names of the health care providers, dates for the next SWR, and the expected discharge, were noted on the whiteboard at the bedside.

Participants and Recruitment

Participants in the field studies were selected through convenience sampling from those present on 3 scheduled data collection days, resulting in the inclusion of 4 doctors, 4 nurses, 16 patients, and 8 relatives willing to participate. Three observers conducted the data collection at data point 1, while 1 observer conducted the observations at data points 2 and 3. To ensure the arrival of new patients for observation, a 3-week interval between the first 2 data points as well as a 1-day interval between data points 2 and 3 were intentionally selected. This design aimed to capture a representative sample of participants over the specified time intervals. Patients and their relatives were also invited to participate in a focus group during or after admission. Initially, 14 patients and 8 relatives agreed to participate, however, 11 patients and 6 relatives later declined due to the patient's health conditions (n=11) or transportation issues to the hospital (n=6). Consequently, the focus group included 5 participants, while 3 patients and their partners opted for dyadic interviews conducted in their own homes after discharge instead. During these interviews, patients and their partners were considered 2 separate respondents. Inclusion criteria for the study were acutely admitted, Danish-speaking patients and relatives aged 18 years or older. Participants were selected to reflect diversity in terms of sex, age, diagnosis, and length of stay (Table 1).

Table . Demographic characteristics of patients and relatives participating in focus groups and dyadic interviews.

Participants	Proportion of males, n (%)	Age (years), mean (SD; range)	Length of stay (days), mean (SD; range)
Total (n=11)	4 (36)	78.2 (8.2; 61–93)	10.0 (4.2; 7–18)
Patients (n=6)[a]	3 (50)	79.2 (5.8; 68–87)	10.7 (4.6; 7–18)
Relatives (n=5)[b]	1 (20)	77.0 (10.2; 61–93)	9.2 (3.5; 7–16)

[a] With a diagnosis of cholecystitis (n=2), diverticulitis (n=1), pancreatitis (n=1) and ileus (n=2)

[b] Partners (n=4) and adult children (n=1).

A total of 8 doctors and 5 nurses were purposively selected to participate in a focus group for the health care providers. In collaboration with the department management, a diverse group was recruited to ensure variation in sex, age, educational level, and length of experience in the ward. The term ”doctor“ will be used to refer to any doctor, regardless of seniority or position, while ”junior” and ”senior“ will indicate different levels of seniority. All nurses were registered nurses, with some holding specialized roles, such as specialist nurses or working environment representatives (Table 2). In total, 44 informants participated in the study, including participants from field studies, focus groups, and dyadic interviews.

Table . Demographic characteristics of health care providers participating in focus groups.

Participants	Proportion of males, n (%)	Age (years), mean (SD; range)	Experience (month), mean (SD; range)
Total (n=13)	6 (46)	33.7 (6.9; 25–47)	46.6 (61.1; 1–246)
Doctors (n=8)[a]	5 (63)	34.4 (6.4; 27–45)	32.0 (24.2; 1–68)
Nurses (n=5)[b]	1 (20)	32.6 (7.6; 25–47)	70.0 (88.7; 8–246)

[a] Junior doctors (n=5) and senior doctors (n=3)

[b]General nurses (n=2), specialist nurses (n=2) and working environment nurse (n=1)

Data Collection

Field Studies

HP, JC, and an innovation consultant conducted 20 hours of ethnographic fieldwork by performing go-along with participants before, during, and after the SWRs. HP is an experienced nurse in the surgical specialty, though no longer involved in clinical work. JC has extensive expertise in qualitative research and participatory design, while the innovation consultant holds a Master’s degree in design management and specializes in co-operative design processes. The go-along method is a hybrid approach combining participant observation and interviewing, in which the fieldworker accompanies informants during their everyday activities, asking questions, listening, and observing to actively explore their experiences and practices as they move through and interact with their physical and social environments [25]. We found this method suitable as it enabled the observation of participants in situ while assessing their interpretations simultaneously. The fieldworkers accompanied doctors and nurses during preparations, patient room visits, and follow-up activities related to SWRs. Informal interviews were conducted to explore the transcendent and reflective aspects of the participants’ lived experiences [25]. To ensure consistency, the interviews were conducted using a set of guiding questions for the observer. These included open-ended questions such as: How did you experience the SWR? What are your needs during SWRs? Were these needs met? Additionally, more specific questions tailored to the observed situations were asked. Observations were recorded in field notes, including jottings, phrases, and additional thoughts, ideas, and questions that arose during the go-along. These jottings were expanded into detailed descriptive field notes as soon as possible [26]. Where feasible, informal interviews were audio taped and transcribed verbatim. For those not audio-recorded, comprehensive field notes were taken to ensure detailed documentation of the interviews.

Focus Groups and Home Visits

Focus groups were selected as a method to gain insight into the experiences and needs of participants at a group level, and to gather knowledge from the social interactions between them [27]. The format allowed each participant to elaborate on or respond to what others had shared. This process of sharing and comparing provided valuable insights into both the similarities and differences in the experiences of each group of participants [28,29]. HP facilitated the first focus group with patients and relatives, while HP and JC jointly facilitated the focus group with health care providers. Preliminary themes, identified in the field notes, were used to develop a semistructured interview guide for each focus group. The topics to discuss with patients and relatives were: preparation, timing, communication with doctors, information needs, visual explanations, role of the nurse, family participation, and digital technologies. For the health care providers, the topics were: organization, prioritizing, supervision, patient involvement, role of the nurse, family participation, visual explanations, and digital technologies. Theme cards with images were used to stimulate and structure the discussions. The focus groups each lasted 90 minutes and were held at the hospital. To supplement the data, HP conducted home visits to patients and their partners 5-16 days after discharge. During the home visits, data collection involved

dyadic interviews, using the same interview guide as in the focus group with patients and relatives. In dyadic interviews, 2 participants respond to open-ended research questions through interaction [30]. This interview format allowed for the collection of in-depth, detailed data, and the interaction between the couples stimulated experiences and insights that one of the participants might not have recalled or recognized. The home visits lasted 60 minutes each, and all interviews were audiotaped and transcribed verbatim. Dot voting was used to help patients and relatives prioritize the themes they considered most important. Each participant received 5 dots and was invited to allocate them to their preferred themes, either by placing all dots on 1 theme, distributing them across multiple themes, or using a combination of these approaches.

Data Analysis

Field notes and transcribed interview material were analyzed as a cohesive data set in an analysis matrix. The analysis followed a 4-step process guided by systematic text condensation, as outlined by Malterud [31]. First, the field notes and transcribed text were read to gain an overall impression and identify preliminary themes related to the research question. Second, meaningful units from each source were extracted to the analysis matrix and coded for classification. Third, subcategories were developed, and these were synthesized into overall categories accompanied by descriptions of the participants' experiences. To minimize additional burden on participants, the transcripts and quotes were not shared with them for review. As a result, step 1 was solely carried out by HP. However, the preliminary themes were presented to the ambassador participants at the beginning of the next phase of the participatory design process. The participants agreed with the identified themes and did not suggest any major changes to the analysis. Nevertheless, their feedback played a crucial role in refining the final interpretation of the themes, ensuring an accurate representation of the participants' perspectives. To ensure diverse analytical perspectives, the second step of the analysis was conducted collaboratively between HP and a research assistant. Preliminary themes, meaningful units, and codes were defined and discussed until a consensus was reached. In the first 2 steps, the data from each participant group were analyzed separately. HP and MW then defined the subcategories and synthesized them into overall categories. In these final steps, subcategories and overall categories were consolidated across all groups. The final analysis was reviewed and approved by all co-authors (Table 3). Further, a copy of the study findings was sent to the ambassador participants at the conclusion of the overall study. The Consolidated Criteria for Reporting Qualitative Studies (COREQ) were followed to promote complete and transparent reporting [32].

Table . Excerpt from the analytical process.

Step 1: Preliminary themes	Step 2: Meaningful units and codes		Step 3: Subcategories	Step 4: Overall category
	Quotes (examples)	Codes		
Prioritizing	"A doctor from the subacute track arrives and selects a patient at random from the list." [Field note] "When we assign patients, even when we sit together, it feels somewhat random." [Junior doctor, focus group]	The allocation of patients appears arbitrary and disorganized	Chaotic and unpredictable	Lack of organization
Organization	"Surgical ward rounds are the most unstructured I have ever encountered." [Junior doctor, go-along interview] "There is no organization in our rounds; it's completely chaotic, like a throwing star." [Senior doctor, focus group]	A more deliberate organization of SWRs[a] is required		
Supervision	"Two junior doctors arrive at 8:30 a.m. One of them asks, 'Isn't there any adult doctor here today?" [Field note] "It feels like you're sailing solo." [Junior doctor, focus group]	Junior doctors face difficulty in obtaining supervision	Being unprepared	
Preparation	"You receive a long list of patients, and there's only time to review if there's something urgent that needs attention." [Nurse, focus group] "If the nurses had time to review patient information, perform basic observations, calculate fluid balance, and so on before the rounds, we wouldn't have to wait for that." [Junior doctor, focus group]	The nurses are inadequately prepared for the SWRs		
Timing	"Suddenly, they appear, and I don't know who they are. It takes me a moment to realize it's a ward round." [Patient, home visit] "They just appeared out of nowhere." (Patient, go-along interview)	The patients are unaware of the SWRs and unprepared for them		
Role of the nurse	"The nurse discusses the patient with the doctor before the round, but does not accompany the doctor to the patient's room." [Field note] "The nurses you need to accompany may be occupied with another doctor." [Junior doctor, focus group]	Often, the nurses are too busy to attend the SWRs, or the junior doctors do not invite them	Absence of nurses and relatives	

Step 1: Preliminary themes	Step 2: Meaningful units and codes		Step 3: Subcategories	Step 4: Overall category
	Quotes (examples)	Codes		
Family participation	"It's very difficult for relatives to participate in the rounds because they span the entire day." [Patient, focus group]	Despite waiting for hours, the relatives rarely manage to attend the SWRs		
	"I haven't seen a doctor at all. We were there every day, and on the first day, we waited for hours." [Relative, home visit]			

[a]SWR: surgical ward round.

Results

Analysis

The analysis identified eight subcategories, which were consolidated into three overall categories: (1) lack of organization, (2) cultural norms, and (3) communication tools. Together, these categories offer an overview of the participants' experiences and needs during SWRs (Textbox 1). Each category is explained in the following, supported by representative interview quotes to ensure transferability.

Textbox 1. Subcategories and overall categories.

Subcategories

- Chaotic and unpredictable
- Being unprepared
- Absence of nurses and relatives
- Routine-driven and treatment-focused
- Passive attendee roles
- Patient Care Boards
- Visual explanations
- Digital technologies

Overall categories

- Lack of organization
- Cultural norms
- Communication tools

Lack of Organization

Lack of organization emerged as a dominant theme across the data, significantly compromising the quality of SWRs in several ways.

Chaotic and Unpredictable

All participants described the SWRs as chaotic and unpredictable. The distribution and order of patients appeared random, with little consideration for patient needs or the complexity of cases on the ward.

> *I find it random which doctors are assigned to which patients, and it's not always based on their competencies. The issue, as I see it, is that sometimes junior doctors end up with relatively complex patients. They have to consult multiple times and struggle to finalize and develop a solid plan for them.* [Junior doctor, focus group]

Junior doctors attempted to assign patients based on their competencies, but their limited experience and knowledge hindered their ability to make appropriate selections. Both doctors and nurses expressed a need for a more deliberate patient allocation, considering patient complexity, doctor competencies, and the operational requirements of the department.

Being Unprepared

When patient cases were complex, junior doctors sought supervision from seniors. However, senior doctors were often preoccupied with their own tasks, making it difficult for junior doctors to receive adequate guidance. As a result, SWRs became time-consuming for junior doctors, requiring them to leave and return to patients multiple times to seek advice from seniors. Patients and their relatives noticed the varying levels of competence among the doctors and reported that inconsistent information caused confusion. All participants believed that the lack of supervision could lead to prolonged admissions, as junior

doctors often delayed difficult treatment decisions. Senior doctors were generally more motivated to assess their own postoperative patients and emphasized the need for greater continuity in SWRs to better familiarize themselves with patients and conduct the rounds more efficiently. Similarly, patients expected doctors to be well-prepared and familiar with their medical histories. They noted that the lack of continuity often required them to repeat themselves. Nurses were frequently contacted by doctors at unscheduled times to participate in SWRs, which made it challenging to be adequately prepared or have in-depth knowledge of the patients. Additionally, nurses were often busy with other patients' care or involved in other SWRs. Doctors required updated patient information from the nurses, and their preparation time was extended when the necessary data was not readily available. The lack of organization also left patients unprepared for the SWRs. They often could not distinguish between the various health care providers visiting their room and had to remain on alert for the doctor to appear at any time. As a result, they were often unaware of when the SWRs occurred and did not always recognize that they had taken place. Patients expressed a need to be notified about SWRs in advance.

> *Then, suddenly, someone comes in and says, 'Hello, I'm the doctor, my name is so-and-so,' and immediately starts talking about what they know. It happens almost before you've fully woken up, so you can't really listen properly… I understand they're busy, but if I could get a little more time to (get ready), or at least have a nurse come in beforehand to let me know the doctor will be arriving shortly.* [Patient, focus group]

Consequently, patients and their relatives expressed a desire for a shorter time window to prepare for and participate in the SWRs.

Absence of Nurses and Relatives

Nurses did not routinely participate in the SWRs, often due to being too busy or not being invited. While senior doctors recognized and valued their contributions, junior doctors typically preferred to conduct the rounds independently, likely due to uncertainty. Both patients and their relatives emphasized the essential role of nurses, viewing them as a crucial link between themselves and the doctors. When nurses attended SWRs, they were able to support patients by clarifying or relaying information to relatives, when needed. However, when nurses were absent, they were unable to contribute to the SWR agenda or properly follow up on prescriptions. As a result, nurses were either forced to contact the doctors later with their questions, or the doctors would reach out to update them on care plans and prescriptions. Occasionally, the nurses were not informed at all.

> *Sometimes, rounds are conducted without my knowledge. I might not find out until I check the medical record at 2 PM, where it notes prescriptions from the morning, like sending a urine sample or other tasks. That gives me only an hour to fix that, and I often can't complete everything (before shift change).* [Nurse, focus group]

Thus, the lack of nurse attendance risks delaying the follow-up on SWRs. Nurses indicated that, if they had known the order of the rounds, they could have prioritized participation and have been better prepared with updated information about each patient. Since SWRs could last all day, relatives often waited for hours in the department yet rarely managed to attend. As a result, they felt uninformed and excluded, despite doctors and nurses generally viewing them as valuable resources for the patients. Nurses attempted to coordinate the rounds to facilitate relatives' participation, but their success varied. Most patients felt responsible for relaying information to their relatives when they were absent during the rounds but struggled to recall the information provided. Consequently, relatives frequently turned to nurses to obtain the information they needed.

Cultural Norms

SWRs were shaped by cultural norms that influenced participants' roles and their ability to partake. Additionally, the rounds were defined by established routines and a narrow, treatment-focused approach.

Routine-Driven and Treatment-Focused

Generally, all patients were included in SWRs every day, with some undergoing unnecessary blood tests or receiving pointless rounds due to automatic processes. Nurses estimated that most patients on the ward required daily rounds, while senior doctors disagreed, arguing that direct patient interaction was not always necessary, especially when a clear treatment plan had already been established, with little or no changes needed. Most senior doctors had a treatment-oriented perspective, primarily focusing on physical symptoms. This was reflected in the patient experience, which indicated that most SWRs concentrated on specific treatments. Patients expressed that information about managing everyday life with the disease was sparse and often came too late. Likewise, nurses expressed that SWRs had a narrow focus, primarily centered on doctors presenting the treatment plan for the patient. Junior doctors were perceived as thorough in creating detailed plans but often needed guidance in prioritizing symptoms related to the immediate situation. In contrast, nurses considered their approach to be more person-centered and holistic. Compared to surgical tasks, SWRs were considered a lower priority, with senior doctors expressing a desire for them to be completed quickly.

> *A real surgical department; It's when you're done with rounds by 9 AM (staff laughs). Then you have time to do other things, right?* [Senior doctor, focus group]

Patients reported that doctors and nurses were frequently interrupted during SWRs, with some leaving midconversation. Senior doctors were observed leaving the ward, either to attend to surgical tasks or to avoid distractions. They described themselves as self-directed and somewhat anarchic, acknowledging that this behavior affected the structure and organization of the SWRs. Patients and their relatives found SWRs to be very brief, with most doctors standing at the bedside. However, when doctors took the time to sit down at eye level with the patient, it not only conveyed a sense of being informed, seen, and heard but also made the patients more aware of the SWR.

> *I thought it was incredible that she took the time to do that (sit down), but she did. It was as if I became myself again… Yes, I got it, this is a round…* [Patient, home visits]

Passive Attendee Roles

Nurses perceived SWRs primarily as a dialogue between the doctor and the patient, adjusting their communication style to align with that of the doctor. When not invited to contribute, or if they felt the doctor was handling the situation well, they typically refrained from speaking out. As a result, when nurses accompany doctors to the patient room, they often adopt a passive, listening role. Similarly, relatives who were able to attend SWRs were generally not actively engaged in the conversation. The time-constrained behavior of doctors, combined with a sense of deference to authority, limited knowledge, and the unpredictability of the rounds, often prevented patients and relatives from asking questions. Allowing them the opportunity to prepare by noting questions in advance could help alleviate this hesitation.

> *If we knew we could speak with the doctor, say at 11 AM, my daughter and I would definitely have prepared. We would have written down a whole list of questions…* [Relative, home visits]

Scheduled SWRs with a clear agenda would help patients and relatives to prepare in advance and feel more confident in asking questions.

Communication Tools

Participants explored various communication tools as potential solutions to address their needs and the challenges encountered during SWRs.

Patient Care Boards (PCB)

Patients and relatives expressed a need for clearer information about care plans and saw the PCB as a useful tool for staying informed. However, they often found it inadequately updated. Some nurses used the PCB before SWRs to identify questions that patients might have for the doctor. While doctors recognized the value of the PCB in aligning expectations and keeping patients informed, they generally preferred that the nurses took responsibility for updating it.

Visual Explanations

Some doctors used visual aids, such as drawings of the gestational system or x-rays, to explain the disease, examinations, or treatments offered to the patients. Most patients and their relatives reported that this approach enhanced their understanding.

> *We don't know what's happening beneath the surface of the skin… A picture would make everything clearer, as I could immediately identify where the stoma is located, which would help me understand the source of the pain.* [Relative, home visits]

Digital Technologies

Patients and relatives saw potential in using digital technologies, such as apps for information or video communication with relatives. They discussed the use of these technologies by combining theme cards they felt were related to one another.

> *If you group these together (points to three theme cards)... it makes a difference, both in terms of the timing of the rounds and the involvement of relatives, if digital technologies could be used.* [Patient, focus group]

Patients and relatives believed that digital technologies could help them engage more actively by providing better access to information about the timing of the SWRs and improving their ability to prepare and attend. However, they noted that older individuals often lack digital competencies and would require guidance or alternative options. While nurses were generally supportive of digital technologies, most doctors viewed them as irrelevant or disruptive. Patients emphasized that while digital technologies could facilitate communication, human interaction, and personal presence remained their top priority.

Discussion

Principal Results

Through our investigation of the experiences and needs of core participants in SWRs, we identified several factors that compromise the quality, efficiency, and overall experience of these rounds. The most significant factors were a lack of organization and the low priority given to the SWRs compared to surgical tasks. Combined with a routine-driven and treatment-oriented focus, along with the influence of cultural and hierarchical norms, these issues create a snowball effect resulting in unpredictability, unprepared participants, and limited opportunities for nurses, patients, and relatives to partake. Assigning a dedicated coordinator to ensure that all participants are informed of the what, when, where, and who of each round will ensure that each team member is invited and leaves with clear takeaways. Further, specific objectives and time frames for each round will help maintain focus and prevent them from extending throughout the day. Patients and their relatives recognized the potential of using digital technologies to enhance their engagement in SWRs. While nurses supported the use of technologies to ensure broader participation, doctors, however, were skeptical about their practical applicability. As highlighted in a feasibility study by Johannink et al [33], medical students preferred face-to-face interactions over digital formats like video-transmitted SWRs. This finding aligns with the perspectives shared by the participants in our study, emphasizing that, while digital tools can assist in enhancing communication, they cannot replace the essential in-person care and interaction required in clinical settings.

Comparison With Prior Work

The low priority given to SWRs is a widely recognized issue. Savage et al [3] and Shetty et al [34] noted that SWRs are commonly perceived by senior doctors as a short activity and they seldom take precedence over other surgical responsibilities. In their study on team dynamics, Bonaconsa et al [13] highlighted the significant pressure placed on seniors due to their numerous competing commitments and informal queries throughout the day. As a result, the organizational structure of

surgical departments limits the availability of senior doctors on the wards. Consequently, junior doctors play a crucial role in conducting SWRs, often learning through hands-on experience or by emulating their senior colleagues [4,6,35-38]. In line with our findings, Monash et al [39] reported that senior doctors generally hold positive attitudes toward interdisciplinary rounds with nurses. However, junior doctors expressed lower satisfaction, perceiving them as more time-consuming. The feasibility of interdisciplinary rounds was therefore positively influenced by the presence of senior doctors. In our study, lack of organization led to nurses often not participating in SWRs, a finding consistent with other studies that identify differing work routines as a major barrier to nurse involvement [4,40-42]. Observational studies further support this issue, showing nurse attendance at SWRs ranging from only 13% to 44% [3,38,41,43]. Interdisciplinary rounds have been shown to decrease mortality rates, reduce hospital stays, and lower health care costs [41]. Such collaboration ensures that all team members, including nurses, patients, and relatives, are prepared and have access to participate meaningfully in SWRs. The lack of organization left nurses in our study unprepared, requiring doctors to spend additional time gathering relevant patient data. Moreover, the absence of nurses during SWRs resulted in gaps in the handover of care plans and delays in follow-up. Consistent with this, Bonaconsa et al [13] found that prescriptions not directly communicated to nurses could delay follow-up by as much as a day. Furthermore, several studies indicate that when nurses attend SWRs, the number of inquiries and calls to doctors later in the day is reduced [7-9,44]. Prioritizing SWRs by allocating dedicated time for them would allow nurses to plan their day effectively, ensuring they are prepared and able to participate. Further, a facilitator might break down malignant power hierarchies and guide the rounds by determining which team members should be involved.

The lack of organization in SWRs is a well-documented challenge for patients and their relatives as well. Swenne et al [45] found that the timing of SWRs varied from day to day. Additionally, Schwartz et al [7] identified several logistical barriers to patient participation, such as patients not being present, sleeping, or lacking interpreter assistance. Despite these challenges, some patients in our study took proactive steps to prepare by noting questions well in advance, often with the support of nurses using the PCB. Walton et al [46] found that patients familiar with the health care system often learn to navigate the SWR process to ensure their needs are met. These patients prepare by considering both the information they need to provide and the questions the doctor may ask. Several studies suggest that adopting a structured approach with a fixed starting time optimizes the use of patients' time, allows them to be better prepared and actively participate, and makes it easier for family members to attend [4,45-47]. Relatives in our study rarely managed to attend the SWRs, a finding consistent with previous research [16], which reported a low relative attendance rate of just 19%. Studies suggest that the presence of relatives enhances communication between doctors and patients, with relatives noting that being present allows them to participate in decision-making [47,48]. In our study, both doctors and nurses acknowledged relatives as valuable resources, but the lack of organization hindered their attendance. However, providing relatives with clear explanations and valuable information during the SWRs can reduce the need for additional meetings outside of rounds [48]. Similarly, we observed that relatives often sought the nurses between rounds to obtain the information they needed. Research highlights the essential role nurses play in ensuring patients fully understand the information provided, bridging the gap between doctors and relatives [4,45]. When nurses were absent from SWRs, the responsibility shifted more heavily to the patients. As a result, many patients in our study felt obligated to relay information to their relatives when neither they nor the nurse were present, yet they often struggled to recall the information given. Coordinating SWRs through digital technologies to connect relatives to the bedside, either physically or digitally, might enhance the overall experience and improve the efficiency of family involvement.

Another crucial aspect is the influence of cultural and hierarchical norms on participants' ability to engage. Studies have shown that nurses often perceive SWRs as primarily belonging to doctors, leading to hesitance in voicing their concerns, even when such omissions could compromise patient safety [3,49]. In our study, we observed nurses adapting their communication style to align with that of the doctors, typically refraining from interrupting. However, when doctors actively involve nurses in SWRs, it fosters more comprehensive discussions about patient or family concerns [50]. Recognizing and valuing nursing input in SWRs is, therefore, essential for improving the focus and quality of these rounds. Patients frequently expressed difficulty distinguishing between the numerous health care providers visiting their rooms. Similarly, Swenne et al [45] found that patients struggled to identify names and professions, with small nametags providing little assistance. Observational studies reveal inconsistent self-introduction practices among health care providers, with rates ranging from 81% to as low as 15% [46,51,52]. Furthermore, our findings revealed that patients perceived SWRs as brief, disruptive, and overly focused on medical issues. Descriptive studies show that the average time spent at the bedside ranges from 7.5 minutes during medical ward rounds to as little as 2.3 minutes during SWRs [34,43,50,53]. Similarly, several studies report that the short duration, frequent interruptions, and emphasis on medical decision-making hinder patients from engaging in a meaningful way [4,45,46,51,52,54]. In contrast, Ratelle et al [55] found no correlation between the duration of the SWR and patient experience, suggesting that the quality of time spent at the bedside is more important. Similarly, Iversen et al [56] discovered that person-centered communication did not affect the length of consultations. In ward rounds, patients emphasize the importance of active listening skills, body language, and the doctor's physical positioning [55]. Consistent with these findings, patients in our study valued when doctors sat at eye level with them, underscoring that human interaction and presence were paramount. Video filming the rounds for training purposes might offer valuable insights [33]. Such recordings could facilitate self-reflection and team feedback, as well as help identify opportunities for further improvement in the structure and effectiveness of future rounds.

Limitations

We successfully recruited a diverse group of health care providers, with variations in sex, age, experience, and education. However, we observed a significant dropout among patients and their relatives, highlighting the challenges of engaging this vulnerable and hard-to-reach group. Furthermore, the majority of relatives in our study were women, with female partners comprising the majority. This aligns with previous studies, which have found that most relatives participating in SWRs are female [16]. As a result, we lack insights into the experiences and needs of male relatives, as well as an understanding of the reasons for their absence. Involving our participants in the very early stages of the study could have provided valuable insights and adjustments to optimize our study design and recruitment process, making it more suitable for our target group. However, we remained adaptable throughout the recruitment process and conducted the home visits, which allowed us to recruit a broader range of patients and enhance the diversity of our sample. Furthermore, the home visits yielded more nuanced data, as the dyadic interview format allowed for in-depth explanations and follow-up questions, providing a richer understanding of the experiences of both patients and their relatives.

The single-center design of our study may limit the generalizability of our findings, as the specific department may have unique workflows and a distinct round culture. However, the alignment of our results with existing literature strengthens the reliability and consistency of our findings. To mitigate the influence of unacknowledged preconceptions of the research team, a diverse group of researchers with varying experiences and expertise conducted the data collection and analysis. This collaborative approach was intended to enhance the credibility and rigor of the study. All authors emphasized maintaining openness to the participants' lived experiences, presenting the data as they emerged rather than allowing personal or theoretical frameworks to shape or interpret the findings. However, our background in participatory design naturally drew our focus toward digital technologies as potential solutions to meet user needs, which we sought to explore through our informants. We chose to analyze the diverse experiences of participants as a single entity, which may have limited the depth and nuances of the results. However, in order to develop high-quality, user-centered SWRs that address the needs of all core participants, we aimed to explore the complexity of experiences and needs in their entirety.

Conclusions

This study highlighted a significant gap between the organizational and cultural frameworks governing the SWRs and the experiences and needs of key participants. To bridge this gap, it is essential to address the lack of organization, prioritization, and timing of the SWRs. Patients and their relatives recognized the potential of using digital technologies to address some of these challenges. However, due to the skepticism toward technology among doctors and the low priority given to SWRs, it is crucial to involve them in developing these technologies. Nurses, on the other hand, expressed support for using digital technologies to enhance broader participation. Therefore, the next phase of this research should focus on co-developing digital technologies that facilitate more structured SWRs, fostering active involvement from all key participants. This approach aims to ensure successful implementation while improving the overall quality, efficiency, and user experience.

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Data Availability

The data is unavailable due to the inclusion of sensitive and confidential information.

Authors' Contributions

HP wrote the original draft of the manuscript. HP and JC collected the data, and HP and MW conducted the formal analysis. All authors contributed to the conceptualization of the study and reviewed the final manuscript.

Conflicts of Interest

None declared.

Checklist 1
Consolidated Criteria for Reporting Qualitative Studies (COREQ) Checklist.
[PDF File, 438 KB - jopm_v17i1e69578_app1.pdf]

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Abbreviations

COREQ: Consolidated Criteria for Reporting Qualitative Studies
PCB: Patient Care Board
SWR: surgical ward round

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Subjective Performance Expectations From and Demographic and Categorical Differences in the Acceptance of Virtual Reality or AI Technologies in Rehabilitation Programs: Cross-Sectional Questionnaire Survey With Rehabilitation Patients

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Abstract

Background: More than a few concepts have been presented in rehabilitation clinics that implement aspects of modern IT in the arrangement of augmented reality or virtual rehabilitation aiming to enhance cognitive or motor learning and rehabilitation motivation. Despite their scientific success, it is currently unknown whether rehabilitants will accept rehabilitation concepts that integrate modern ITs.

Objective: This study aims to investigate the subjective performance expectations of rehabilitation patients regarding the application of virtual reality (VR) or artificial intelligence technologies across various therapeutic fields, and to identify demographic and categorical differences in acceptance to inform the development and implementation of VR-based rehabilitation programs.

Methods: In total, 111 rehabilitation patients were surveyed about their subjective performance expectations of VR in 15 therapeutic fields with a questionnaire. The distribution of the responses was evaluated using box plots. The relationship between the subjective performance expectations for the 15 therapeutic fields was analyzed using the Spearman ρ coefficient, while the Mann-Whitney *U* test was used to compare subjective performance expectations between age groups and between genders.

Results: For all 15 therapeutic fields, the median of the subjective performance expectations was between 2 and 3, while therapeutic fields in the categories “activity/movement,” “competence in daily life/communication,” and “education” tended to be rated higher than therapeutic fields in the categories “relaxation/passive measures” and “advisory/conversation.” A significant rank correlation was observed for 103 out of 105 pairwise comparisons of the therapeutic fields, with distinct patterns of effects sizes within the chosen categories. There was no significant difference in the evaluation between rehabilitants of employable age and those aged 68 years or older. Male rehabilitation patients reported greater subjective expectations for virtual rehabilitation than female patients, but there was only a significant difference with small effect sizes for 3 of the 15 therapeutic fields.

Conclusions: The general trend is that patients can imagine taking part in VR in rehabilitation activities involving active movement (physiotherapy, sports and exercise therapy, and occupational therapy) and health education. The results of the survey show that there is also a high level of support for the therapeutic field advisory/conversation. Current circumstances have led to substantial use of virtual offerings in practice. The limited data available may have encouraged the professional development of VR systems and their widespread use in medical rehabilitation follow-up in the home setting.

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KEYWORDS

virtual reality; expectation of success; computer-assisted rehabilitation; motivation; neurologic rehabilitation

Introduction

Didactic principles and learning strategies play a vital role in medical rehabilitation, whereby the path for knowledge acquisition differs for young and old individuals. These age-specific differences in learning appear to be due to changes in neural systems that assess how much should be learned from changes in the environment [1]. In rehabilitation, the advantages of virtual environments and training programs with a high interactive content can be used for such knowledge acquisition. Positive transfer effects from a virtual space to the real environment are already known. In addition, a virtual training environment can be designed to provide motivational feedback and to directly control the complexity of a therapeutic content

or environmental changes according to the patient's performance. In virtual environments, both lessons and practice sequences can be repeated as often as required, and incorrect actions are reversible and have no consequences. Learning from faults and training at performance limits can be easily controlled. Such learning environments are free of charge and, in principle, have unlimited availability.

Perception and learning under virtual reality (VR) conditions have been studied not only in healthy individuals but also in those with brain injury [2-6]. This indicates that approaches to VR in brain injury rehabilitation are already established in terms of cognitive assessment and cognitive rehabilitation with technically simple systems. However, VR systems have not yet been established in motor rehabilitation. Studies with immersive systems have shown at least preliminary positive effects in upper extremity rehabilitation training [6]. For a general integration into rehabilitation concepts, a comfortable technical applicability and obvious motion detection are central requirements. Therapist-assisted rehabilitation interventions are often superior to purely technical interventions or virtual environments in everyday life. The development of new motion recognition systems for the gaming industry in recent years has made it possible to develop new everyday conditions for the use of virtual environments in motor rehabilitation [7,8]. However, the motivation and acceptance of people confronted with this technology in a therapeutic setting have not been sufficiently investigated. Key questions in this context are as follows:

1. Can neurological rehabilitation patients imagine that virtual rehabilitation will be developed as a new rehabilitation concept?
2. How do rehabilitation patients rate this vision in terms of different therapeutic areas and perceived therapeutic success?
3. Can virtual training lead to increased motivation and cooperation among rehabilitation patients in terms of therapeutic participation or self-regulated training?

In complex models describing the probability of user acceptance with an innovation, subjective performance expectancy regarding the benefits of a system is the strongest predictor of behavioral intention to accept an innovation [9-11]. Therefore, in this work, a survey of the subjective performance expectancy of virtual rehabilitation is conducted to provide a basis for the systematic evaluation of the benefits that VR can bring to various areas of medical rehabilitation.

Methods

Research Questionnaire and Survey

A questionnaire was developed to measure patients' subjective performance expectations from virtual rehabilitation in 15 therapeutic fields using a Likert scale [12] with ratings 1=excellent, 2=good, 3=adequate, 4=unsatisfactory, and 5=poor. Table 1 provides an overview of the selected therapeutic fields as well as a classification into 5 basic categories, illustrating that the full spectrum of therapeutic measures is covered by the questionnaire. In version 1.1 of the questionnaire, 2 questions were added: "Do you think that virtual reality can be used to achieve higher motivation for cooperation and training?" "Do you have any experience with computers or game consoles? (Yes/No)?"

Table . Categorization of therapeutic fields.

Therapeutic fields	Categories
Physiotherapy	Activity/movement
Sports and exercise therapy	Activity/movement
Occupational therapy	Competence in daily life/communication
Speech therapy	Competence in daily life/communication
Relaxation techniques	Relaxation/passive measures
Physical therapy	Relaxation/passive measures
Psychological individual therapy	Advisory/conversation
Psychological group therapy	Advisory/conversation
Discussion groups on disease management	Advisory/conversation
Advice from social services	Advisory/conversation
Health seminars and education	Education
Nutrition advisory	Education
Patient education for back pain	Education
Diabetic training	Education
Education in sport and movement therapy	Education

Ethical Considerations

A survey based on the developed questionnaire was reviewed for its ethical acceptability, particularly concerning the protection of participants' social and psychological integrity by the Senate Commission for Research Ethics of Ostfalia University of Applied Sciences, University of Braunschweig/Wolfenbüttel. In accordance with national

regulations and institutional policies, no institutional review board name or number was assigned, as the survey was anonymous and involved no interventions. The survey was conducted in accordance with the ethical principles of the Declaration of Helsinki. All participants provided informed consent prior to participation.

Population

A total of 126 patients of a neurological rehabilitation clinic were interviewed with the questionnaire from 2013 to 2015. After data cleansing, 111 questionnaires could be used for analysis. In total, 15 questionnaires were refused or incomplete. Overall, 61 patients were evaluated with version 1.0 of the questionnaire, and 50 patients were evaluated with version 1.1 of the questionnaire. Patients' diagnoses varied widely (stroke, intracerebral bleeding, encephalitis, myopathy, motoneuron disease, polyradiculitis, encephalomyelitis disseminata, myelopathy, and tumors of neurological tissue).

Statistical Analysis

Nonparametric statistical methods were chosen due to the ordinal rating scale. Rank correlation with the Spearman ρ coefficient was used to assess the relationship between the subjective performance expectations for the 15 therapeutic fields, while the Mann-Whitney *U* test was used for group comparisons, and the chi-square test was used to compare the contingency of patients' responses. Effect sizes were interpreted in accordance with Cohen [13]. All statistics were calculated with IBM SPSS Statistics (version 29). A critical level of $P<.05$ was considered significant for all statistics.

Results

Patients' demographic data are shown in Table 2. The patients' age ranged from 32 to 86 (mean 65.3, SD 12.2) years. In total, 62 patients were male and 49 were female. The age distribution in the male and female groups was balanced (mean 65.4 vs 65.2, SD 11.5 y vs 13.1 years). The gender distribution in the age groups "<68 years" and "≥68 years" was similar, with slightly more males than females (male:female 31:26 versus 31:23).

Table . Demographic data.

	Total	Age (years)		Gender	
		<68	≥68	Male	Female
Age (years), mean (SD); range	65.3 (12.2); 32-86	55.8 (8.9); 32-67	75.4 (4.8); 68-86	65.4 (11.5); 32-86	65.2 (13.1); 33-85
Gender (male/female), n/n	62/49	31/26	31/23	—[a]	—

[a]Not applicable.

Overall, 56% of respondents were undergoing inpatient medical rehabilitation for the first time. Further, 38% of respondents had been to an inpatient medical rehabilitation facility at least twice, regardless of specialty or diagnosis, and 92% of respondents said they had not heard of virtual rehabilitation and needed an explanation. In these explanations, we followed the definition of VR in the context of neuroplasticity by Weiss et al [14]: "Virtual reality is defined as an approach to a user-computer interface that creates a real-time simulation of an environment, scenario, or activity, allowing the user to perform complex interactions using multiple sensory channels. Virtual rehabilitation training approaches use the latest VR technologies, improved robotic design, the development of haptic interfaces, and modern human-machine interactions for meaningful stimulation of the nervous system, thereby promoting brain plasticity."

An overview of the patients' ratings is provided in Figure 1. In general, rehabilitants can imagine the use of VR in rehabilitation. This particularly applies to all items in the categories "activity/movement," "competence in daily life/communication," and "education" as well as for the occupational therapy (all these therapeutic measures have median score of 2, which represents the rating "good"), whereas physical therapy and all items in the category "advisory/conversation" exhibited a mean score of 3, which corresponds the rating "adequate."

The monotonic relationship among the 15 therapeutic fields is displayed in Figure 2. Except for the 2 combinations of therapeutic fields displayed in white, all correlations are significant at a .05 level (2-tailed). A rank correlation with a large effect size can be observed within the categories "activity/movement" and "advisory/conversation" as well within the category "education" but only among the therapeutic fields "health seminars and education," "nutrition advisory," and "diabetic training." The monotonic relationship between the items of the category "competence in daily life/communication" is medium, while there is no significant rank correlation between "relaxation techniques" and "physical therapy."

Table 3 shows the results of the group comparisons. There was no significant difference in the evaluation of VR between rehabilitants of employable age (aged <68 years) and those aged 68 years or older (Mann-Whitney *U* test, z=−.137 to −1.802, $P=.07$ to .90). Regarding the evaluation based on gender, it should be noted that male rehabilitation patients generally report greater subjective expectations for virtual rehabilitation than female patients, but there was only a significant difference with small effect sizes for "sports and exercise therapy," "psychological individual therapy," and "psychological group therapy."

Figure 1. Distribution of patients' evaluation of therapeutic fields with regard to possible benefits of using virtual reality.

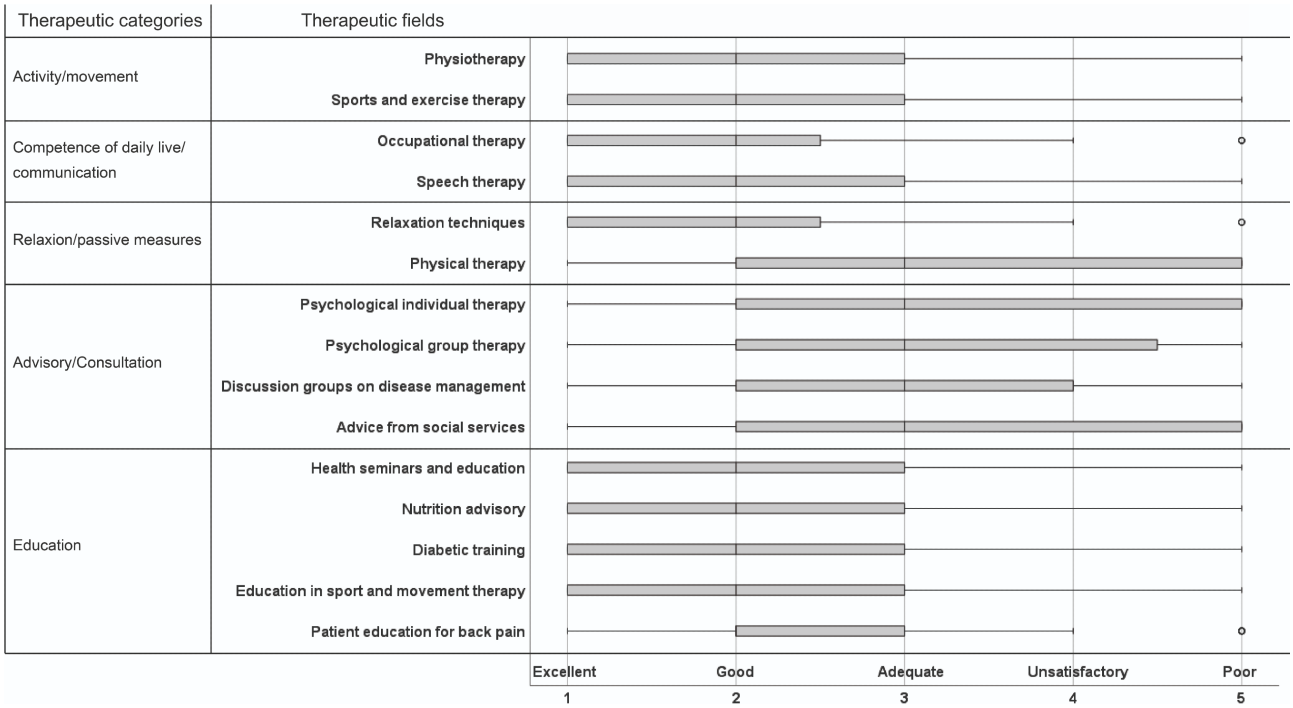

Figure 2. Rank correlation between patients' evaluation of therapeutic fields and the monotonic relationship among the 15 therapeutic fields. Dark gray: large monotonic relationship (0.5≤|ρ|≤1.0); medium gray: medium monotonic relationship (0.3≤|ρ|<0.5); light gray: small monotonic relationship (small monotonic relationship); and white: no significant rank correlation.

		Activity/ movement		Competence of daily live/ communication		Relaxation/ passive measures		Advisory/conversation				Education				
		Physiotherapy	Sports and exercise therapy	Occupational therapy	Speech therapy	Relaxation techniques	Physical therapy	Psychological individual therapy	Psychological group therapy	Discussion groups on disease management	Advice from social services	Health seminars and education	Nutrition advisory	Diabetic training	Education in sport and movement therapy	Patient education for back pain
Activity/movement	Physiotherapy	x	0,634	0,311	0,380	0,291	0,411	0,410	0,435	0,301	0,339	0,336	0,350	0,307	0,298	0,556
	Sports and exercise therapy	0,634	x	0,364	0,306	0,285	0,347	0,401	0,454	0,361	0,296	0,259	0,318	0,362	0,263	0,484
Competence of daily live/communication	Occupational therapy	0,311	0,364	x	0,337	0,328	0,231	0,338	0,343	0,323	0,338	0,322	0,393	0,234	0,412	0,419
	Speech therapy	0,380	0,306	0,337	x	0,294	0,353	0,333	0,374	0,290	0,503	0,302	0,358	0,390	0,328	0,434
Relaxation/ passive measures	Relaxation techniques	0,291	0,285	0,328	0,294	x	-	0,291	0,241	0,221	0,358	0,400	0,551	0,411	0,489	-
	Physical therapy	0,411	0,347	0,231	0,353	-	x	0,522	0,531	0,565	0,490	0,357	0,280	0,398	0,258	0,434
Advisory/ conversation	Psychological individual therapy	0,410	0,401	0,338	0,333	0,291	0,522	x	0,816	0,619	0,594	0,369	0,304	0,367	0,394	0,452
	Psychological group therapy	0,435	0,454	0,343	0,374	0,241	0,531	0,816	x	0,632	0,589	0,343	0,254	0,394	0,309	0,508
	Discussion groups on disease management	0,301	0,361	0,323	0,290	0,221	0,565	0,619	0,632	x	0,569	0,418	0,333	0,457	0,332	0,519
	Advice from social services	0,339	0,296	0,338	0,503	0,358	0,490	0,594	0,589	0,569	x	0,470	0,368	0,461	0,385	0,478
Education	Health seminars and education	0,336	0,259	0,322	0,302	0,400	0,357	0,369	0,343	0,418	0,470	x	0,728	0,592	0,685	0,248
	Nutrition advisory	0,350	0,318	0,393	0,358	0,551	0,280	0,304	0,254	0,333	0,368	0,728	x	0,674	0,640	0,209
	Diabetic training	0,307	0,362	0,234	0,390	0,411	0,398	0,367	0,394	0,457	0,461	0,592	0,674	x	0,443	0,335
	Education in sport and movement therapy	0,298	0,263	0,412	0,328	0,489	0,258	0,394	0,309	0,332	0,385	0,685	0,640	0,443	x	0,204
	Patient education for back pain	0,556	0,484	0,419	0,434	-	0,434	0,452	0,508	0,519	0,478	0,248	0,209	0,335	0,204	x

Table . Group comparisons (age and gender).

	Age			Gender		
	P value	z	Effect size r	*P* value	z	Effect size r
Physiotherapy	.21	−1267	—[a]	.07	1841	—
Sports and exercise therapy	.07	−1802	—	.006	−2726	.259
Occupational therapy	.82	−.222	—	.10	−1644	—
Speech therapy	.77	−.297	—	.43	−.786	—
Relaxation techniques	.20	−1291	—	.08	−1725	—
Physical therapy	.44	−.783	—	.28	−1092	—
Psychological individual therapy	.90	−.137	—	.007	−2699	.256
Psychological group therapy	.75	−.325	—	.005	−2761	.262
Discussion groups on disease management	.75	−.305	—	.21	−1256	—
Advice from social services	.50	−.677	—	.13	−1523	—
Health seminars and education	.13	−1506	—	.51	−.667	—
Nutrition advisory	.15	−1450	—	.38	−.871	—
Diabetic training	.71	−.378	—	.81	−.245	—
Education in sport and movement therapy	.13	−1501	—	.34	−.964	—
Patient education for back pain	.54	−.622	—	.20	−1288	—

[a]Not applicable.

Table 4 shows the distribution of patients' answers regarding the additional questions. Overall, 78% of the patients believe, that VR can be used to achieve higher motivation and willingness to participate in medical rehabilitation therapy. There is no significant correlation with this answer and the experience with computers or game consoles (*P*=.08 [Fisher exact chi-square test]; expected cell frequencies were below 5).

Table . Patients' responses to 2 questions: (1) Do you think you can achieve a higher motivation for cooperation and training using virtual reality? (2) Do you have any experiences with computers or game consoles? (Cross table; N=50).

	Do you have any experiences with computers or game consoles?, n (%)		
	Yes	No	Total
Do you think you can achieve a higher motivation for cooperation and training using virtual reality?			
Yes	27 (54)	12 (24)	39 (78)
No	4 (8)	7 (14)	11 (22)
Total	31 (62)	19 (38)	50 (100)

Discussion

Principal Findings

No other publication has addressed the subjective performance expectancy of virtual rehabilitation in rehabilitation patients. A possible limitation of this study is that the diagnoses of the rehabilitants and the amount of rehabilitation performed up to the time of the survey differed between the rehabilitants. The influence of this cofactors could not be evaluated with the given database. However, the results indicate a general willingness of rehabilitation patients to accept VR in the medical rehabilitation process. Since game consoles with motion-enhancing applications are well known in the population,

it is not surprising that motion-enhancing VR is associated with a higher subjective performance expectancy than passive applications.

The results of the rank correlation suggest that when implementing VR strategies, certain areas of therapy could be linked for particular motivational support. This applies, for example, to activity/movement and education or competence in daily life/communication. A joint virtual therapeutic strategy for physical therapy and advisory/conversation is also conceivable.

Patients' age and previous experience with computers or game consoles are not prerequisites for special motivation. This is an important aspect for the decision to treat certain patient groups separately. Measures with high information content and measures that require a high degree of imagination are also considered suitable for VR [15].

However, the responses represent only an imagined virtual rehabilitation. Patients were given a glimpse into the future. Ultimately, the concrete design of the motivating interaction, the social relationship, and the (immediate) reward determine the acceptance of new forms of therapy—virtual or real.

Limitations

A major limitation of this study is that the survey was conducted 10 years ago. However, the authors still consider the prospective analysis of the existing data to be meaningful because no comparable studies have been published to date. Furthermore, existing health applications for virtual rehabilitation, such as the digital rehabilitation after care by CASPAR/MediClin GmbH [16], show, that the topic of subjective performance expectancy is highly relevant for current applications.

Conclusion

Rehabilitation time is a valuable commodity, and rapid recovery means greater financial security for the individual and more lifetime in health. The benefits and efficiencies that VR can bring to various areas of medical rehabilitation need to be explored. Rehabilitation institutions are already gaining experience with professional systems or equipment from the gaming industry. However, considering the limited data available on acceptance, implementation and therapy outcomes have not yet been able to support large-scale industrial development and widespread use of virtual medical rehabilitation systems. To gain knowledge about the willingness of rehabilitation patients to accept VR systems, it was necessary to analyze their subjective performance expectations. This knowledge is also an important prerequisite for the acceptance of modern rehabilitation measures by health care payers and health insurance companies. An increasing trend toward the use of tele-rehabilitation confirms the results of the survey. The current trend toward virtual aftercare, especially via the internet, is showing increasing acceptance by both patients and health care payers.

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Conflicts of Interest

None declared.

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Abbreviations

VR: virtual reality

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Original Paper

Value Propositions for Digital Shared Medication Plans to Boost Patient–Health Care Professional Partnerships: Co-Design Study

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Abstract

Background: Health authorities worldwide have invested in digital technologies to establish robust information exchange systems for improving the safety and efficiency of medication management. Nevertheless, inaccurate medication lists and information gaps are common, particularly during care transitions, leading to avoidable harm, inefficiencies, and increased costs. Besides fragmented health care processes, the inconsistent incorporation of patient-driven changes contributes to these problems. Concurrently, patient-empowerment tools, such as mobile apps, are often not integrated into health care professional workflows. Leveraging coproduction by allowing patients to update their digital shared medication plans (SMPs) is a promising but underused and challenging approach.

Objective: This study aimed to determine the value propositions of a digital tool enabling patients, family caregivers, and health care professionals to coproduce and co-manage medication plans within Switzerland's national eHealth architecture.

Methods: We used an experience-based co-design approach in the French-speaking region of Switzerland. The multidisciplinary research team included 5 patients as co-researchers. We recruited polypharmacy patients, family caregivers, and health care professionals with a broad range of experiences, diseases, and ages. The experience-based co-design had 4 phases: capturing, understanding, and improving experiences, followed by preparing recommendations and next steps. A qualitative, participatory methodology was used to iteratively explore collaborative medication management experiences and identify barriers and enabling mechanisms, including technology. We conducted a thematic analysis of participant interviews to develop value propositions for digital SMPs.

Results: In total, 31 persons participated in 9 interviews, 5 focus groups, and 2 co-design workshops. We identified four value propositions for involving patients and family caregivers in digital SMP management: (1) comprehensive, accessible information about patients' current medication plans and histories, enabling streamlined access and reconciliation on a single platform; (2) patient and health care professional empowerment through the explicit co-ownership of SMPs, fostering coresponsibility, accountability, and transparent collaboration; (3) a means of supporting collaborative interprofessional medication management,

including tailored access to information and improved communication across stakeholders; and (4) an opportunity to improve the quality of care and catalyze digital health innovations. Participants discussed types of patient involvement in editing shared information and emphasized the importance of tailoring SMPs to individual abilities and preferences to foster health equity. Integrating co-management into the clinical routine and creating supportive conditions were deemed important.

Conclusions: Coproduced SMPs can improve medication management by fostering trust and collaboration between patients and health care professionals. Successful implementation will require eHealth interoperability frameworks that embrace the complexity of medication management and support diverse use configurations. Our findings underscored the shared responsibility of all stakeholders, including policy makers and technology providers, for the effective and safe use of SMPs. The 4 value propositions offer strategic guidance, while highlighting the need for further research in different health care settings.

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KEYWORDS

digital shared medication plan; medication records; medication list; e-medication; interoperability; electronic patient records; patient involvement; partnership; coproduction; medication safety

Introduction

Background

Lost or inaccurate medication information can cause patients and health care professionals significant difficulties [1-3] and lead to avoidable harm and costs [4-6]. Addressing these problems by improving timely access to and seamless communication of patient medication lists is a priority for medication safety everywhere [5,7]. However, personal, organizational, and contextual barriers often stand in the way, especially during transitions of care [8-10]. The growing burdens of chronic diseases and polypharmacy among aging populations add to these challenges. Thus, governments worldwide are investing in digital interoperability and data exchange systems to improve the quality of and access to information about patient medication lists [11].

Information systems in some countries support the management of digital shared medication plans (SMPs) based on treatment decisions and are usually embedded in patients' electronic health records. These enable timely access to and updates of the list of medicines that a patient is currently taking by authorized health care providers. Some systems incorporate histories of recent changes in medication [12-14]. Other systems generate medication lists with administrative data from pharmacy dispensing records [15-17] or central prescribing databases [18]. The latter are less demanding for health care professionals but cannot ensure that the current treatment plan is up-to-date after changes have been made by patients, pharmacists, or other prescribers [18-20]. Furthermore, an SMP can encompass the administrative workflows of prescribing and dispensing [21]. The terms *plan* and *list* are used interchangeably in the literature. We prefer "plan" because it emphasizes the clinical focus on decisions and the active role of users. Patients and health care professionals can access plans through a web portal, a mobile app, or an established clinical information system. Health care professionals appreciate these systems [22-24], especially for medication reconciliation [25-27]. Digital SMPs have been implemented in Australia [28], Austria [23], Denmark [29], the United Kingdom [30], and Norway [26], among other countries.

Introducing a digital SMP poses significant challenges in health care settings worldwide, where fragmented and heterogeneous communication practices between health care professionals and patients are common. Switzerland exemplifies these challenges: prescriptions are the primary means of sharing medical orders but fail to account for changes when treatments are stopped. Moreover, medication plans are not consistently used by health care professionals and are often exchanged via email, fax, or on a piece of paper handed directly to the patient. This leaves patients largely responsible for managing their medication intake and sharing related information with health care professionals, relying on digital tools, handwritten or printed notes, or no tools at all.

Integrating a shared platform suitable for every actor is a complex challenge, which extends beyond ensuring medication data interoperability. Currently, despite the administrative, organizational, and management advantages of SMPs, medication list inaccuracies remain common because they are not systematically updated in health care services, over-the-counter medications are omitted, and patient-driven changes are inconsistently integrated [25,27,31]. Assigning the task of overseeing and updating medication lists can also be problematic. When general practitioners are solely responsible for this, specialist physicians, pharmacists, and nurses cannot document their changes and underlying reasoning because they can neither access nor edit the SMP [26,27,32]. Other systems require pharmacists to update SMPs when they provide medicines, give advice on over-the-counter medications, or conduct a medication review [23,33].

Currently, there are no national eHealth platforms that allow patients to change their medication plans independently [13,14,34], despite growing acknowledgment of how patients and families can contribute to improving medication safety [7,35,36]. Both digital and paper-based patient-held medication lists can strengthen patient self-management and enhance communication with their health care professionals [37-39].

This lack of patient involvement in established medication systems contrasts with the proliferation of smartphone apps for medication management [40] and web portals giving patients access to their clinical records and supporting their contributions to medication reconciliation [41-43]. This paradox should alert health technology developers and policy makers to the need for research and innovation in digital SMP design, use, and

implementation. An SMP could leverage cooperation between patients and health care professionals to enhance the continuity of information and improve medication safety [14,27,44].

Some researchers have evoked the need to involve patients [25,27,31], but very few studies have sought out their opinions or tested the coproduction of medication plans [13]. Shifting to patient–health care professional coproduction would require considerable digital SMP redesigns in countries with established systems. However, Switzerland, having only recently introduced national shared electronic health records, known as "electronic patient records" (EPRs), has not yet implemented national e-medication or e-prescribing systems. One regional pilot project pointed out the poor engagement of patients whose SMPs provided no interactive features [14]. Finally, Switzerland's eHealth interoperability framework provides an opportunity to design the digital capacity for coproducing medication plans and potentially inform similar developments in other countries [45].

This Study

We aimed to explore and leverage the potential for patients' contributions to SMPs. We used an experience-based co-design (EBCD) methodology to identify value propositions for a digital tool enabling patients, family caregivers, and health care professionals to coproduce and co-manage medication plans within Switzerland's existing national eHealth architecture. We worked with polypharmacy patients, family caregivers, health care professionals, and digital health and quality experts.

Methods

Theoretical and Conceptual Framework

We used the coproduction in health care services framework model [46,47] and the Montreal Model [48] to embrace 3 types of coproduction: coproduction within our research team itself, coproduction to improve health care delivery, and coproduction during clinical interactions. Both models highlight the collaborative nature of health care services, emphasizing the need for greater patient involvement in research and innovation. The Montreal Model specifically underscores patients' and family caregivers' experiential knowledge. It describes their involvement as a continuum across various domains. Overall, the coproduction paradigm provides a valuable lens through which one can investigate the need for and benefits of collaboration between health care professionals, patients, and their relatives in daily practice.

Research Team

The research team included a pharmacist with a master's degree in health care service innovation (BB) and a physician with expertise in quality improvement, patient safety, and the coproduction of health care services (CvP). Both worked for the health authorities of the Canton of Vaud, one of the cantons making up the Swiss Confederation. Other members comprised a philosopher-ethicist, a health psychologist specializing in the sociology of technology (FB), and a sociologist (AK), all of whom worked at the University of Lausanne's Participatory and Collaborative Action-Research Unit. There was also a physician specializing in digital health (AG) and a pharmacist specializing in medication safety (PB). The team had significant experience in qualitative research.

In total, 4 patients and 1 informal caregiver who had all participated in workshops about the rollout of a regional EPR system [49] were included as co-researchers in the study. They contributed to the study design; the preparation, facilitation, and debriefing of focus groups; and the writing and presentation of a synthesis for all the participants during the co-design workshops.

Study Design

Overview

We applied the EBCD methodology in 4 phases [50-52] and conducted interviews and focus groups to develop "value propositions" for SMPs. Determining value propositions for new digital health tools is critical to their successful design and implementation. However, persistent misalignments between stakeholders' views and the lack of measured evidence indicated that this task had often been overlooked in earlier projects [53,54]. Experts have argued that designing value propositions is a way of expressing how the development and implementation of a technology is worthwhile and a way of identifying for whom it creates value. Value describes what users or customers are attracted by (the demand side) and what benefits the solution can bring to their work, including its overall impact on the health system (the supply side). Value can have different meanings for different stakeholders and may involve trade-offs, such as the investment required to adopt and regularly use a tool. Furthermore, applying a service-design perspective to explore how different stakeholders understand a technology's value proposition and its implications for their usual workflows can help rethink how health care services should evolve alongside the implementation of such digital solutions [54].

EBCD Phase 1: Capturing Experiences

In total, 5 patients and 1 family caregiver were interviewed individually to elicit their experiences of four common medication management situations previously identified through our literature review: (1) routine self-management using a medication plan, (2) patient-physician interactions about medications during consultations, (3) medication management after a major change in medication (eg, at hospital discharge), and (4) managing new drugs. Using their narratives and the literature, we developed fictitious but typical patient vignettes for each of the 4 key situations as the basis for initiating the ensuing focus groups.

EBCD Phase 2: Understanding Experiences

In total, 13 patients and 2 family caregivers were invited to participate in 2 parallel sets of focus groups (1 in Lausanne and 1 in Geneva). By discussing the 4 patient vignettes, the first focus group explored what "mattered" to these participants when they used a medication plan and collaborated with their health care professionals. We focused discussions on experiences and expected clinical outcomes and to identify key moments in the collaboration (touch points) that had significantly affected them. Participants' questions and aspirations regarding a digital SMP were retained for the next phase.

A synthesis of the touch points identified served as the basis for initiating focus group discussions with 10 health care professionals. In a single, longer focus group, they discussed their understanding of patients' and caregivers' experiences and the potential for improvements by introducing a digital SMP (phase 3).

EBCD Phase 3: Improving Experiences

The same patients and family caregivers participated in 2 further parallel focus groups to explore potential improvements and problems that a shared digital tool might bring. The first part of each focus group provided participants with background information about Switzerland's EPR systems and the policy context. In the second part, participants discussed how an SMP could facilitate the collaborative management of medication plans, with an eye to the 4 situations in phases 1 and 2. Participants were encouraged to describe the potential benefits of, enabling mechanisms for, and barriers to SMPs. Participants then gathered for the first co-design workshop to further discuss, reflect on, and synthesize their understandings and the potential for improvements due to the introduction of a digital SMP.

EBCD Phase 4: Preparing Recommendations and Follow-Up

Patients, caregivers, and health care professionals convened for the second workshop to discuss the synthesis of the results from the preceding phases and to make recommendations on developing an SMP.

Consistent with the principles of coproduction and the Montreal Model, we involved researchers and coresearchers in each step of the EBCD methodology, using iterative cycles of implementation, assessment, and adjustment to the approach and its associated documents. We aimed to create the best possible conditions for coproduction and patient involvement within both the project and future health care services using an SMP.

Context and Setting

This study was conducted in the cantons of Vaud and Geneva in the Swiss Confederation's French-speaking region between October 2020 and February 2021. Interviews, focus groups, and the EBCD workshops took place according to the COVID-19 regulations that were in place at the time and in calm settings at the University of Lausanne, Geneva University Hospitals' innovation center, and Lausanne University Hospital.

The launch of a regional EPR platform for the secure storage and exchange of health data, as mandated by federal law, was in preparation in the region [55]. In total, 8 "communities" implement and manage EPRs in different regions of Switzerland. Currently, these EPRs function solely as repositories for clinical documents (Clinical Document Architecture level 1), generally PDFs, but the development of capabilities for sharing structured data within the national interoperability framework is underway. Medication and vaccination plans are priorities because of their implications for patient safety and clinical practice.

Our study was conducted in coordination with one of these communities, named CARA [56], which was piloting the development of a new SMP approach [57]. In cooperation with national bodies, it will apply international Integrating the Healthcare Enterprise pharmacy profiles [58] and the Swiss medication data exchange format based on the Fast Healthcare Interoperability Resources Foundation's Health Level 7 specifications [59]. The architecture prepared by a formal national working group respects the patient-centered, decentralized design required by federal law. Technical details have been published previously [45].

The Swiss health care system is fragmented and has no national guidelines or policies for practices such as medication reconciliation and interprofessional communication. Legal reforms to safeguard the rights of polypharmacy patients to a medication plan and enhance medication safety have been proposed but have not yet been implemented, and the debate about them is ongoing [60].

Participant Selection

Patients were invited to participate in the study if they (1) were capable of managing their medications autonomously (ie, they were not institutionalized), (2) regularly took ≥3 medications, and (3) had experienced transitions of care, such as hospital admissions and discharges that involved changes to medications. Family caregivers could participate if they regularly supported such a patient in taking medications.

Recruitment emails were sent to existing pools of volunteers affiliated with a regional consumer rights association, patients and family caregiver associations, and a local university hospital. The emails introduced the study topic and outlined the inclusion criteria. Once individuals had expressed interest to the concerned person in their respective organizations, the research team received their contact details and followed up via email or telephone, as preferred, to propose dates for the focus groups (scheduled 1 month in advance) and the co-design workshop with health care professionals (scheduled 2-3 months in advance). This follow-up step also confirmed their eligibility, interest, and availability.

We aimed for diversity of experiences, diseases, gender and age. To achieve this, we also contacted individuals already involved in existing initiatives directly, such as peer support, teaching, or research projects. Our initial goal was to organize 3 to 5 local groups of 5 to 9 participants each, for a total sample size of approximately 15 to 30 individuals.

The inclusion criteria for health care professionals were (1) previous participation in improvement projects on medication management, transitions of care, or care coordination; or (2) involvement in medication prescription, delivery, or management in their current occupation. They were recruited through the professional networks of the authors.

Data Collection

Data were collected through individual interviews, focus groups, and workshops with patients, caregivers, and health care professionals per the 4 phases of EBCD. Guides were prepared for each phase by the research team and refined between interviews (Multimedia Appendix 1). Focus groups in phase 2 were based on the patient vignettes built up from the available literature and narratives collected in phase 1. The focus groups

with health care professionals were guided by the key touch points revealed by the focus groups with patients' informal caregivers.

At least 1 coresearcher participated in each focus group, asking follow-up questions and taking notes that were shared with the team. Coresearchers participated in preparing and debriefing each focus group and workshop during team meetings. The division of tasks is provided in the Authors' Contributions section.

Data Analysis

We conducted an in-depth thematic analysis of our transcriptions per the recommendations of Braun and Clarke [61]. Two researchers independently coded the different series of patient focus groups in parallel. They compared codes and discussed disagreements regarding the raw data until they reached a consensus. One then finalized the coding for the 5 focus groups. Subsequently, we developed themes (also using personal notes and intermediate outputs from the co-design process) that had repeatedly been raised, discussed, and validated by the research team and by the workshop participants. The review, definition, and final naming of the themes were done iteratively by the authors. Analyses were structured using MaxQDA software (VERBI GmbH). We followed the COREQ (Consolidated Criteria for Reporting Qualitative Research) guidelines [62].

A professional interpreter translated selected citations for this paper from French to English. Bilingual team members verified the content.

Ethical Considerations

Our regional ethics review board formally confirmed that it did not need to review and approve the study, as per the Swiss Federal Human Research Act (Req-2020-00591). Each participant received oral and written information about the study and signed the consent form before participation. The consent form specified that, after recording, transcripts would be deidentified, and no personal statements would show names for any purpose. To ensure a safe and open environment for discussion, participants were asked not to share specific sensitive personal information; instead, they were encouraged to draw on their experiences to guide their contributions. At the beginning and end of each discussion, participants were reminded to ensure the confidentiality of the content shared. All data were securely stored within the research university's information system. Transportation costs were reimbursed according to university guidelines based on public transport fares. Parking costs at the university site were also covered. No other financial compensation was provided; however, participants were offered an aperitif after the workshop.

Results

Participants and Data

Between August and October 2020, we recruited 31 individuals (patients: n=18, 58%; caregivers: n=3, 10%; health care professionals: n=10, 32%) with a broad range of experiences regarding medication management plans from a variety of care settings (Table 1).

We formed 2 local groups of patients and caregivers, one less than initially planned, but COVID-19 complicated the recruitment of people with respiratory diseases.

Individual interviews in phase 1 lasted from 43 to 71 minutes. Focus groups in phases 2 and 3 lasted from 115 to 130 minutes, and EBCD workshops lasted from 120 to 210 minutes. Table 2 summarizes the participation in each phase of the EBCD workshops. Three individual interviews were conducted as a backup for participants who could not attend a focus group.

Table 1. Focus group and interview participant characteristics.

Characteristics	Patients[a] and caregivers (n=21)	Health care professionals (n=10)[b]
Gender, n (%)		
Women	7 (33)	6 (60)
Men	14 (67)	4 (40)
Age range (y), n (%)		
36-50	4 (19)	8 (80)
51-65	10 (48)	1 (10)
66-78	7 (33)	1 (10)

[a]Health conditions were autoimmune, blood, musculoskeletal, gastrointestinal, rare neurological and mental health diseases, as well as cancer, and diabetes. One person had undergone a renal transplantation.

[b]The clinical backgrounds of the 10 health care professionals were medical secretary working as case manager 1 (10%); 2 (20%) nurses in gerontology and primary care; 3 (30%) community and hospital pharmacists; and 4 (40%) physicians in hospital internal medicine and general practice.

Table 2. Participation in focus groups and interviews related to the phases of experience-based co-design (EBCD).

EBCD phase	Type of interview	Participants
Capturing experiences (phase 1)	Individual interview	6 patients and caregivers
Understanding experiences (phase 2)	Focus group	15 patients and caregivers divided into 2 groups and 1 group of 10 health care professionals
Improving experiences (phase 3)	Focus group with individual interviews as backup	Same groups as phase 2
Improving experiences (phase 3)	First EBCD workshop	All 31 participants together
Recommendations on improving experiences and follow-up (phase 4)	Second EBCD workshop	All participants were invited: 19 patients and caregivers and 10 health care professionals

The subsequent sections highlight the main results from our analysis of the discussions with participants in phases 1 to 3, summarized in Textbox 1. Recommendations for action codeveloped with participants during phase 4 are briefly described in the Recommendations for Action section, alongside the value propositions.

Textbox 1. Summary of the value propositions for digital shared medication plans (SMPs).

Comprehensive and accessible information about patients' current medication plans and histories

- Streamlined access and transmission of medication information
- Shared comprehensive medication information going beyond prescriptions
- Reconciled medication information using a common platform

Patient and health care professional empowerment through the explicit co-ownership of medication plans

- Shared responsibility for medication management plans is made explicit
- Defined depth of patient involvement in editing the information shared
- Enhanced visibility of the contributions to building an accountable interprofessional team

A means of supporting collaborative medication management

- Enhanced joint planning, execution, and monitoring using a medication plan
- Tailored access to medication information within the SMP
- Facilitated interprofessional coordination with lower patient and family burdens

Quality improvement and innovation

- Strengthened care partnerships
- Improved integration of care, efficiency, and patient safety
- Catalyzation of digital health innovations

Value Propositions for the Joint Management of Digital SMPs by Patients and Health Care Professionals

The thematic analysis of each value proposition for the joint management of SMPs resulted in 4 themes and their subthemes, as summarized in Textbox 1.

Comprehensive and Accessible Information About Patients' Current Medication Plans and Histories

Participants emphasized the importance of having digital medication plans and histories on a common eHealth platform, where information is accessible, complete, and regularly updated. The added value lies in the information mentioned subsequently.

Streamlined Access and Transmission of Medication Information

The continuity of information transmission is key throughout patients' care trajectories. That transmission often depends on a patient or a caregiver acting as the link (patient, focus group, Lausanne 1). This was perceived as being a major burden on them. In addition, information transfer is at risk when patients cannot fulfill this task:

> *So, for me, I've...I see a rheumatology specialist for my polymyalgia, and I realize that afterwards, when I consult my doctor, my GP, well, it's me who has to tell her everything I'm taking, everything the other doctor did, et cetera. So, it works very well, because I make the link. But I don't understand why we still don't have that electronic patient record and other stuff containing all the information, so that the doctors*

> *you give access to—because you have to give them access—can see what's going on for themselves and intervene if necessary. It seems like an essential project, to me.* [Patient, focus group, Geneva 1]

Health care professional communication with patients is mainly oral, except for written prescriptions and, in some cases, a medication chart. This was problematic for some patients, especially if they were taking many different medications over long periods and these were frequently modified:

> *[With regards to healthcare professionals not communicating with each other], the patient is there in the middle and just has to get on with it...must sort out their emotions and then make some sense out of all those words, and the jargon, and the protocols, and the processes that they've been given, and then, what's more, they've got to try to understand...* [Patient, focus group, Lausanne 1]

Patients develop and use tools that help them in their roles as transmitters of information, such as taking photographs on their smartphones "to remember names" (patient, focus group, Lausanne 1), making lists on their computers (patient, interviews 3 and 4), or keeping printouts in their wallets (patient, interviews 2 and 5). However, these tools are unreliable in emergency situations or during travel, when access to them is not guaranteed and their validity cannot be checked. Secure web-based access to precise information about a patient's current medications and a history of their modification could provide a practical tool that embraces patients' key role in transmitting information, with potentially major improvements to patient safety.

Shared Comprehensive Medication Information Going Beyond Prescriptions

Prescriptions are usually available in writing, yet they only include a fraction of the information required for medication management:

> *A prescription might only be partial; a final treatment plan should really summarize all the medications that patients are taking: the medications that are prescribed, but sometimes also those that aren't prescribed and that have been ordered online, as you said, or lastly, self-medication, and alternative and complementary medicines.* [Nurse, focus group, health care professionals]

Major deficiencies in information include missing not only indications or justifications for prescriptions, dose adjustments, and cessations of medications but also diagnoses, laboratory values, or drug allergies, none of which is usually included in prescriptions, in communications with patients, or between all the health care professionals involved.

Reconciled Medication Information Using a Common Platform

An SMP enables the reconciliation of all the information from all the contributors to a patient's medication in a single location. Health care professionals can thus rapidly find useful information that is particularly relevant during transitions of care and emergencies:

> *The patient leaves hospital with their prescription, arrives at the community pharmacy, and then there are a certain number of interactions that take place there, questions, and they can't answer them or fill in the missing information...The assistant physician isn't contactable, so they'll call the treating physician. But it's Saturday...So, because of this fragmentation, it becomes indispensable for everybody to be available.* [Pharmacist, focus group, professionals]

Health care professionals highlighted that the necessity to regularly update an SMP depended on its use being appropriate to the setting and context, including aspects of the information systems used (eg, interoperability), the clinical processes in place (eg, trained staff), and the framework conditions (eg, financing and legal duties).. Health care professionals hoped for an SMP that would simplify their daily practice and be user-friendly. Digital technologies also introduce additional concerns about data security and confidentiality.

Patient and Health Care Professional Empowerment Through the Explicit Co-Ownership of Medication Plans

Participants recognized the intrinsic coproduction existing between patients, caregivers, and health care professionals preparing and using medication plans. They emphasized the importance of empowering individuals to fulfill their roles in this coproductive effort and boosting their sense of shared ownership.

Shared Responsibility for Medication Management Plans Is Made Explicit

The patient, family caregivers, and health care professionals already "share responsibilities" (patient, focus group, Lausanne 1) for the continuity of information transmission and for being "on the same page" (patient, interview 2), with or without an SMP. Patients must share their health information with health care professionals, who, in turn, must obtain medication information, document interventions, and communicate with their patients. Pharmacists verify prescribed medications and explain appropriate medication use during dispensing to ensure safe medication practices. Patients are ultimately responsible for taking their medication, whereas family members may assist or "negotiate" administration and intake (family caregiver, interview 5). Both health care professionals and patients make decisions and act on information, but patients are the most affected by the outcomes.

An SMP can increase transparency and contribute to raising awareness of the importance of communication about medications between patients and their health care professionals. However, it requires open, trusting, and caring relationships for patients not to modify or discontinue their medication without informing health care professionals:

> *In an electronic patient record, if they don't take [their medication], you should be able to see that fairly easily, theoretically. They won't be judged, but you'll be able to tell whether they are able to follow the guidelines. They have every right to stop [their medication].... They should be able to discuss this*

> *easily with the professional...* [Physician, focus group, professionals]

Furthermore, an SMP giving the relevant stakeholders the right to view and update shared information could empower patients and health care professionals to develop a shared sense of responsibility for medication management. The traceability of the authorship of modifications is crucial in this regard. Assuming joint responsibility could improve how different stakeholders learn from each other, leveraging their respective resources and building mutual trust in their collaborative partnership. The opportunity to participate could balance patient-health care professional power dynamics and increase patient autonomy:

> *...once that responsibility has been rebalanced and truly shared, I think that, well, trust should come as a matter of course. Because if the patient has come far enough, is sufficiently mature to realize that it's for their benefit, if the physician has sufficient trust that their patient is a stakeholder in their treatment management, in their healthcare trajectory, well, then there's no need to discuss sharing responsibility because everybody's got some...* [Patient 1, focus group, Lausanne 1]

> *The patient has also got to have their share of responsibility, because when you feel responsible, you feel like getting involved.* [Patient 3, focus group, Lausanne 1]

Thus, the co-ownership of an SMP provides practical ways of partnering and assuming shared responsibility for medication management plans.

Defined Depth of Patient Involvement in Editing the Information Shared

Discussions on the breadth of possibilities for patients and family caregivers to update an SMP were recurring. Given that patients are the end users of medications, it seemed relevant that they could document changes and rapidly report self-medication in an SMP themselves. Such access would also enable patients to verify their current medication plans and rectify any communication errors made by health care professionals, potentially preventing harm. Similarly, health care professionals could identify and correct errors, ensuring that medication plans are up-to-date and accurate. In contrast, patients having editing access also raised concerns about introducing new errors or causing adherence problems. The debate for and against patients' editing rights is well described in this discussion:

> *If there's no legal basis for it, well, it can't work...it [will be]...the law of the jungle, because if everybody goes off on their own, adding everything and anything, that can be dangerous too if the poor physician at the emergency department finds that everything's been modified.... If they want to stop a medication, well, me, I'd telephone my physician. But I wouldn't document, "Well, I'm stopping," off my own bat. Like you said, we're not doctors.* [Patient 1, focus group, Geneva 2]

> *I see it exactly in the same way.* [Patient 7, focus group, Geneva 2]

> *For people who've been taking the same treatment for a long time, I think things are different because you know very well how you react. Your physician knows very well that sometimes you get fed up.... I think that it's good that you're able to do it and to inform the practitioner.* [Patient 6, focus group, Geneva 2]

Participants agreed that clear responsibility for changes and their consequences was needed. Ideally, each partner should contribute to and share in that responsibility. At the same time, joint management of an SMP places a significant responsibility on patients, and their level of involvement must align with their personal resources and preferences. Thus, joint management should be a right and an ideal to strive for rather than an obligation. Likewise, health care professionals should be well-trained and well-equipped. "Ethical and legal questions" (pharmacist, focus group, professionals) include careful consideration of health care professionals' responsibilities, the confidentiality of sensitive information, and situations where patients choose to or are incapable of transmitting information and sharing responsibility for medication management planning. These questions are intimately linked to health policies and legal requirements:

> *But in some precise cases, can we make it obligatory? That's to say, me, for example, when it comes down to it, I'm aware of it, so, in the end, I'm for this record. I'll even push all my physicians to complete it because I think it's pretty important. But couldn't somebody who's losing their marbles a little bit...in this particular case, couldn't it be made obligatory for them, and for their physicians to do all this follow-up?* [Patient, focus group, Geneva 2]

As a compromise, participants proposed that patients' and family caregivers' editing rights could be activated flexibly or be confined to the medication they have added, such as self-medication. Furthermore, they emphasized that an SMP solution should support health care professionals and patients in fulfilling their responsibilities through, for example, cues and reminders about medication reconciliation.

Enhanced Visibility of the Contributions Toward Building an Accountable Interprofessional Team

SMPs have the potential to stimulate interprofessional and patient collaboration by enabling better visibility of the contributors and their actions, thereby fostering a sense of accountability. SMPs promote transparency and encourage active participation, making everyone's contributions visible and tangible. However, it is important to acknowledge that this transparency may encounter some resistance among health care professionals due to concerns about their legal exposure and the potential disregard of their clinical judgment by patients or peers. Similarly, patients might not trust health care professionals or the health care system itself, and they may not want every detail of their EPR to be available to every health care actor. Nevertheless, participants agreed that information

sharing was crucial to effective interprofessional collaboration and patient-centered care:

> *Well, the electronic patient record and this medication management and whatnot, et cetera, got me interested straight away, and I said to myself, "Well, there's really something to be done here." Finding solutions isn't straightforward because you have to get healthcare specialists to talk with each other and to speak a common language. Because, very often, they've each got their own jargon, and the specialist will say, "Anyway, I did not study gastroenterology, so it's not directly my problem." Or often, in my case, I hear, "It's due to the diabetes."* [Patient, focus group, Lausanne 1]

Patients stated that having everyone working for and with them, as a "team," was a great privilege. Team members using an SMP might have more clearly apparent bonds thanks to shared, transparent information (patient, focus group, Geneva 1 and 2).

A Means of Supporting Collaborative Medication Management

According to the study participants, an SMP is a means to develop and support collaboration in daily practice.

Enhanced Joint Planning, Execution, and Monitoring Using a Medication Plan

Participants perceived SMPs as valuable aids in preparing for consultations with health care professionals and for use with them during these interactions. These tools should be designed and implemented to enhance reviews of and communication about medication:

> *Well, it's a reminder. I mean to say, when I get to the doctor's, it's kind of my roadmap. We'll open it up together. We'll say, "Well, so, how's it going? Have these medications here been taken? Oh, look, so you've got a new medication?" Or, in my case, "Oh, so you've stopped this medication?" Well, to start with, you get yourself into the situation. I think it's a good place to start...* [Patient 4, focus group, Geneva 2]

> *What's important is that you said, "Open it up together," you see?* [Patient 2, focus group, Geneva 2]

SMPs could also increase medication follow-up by supporting patient self-monitoring and management as well as interprofessional communication. This could be particularly important when dealing with major changes, such as a hospital discharge:

> *It's certain that the time for preparing a [hospital] discharge goes by pretty quickly, and we have to manage the patient's medications right up to the end [of their stay], ... we completely take over their role. If this tool [an SMP] could be used several days before the discharge...with the treatment management plan updating itself, we could also end up evaluating the patient's true level of understanding a few days before their discharge, and whether they'll be able to get by with their medications.... And then we could implement the proper interventions.... That really could be super interesting at care transition time.* [Nurse, focus group, professionals]

Participants suggested that SMPs could also help existing coproduction practices, such as negotiating a "break" from usual medications (patient, focus group, Geneva 2) by checking boxes next to vital medications. SMPs could include action plans for rescue medications, such as for "...antibiotics. I know exactly when to take them and at what dosage. I inform (my treating physician) afterwards" (patient, focus group, Lausanne 1). Finally, SMPs could foster discussions about medicines and encourage regular reviews of medication management plans by clinicians, as this patient described the following:

> *Every two consultations, I ask the physician, "Which medications could we eliminate?"[Patient, focus group, Lausanne 1]*

Tailored Access to Medication Information Within the SMP

The same medication information, held within an SMP, could be presented in a manner tailored to each user, health care professional, or patient. Personalization according to patient preferences and different users' levels of health literacy would thus be possible. These functions would help patients to more easily remember the medications they want to discuss with their health care professionals:

> *...when I go to a new physician and he asks me which medication I take, well, I take photos of my medication boxes, because one time in ten I'm incapable of either pronouncing the name or remembering what I've got to take. For me, it's just the green pill.* [Patient, focus group, Lausanne 1]

Furthermore, an SMP platform could improve medication safety by giving advice, preventive messages, and explanations. Health care professionals could also use SMPs to personalize the written information patients receive about their medication use and, importantly, to ensure that interprofessional communication is more consistent. The platform could also help to provide treatment options and possibilities for shared decision-making. Although everyone should have access to information about their medications, the technical level of the information provided needs to be tailored to individuals' needs, capacities, and expectations. The inclusion of pictograms, videos, and translations into different languages might help to meet patients' diverse needs. Tailored and flexible features, rights, and decision-making aids could help to create equitable medication management systems.

Facilitated Interprofessional Coordination With Lower Patient and Family Burdens

Communication gaps and fragmented documentation hinder coordinated, collaborative care. Using SMPs could improve this by including the reasons why a medication needs to be taken and ensuring that instructions about medications align with the recommendations of different health care professionals, as a pharmacist highlighted the following:

> *...typically, the patient should have properly understood that, despite the side-effects or the*

> *drug-drug interactions, the physician wants to try it [the newly prescribed treatment] out for two weeks, and that they [the patient] have thus accepted [the risk]...even though they'll have to answer [the question about the treatment decision] again [at the pharmacy], because we'll ask them the same question, just using other words...probably...which can cause some confusion, unsettle the patient, and increase the risk of giving contradictory information.* [Pharmacist, focus group, professionals]

Furthermore, patients and health care professionals expect SMPs to facilitate planning and discussions between different health care professionals, allowing for more consistency and coordination in the treatment:

> *So, the advantage of a medication plan—because a medication plan means that you're also planning a treatment—and because that plan is available to all the specialists, because it's electronic, well, so, its advantage is that the specialist can, at any given moment, ask questions, because not every specialist necessarily knows what medications the patient is taking.* [Patient, focus group, Lausanne 1]

Finally, SMPs could decrease the coordination burden for patients and family caregivers, thus reducing the risks of disengagement or distress:

> *Because you're fighting and struggling with each of the physicians, at the pharmacy, at the hospital...repeating the same info, explaining why the plan isn't a standard one but is the best suited to you...What's more, you have to convince [them] that you know what you're talking about, because, yes, there are some drug-drug interactions, but it's the combination that has suited me best for a long time...After a while, you just feel like letting everything go to hell—giving up on everything.... Me, I'm not at all surprised when you read in the papers that 50% of the medications prescribed don't get taken and when you hear that therapeutic adherence is a real problem.* [Patient, interview 4]

Quality Improvement and Innovation

SMPs provide new opportunities and can enable quality improvement and innovation.

Strengthened Care Partnerships

Participants highlighted the growing interest in "health partnerships" (patients, focus groups Lausanne 1 and Geneva 1), emphasizing that SMPs not only enable patients and health care professionals to partner around a medication plan but also promote a more collaborative health care paradigm:

> *...you should explain it to them from the outset, because afterwards, when you're using the tool, you're obviously going to have to work in partnership with them.* [Patient 7, focus group, Geneva 2]
>
> *It's all about a change in mentality.* [Patient 2, focus group, Geneva 2]

Improved Integration of Care, Efficiency, and Patient Safety

SMPs can improve efficiency, patient safety, and the integration of care. Nevertheless, the added value of an SMP depends on a favorable context and well-executed implementation. Participants emphasized the importance of promoting and then managing change. Incentives, including legal obligations, were mentioned several times:

> *So, obviously, among the barriers, there's time. The time it takes to fill in all the information. Who's the guarantor of that information? What competencies do you need? And who reimburses us for doing it?* [Pharmacist, focus group, professionals]
>
> *It's like any change in your life. Change is hard; it takes a certain amount of time to adapt.* [Patient, focus group, Geneva 2]

Health care professionals emphasized that SMPs would be particularly beneficial when combined with clinical interventions such as medication reconciliations, medication reviews, care coordination by a case manager, patient education, or support for medication self-management.

Catalyzation of Digital Health Innovations

SMPs could serve as springboards for creating and scaling up digital solutions for patients and data-driven innovation. Augmenting the platform with additional features could help patients in their medication self-management and foster better communication with health care professionals, for example, by tracking medication intake and symptoms. Furthermore, leveraging data from an SMP could stimulate innovation and bolster research, pharmacovigilance, and other continuous improvements:

> *I'd add...and clinical research. Because medications are tested one compound at a time, if you like, then in an age when you've got multimorbid patients who've got several types of medications to take, there's no clinical research on the cumulative side-effects of these different medications, and shared medication plans could be an extremely rich source of information.* [Physician, focus group, professionals]

Recommendations for Action

During the final co-design workshop, participants reached a consensus on three key actions to advance toward the joint management of SMPs: (1) the cocreation of an accessible and empowering platform for SMPs that accommodates diverse patient population groups, (2) the promotion of best (clinical) practices that emphasize the use of collaborative SMPs with patients and health care professionals working in partnership, and (3) stakeholder dialogues to establish the necessary enabling environment.

Discussion

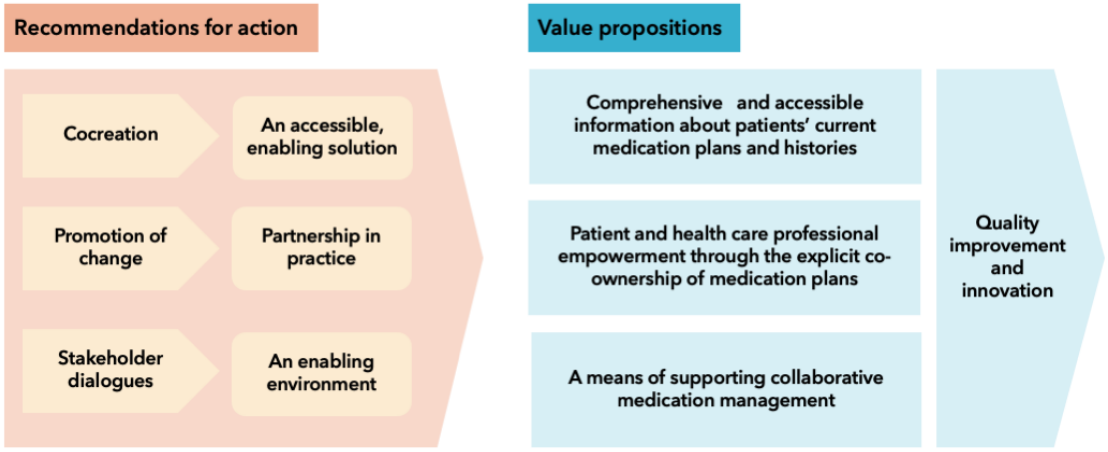
Principal Findings

Our findings underscored the importance of explicitly recognizing and promoting the co-ownership of medication plans. The value of digital SMPs lies in making it easy for patients, family caregivers, and health care professionals to

create and update medication plans, for example, via the possibility of adding over-the-counter medications. Apart from improving the quality and safety of medication management, this could strengthen interprofessional and patient collaboration, enhance medication self-management, and facilitate innovations in care coordination and medication safety. To succeed, the co-management of medication plans must be integrated into clinical practice and supported by interactive information systems that can be tailored to individual capabilities and preferences. The value propositions from our analysis and the recommendations for action defined by the participants are summarized in Figure 1.

The core value of digital SMPs lies in facilitating the navigation of a patient's current medications and medication history. Both patients and health care professionals would benefit from a clear overview of recent changes and the possibility of distinguishing between changes made by the patient and health care professionals. Additional features, such as reminders to administer medication, self-management guidelines, patient education resources, self-monitoring tools, and secure messaging, could further enhance the practical and safety values of such systems. For patients who might be less comfortable updating their medication plans alone, guided assistance should be provided, such as scheduling medication reviews or reconciliation appointments where a health care professional can verify and upload information. Preparing a well-structured, shared outline of how these appointments might work could enhance patient involvement and empowerment, improving the efficiency of clinical interventions. Certain digital patient mobile apps offer some of these features [40,63] and could be incorporated into a web-based SMP platform for patients that would facilitate effective collaboration between them and health care professionals.

Figure 1. Summary of the value propositions for digital shared medication plans and the actions recommended for their implementation.



Value Propositions

Our findings challenge the prevailing prescriber-centric paradigm of existing SMP platforms that do not ensure the accuracy and safety of medication information. For example in Denmark, a world leader of digital medication information, 78% of hospitalized patients had at least 1 discrepancy between their actual medication intake and the documented list in the national shared record that can be accessed by health care providers. Nearly half of these discrepancies were due to changes made by patients, that were not known and registered by the physicians [31]. More recent initiatives in neighboring Nordic countries continue to use SMPs that limit active contributions of patients [21]. Once we understand the limitations of SMPs managed solely by physicians [24,27], a more collaborative approach seems to be worthy of further exploration.

The co-management of SMPs could be a game changer in ensuring the accurate transfer of information at care transitions, enabling synergies, and benefitting from the accumulated efforts of all the stakeholders. Reconciling discrepancies in medication lists and dealing with their consequences cost health care professionals precious time [1,8]. An SMP would facilitate information flows along patients' clinical trajectories [18,26,64]. Information system interoperability, supportive digital functionalities, and patient involvement are known facilitators of broad-based medication reconciliation [8,65,66]. Accordingly, the World Health Organization promotes collaborative medication management involving patients and their families as partners [7]. Nevertheless, determining whether SMPs effectively reduce discrepancies requires further research and evaluation.

Patient-held medication lists are widely endorsed as a strategy to improve medication safety [7,37]. Patients actively manage and communicate medication information, and they prevent and mitigate medication errors [2,35,67]. Compared with other patient tools [37,63], the added value of an SMP lies in its 2-way link between patients and health care professionals and in the secure web-based storage of current medication lists and histories of changes. A partnership with patients that goes beyond holding lists could enhance the effects of such systems [36,68].

Indeed, an expanding body of evidence supports the argument for patients managing their medication plans. Patient-held medication lists have made them feel empowered and increased their self-confidence [22,37,39]. Involving patients in digital medication processes has facilitated medication reconciliation [63], saved time, and reduced medication errors [66,69,70]. Likewise, access to clinical notes has benefitted communication,

trust, and medication adherence [71-73]. One quasi-experimental study showed that giving patients access to shared records through a platform integrating their interactions with health care professionals improved medication adherence [71]. The ability to edit lists seemed to be more motivational than read-only access [14,34].

Notwithstanding the potential advantages of shared medication lists [38], their implementation requires very careful attention. Variable levels of health literacy and a general lack of engagement are recognized as barriers to implementation and use. In one German study [74], <50% of patients had a comprehensive understanding of the medication plan that their general practitioner was legally obliged to share with them. Thus, strategies for medication management must be thoughtfully designed and implemented to accommodate diverse users and preferences [63]. Co-designing systems with the aid of patients with diverse backgrounds and integrating artificial intelligence solutions could prove pivotal to the successful adoption of such tools and may help avoid any unintended exacerbations of health inequalities due to digitalization.

We argue for a system design that empowers the collaboration of all the stakeholders in medication management. Such an approach needs effective leadership and change management to accompany the required organizational and sociocultural adaptations to clinical practice. In processes like this, trust between stakeholders and in the technology is critical for successful system implementation and use [14,75]. However, trust cannot be decreed. Notably, the inability to correct obvious errors in a medication list may create mistrust [76]. Finally, a shared platform may promote good practices and aid advocacy for medication safety being “everyone’s business” [77]. SMP systems involving every stakeholder can be disruptive, and we hope that our value propositions will encourage experimentation and open innovation in the field.

Strengths

By engaging with patients, caregivers, and health care professionals, we leveraged coproduction and diverse participant experiences to elicit innovative value propositions for a digital SMP system. Collaborating with coresearchers and a multidisciplinary research team provided complementary perspectives and enhanced reflexivity throughout the study. Exchanges within parallel groups, composed of participants with profound experiential and professional knowledge, enriched the discussions on medication management. Experienced participants were rapidly able to contribute effectively to the focus groups and EBCD workshops, motivated by the rare opportunity to discuss with both patients and health care professionals. In future codesign initiatives, we recommend including additional meetings with participants if fostering group dynamics and collaborative engagement requires more time. Interestingly, our approach cultivated a sense of shared responsibility among the participants, as observed in earlier co-design processes [78]. Most (21/31, 68%) of the participants have since continued working on the implementation of SMPs and EPRs in different advisory and networking groups.

Limitations

One limitation of this study was its relatively small and selected group of participants. They will likely be early adopters [79]. Thus we may have overlooked some issues affecting more disadvantaged patients or uninterested health care professionals. Second, EBCD relies strongly on group dynamics and iteration, which may hinder the replicability of our findings. We mitigated these limitations by ensuring the diversity of participants, including some who had experienced critical situations or supported others during such times. Participants also seemed sensitive to the issue of equity as they frequently pointed it out during the interviews and workshops. Finally, the specificities of the health context in Switzerland might limit the transferability of our findings to other settings. However, the basic clinical process of managing and sharing complex information about medications is universal. Thus we are confident that our value propositions can be useful for other settings.

Implications for Research and Practice

Future research should examine how the coproduction of medication plans changes the management of clinical information and investigate the implications for professional responsibilities and task division [80,81]. In addition, the potential for unintended consequences needs to be studied [82]. Our study’s value propositions could be used in logic models and midrange theories for the implementation and evaluation of medication systems.

Moreover, our value propositions and functionalities should be tested under a variety of conditions, including with diverse, vulnerable groups of medication users and in high-risk situations. Ongoing studies [34,44,63] and a planned proof-of-concept project in Switzerland [45] will provide additional empirical results.

Policy makers and technology vendors must establish the conditions for leveraging the potential of SMP systems to improve medication reconciliation across health care institutions and organizations [83]. In doing so, decision makers must acknowledge the complexity of medication management and invest in adaptable solutions that can accommodate collaboration between health care professionals and patients. We argue for the development of interoperability frameworks enabling the collaborative management of a digital medication plan, with patients as partners. Community Medication Prescription and Dispense profile of Integrating the Healthcare Enterprise [58] supports this by focusing on clinical decisions and treatment planning as its core; however, most public authorities in the world do not currently endorse it. Switzerland’s concept of interoperability in the context of its EPR system is based on the Community Medication Prescription and Dispense profile and Health Level 7 Fast Health care Interoperability Resources specifications [45,57]. The proof of concept and a pilot are currently being implemented by CARA and first volunteering health care providers and their technology providers.

Conclusions

Modern SMPs should function as digital platforms with adaptable features that facilitate joint medication management

and empower patients to be true partners. They should promote and not hinder patient engagement while embracing the shared responsibilities of patients and health care professionals. This shared responsibility should also encompass public health authorities and technological stakeholders, who each play a critical role in creating the conditions for the efficient and safe use of SMPs in daily practice. Introducing SMPs could strengthen partnerships, enhance patient self-management, and improve interprofessional collaboration. SMPs and their use must be tailored to patients' different levels of health and digital literacy and their personal preferences. The value propositions identified in this study should provide inspiration and guidance for stakeholders and researchers on how to enhance the coproduction of medication management by health care professionals and patients via digital technologies.

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Data Availability

The datasets generated during and analyzed during this study are available from the corresponding author on reasonable request. French versions of the citations are also available upon request.

Authors' Contributions

All authors contributed to the conceptualization of the study and reviewed the final manuscript. BB administered the project with support from AK. BB, FB, AK, CvP, and patient coresearchers designed the study's methodology and contributed to the investigation. CvP, AG, and PB supervised the project. BB drafted the initial manuscript with contributions from FB.

Conflicts of Interest

None declared.

Multimedia Appendix 1
Summary and translation of the interview guides.
[DOCX File , 163 KB - jopm_v17i1e50828_app1.docx]

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Abbreviations

COREQ: Consolidated Criteria for Reporting Qualitative Research
EBCD: experience-based co-design
EPR: electronic patient record
SMP: shared medication plan

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Original Paper

A Brief Video-Based Intervention to Improve Digital Health Literacy for Individuals With Bipolar Disorder: Intervention Development and Results of a Single-Arm Quantitative Pilot Study

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Abstract

Background: Smartphone apps can improve access to bipolar disorder (BD) care by delivering elements of effective psychological interventions, thereby promoting quality of life and reducing relapse risk and mood instability in BD. While many people with BD are interested in using publicly available mental health smartphone apps, without guidance, they risk selecting apps that are unsafe or ineffective.

Objective: This study aimed to co-design a brief educational video on identifying appropriate mental health apps and to evaluate the acceptability and impact of this video among individuals with BD.

Methods: Individuals with lived experience of BD, including 2 peer researchers and members of 2 advisory groups (n=4 and n=7), were consulted to develop a video with information on selecting safe, effective, and engaging mental health apps for BD. Video acceptability and impact on self-reported digital health literacy (including both general eHealth literacy and more specific mobile health literacy) were evaluated via a web-based survey, including both a validated measure and complementary items developed by the research team.

Results: In total, 42 individuals with BD completed the evaluation survey (n=29, 69% women, mean age 38.6, SD 12.0 years). Digital health literacy, measured using the self-report eHealth Literacy Scale, significantly improved after viewing the video (pre: mean 32.40, SD 4.87 and post: mean 33.57, SD 4.67; t_{41}=–3.236; *P*=.002; d=–0.50). Feedback supported the acceptability of the video content and format. Self-report items developed by the study team to assess mobile health literacy showed that individuals felt better able to determine which apps would protect their data (*P*=.004) and to ask their health care provider for support in choosing apps (*P*<.001) after watching the video.

Conclusions: This study found preliminary evidence that an educational video can help people with BD improve their ability to identify, apply, and evaluate the quality of digital health resources. The video and a supplementary web-based educational module are freely available for implementation in health care settings and have the potential to be a cost-effective and accessible resource for clinicians to support patients with BD to navigate the public app marketplace in support of their self-management goals.

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KEYWORDS

mHealth; bipolar disorder; self-management; apps; digital health literacy; video-based intervention; bipolar; single-arm pilot trial; smartphone apps; mental health; psychological; quality of life; mood instability; effectiveness; acceptability; mental health apps; patient education; intervention

Introduction

Bipolar disorder (BD) is a mental health disorder characterized by recurring periods of depressed or elevated moods, which can range in severity from mild mood elevation (BD type II; BD-II) to severely disruptive manic symptoms that may even necessitate hospitalization (BD type I; BD-I). Adjunctive psychological interventions for BD can delay episode recurrence and reduce symptom severity [1]. However, only 54% of individuals with BD receiving pharmacological treatment have accessed psychosocial services [2]. Smartphone apps could improve access to care by facilitating mood and sleep monitoring, providing psychoeducation, supporting medication adherence, and enabling in-the-moment application of coping skills [3] and may benefit quality of life, relapse risk, and mood instability in BD [4-6].

Unfortunately, research-led efforts to develop evidence-based mental health apps are rarely made publicly available. For example, a review of apps for psychosis found that only 15% of research apps were accessible on the public marketplace [7]. In contrast, there is a boom in commercial mental health apps [8,9]. The acceptability and uptake of apps in people with BD are high, with 77% expressing interest in receiving mental health treatment via their mobile device [10], and 42% reporting use of an app to support mood or sleep self-management [11].

There are drawbacks to consider in regard to the safety, efficacy, and feasibility of apps for BD. A review of the top 98 apps returned for the search term “bipolar” found that almost half were not clearly relevant to BD, no patient-facing apps were developed by a university or health care organization, and only 1 app had peer-reviewed literature to support its efficacy [12]. Two-thirds of apps offered privacy policies, of which 41% shared personal data with third parties. Some apps contained potentially harmful content such as advice misaligned with treatment guidelines and stigmatizing or triggering content. Further, the majority of apps for BD did not contain features to support user engagement, despite the fact that many commercial apps report poor user retention [13].

Given the variable quality of publicly available apps for BD, it is unsurprising that consumers experience challenges in selecting appropriate options. Results from an international survey regarding app use among people with BD found that younger age, education below a postgraduate level, and lack of experience using mood or sleep self-management apps were associated with lower levels of digital health literacy (the ability to identify, evaluate, and use health information in an online context) [14]. Individuals with lower health literacy are less likely to adopt eHealth resources or perceive them as useful while simultaneously overestimating the privacy protections offered by health apps [15]. As such, these groups are at risk of selecting unsafe or inappropriate apps (or conversely, not using potentially helpful apps).

Supporting informed decision-making in mental health app use through developing digital health literacy skills is necessary for an equitable digital mental health ecosystem [16]. Ideally, clinicians would play a role in referring individuals with BD to credible, safe, and engaging apps, given their role as a trusted information source [9,17]. In practice, a web-based survey of health care providers found that only 50% had discussed or recommended smartphone apps to patients with BD [18]. Alternative information sources accessible to patients include expert-reviewed app libraries, such as Psyberguide [19,20], the mHealth Index and Navigation Database [21,22], and the Organisation for the Review of Care and Health Apps [23]. Individuals with BD rarely sought information on health apps from such resources, preferring to seek recommendations from others with BD, app store reviews, or family or friends [14].

An alternative strategy to relying on health care provider recommendations or app libraries is to enhance digital health literacy skills in patients. One such intervention targeting people with serious mental illness is the 4-week Digital Opportunities for Outcomes in Recovery Services (DOORS) course [24]. However, the length and foundational content of this program (eg, basic smartphone functions) may not be suitable for all individuals with BD, given research showing people with BD have high levels of smartphone ownership [14] and higher digital health literacy than people with psychosis [25].

Brief videos may be an acceptable method to succinctly communicate key messages regarding mental health app selection and have previously been shown to be an effective knowledge translation strategy for people with BD [26]. They require a lower time commitment to learning than an in-person course such as DOORS and may be shared easily across a wide range of electronic devices (eg, phones and computers), potentially enhancing their reach and accessibility. Brief videos could also be embedded in psychological interventions for BD or provided as a supplementary resource, as a way to support individuals with BD to self-identify smartphone apps relevant to the self-management strategies taught in psychoeducation or in psychotherapy [3].

This study aimed (1) to develop a brief educational video describing strategies for selecting safe, effective, and engaging mental health apps and (2) to evaluate the acceptability and impacts of this intervention among people with BD.

Methods

Ethical Considerations

Ethics approval for the video evaluation was granted by the University of British Columbia Behavioral Research Ethics Board (H21-03767) on January 19, 2022. All participants received written information about the study and provided written consent before proceeding. Data in the study were treated confidentially and stored on a secure server in Canada.

Participants were entered into a prize draw for 1 of 2 CAD $50 (approximately US $35) Visa gift cards. The authors assert that all procedures contributing to this work comply with the ethical standards of the relevant national and institutional committees on human experimentation and with the Helsinki Declaration of 1975, as revised in 2008.

Study Design

Overview

The project was implemented across 2 phases. In the first phase, we applied principles of community-based participatory research (CBPR) to develop a brief video promoting awareness of the potential risks and benefits of mental health apps for individuals with BD and strategies to select appropriate apps. In the second phase, we conducted a quantitative evaluation of the acceptability and impact of the brief psychoeducation video.

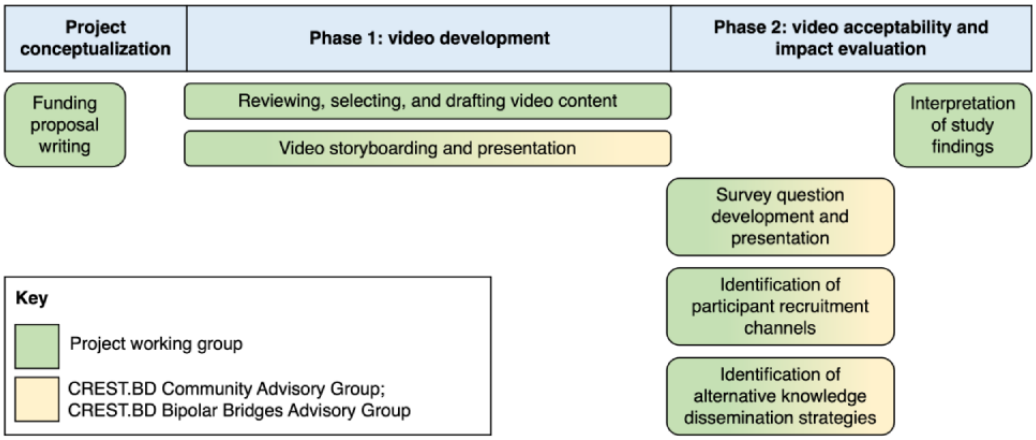
CBPR Framework

The study was conducted using a CBPR framework: academic researchers or clinicians and those with lived experience worked in partnership to identify research priorities, conduct research, and disseminate findings [27]. The approach used was informed by 20 years of experiential knowledge of applying CBPR methods in BD research and knowledge translation by the Collaborative Research Team to Study Psychosocial Issues in Bipolar Disorder (CREST.BD) research network [28]. Details of the CREST.BD network are summarized below; a fulsome case study describing the network's history and use of CBPR methods to determine network priorities has been previously published [29], along with papers describing the network's approach to CBPR in a BD context [28,30].

The CREST.BD network was established in 2005 as a British Columbia–focused team of clinicians and researchers with expertise in BD and psychosocial treatments, with an emphasis on community-engaged research. In 2010, it expanded to a Canada-wide network and formally established advisory groups consisting primarily of individuals with lived experience of BD as well as clinicians and representatives of community organizations. Since then, the network has expanded its scope and geographic representation: team members specialize in a range of disciplines (ie, psychology, psychiatry, criminology, nursing, social work, gerontology, occupational therapy, and genetic counseling) and are located internationally, with particularly strong representation in the United States, the United Kingdom, and Australia. The current membership of CREST.BD can be viewed on the website [31]. Membership of the CREST.BD advisory groups has changed over the years, and project-specific advisory groups have also contributed to network activities. As some members are not publicly disclosed as living with BD, the identities of advisory group members are not detailed on the website.

In this work, CBPR activities were led by a subset of CREST.BD members (EM or EEM) and peer researchers through a project working group. In addition, 2 CREST.BD advisory groups were actively consulted on project activities. The membership of these groups and their involvement in the project, from conceptualization and funding acquisition through to the preparation of study findings, is summarized in Figure 1 and described further below.

Figure 1. Involvement of lived experience and community perspectives across the project phases. CREST.BD: Collaborative Research Team to Study Psychosocial Issues in Bipolar Disorder.



The Project Working Group

Following the principles of CBPR, the video-based intervention was developed using the combined expertise of academic researchers, people with BD, and health care providers. The roles and experiences of all project working group members are described in detail in Table 1. The project working group met 4 times over Zoom (Zoom Video Communications) over the course of the project. Additional collaboration occurred asynchronously over email and shared Google Documents.

In this project, peer researchers were active members of the research team who drew on their lived experience of BD, and the unique sociocultural contexts they live and work in, to ensure the video and its corresponding evaluation aligned with the needs and values of people living with BD. Specifically, they contributed to the development of the funding proposal, selection and drafting of video content, consultation regarding video presentation, and interpretation of study findings. They also provided feedback on the evaluation study, including the selection and presentation of evaluation survey items and the identification of recruitment avenues. On the spectrum of public

participation [32], the peer researchers were involved at the "collaborate" level; they contributed to all decisions regarding video content and presentation and informed the evaluation component. In recognition of their high degree of involvement, they are coauthors of this publication.

Table 1. Project working group membership.

Group member	Role	Relevant experiences
ND	Peer researcher	ND has 7 years of lived experience of BD[a]-II, and many more years of experience of being a supporter of someone living with BD. She has been a CREST.BD[b] peer researcher since May 2020; she is a member of the PolarUs User Group and has contributed to writing content for the app. Along with her lived experience, she brought her experience in user experience and content design to the project.
RXH	Peer researcher	RXH is a Chinese immigrant who lives well with BD. She is a law student and was a member of CREST.BD advisory groups between 2020 and 2024.
EM	Academic or clinician	EM is a psychologist and researcher. At the time of this project, she was a postdoctoral fellow in the Department of Psychiatry at the University of British Columbia. Her research expertise lies in mood disorders, quality of life and patient-centered outcomes, psychosocial interventions, and digital mental health. She has been a CREST.BD member since 2015.
EEM	Academic	EEM is a professor in the Department of Psychiatry at the University of British Columbia. Her research expertise lies in mood disorders, digital mental health, patient engagement in research, knowledge translation, quality of life, and global mental health. She is the founder and network lead of CREST.BD.

[a]BD: bipolar disorder.

[b]CREST.BD: Collaborative Research Team to Study Psychosocial Issues in Bipolar Disorder.

Consultation With CREST.BD Advisory Groups

Two CREST.BD advisory groups were actively consulted on the content and delivery of the video, the selection and presentation of evaluation survey items, and the identification of recruitment avenues. One advisory group (Community Advisory Group) consulted at a high level on the network's program of research and was primarily comprised of people living with BD; other group members were a clinician, representatives of community organizations, and a community engagement and knowledge translation coordinator with a specialty focus on diverse and marginalized communities [29]. The other advisory group (Bipolar Bridges Advisory Group) consulted specifically on the development of an app for BD and was comprised only of people with lived experience of BD [33]; feedback was therefore obtained from individuals with varying degrees of interest in and familiarity with apps. Membership of the Bipolar Bridges Advisory Group specifically privileged individuals of diverse genders, sexual orientations, ethnicities, and cultural backgrounds.

Here, the advisory groups provided feedback on specific decisions about the video content and presentation and the evaluation strategy (including questionnaire wording and recruitment avenues). The groups also generated new ideas for alternative knowledge dissemination strategies that were the focus of later development efforts (see Discussion section). The advisory groups were consulted on 3 occasions over Zoom over the course of the project (attendance ranged from n=4 to n=7). Additional feedback was obtained asynchronously via email. On the spectrum of public participation [32], the advisory groups contributed at both the "consult" and the "involve" level in the context of their longstanding contributions to establishing the CREST.BD strategic plan, research priorities, and ways of working, a process that has been documented in detail elsewhere [28]. All members of the advisory groups share the same scope of decision-making power.

Phase 1: Development of the Video

Overview

Video development occurred between October 2021 and December 2022. Key messages and strategies for the video content were informed by the working group collaboratively reviewing and discussing existing resources (eg, the mHealth Index and Navigation Database and the DOORS curriculum [22,24]), research on specific digital health needs of people with BD and depression [34,35], and peer researcher reflections on their own lived experiences. The script was then drafted by EM and revised with input from EEM, ND, and RXH. Peer researchers were also involved in facilitating consultations with the CREST.BD advisory groups regarding the draft script and storyboard, with feedback integrated into the final video. Decisions regarding video look and feel were driven by peer researchers ND and RXH, who reviewed mood boards and previous videos by the artist to inform decisions regarding video presentation.

The guiding principles for video presentation were collaboratively decided by the project working group: the aim was to keep the video short, simple, and informative to make it easy for people living with BD to understand and apply the recommendations. Reflecting the values expressed by peer researchers, we deliberately targeted a wide range of patient demographics, and accessibility concerns (eg, cognitive difficulties, color blindness, hearing problems, and English as a second or foreign language) were considered in script development, storyboarding, and dissemination plans. For example, we used representative images rather than text wherever possible to minimize demands on working memory and facilitate subtitling and translation (Figure 2). The final

video can be viewed on YouTube [36], and the script is available in Multimedia Appendix 1.

Figure 2. Stills from the video-based intervention illustrating topics covered including assessing privacy and security, use of evidence-based techniques, and ease of use.

Video Content

Overview

The video content was informed by key app evaluation frameworks, in combination with previous research (both specific to BD and relevant to the use of apps in other populations), and refined through repeated consultation with peer researchers and the CREST.BD advisory groups. Broad topic areas addressed in the video were informed by the American Psychiatric Association (APA) app evaluation model, which in itself was developed by harmonizing 45 different app evaluation frameworks [37,38], and consist of five different levels: (1) background information (eg, cost, accessibility, developer information, and system requirements), (2) privacy and security (eg, availability of a privacy policy, collection and use of data, data protection, and management of safety risks), (3) evidence base (eg, clinical foundation and evidence of efficacy or feasibility), (4) ease of use (eg, usability and engagement features), and (5) data integration. Video content centered on privacy and security, evidence base, and ease of use, as there is growing consensus between approaches to app evaluation that data security measures and clinical foundations are of central importance [39,40]. Similarly, engagement with content and features is necessary for apps to have beneficial effects [41,42]. The decision to emphasize these topics is reinforced by data, showing that people with BD report content quality or accuracy, ease of use, and control over information privacy or security among the top 4 most important mental health app features [34]. Specific recommendations relevant to each chosen level of the APA app evaluation model are informed by the following considerations:

Privacy and Security

We represented mHealth Index and Navigation Database criteria deemed essential by a previous review [22,43]: having a privacy policy, reporting security measures, declaring data use and purpose, allowing for the deletion of data, and allowing users to opt out of data collection. Feedback from peer researchers was that difficulties in interpreting the complex regulatory language of privacy policies should be normalized and that viewers could be directed to look for key phrases or to seek additional help from health care providers.

Evidence Base

To support viewers in evaluating the clinical foundations of an app, we described features with the potential to facilitate key mediating mechanisms of evidence-supported psychosocial interventions [3]. In addition, feedback from peer researchers was that peer-reviewed literature is often difficult for a layperson to access or understand and that viewers should be encouraged to seek support from health care providers in reviewing research evidence.

Ease of Use

We highlighted features with the potential to support engagement (notifications, meaningful use of self-monitoring data, and gamification elements like streak counters), drawn from an international survey of people with BD [34]. Based on prior research on barriers to app engagement in people with a mood disorder [34,35], as well as feedback from peer researchers, we strove to normalize BD-related fluctuations in mood and energy and their consequent impacts on engagement.

Phase 2: Evaluation of the Video-Based Intervention

Overview

Evaluation of the video-based intervention was conducted using the web-based Qualtrics platform. Participants provided demographic information, completed baseline assessments, viewed the video, and responded to evaluation items immediately afterward. Data collection occurred between February and October 2023.

Participants and Recruitment

Participant recruitment occurred via promotion on CREST.BD social media pages, paid advertisements on Facebook, Instagram, and Twitter, emails to the CREST.BD mailing list, and health care providers or organizations associated with the

CREST.BD network (eg, Hope+Me, a Toronto-based community organization offering peer support and counseling; Bipolar Support Club International, an online, peer-led organization offering support and education; and the John Hopkins Bipolar Disorder clinic, an academic psychiatry center offering BD-specific consultation and care). CREST.BD network members based internationally (including academics, clinicians, representatives of mental health advocacy organizations, people with lived experience of BD, and caregivers or supports of individuals with BD) were invited to disseminate the recruitment materials through their networks.

Inclusion criteria were (1) age 19 years or older, (2) a self-reported diagnosis of BD, and (3) access to a personal smartphone device. The evaluation survey was open internationally.

Data Collection

Overview

A web-based survey was developed based on previous literature and refined through peer researcher and advisory group input (Multimedia Appendix 2). At baseline, individuals were asked to provide information on demographics (age, gender, cultural and racial background, education, and occupation), clinical characteristics (BD diagnosis and current treatment), and technology use (use of self-management apps and preferred information sources). Questions related to eHealth literacy and mobile health (mHealth) literacy (described below) were asked before and after viewing the video. After the video, 6 Likert-scale statements developed by the researchers (EM or EEM) were used to obtain video acceptability ratings (1=strongly disagree to 5=strongly agree).

eHealth Literacy

The eHealth Literacy Scale (eHEALS) was used to evaluate self-assessed knowledge and confidence in identifying, applying, and evaluating the quality of digital health resources [44]. Eight self-report Likert-type items (1=strongly disagree to 5=strongly agree) are summed to create an overall score (range 8-40), with higher scores indicating greater digital health literacy. Two additional Likert-type items assess respondents' perception of the utility and importance of digital health resources; these are not included in the overall score calculation. The 1-factor structure and reliability of the eHEALS have been demonstrated in the general population [44-46] and populations with health conditions [47-49].

mHealth Literacy

While the eHEALS is the most commonly used measure of digital health literacy [50], it was developed prior to the widespread use of apps and therefore may not encompass all relevant aspects of mHealth literacy. To address this, 6 additional items (using the same 5-point Likert scale as the eHEALS) were developed by the researchers (EM or EEM) to assess self-perceived knowledge and confidence specific to searching for, evaluating, and using self-management apps (Multimedia Appendix 2). These items were not validated.

Data Analysis

Data were analyzed using SPSS (version 29; IBM Corp). Descriptive statistics were used to summarize demographics and feedback regarding video acceptability. Paired-sample *t* tests were used to compare summary scores on the eHEALS before and after viewing the video. The ordinal nature of mHealth literacy items warranted the use of a nonparametric, 2-sample paired sign test to assess video impacts. Significance was set at $P=.05$, and all analyses were 2-tailed. Effect sizes for paired-sample *t* tests were estimated using Cohen *d*, and effect sizes for nonparametric, 2-sample paired sign tests were estimated using Cliff δ, given the nonnormal distribution of the difference scores [51,52]. Sensitivity analyses (Multimedia Appendix 3) were conducted to evaluate the potential influence of key demographic and baseline variables on missing data, the impact of outliers, and the influence of missing data [53].

Results

Survey Sample

Of individuals who consented to the survey (n=77), suspected fraudulent responses (n=23) were removed based on indicators including duplicate IP addresses, email addresses that did not match provided names, infeasible completion times, and duplicate responses to open-ended survey items [54,55], leaving 54 valid entries. In total, 42 respondents completed the survey; their data were used for analyses of acceptability and changes in digital health literacy.

Demographics are summarized in Table 2. Survey completers were primarily women (n=29, 69%), White (n=31, 74%), and residing in North America (n=34, 81%), with a mean age of 38.6 (SD 12) years. Under half the sample self-reported a BD-II diagnosis (n=19, 45%), and most participants were receiving psychiatric treatment, including medication (n=38, 90%) and counseling (n=25, 60%). The majority of the sample had completed postsecondary education (n=34, 81%).

To provide some insights into whether data were missing in a systematic fashion (Multimedia Appendix 3), we compared those who dropped out prior to survey completion and those who completed the study using independent *t* tests for age and baseline eHEALS. Chi-square tests were used to assess for differences in survey completion rates related to gender and previous use of BD-related health apps, as this was found to be associated with digital health literacy in a previous analysis [14]. We did not assess for differences between BD-I and BD-II, as in the same previous analysis, when BD-I was used as the reference category in our regression model BD-II did not emerge as a significant predictor of eHEALS scores [14]. No significant differences were found between completers and noncompleters, suggesting that missing data were not associated with these demographic characteristics.

Table 2. Demographic and clinical characteristics of survey participants.

Demographic or clinical variable	Total sample (N=54)	Survey completers (n=42)
Age (years), mean (SD)	40.1 (12.0)	38.6 (11.8)
Gender, n (%)		
Woman	35 (65)	29 (69)
Man	15 (28)	10 (24)
Nonbinary or gender nonconforming	3 (6)	2 (5)
Other or prefer not to answer	1 (2)	1 (2)
Country or region of residence, n (%)		
Canada	24 (44)	20 (48)
United States	19 (35)	14 (33)
United Kingdom and Northern Ireland	5 (9)	4 (10)
Asia	3 (6)	2 (5)
Africa	2 (4)	1 (2)
Australia	1 (2)	1 (2)
Race or ethnicity, n (%)		
Asian	4 (7)	3 (7)
Black	5 (9)	3 (7)
Hispanic	2 (4)	2 (5)
White	39 (72)	31 (74)
Multiple ethnicities	3 (6)	2 (5)
Other or prefer not to answer	1 (2)	1 (2)
Highest level of education, n (%)		
Did not finish high school	1 (2)	0 (0)
High school	1 (2)	1 (2)
Did not finish postsecondary	9 (17)	7 (17)
Postsecondary diploma or certificate or associate degree	7 (13)	5 (12)
Undergraduate (bachelor degree)	25 (46)	19 (45)
Master degree or doctorate (PhD)	11 (20)	10 (24)
Employment status, n (%)		
Employed full-time	21 (39)	16 (38)
Employed part-time or casual	17 (31)	15 (36)
Student	5 (9)	4 (10)
Not in paid employment	7 (13)	4 (10)
Retired	4 (7)	3 (7)
Marital status, n (%)		
Single	21 (39)	18 (43)
Committed or common-law relationship	13 (24)	10 (24)
Married	12 (22)	10 (24)
Divorced or separated	5 (9)	2 (5)
Other or prefer not to answer	3 (6)	2 (5)
BD [a] diagnosis, n (%)		
BD-I	26 (48)	21 (50)
BD-II	24 (44)	19 (45)

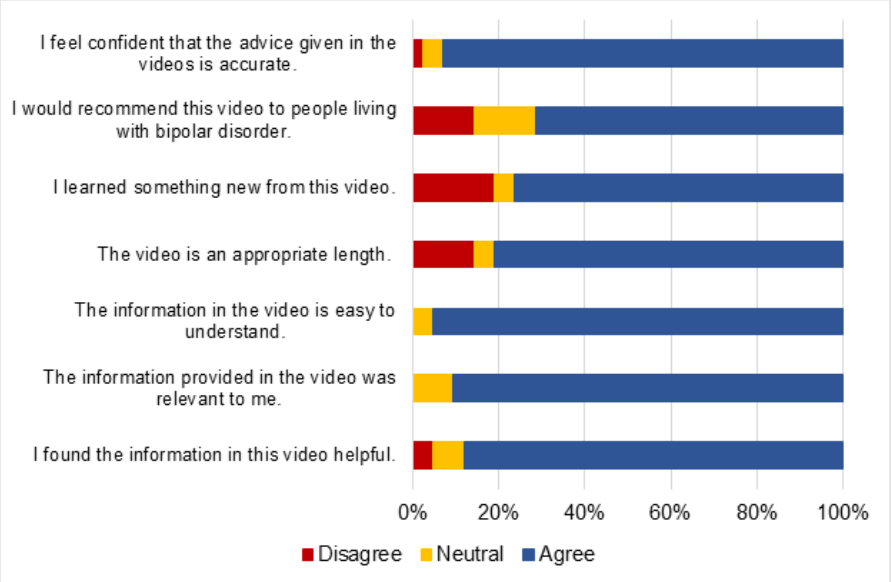
Demographic or clinical variable	Total sample (N=54)	Survey completers (n=42)
Other or do not know	4 (7)	2 (5)
Receiving treatment for BD, n (%)	50 (93)	40 (95)
Type of treatment, n (%)		
Pharmacological	48 (89)	38 (90)
Counseling or psychotherapy	28 (52)	25 (60)
Peer support	7 (13)	6 (14)
Other	2 (4)	1 (2)
Previous use of apps for BD, n (%)		
Yes	29 (54)	24 (57)
No	25 (46)	18 (43)

[a]BD: bipolar disorder.

Video Acceptability

Perceptions of the content, length, and presentation of the video were overall positive (Figure 3). Ratings of video acceptability were collapsed to simplify the presentation (strongly agree or agree=agree and strongly disagree or disagree=disagree).

Figure 3. Survey completers' responses (disagree or neutral or agree) to 6 survey questions evaluating video acceptability.



Changes in eHealth Literacy

A paired-sample *t* test was used to assess the impacts of the video on eHEALS scores. No evidence of nonnormality was detected according to the Shapiro-Wilk test (W=0.96; P=.11) nor visual examination of the histogram and quantile-quantile plot. eHEALS scores of the survey completers were significantly higher after watching the video (mean 33.57, SD 4.67) than at baseline (mean 32.40, SD 4.87; t_{41}=–3.236; P=.002; d=–0.50). The influence of 2 potential outliers was evaluated via a paired-sample *t* test with outliers removed. As overall findings remained unchanged (Multimedia Appendix 3), these cases were retained.

For a conservative estimate of the impact of missing data [53,56], the paired-sample *t* test was repeated with posttest data for survey noncompleters imputed using the last observation carried forward. Results from this sensitivity analysis showed a significant improvement in eHEALS scores after viewing the video (Multimedia Appendix 3).

Changes in mHealth Literacy

Responses of survey completers to mHealth literacy items before and after viewing the video are summarized in Table 3. A Shapiro-Wilk test showed that the distribution of the difference scores of evaluation items departed significantly from normality (question 1: W=0.74; P<.001; question 2: W=0.70; P<.001; question 3: W=0.87; P<.001; question 4: W=0.88; P<.001; question 5: W=0.92; P=.007; and question 6: W=0.77; P<.001). Distributions of the difference scores were found to be nonsymmetrical from visual inspection of the histograms.

Based on the skewed and nonnormal distribution of the differences, a nonparametric, 2-sample paired sign test was used to evaluate changes in participant responses to mHealth literacy items (Table 3). Positive differences indicate the number of

cases where responses were higher after watching the video compared to before. Negative differences indicate the number of cases where responses were lower after watching the video than before. Ties indicate no change in ranking. After watching the video, survey respondents felt better able to determine which apps would protect their data (P=.004; δ=.417) and were more empowered to ask their health care provider for support in choosing an app (P<.001; δ=.253). The median response to these items changed from neither agree nor disagree to agree.

Table 3. Median rankings and 2-sample paired sign test results comparing respondent's ranking of mobile health (mHealth) literacy items before and after watching the video-based intervention[a].

mHealth literacy item	Survey completers (n=42)						
	Median previdео (IQR)	Median postvideo (IQR)	Positive differences, n (%)	Negative differences, n (%)	Ties, n (%)	*P* value (2-tailed)	δ
Question 1: I know how to use smartphone apps to optimize my health and well-being.	5.00 (4.00-5.00)	4.00 (4.00-5.00)	5 (12)	13 (31)	24 (57)	.096	–0.130
Question 2: I feel motivated to use smartphone apps to optimize my health and well-being.	4.00 (4.00-5.00)	4.00 (4.00-5.00)	5 (12)	8 (19)	29 (69)	.58	–0.0306
Question 3: I am able to find and download a mental health app that fits my needs.	4.00 (3.00-5.00)	4.00 (3.00-5.00)	13 (31)	8 (19)	21 (50)	.38	0.0459
Question 4: I am able to differentiate between apps that protect my data and apps that do not.	3.00 (2.00-4.00)	4.00 (3.00-4.00)	20 (48)	5 (12)	17 (40)	.004	0.417
Question 5: I am aware of resources that can help me evaluate mental health apps.	4.00 (3.00-4.00)	4.00 (3.00-5.00)	17 (40)	7 (17)	18 (43)	.06	0.223
Question 6: I am able to ask my health care provider for support with finding and evaluating mental health apps.	3.00 (2.00-4.00)	4.00 (2.00-4.00)	17 (40)	2 (5)	23 (55)	<.001	0.253

[a]Items are scored on a 5-point Likert scale, where 1=strongly disagree, 2=disagree, 3=neither agree nor disagree, 4=agree, and 5=strongly agree.

Discussion

Principal Findings

With the input of people living with BD, we developed a brief psychoeducational video designed to support individuals with this condition in selecting safe, effective, and engaging mental health apps. Preliminary evaluation data show that the video was largely perceived as acceptable, and viewing the video resulted in improvements to eHealth literacy. This study adds to a body of research showing that educational initiatives can improve digital health literacy for people with chronic health conditions. A previous scoping review identified 9 interventions aimed at improving digital health literacy that were grouped into 2 categories: those providing education and training and those providing social support, with education and training initiatives (including videos, workshops, and massive open online courses) showing greater benefits for digital health literacy [50]. We are only aware of 2 interventions developed to address digital health literacy in individuals with mental health conditions, including DOORS (developed to support individuals with psychosis to use smartphones and apps) [24] and video-based training to use a patient portal for people with chronic conditions (including depression and anxiety, among other physical health conditions) [57]. While these interventions reported positive effects for eHealth literacy measures, neither were developed with specific consideration of the app-related preferences and information needs of people living with BD, a gap addressed by our video-based intervention.

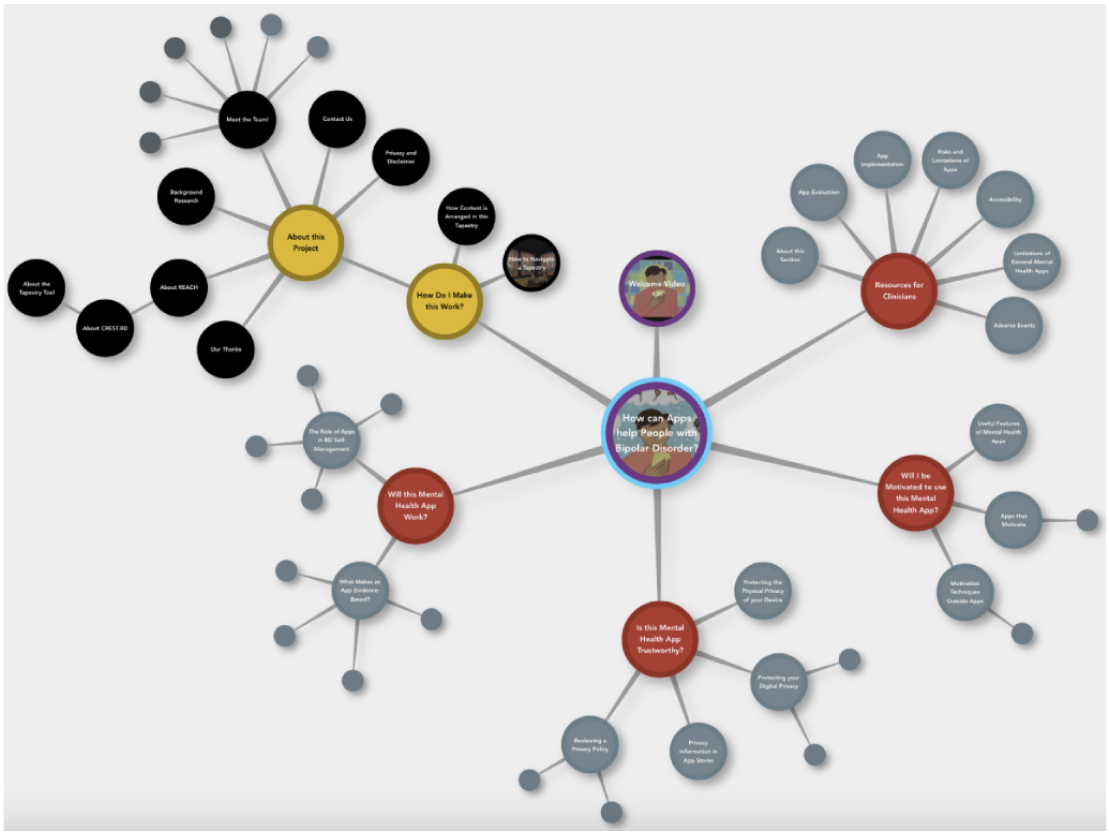
To complement the eHEALS, which is focused on digital health literacy more broadly, we also included some researcher-developed items to evaluate change in smartphone-specific competencies, such as searching for and evaluating apps. Positively, we observed improvements to some aspects of mHealth literacy, such as willingness to ask a health care provider for support and confidence in evaluating app privacy policies. We note that our previous web-based survey of health care providers found a common barrier to discussing or recommending smartphone apps to patients with BD was practitioner knowledge [18]—our findings therefore suggest that clinician education efforts are also needed in order for patients to receive the desired support from health care providers regarding app selection. Furthermore, in light of consensus that the presence of privacy and data security protections is of foundational importance in the decision of whether or not to use apps [39,40], and BD-specific literature showing control over information privacy or security ranks among the top 4 most important mental health app features [34], the finding that confidence evaluating privacy policies improved after the video is of particular note. As we included several strategies to support viewers in evaluating privacy policies (ie, key aspects of privacy

policies, encouragement to seek the support of health care providers, and links to app libraries), future qualitative evaluations could explore which of these were most impactful from a viewer perspective, which could inform refinements to this and similar digital health literacy interventions.

It is important to acknowledge that not all aspects of mHealth literacy demonstrated improvements. Potentially, this may be indicative of some ceiling effects, given median baseline responses to items that did not demonstrate change were "agree" or "strongly agree." We acknowledge the possibility that the use of web-based recruitment methods may have biased the participating sample to individuals with higher baseline digital health literacy as well as interest in app-based tools (described further in the Limitations section). However, it is also possible that the brief video-based intervention was not detailed enough to result in changes to self-perceived knowledge. Indeed, while video acceptability ratings were overall positive, some minor disagreement was observed regarding the appropriateness of the length of the video. Our own CREST.BD advisory groups offered similar reflections regarding the need to offer more in-depth learning opportunities for specific subgroups; the development of a suite of self-guided educational resources to address this feedback is detailed below.

Our project adds to a body of literature on the utility of CBPR frameworks for developing educational outputs that are well-received and impactful in the target population [58-60]. Input from peer researchers and advisory groups helped to ensure that the video focused on issues of primary importance to people with BD, that recommendations were feasible and practical, and that video delivery was engaging and accessible. Participatory research activities in this study also highlighted challenges in planning the timelines and scope of projects developing and evaluating interventions using CBPR frameworks. For example, discussion with peer researchers and advisory groups identified potential user groups whose needs may not be sufficiently met by the intervention as originally conceptualized (ie, a brief video). It was noted that specific subgroups, such as those impacted by the digital divide, may need guidance in basic phone features or additional resources to support the application of strategies. The informational needs of health care providers were also highlighted via consultation activities and a prior survey [18]. To address this feedback, coauthors EM, EEM, and SSK created a complementary suite of self-guided resources for people with BD and health care providers, structured around the video themes (ie, privacy, efficacy, and engagement) and levels of the APA app evaluation framework not covered in the video (ie, background information and data integration). Emerging information regarding the potential risks of apps in BD, such as the potential for mood monitoring to reinforce depressive symptoms in vulnerable individuals [61] and the limitations of using apps designed for the general population for BD concerns [11], was also detailed. These resources were hosted on an innovative learning platform, the Tapestry Tool [62], where hierarchical relationships between concepts are represented spatially similar to a mind map (Figure 4), and multimodal resources including text, videos, and web articles can be linked. Similar online courses to support digital health literacy have been shown to improve eHEALS scores in specific populations, such as people with type 1 and 2 diabetes [63]. Combining this brief video with a self-guided exploration of the Tapestry Tool educational module could therefore further enhance impacts on digital health literacy. However, as this Tapestry Tool educational module was developed in addition to the planned, funded activities (ie, development of the brief video), we did not have the resources to evaluate the impacts of these resources separately and in combination. This illustrates a common tension in CBPR research: extensive consultation with communities is needed to inform grant applications; yet, this can be difficult to resource before grant funding is available [64]. To avoid situations where there are not sufficient resources to fund research priorities identified by the community, we suggest a need for more funding opportunities specifically supporting CBPR during project conceptualization.

Figure 4. Navigation structure of the Tapestry Tool educational module containing resources for people with BD and health care providers (to view module content, please visit [62]). BD: bipolar disorder; CREST.BD: Collaborative Research Team to Study Psychosocial Issues in Bipolar Disorder.



Limitations

A number of limitations to this study should be noted. For context, we note that the grant provided to fund this project (Michael Smith Health Research BC REACH Grant) was specifically intended to cover costs associated with the development of the educational resources (including payment of peer researchers). For this grant, costs associated with research studies are noneligible expenses and were covered in kind by CREST.BD. This limited our ability to conduct a more fulsome randomized controlled trial, as we did not have sufficient funds to fairly compensate participants for their involvement in a study where they may not have received exposure to the intervention. In addition, it limited our ability to conduct more resource-intensive recruitment strategies, such as outreach into face-to-face settings. The implications of this for the study limitations are described in more detail below.

First and foremost, this was a nonrandomized pilot evaluation; findings should therefore be interpreted with caution. In the absence of a control group, spontaneous improvements due to expectancy effects, baseline sample characteristics, or other confounding variables cannot be ruled out. In addition, the small sample size limits generalizability. Removal of suspected fraudulent responses detected on review of the data (n=23) reduced the total valid survey entries (n=54). This finding emphasizes the importance of applying additional strategies to ensure sample validity, such as rigorous screening procedures, inclusion of questions to detect poor quality or inattentive responses, and restrictions on where and how surveys are advertised [65]. Although our sample was small, it is comparable to other evaluations of digital health literacy interventions in serious mental illness populations [24,66]. Unfortunately, this sample was too small to conduct additional subgroup analyses, including gender-based comparisons.

Our sample was predominantly White and had completed some form of postsecondary education; efforts are needed to ensure that digital health literacy interventions are accessible to those with limited English proficiency. A survey of established (living in Canada for >10 years) senior Punjabi and Chinese immigrants (n=896) found that only one-quarter of participants reported advanced reading and writing proficiencies in English, and lower levels of education were associated with poorer eHEALS scores. As 65% of participants expressed an interest in using a smartphone to improve their health [67], this group may benefit from support to develop digital health literacy. To support equitable access to intervention content in Canada, we have translated the video into Mandarin, Punjabi, and American Sign Language, although we note that the evaluation was only conducted in English, limiting ability to generalize findings to other language groups.

Funding restrictions and issues of feasibility influenced our choice of recruitment strategy: we used a web-based survey to increase the likelihood of reaching a target sample size, given the relatively low prevalence of BD [68]. It may be that the use of web-based recruitment methods biased our sample toward individuals with higher pre-existing levels of digital health literacy. Relatedly, one survey that used telephone, hard-copy, and online data collection methods to assess digital health literacy and digital engagement for people with severe mental illnesses (including BD) found that higher levels of digital health

literacy were associated with having outstanding or good self-reported knowledge of the internet [25]. As such, future studies should consider evaluating the impact of this video-based resource using alternative dissemination methods, such as DVDs that can be played in mental health clinics, or one-on-one consultations with health care providers.

The eHEALS measures self-perceived digital health literacy and not necessarily the actual performance of these skills; it is therefore possible that participants may experience an increase in self-perceived competencies without a concordant improvement in the real-world application of their skills. Future studies may wish to use procedural assessments of digital health literacy competencies. Approaches to performance-based assessments of digital health literacy are highly heterogenous and include simulated behavioral tasks, knowledge assessments, and evaluation tasks [69]. For example, previous studies have provided participants with a list of both high- and low-quality health information websites [70,71]; the concordance of participants' evaluation of these websites with researcher ratings (as based on a standardized framework) was used to evaluate eHealth literacy skills. A similar approach could be used in the future to compare participants' evaluations of apps with expert ratings as a proxy for mHealth literacy skills. Alternatively, comparing eHEALS scores to skills-based assessments may improve confidence about the real-world implications of improvements on this measure. While some work has been conducted to demonstrate modest correlations between perceived and performed eHealth literacy [72], we acknowledge that additional external validation is required. Unfortunately, we are not aware of any validated measures of mHealth literacy (performance-based or self-assessment)—a clear priority for future research. Our own in-house items were developed, given the dearth of available instruments; however, the fact that they were not validated remains a limitation of this study.

Conclusions

Interventions are needed to help address the digital divide by promoting the skills and knowledge needed to take advantage of digital mental health tools and enhance the uptake of safe and effective mental health apps by people with BD. In this study, receiving only 4.5 minutes of psychoeducation about the risks and benefits of mental health apps for BD was found to improve self-perceived eHealth literacy and some aspects of mHealth literacy in individuals with this diagnosis. However, it must be noted that multiple aspects of mHealth literacy remained unchanged, and 19% (n=8) of the survey completers denied learning anything new as a result of the video. While findings remain preliminary due to the small sample size, nonrandomized design, and the use of nonvalidated mHealth literacy items, they are encouraging for future evaluations. To support the reach of the video and the accompanying web-based educational module, we have made these resources freely available for health care providers and patients [36,62].

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Data Availability

The datasets generated or analyzed during this study are not publicly available in accordance with ethics approval given by the ethics board from the participating university but are available from the corresponding author on reasonable request.

Authors' Contributions

EM conceptualized the project, contributed to funding acquisition, designed the methodology, conducted the investigation, supported the statistical analysis, and wrote the original manuscript draft. SSK contributed to data curation, conducted the statistical analysis, conducted data visualization, and contributed to writing the original manuscript draft. ND contributed to the project conceptualization, funding acquisition, development of the intervention and methodology, and editing of the manuscript. RXH contributed to the project conceptualization, funding acquisition, development of the intervention and methodology, and editing of the manuscript. EEM contributed to project conceptualization, funding acquisition, and editing of the manuscript. All authors reviewed the final manuscript.

Conflicts of Interest

SSK, ND, and RXH declared no potential conflicts of interest with respect to the research, authorship, and publication of this paper. EM has received an honorarium for advising on the development of unrelated educational materials for Neurotorium, a web-based educational platform supported by the Lundbeck Foundation. EEM has received funding to support unrelated patient education initiatives from Otsuka-Lundbeck.

Multimedia Appendix 1

"Choosing a bipolar disorder app that works for you" script.
[PDF File (Adobe PDF File), 516 KB - jopm_v17i1e59806_app1.pdf]

Multimedia Appendix 2
Video-based intervention evaluation surveys.
[DOCX File , 25 KB - jopm_v17i1e59806_app2.docx]

Multimedia Appendix 3
Sensitivity analyses.
[DOCX File , 17 KB - jopm_v17i1e59806_app3.docx]

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Abbreviations

APA: American Psychiatric Association
BD: bipolar disorder
CBPR: community-based participatory research
CREST.BD: Collaborative Research Team to Study Psychosocial Issues in Bipolar Disorder
DOORS: Digital Opportunities for Outcomes in Recovery Services
eHEALS: eHealth Literacy Scale
mHealth: mobile health

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Original Paper

Engaging Young People With Mental Health Needs and Exploring Outputs From a Resource Development Project: Qualitative Interview Study

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Abstract

Background: Recommendations from professional bodies, including the Royal College of Psychiatrists, advise mental health practitioners to discuss problematic online use with children and young people. However, barriers such as knowledge gaps and low confidence in initiating discussions often prevent these conversations from happening.

Objective: The Digital Dialogues project used a knowledge exchange approach, cocreating resources with young people, to support professionals in overcoming these challenges. This paper details the project design and reflects on the perspectives of the young people involved.

Methods: The project was guided by the "children and young people have ownership" model of cocreation. A total of 11 participants were purposively sampled to take part in the Digital Dialogues Young Persons Group (DDYPG) and were actively involved in the study workshops, creative tasks, and resource design and development. In total, 6 (55%) DDYPG members took part in interviews, and 2 (18%) also completed an anonymous survey evaluating their time in the DDYPG. Thematic analysis was used to explore data from interviews and qualitative survey responses together.

Results: The DDYPG successfully created several resources to support practitioners in addressing problematic online use with young people. Reflections from DDYPG members showed that creative engagement, meaningful involvement, and peer interactions were key motivators for participation and led to benefits, including feelings of empowerment and personal development. Anxiety, time demands, and potential exposure to triggering content could act as barriers. However, structured tasks, positive rapport with researchers, and flexible participation helped to mitigate these challenges.

Conclusions: The findings highlight ethical considerations and potential strategies for involving young people in resource development research projects in the future.

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KEYWORDS

qualitative; resource development; children and young people; mental health; research design; participatory research; codevelopment

Introduction

Background

Online use can offer opportunities to children and young people, including learning, connectedness, and fun. In relation to their mental health, it can also encourage access to helpful information and peer support [1,2]. However, there are concerns about the risks associated with online use in children and young people. For instance, links exist between engaging with harmful or distressing images and maladaptive behaviors, including self-harm and disordered eating [3,4]. In addition, negative online experiences have been significantly associated with increased psychiatric symptoms in children and young people [5].

Therefore, recommendations have been made for mental health professionals (MHPs) working with children and young people to support their online use. This includes advice from the Royal College of Psychiatrists [6] for psychiatrists to inquire about online use during all consultations with young people. Research has also shown a willingness among MHPs to discuss this topic with young people [7], but several barriers, including knowledge gaps, time constraints, and a lack of confidence, prevent them from doing so [8,9]. As a result, guidelines have been developed, such as the good practice indicators, which act as advice for those managing these conversations in mental health practice [10]. However, little is known about their implementation in practice, and MHPs continue to lack practical and accessible resources to navigate these conversations effectively [11]; MHPs have expressed a clear interest in tailored training, assessment tools, and evidence-based resources to support their work in this area [11]. Research has highlighted the value of involving children and young people in mental health resource development, showing that such participation can lead to more effective outcomes and promote a sense of empowerment among children and young people [12,13]. At the same time, challenges persist regarding meaningful engagement, with studies emphasizing the importance of nontokenistic involvement and the need for innovative methods of participation [12,13]. Despite these insights, to the best of our knowledge, no project has directly codeveloped practical tools for MHPs to use with children and young people, addressing their online experiences and mental health.

The Digital Dialogues project aimed to use a knowledge exchange approach [14] to develop additional resources for MHPs, aiding their discussions with young people regarding online use. This method was used as it encourages a dialogue between populations, allowing for the integration of both lived experience and professional perspectives and ensuring the resources developed are relevant to both. First, in an evidence-synthesis phase, we conducted 2 nationwide surveys to inquire about (1) what resources and training MHPs want and need [11] and (2) what thoughts and feelings children and young people have about professionals working with them regarding this topic. Second, in a resource development phase, we collaborated with young people, using creative methods, such as art, poetry, and drama, to engage them and allow for self-expression of thoughts and ideas through a variety of means [15]. During this phase, we established the Digital Dialogues Young Persons Group (DDYPG), providing a space for young people with lived and living experience of mental health needs to contribute to Digital Dialogues in member roles.

This Study

This paper aims to outline and evaluate ways DDYPG members were involved as members in the Digital Dialogues resource development phase. We present details of the workshops, creative tasks, and project processes to demonstrate how we involved and engaged young people, alongside interview data in which participants reflect on their experiences.

Methods

Collaborative Approach

We aimed to collaborate with children and young people with lived and living experiences of mental health needs to generate ideas for potential resources based on their experiences and perspectives. Drawing on the *Guidelines for Research with Children and Young People* [16], we focused on approaching the study with the "children and young people have ownership" model of involvement. By doing so, we hoped to provide children and young people with agency over the research process and embed them as research team members while providing guidance and support from the trained research team who helped them navigate [17].

DDYPG Recruitment

The DDYPG aimed to recruit 8 to 12 young people. A digital recruitment advertisement was distributed via various young people's groups, including Arts Emergency, Partnership for Young London, and the National Youth Agency, as well as specific mental health organizations, including McPin, OCD Youth, Body Dysmorphic Disorder Foundation, What Works Wellbeing, Mental Movement Magazine, and Beyond. In addition, the advertisement was shared through the Epigram University of Bristol student newspaper and relevant societies at universities across the United Kingdom, including the ThinkMental King's College London Society, Beat This Together University of Bristol Society, and Student Minds University of York Society.

Potential DDYPG members completed an expression of interest form, detailing their name, email address, age, lived experiences of mental health and online use, and creative interests. They were then assessed against eligibility criteria for involvement (Textbox 1).

After 3 expressions of interest were deemed ineligible, study information sheets were sent to all eligible potential participants (N=45), and of those, 20 (44%) continued to express an interest in participating. After reviewing prospective participants, we selected individuals through purposive sampling and invited

them for an individual introductory session with researcher ZH. Purposive sampling was used to ensure a diverse population, prioritizing variation in mental health experiences while also attempting to include a range of demographics and creative interests to enrich the perspectives within the study. During introductory sessions, potential members were able to ask questions, learn about the safety plan and consent process, and provide brief information regarding their online use and mental health experiences.

Following these sessions, the first 11 potential DDYPG members provided consent to take part in the DDYPG, and recruitment was closed as researchers felt confident the group reflected a broad range of relevant experiences. During this process, members gave consent for their contributions to be used and shared in resources and provided separate consent for any potential sharing of their creative work. At this point, they also completed a survey that informed researchers of specific triggers they may have related to mental health content. Recruitment took place over a brief period between October 2023 and November 2023 and was closed once all members had provided informed consent.

Textbox 1. Eligibility criteria.

- Aged 14 to 25 years
- Lived or living experience of engaging online regarding their own mental health
- Willingness to participate for up to 7 months
- Access to a stable internet connection
- Adequate understanding of the English language
- Currently residing in the United Kingdom

Ethical Considerations

Ethics approval was given by the Faculty of Health Research Ethics Committee at the University of Bristol (15930). Although this was public engagement work, ethics approval was sought due to the involvement of vulnerable young people with mental health needs, the planned creative outputs, and our intention to evaluate the collaborative work. We wanted to ensure group members were appropriately safeguarded and fully informed about their rights regarding the creation and sharing of materials during the study. Participants provided informed consent on two occasions: initially upon entering the study, and again prior to the creation of resources. The first consent form addressed their involvement as research participants, while the second outlined their rights regarding any intellectual property generated during resource development. Participants were informed that they could withdraw from the study at any time; however, content they contributed to the co-created resources could not be withdrawn. All participant data were handled in accordance with data protection legislation. To ensure confidentiality in this paper, participants have been assigned unique identifiers in place of their names. The young people involved in the study were reimbursed for any time contributed to research or resource development, at a rate of £25 (US $33.23) in vouchers per hour.

As part of our ethical approach, we made it a requirement for the DDYPG members to complete an individual safety plan (Multimedia Appendix 1). In this plan, members provided details of an emergency contact and their general practitioner to be used if researchers identified an immediate risk of harm to themselves or others. In addition, they could create a personalized care plan and access a range of well-being resources. Researchers also followed a distress protocol during the project, including following up with members individually after each workshop.

Online Platform Communication

As part of this study, we set up a private server on the online communication platform, Discord. The Discord platform supports discussions and has features enabling file sharing. In addition, Discord is a popular platform among young people that has been shown to enhance digital collaboration [18]. We believed this would be an effective way to encourage conversations among young people, engagement with study materials, and sharing of information. While there are other platforms with similar functionalities (eg, Slack and Microsoft Teams), Discord's widespread use among our target demographic and its intuitive features made it particularly suitable for this study. All DDYPG members and Digital Dialogues researchers were invited to join if they wished, with ZH moderating content. Platform discussions were restricted during nonworking hours.

DDYPG Procedure

Three DDYPG workshops (Table 1) took place via the online videoconferencing platform Microsoft Teams between November 2023 and January 2024. All workshops were audio recorded, and the audio was transcribed by ZH, who then created and shared a workshop summary with all DDYPG members.

Where young people were unable to attend or preferred not to be involved in workshops, they were given the opportunity to take part in alternative ways, such as involvement in discussions over Discord or creating, revising, and editing documents and resources.

Throughout the project, young people also took part in several creative tasks (refer to the Results section). Instructions for tasks were shared via Discord and email, and for task 1, they were posted to a given address, alongside some creative materials. Creative work was used to encourage young people's involvement in discussions related to their experiences and encourage idea generation for the resulting resources [20].

After the final workshop in which shared decision-making allowed researchers and DDYPG members to outline what resources the group would create, ZH contacted DDYPG members individually about their involvement. In some cases, members also approached ZH with ideas for resources to develop. Members worked on resources independently or in groups, alongside input from researchers, where indicated as necessary by the young people, between January 2024 and May 2024.

A total of 7 (64%) of the 11 DDYPG members also received training in content analysis methods and contributed to a separate manuscript, and 3 (27%) made content for Digital Dialogues presentations at conferences. In addition, creative outputs by DDYPG members were displayed in a web-based exhibition that members reviewed and provided feedback on.

Following the creation of the resources, Digital Dialogues 2 has been funded, and it commenced in November 2024. This project aims to develop a training package and session for MHPs that incorporates the Digital Dialogues resources. Dissemination of the Digital Dialogues resources is therefore ongoing, with DDYPG members being consulted on an ongoing basis.

Table 1. Task aims and instructions.

Task	Aim	Instructions
Task 1: GPI[a] creative work	Create a visual or written piece reflecting on a GPI [10]	Members received a welcome pack with creative materials and two suggested methods: (1) erasure poems (using pages from books) and (2) smartphone template drawings. They could also use their own artistic style. Creations were shared in workshop 1.
Task 2: survey	Gather young people's views on online culture, mental health, and digital communication	There was a short survey exploring emoji meanings, mental health platforms, online trends, influencers, and experiences with MHPs[b]. Results were discussed in workshop 2.
Task 3: search history poems	Use list-style poetry to reflect on online searches and mental health experiences	Inspired by poems by Vuong [19] and members created poems using real or fictional search histories to narrate their online journeys. Results were discussed in workshop 3.
Task 4: character development	Develop a character for a mental health video resource	During workshop 3, members brainstormed a "day in the life" concept. They completed character profiles, covering backstory, social media habits, daily experiences, and an MHP interaction (both positive and negative scenarios).

[a]GPI: good practice indicator.

[b]MHP: mental health professional.

Workshops

DDYPG members took part in 3 online workshops designed to create a space for young people to share their experiences with online use and mental health while also considering the perspectives of MHPs. Before each workshop, DDYPG members received details about preworkshop tasks, what would happen during the workshop, and postworkshop follow-ups (Table S1 in Multimedia Appendix 2 [10,11,19,21-24]). The primary aim of the workshops was to work toward idea generation for resource creation and prepare members to bring their own experiences and insights into the resource development phase.

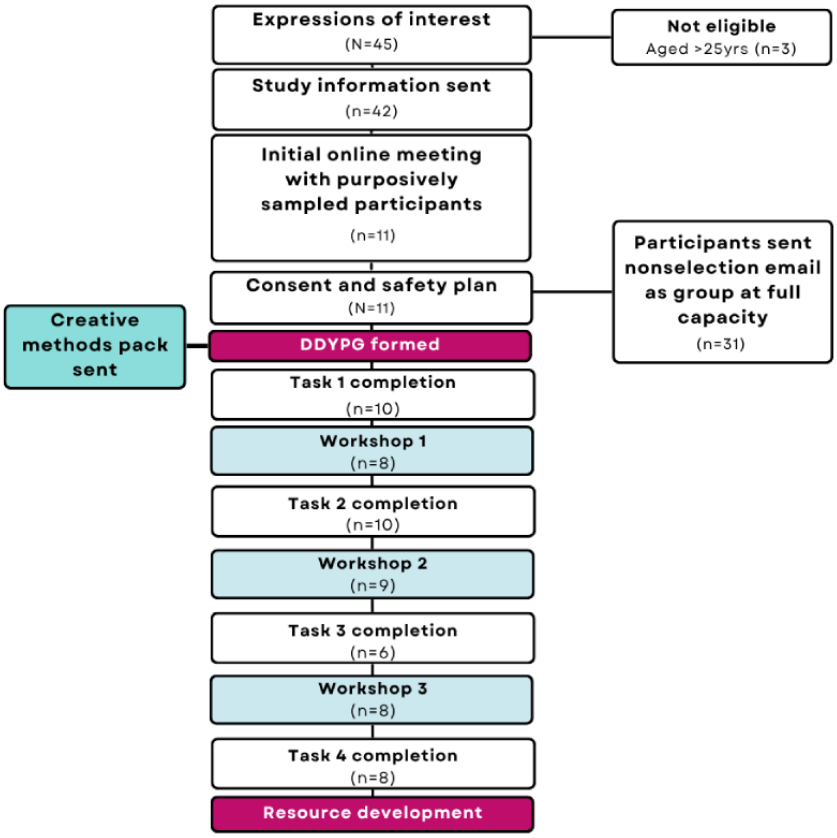
Tasks

Tasks were completed to help young people reflect on their personal experiences, with creative methods used to allow novel ways of self-expression. Ultimately, the information gained through workshop discussions of tasks informed the conception and development of resources, ensuring that the perspectives and experiences of all DDYPG members were incorporated. Tasks are described in Table 1, and the details are provided in Table S2 in Multimedia Appendix 2.

Study Flow

The participant study flow is detailed in Figure 1.

Figure 1. Digital Dialogues Young Persons Group (DDYPG) study participant flow.



Evaluation of Involvement in Digital Dialogues

All DDYPG members (n=11) were invited to evaluate their time in the study via a one-to-one online interview and by completing an anonymous survey with similar questions, allowing for additional feedback. Interviews were semistructured and conducted by ZH using a topic guide exploring the positives and negatives of involvement in the DDYPG, suggested changes for the DDYPG, reflections on specific workshops and tasks, and opinions on the resulting resources. In addition, all members were invited to complete an anonymous survey, which was designed to provide an additional route for feedback from participants who may have felt less comfortable sharing openly in interviews due to their existing relationships with the researchers. Audio from interviews was transcribed by ZH.

Interview participants are referred to in the results using participant IDs (eg, P01 and P02), while survey responses are labeled with anonymous IDs (eg, anonymous 1).

Researcher CC joined the Digital Dialogues project after the evaluation interviews had been conducted and carried out the initial coding of transcripts using thematic analysis [25]. The involvement of CC ensured a layer of analysis from a researcher not involved with the data collection, helping to enhance rigor and reduce bias. Thematic analysis was chosen for its flexibility and systematic approach. After initial coding, CC then organized the codes and generated themes, which went through an iterative process following feedback from ZH. Coding was conducted in Microsoft Word, and Microsoft Excel was used to organize the data. Then, there was a member-checking phase, where 3 DDYPG members were invited to review the resulting data to ensure accurate representation. This led to minor refinements, such as adding detail to positive changes in online behavior and including more information on flexibility toward member involvement.

Results

DDYPG Member Demographics

In total, 8 (72%) of the 11 members identified as female, 2 (18%) as male, and 1 (9%) as nonbinary. All were aged between 18 and 24 years and based in the United Kingdom. Members had experience with a range of mental health difficulties, including anxiety, depression, personality disorders, eating disorders, and obsessive-compulsive disorder.

Resources

Table 2 presents details of the resources that were conceptualized, designed, and created during this project, with contributions by the DDYPG members given in detail. Resources were created simultaneously, over a period of 5 months, to ensure young people had time to contribute alongside other commitments. Researchers provided feedback and editorial input on resources, which were then reviewed and amended by the group members before a resource was finalized.

Table 2. Details of resources developed during the Digital Dialogues project.

Resource	Description	DDYPG[a] involvement
Flash cards and road maps	These resources included 20 flash cards representing a safety mechanism related to online use, with a lived experience account detailing children's and young people's experience of using it; road maps outlined a potential online scenario and the relevant flash cards for MHPs[b] to use with it.	• Three members contributed lived experience content. • Five members selected the flash card design. • One member conceptualized the creation of road maps and designed them. • One member reviewed and edited the road maps. They also reviewed researchers' changes and made amendments.
Content creator advice poster and additional information	The poster outlined considerations for MHPs when children and young people were following a content creator who posted mental health–related content; a document with more detailed guidance was also created.	• One member conceptualized and designed the poster. They also reviewed researcher changes and made amendments. • One member developed a detailed information document to complement the poster.
Comfortable conversations with MHP poster and question prompt bank	Poster outlined strategies that MHPs could use to help children and young people feel comfortable during conversations about their online use. The question prompt bank offered MHPs a curated list of important questions to ask children and young people.	• Eight members conducted content analysis of a children and young people survey. • One member conceptualized and designed the poster. They also reviewed researcher changes and made amendments. • One member developed the question prompt bank. They also reviewed researchers' changes and made amendments.
Video	Video portrayed a "day in the life" of a young person whose behaviors and mood were both positively and negatively impacted by her online engagement, particularly in relation to eating	• Eight members produced character descriptions (task 4), which researchers merged to form the lead character. • Two reviewed, discussed, and edited the script (made by the research team). • One member helped audition potential actors. • Eight members provided voice-overs for the video.
Web-based exhibition	The web-based exhibition served as a platform to display the creative outputs produced by DDYPG members throughout the study.	• Seven members reviewed the web-based exhibition and gave feedback on changes.

[a]DDYPG: Digital Dialogues Young Persons Group.

[b]MHP: mental health professional.

Evaluation

A total of 6 (54%) of the 11 DDYPG members completed evaluation interviews, and 2 (18%) took part in the anonymous survey. Results from the thematic analysis of the qualitative response data are presented subsequently by theme.

Reflecting on Involvement in Creative Tasks

DDYPG members gave mixed feedback when reflecting on task 1 (Table 2). When approaching the task, one (P03) participant felt completely unable to finish it, and others expressed struggling with it, feeling they lacked the necessary artistic ability:

> *I've never done anything like that before. I guess I am a creative person, but I'm not an arty person, so it was a bit out of my comfort zone.* [P01]

Another participant (P05) found the task somewhat restrictive due to instructions limiting what content they could focus on, and one delayed the task, which seemed to stem from concerns about how others in the group may perceive their experiences:

> *I couldn't decide what I wanted to talk about. At that time, I was aware of my online use and how negative it was when I was younger, there was still a stigma.* [P06]

However, those who completed the task and presented it during workshop 1, including members who were originally reluctant, named several benefits of involvement. This included giving and receiving positive feedback and discovering new ways to express themselves. A few found the completion of erasure poems during task 1 particularly helpful, as the constraints of the task made it easier to articulate complex thoughts and feelings:

> *Sometimes with these sensitive topics, if you've been through a lot there's so much to say, that if you're given text and you have to erase words and work with what you've got it forces you to express yourself a certain way…I was expecting it to be difficult because obviously you're limited, but I thought it was a really good exercise.* [P04]

In task 3, members were invited to write "search poems" about their online experiences related to mental health. Several also enjoyed the reflective nature of this task:

> *It wasn't creating as much as thinking or forcing yourself to reflect on how you use the internet. It's something you don't really think about because we use it all the time, but I had to pick out certain things that were common threads for me…it forced me to reflect on the things that I'm actually searching for.* [P04]

However, one member had a more nuanced reaction. While they recognized the beneficial nature of the reflection, this was balanced with the acknowledgment that revisiting these periods of poor mental health could have had a negative impact if their personal resilience was not as strong:

> *I think it would depend on someone's mental state at the time. I can see how that might be slightly triggering, I mean it was quite sad for me to do. It also was a bit of a blur, the period I chose because I was quite unwell, but then it did help clarify that a bit.* [P05]

In addition, this task was described as "tricky" (P06) due to the challenge of connecting online use with mental health, and P03 struggled with the directions. While fewer members reflected on tasks 2 and 4, P05 found that the character development work (task 4) was "really fun," and P02 remarked, "I really liked taking part in the survey [task 2] too".

Facilitators of and Barriers to Member Involvement in the DDYPG

We identified several key factors that facilitated as well as posed barriers to successful involvement in the DDYPG.

Building Safety and Trust

First, ensuring a safe and trusting environment was integral to DDYPG members' involvement. Members expressed feeling "it [was] a very safe space, safeguarding was great and was inclusive to all" (anon1), and the requirement to complete a safety plan before involvement reassured members, "it was good to have that precaution" (P06).

Others noted how completing a safety plan would be a "good idea" (P02 and P03) for any mental health research involving young people, and one identified how it helped build rapport between the researcher and the member:

> *It's always good to have a safety plan for the young person but also the person doing the research because then at least you have that mutual understanding of what can be helpful and unhelpful during the involvement.* [P03]

None of the DDYPG members reported needing to access the safety plan during the study. This aligned with their self-perception of being comfortable and "confident" (P06) while discussing sensitive topics.

Positive Group Dynamics

The perception of safety was reinforced by the positive group dynamics. Members particularly appreciated the "non-judgemental" attitudes from peers (P01 and P03). The mutual awareness and understanding of handling potentially harmful information also played a role:

> *Luckily everyone else in the group was probably quite aware of sensitive topics we were discussing and perhaps not going into too much unnecessary detail that might be triggering. So, I've never felt super uncomfortable.* [P05]

An additional factor that influenced DDYPG involvement was the opportunity for members to engage with peers without researchers being present. This facilitated open conversations and allowed for organic idea generation:

> *I liked how we went into breakout rooms without the researchers, it felt like we were just talking young person to young person. Although the researchers are here and they understand the topic and they want to make a difference and make a change, a lot of the time they won't have had these experiences before, sometimes that can make it difficult to talk to them.* [P06]

Members also emphasized the value of contributing to research that could help others. This sense of purpose encouraged their involvement and made them feel connected to a group of like-minded individuals:

> *It was good to talk to young people who want to be involved in a project to make a difference and therefore are happy to talk about and share their experiences.* [P06]

Valued Members of the Project Team

DDYPG members consistently mentioned the quality of their involvement in the project as a significant motivator. The supportive relationships with researchers were a key factor, "I felt very cared for and valued." (anon2), and researcher responsiveness also played a role:

> *There were times where I would send you these huge rants in emails of all this stuff I noticed online, and you [the researcher] made sure I felt validated and I felt heard, which is really important for me.* [P02]

In addition, the high level of DDYPG involvement in the study process was crucial. One participant remarked as follows:

> *I feel like we've genuinely been quite equal partners in all of it, which is really cool.* [P01]

This level of involvement was directly compared to other cocreation roles the group had been involved in:

> *[The DDYPG] were different to other young people's co-creation, they had a variety of different methods and options to choose from. I didn't feel limited in any way.* [anonymous 1]

This promoted a sense of empowerment and encouraged the DDYPG members to question their other cocreation roles:

> *The level of involvement we've had has made me challenge a little bit [in other cocreation roles], like, "Why can't we have more involvement? Why can't*

> *we be doing this? Why can't we be involved in that?"* [P01]

Time Management

Scheduling flexibility also facilitated involvement in this project and individual tasks. Members generally felt that their commitment to the DDYPG was "manageable" (P01), as "involvement was fairly spaced out" (P03), and they could "balance" (P04) it with other work, including university and jobs. In addition, the ability to continue conversations about task work on the Discord platform facilitated this flexibility:

> *I appreciated the opportunity to participate in the tasks but then not necessarily have to be in the meetings to have discussions because they could move to Discord...I felt like we had good opportunities to participate in various different ways.* [P01]

A few members also noted that if tasks had shorter deadlines or were set all at once, it may have been "overwhelming" (P03) and could have hindered their involvement. However, one member (P04) did feel they missed out on some involvement due to university obligations.

A couple of members observed that it was their responsibility to manage time and assess their capacity to complete DDYPG tasks alongside their daily lives. One recalled declining involvement comfortably:

> *There was a time I remember where you sent two tasks, and I was like to be completely honest I only really have time to do one, and you were like that's absolutely fine just do the one. That was quite nice, as much as I wanted to do the other one, I had to be realistic, you know, I've got a bunch of exams coming up, I don't know if I can do both of those.* [P02]

However, the other participant felt less comfortable rejecting tasks, though they appreciated that presenting them as optional made decision-making less pressured:

> *You gave me the option, "would you like to do this" rather than "we're going to do this," I felt more able to say no. Although I never said no because I liked the project and I wanted to be involved, but I did like that I had the opportunity to say no or later on down the line I could be like "I don't have time to do this, I'm sorry."* [P06]

Anxiety

Most members expressed initial anxiety about attending the first DDYPG meeting, which could have acted as a barrier to involvement. While 2 participants (P02 and P03) attributed their apprehension to social anxiety diagnoses, others (P01, P03, P05, anon1, and P06) shared similar concerns. They mentioned unfamiliarity with group members, fears that conversations might be triggering, and anxiety about presenting their creative work, especially when comparing it to the unknown pieces others had produced. However, all of these members also mentioned that the anxiety quickly dissipated once the first meeting began:

> *I'd say just the nervousness of going on a zoom call with loads of people I don't know and wondering if it's going to be triggering or if it's going to have an impact. And the nervousness of taking a piece of art and wondering what is this going to look like compared to everyone else...but I think that disappeared within five minutes of being on the call because everyone was just so nice and it was great to get to know everyone a little bit.* [P01]

Another concern that was mentioned by a couple of members was that their experiences would not align with the group's "norm" regarding mental health and online use:

> *What if my idea about being chronically online and how harmful it is isn't the norm?* [P06]

In addition, one member expressed concern that their perspective might be "a really bad representation of people's experiences" (P05). This worry persisted throughout the project, as they explained the following:

> *It was in the back of my head that I didn't want to say something—not wrong, but different or not representative enough.* [P05]

Member involvement in the DDYPG: Benefits and Risks

Validating Experiences

One of the primary benefits identified by DDYPG members was the opportunity to engage with individuals who had similar stories to theirs. This was seen as a chance to honestly talk about their mental health and online use ("I felt positive about being able to share my experiences" [anonymous 2]) and hear from others, which many described as "validating" (P01, P02, P04, and P06). One communicated how this shared understanding helped them gain deeper insights into their own experiences:

> *I really enjoyed seeing the perspectives of people who'd been in similar situations to me and that helped me understand that side of using the internet in relation to my mental health a bit more.* [P04]

Young people also appreciated the chance to engage with peers who may have had different experiences from them, finding it valuable and "interesting" (P04) to "[learn] more about other people's perspectives" (P01). This not only broadened their understanding of mental health but also helped them challenge their own preconceptions:

> *it was cool to know more things about them [DDYPG members' mental health conditions], and probably addressing some of my own assumptions about them too...* [P05]

Positive Change in Online Behaviors and Mental Health

In addition, involvement in the DDYPG led some members to reflect on and adjust their own behaviors to become more deliberate with how they navigated the online world, such as by spending less time online or changing the content they engaged with. For instance, one member stated the following:

> *I became more reflective about how I use my time online. I'm someone who likes to do scrolling like everyone else, so it felt a bit more intentional.* [P02]

Another noted that they started to critically evaluate other online users, which impacted their time spent online:

> *I noticed in my [online] use as well, that person is doing that that doesn't make them a very good influencer, so thinking about this [research] was impacting my use too.* [P06]

Some of the members also reflected on the potential "therapeutic" (P01) value of involvement in Digital Dialogues, specifically in the creative tasks. One shared how writing the "search poem" allowed them to access and reconnect with their mental state during a difficult time, which had an overall positive impact:

> *My poem was about self-harming, and I think about it from my perspective now quite logically but my poem was that voice from when I was going through it. That made me connect to that situation more. I went back to how I was feeling rather than trying to intellectualise it...Just going back to how I felt and what it meant and why it happened, that was difficult but quite therapeutic and overall positive.* [P04]

Another member, who had some previous experience using creative methods to support their mental health, valued the option to explore a new outlet:

> *I've never really written poetry it was kind of therapeutic and I have now considered it.* [P05]

One participant started using poetry as a therapeutic tool as a direct result of their involvement:

> *I tend to write poetry now...Sometimes it's around online use and sometimes generally mental health but I hadn't thought about using creative outlets like poems until after I'd started in the Digital Dialogues project.* [P06]

Personal Development Opportunities

DDYPG members also highlighted how their involvement in Digital Dialogues positively impacted their individual development. One noted that being listened to and seeing their contributions being used gave them self-assurance:

> *I think it helped my confidence quite a lot. Like I've said, knowing that my opinions were being heard and valued and they weren't just thoughts I have that would fall on deaf ears and would never really make a change or anything.* [P02]

A participant also felt valued during the study and had pride in their role:

> *Being involved has allowed me to feel like I've had a sense of purpose and more fulfilment in life. It's helped with my general mood and feeling like I'm actually trying to make a difference. That's the main thing that's been positive, just that sort of feeling that I'm doing something that's productive.* [P03]

Interestingly, 3 DDYPG members also mentioned how involvement in the project helped them overcome internalized stigma, which had previously stopped them from talking openly about their mental health and online use:

> *It was difficult talking to people [in the group] originally about my experiences because I'd had this negative experience [talking to friends] in the past. But that was cleared up as soon as people started talking and I was like it's not just a me thing, other people have experienced this and I'm not alone in this situation.* [P08]

Triggering Effect of Conversations

Members identified that being in this project could also involve risks, including them being triggered by mental health–related discussions. One participant shared that involvement in the study heightened their awareness of the online world, which left them more inclined to occasionally attend to potentially harmful content:

> *I guess on the negative side, particularly things about suicide these things are darker and deeper than it may appear to be, so when you notice that it can make you feel a bit sad.* [P02]

In addition, one participant reflected on the potential negative impact that discussions about specific platforms or content could have, noting that this may be dependent on their stage of recovery:

> *I would still say I'm recovering from an eating disorder so to be given a list of like "so I had difficulty with these specific forums or these websites," if I was worse, I probably would have looked them up. You have no way of knowing with all the other participants what level of recovery they're at and if they might use that as a source...I definitely think it could have potentially done that for some people...I think there's definitely a risk there.* [P05]

This member suggested researchers "ask people to explicitly avoid naming websites" to avoid these triggers during conversations.

One participant also acknowledged that comparison to other members and triggering content were inherent risks in such discussions but felt these were managed well in the project through the use of content warnings and the availability of researchers:

> *There were aspects of that that were a bit like oh okay this doesn't feel quite so nice, and I think that's always a potential when working with other people with that comparison and that triggering element. But I think overall, that was managed really well in terms of having trigger and content warnings and researchers in the meeting to talk to separately. So, I don't think it's had any negative impacts on me.* [P01]

Young Persons' Reflections on Resource Development

Thoughts on the Resource Development Process

The resource development period was viewed positively by members, such as P02, "I think I most enjoyed creating the resources," and anon1, "it had a great positive impact, I felt included, heard and seen." Before beginning this part of the

project, members were asked to identify the types of resources they would be interested in working on. Following this information, ZH approached members of the DDYPG to contribute either together or individually to the different stages of resource development. Members of the group who worked on specific tasks shared some reflections.

P05 described developing the video script alongside P01, highlighting how they were able to bring their own lived experience to the work and felt free to give honest input on the existing script. They appreciated the collaborative atmosphere, where they could engage critically while also sharing moments of humor related to their online use and mental health:

> *It was good to do the scriptwriting with [P01] too, that was really interesting. I enjoyed the conversation because it was funny and we could have a laugh, but also, we were able to be quite critical of the script. Again, some of my ideas were probably quite different to her and that reflects how everyone's experiences are very different.* [P05]

One participant also reflected on this collaborative relationship, noting the value of both being able to contribute their own perspectives:

> *The fact [P05] did the video script with me, I think it was really nice that we were the ones who had that kind of experience so we got to do the scriptwriting.* [P01]

A participant also described their involvement in the actor audition process, noting, "[I found] auditioning the actor really fun, I've never had to audition someone before, and I really enjoyed that actually" (P05). This involvement also prompted a deeper reflection on the representation of mental health in resources, such as those we created:

> *The last thing I wanted to do [while writing the script] was stereotype. I think that's why it was important I was there for the auditions because I think some candidates erred on that side of it becoming a bit of a caricature, which we didn't really want, and it also helped me think a bit more critically about portrayals of mental health.* [P05]

One participant also reflected on their individual role in designing and developing a poster and question bank directed at MHPs having comfortable conversations with young people about their mental health and online use. They noted that this was not an easy process for them due to concerns that it would not be what the group hoped for:

> *The question bank as well. To me the question bank was really important, which is why it took me so long to do, I procrastinated on it for so long because I felt like it needed to be perfect.* [P06]

In addition, members generally reported their appreciation for the diverse roles they were able to have during resource development:

> *I think it was great to give young people choice and options to co-create through a variety of means and at a time and pace that works for them.* [anonymous 1]

Children's and Young People's Perception of Resource Use by MHPs

In total, 5 members expressed hopes that the resources created would provide an opportunity to improve the experience of children and young people accessing support from MHPs. A participant reflected on the potential for MHPs to use them as communication aids, facilitating conversations:

> *I hope it'll build communication and help MHPs to be a bit more comforting with the language that is used and the questions that are asked. I'm hoping it'll be a good way to educate MHPs on how they can support younger people, as that's the main aim of it, and hopefully the outcome.* [P03]

Another expressed similar hopes, suggesting that resources could provide practitioners, specifically those working in children and adolescent mental health services, with a "different lens" through which they could understand and talk to young people about online use:

> *I'm hoping these will be a great prompt for people to take into their own practice and use to make young people feel more comfortable and not judged, because ultimately that'll be the difference between them engaging with you and completely not.* [P05]

However, one member noted that the plans for disseminating resources to professionals were unclear to them, which meant they were uncertain about the potential impact:

> *I guess I wasn't entirely sure what the plans were in terms of how you send them out. As in, is it every mental health professional, how is that possible? How do you even begin a task like that? That's the only slightly grey area that once we've made these things, I wasn't entirely sure how they would then get sent to people.* [P02]

Discussion

Principal Findings

Using creative methods, the Digital Dialogues project engaged young people in a research group where they shared their experiences and perspectives on online use and mental health. These discussions resulted in the iterative development of resources for practitioners, a web-based exhibition of creative works, and additional outputs. Findings from interviews with DDYPG members revealed that key motivators for participation included creative engagement, quality of involvement, and peer interaction, which contributed to perceived benefits such as personal development, empowerment, and positive therapeutic outcomes. However, anxiety and time demands were identified as potential barriers to involvement, along with risks, such as exposure to triggering or harmful content. Notably, the data also provide some evidence of steps that helped mitigate these barriers, allowing us to highlight key ethical considerations and potential strategies for future resource development projects.

The Creative Process

Creative methods enabled young people to articulate their perspectives on online use and mental health within the group. This approach became an effective way to explore complex emotions and experiences [20]. Generally, children and young people appreciated the novel approach, with high levels of task engagement. This was consistent with research showing that creative methods can enhance research involvement by offering alternative forms of expression [26]. DDYPG members also described how they particularly valued constraint-based creative tasks, such as poetry writing. Here, structure helped them describe their personal stories and communicate emotions that might otherwise remain intangible [27]. In addition, young people reported that reflective aspects of creative tasks led to positive changes in online behaviors. This reflects findings from the Delve study [27] where increased metacognitive skills led to positive behavioral changes online.

However, several DDYPG members also reported initial anxiety regarding producing or sharing their creative work, reflecting what Hochman and Esteves [28] term "art fear." This also echoed observations by Novak-Leonard and Robinson [29] that individuals with limited perceptions of themselves as artists are less likely to engage in arts-based activities. To address this challenge, we adopted several strategies that had a positive impact on facilitating involvement and reducing negative emotions regarding the creative tasks. First, we gave members flexibility by allowing them to use their preferred creative method to complete task 1. This gave them the opportunity to draw on their strengths and work in a familiar way, using an assets-based approach [30]. Similarly, tasks were framed as reflective rather than evaluative, aiming to mitigate performance-related anxiety [31]. Finally, we modeled involvement by having researchers share their own work first, a practice highlighted by Leavy [32] as effective in normalizing creative engagement and reducing power imbalances.

Relationships Within the Research Team

A key facilitating factor for member involvement included the positive peer relationships they built and were able to rely on during the project. This led to feelings of safety, recognition, and validation among the young people, which may have enhanced engagement and confidence [12]. This was further reflected through members' appreciation for opportunities to work independently with their peers. This movement away from researcher-led formats of collaboration better recognizes the competency of children and young people and may also improve their commitment to the research [33]. However, although young people were able to work and contribute individually to resources, some hesitated to share their input due to concerns about not meeting group expectations or fear of being judged. This anxiety could sometimes delay contributions and may have led members to withhold valuable ideas. Such challenges have been reported in previous research [34].

Rapport between DDYPG members and researchers was also integral to the young people's active involvement in this project. Members reported that researchers were approachable and responsive, facilitating ongoing discussion, taking them seriously, and making them feel safe. This highlights the importance of researchers having the skills necessary to effectively collaborate with young people in their research, demonstrating a genuine commitment to authentic engagement, addressing power imbalances, and dedicating time to meaningful interactions [17].

Ways of Working

Members also valued the responsibility and trust placed on them in their roles on this project as well as the flexibility to contribute through various means. Other studies have also shown that offering several options for involvement in engagement work can improve inclusion [35], and using online communication platforms, such as Discord, can enhance this collaboration [18]. In addition, members reported feelings of empowerment comparable to those experienced by others who have participated in meaningful coproduction projects [36]. Furthermore, our members highlighted flaws in other collaborative roles they had undertaken, revealing how effective collaboration can inspire critical reflection on past experiences and empower children and young people to challenge insufficient involvement.

Our working approach adhered closely to the principles outlined in the *Guidelines for Research with Children and Young People* [16]. Specifically, the development phase followed the "children and young people have ownership of the research" model, which emphasized providing children and young people with as much agency as possible. This approach empowered members, giving them a sense of fulfillment in their role. However, despite researchers' efforts to maintain a manageable workload for children and young people, one individual reported occasionally taking on more work than they could accommodate, driven by their enthusiasm for the study and desire to contribute. This emphasizes the need for researchers to continually balance giving children and young people agency with protecting their well-being [33].

Managing Sensitive Content Discussions

DDYPG members appreciated how peers were mindful during discussions to avoid triggering content, interpreting this as a skillful use of boundaries grounded in a shared understanding of mental health challenges. In addition, they recognized that their own stage of recovery was likely a key factor in their ability to cope with the discussions and tasks. This may reflect our group composition, as the recruitment strategy targeted children and young people within mental health organizations or groups, where previous experiences may have helped them develop skills in navigating boundaries, addressing sensitive topics, and working collaboratively. It could also reflect the influence of group rules introduced and discussed during the initial workshop.

However, some members noted that despite efforts to avoid triggering content, information that could be potentially harmful was still shared. This suggests that the nature of conversations about mental health and online use may inherently involve exploring difficult or potentially triggering topics, which presents a challenge for researchers in balancing open dialogue and the emotional safety of children and young people. Considering participants' recovery stage during recruitment

may therefore be an important factor. Research shows that those with lived experience of mental health conditions experience varying levels of hope (meaning confidence and symptoms) at different stages of recovery, likely meaning they are able to contribute and cope to varying extents in research roles [37].

In an attempt to overcome potential risks of triggering content in this study, we provided opportunities for members to take breaks and access researchers for support during discussions in separate web-based breakout rooms and ensured postmeeting check-ins. However, it remains unclear whether there may be longer-term negative or positive effects on children's and young people's well-being or behaviors because of their involvement in research of this nature.

Adhering to Perceived Norms

Some members expressed concerns about accurately representing their mental health experiences, reporting a perceived pressure to conform to a "norm" associated with their diagnosis. Notably, this conformity to align with a mental health identity has recently been observed in individuals using social media, where online moderation and in-group formation play key roles in reinforcing diagnostic "norms," particularly among young people [38,39]. These findings also reflect broader concerns with research engagement, such as the influence of Western societal expectations and desirability biases on participants' willingness to engage in honest disclosures during mental health discussions [40]. In addition, our efforts to minimize harm by introducing rules to avoid discussing triggering content may have created pressure for members to conform to a sanitized narrative.

Therefore, the inclusion of children and young people with diverse mental health conditions had the potential to create a dynamic where individuals with less common diagnoses felt pressure to represent their condition. However, while this was an anticipated concern among members, it did not appear to be an influence once they took part in tasks and workshops. The group diversity also provided benefits, offering valuable peer learning opportunities and contributing to a potentially destigmatizing environment. This supports research suggesting that diversity in groups can encourage broader perspectives and reduce stigma by exposing individuals to varied lived experiences [41]. Similarly, such diversity may enhance the generalizability of research insights by incorporating a wider range of perspectives.

Perceptions of Project Outcomes

Members gained confidence from their involvement in this study, reflecting the concept that seeing ideas transformed into practical and tangible outcomes is empowering [42]. They took pride in the resources created and felt hope that they would have an impact on MHPs, improving the ways they speak to children and young people about their online use and mental health. However, members noted gaps in their understanding of how we planned to disseminate the resources to MHPs, a feature previously highlighted as important in collaborative research with young people [43].

Limitations

This project successfully engaged young people as active contributors to the research through open discussions and creative work. DDYPG members played a key role in developing several resources for MHPs. However, the limitations mentioned subsequently highlight areas for reflection and potential improvements in resource development work with young people.

Members in this study generally reported a willingness to talk about their mental health with others, which made open and constructive discussions possible within the group. However, this also highlighted a potential self-selection bias in this type of research where those more comfortable discussing sensitive topics are more likely to be involved, and individuals who are less inclined to talk about their experiences may be underrepresented [17]. We tried to overcome this limitation by allowing children and young people to be involved in the study in a variety of ways, including through an online discussion platform (Discord) and by commenting on and editing documents.

In addition, one member noted uncertainty about the process for disseminating the resources to MHPs. While this was a general limitation of the project, due to the need for additional funding to support this stage, it is important to consider that the lack of a clear dissemination plan from the outset may have reduced children's and young people's sense of ownership or purpose in relation to the resources.

Finally, not all members participated in the evaluation interviews or the anonymous survey. Due to the anonymity of the survey, we cannot confirm whether those who completed it differed from those who took part in the interviews. As a result, we may have missed valuable perspectives from some members that could have provided additional insights.

Future Directions

This study enabled the creation of several freely available resources for mental health practitioners, hosted on the Digital Dialogues website [44]. It has also informed the Digital Dialogues 2 project, an ongoing research study codeveloping a training package and toolkit in collaboration with MHPs, into which several of these resources will be incorporated. To build on this work and address limitations identified in this study, ongoing dissemination efforts are needed to ensure that these resources are being used meaningfully in practice. As part of Digital Dialogues 2, we will begin exploring how the co-created resources are used and experienced in practice by evaluating the experiences of MHPs who attend our pilot training. Future knowledge exchange projects in this field should continue to prioritize the coproduction and creative methodologies highlighted in this study.

Conclusion

Involving young people with lived and living experience of mental health difficulties as research team members in a resource development project can be mutually beneficial for researchers and members. Using a structured format of workshops and creative tasks can encourage active involvement and result in

collaboratively conceptualized and designed resources being created, with an enhanced level of authenticity. According to DDYPG members, their role in this project was associated with positive outcomes, including empowerment, improved mental health, and a sense of validation. To enable this, it was important that researchers created a safe space and encouraged children's and young people's agency and ownership over project decisions. However, challenges remained, including exposure to potentially triggering content, the fear of judgment, anxiety about participation, and concerns about the impact of the developed resources. Through this evaluation, we have identified several mechanisms, as highlighted by children and young people, to navigate and overcome some of these difficulties.

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Data Availability

Data generated during this study are not publicly available due to the sensitive nature of participant contributions and original intellectual property generation, as agreed with University of Bristol data protection services. However, anonymized interview transcripts and qualitative survey response data are available from the corresponding author on reasonable request.

Conflicts of Interest

None declared.

Multimedia Appendix 1
Safety plan template.
[PDF File (Adobe PDF File), 240 KB - jopm_v17i1e74258_app1.pdf]

Multimedia Appendix 2
Workshop and task design.
[DOCX File , 28 KB - jopm_v17i1e74258_app2.docx]

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Abbreviations

DDYPG: Digital Dialogues Young Persons Group
MHP: mental health professional

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Integrating Patient Choice and Collaborative Care Managers to Implement eHealth Tools in Depression: Self-Report Pilot Study

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Abstract

Background: Improving mental health treatment within the collaborative care model (CoCM) may be achieved by using e-mental health (e-MH) tools and addressing the challenges to their integration.

Objective: This study aims to understand how patients select, engage, and use three self-help e-MH tools for depression, and to explore satisfaction with e-MH tools, with a particular emphasis on care manager interactions.

Methods: This was a single-center, nonrandomized, preferred assignment study of two cognitive behavioral therapy–based tools (Moodkit and moodgym) and an educational website (the Depression Center Toolkit). The tools were recommended for use in 15-minute sessions 3 times a week, for 6 weeks, coupled with low-intensity care manager coaching. Utilization of e-MH was also captured during an additional 4 weeks without coaching. Self-report outcome measures were gathered at baseline, weekly for 6 weeks, at week 10, and through activities suggested by the tool.

Results: The 32 participants enrolled were predominantly female (n=27, 84%), non-Hispanic Caucasian (n=29, 91%), with a mean age of 41.8 (SD 16.1; range 20 to 78) years. Most participants (n=26, 81%) presented with moderate to moderately severe depression (Patient Health Questionnaire-9=11 - 19) and a marked level of impairment in different areas of functioning. About 81% (n=26) of the participants initially selected a cognitive behavioral therapy–based tool, and 19% (n=6) selected the educational website. In total, 4 of 32 (12%) participants switched tools within the first week, 6 of 32 (22%) participants dropped out, and one was removed. The remaining 25 active individuals used tools on average 3.0 (SD 2.4) times per week, most time (67%), for 11 to 20 minutes or more at a time. Of the 19 participants reached and surveyed at week 6, 52% (16/31) remained actively engaged with their tools, including 2 users who had switched tools and 8 between 45 and 78 years old. At week 10, about 75% (12/16) of this subgroup were using their tools with no coaching; this represented 49% of the cohort. Satisfaction increased with progressive use of the tool. The care manager's low-intensity coaching lasted on average 7.9 (SD 3.9) minutes and promoted better understanding and greater use of the tools. Other facilitators to adherence consisted of organization, convenience, ease, accessibility, and privacy policies of the tools, while barriers included time constraints, depressive symptoms, and uncertainty about the efficacy of the tool.

Conclusions: Uptake of e-MH tools for depression is feasible and associated with significant user satisfaction in CoCM. Low-intensity care manager coaching is consistent with the CoCM and is associated with uptake and ongoing use of e-MH tools. To our knowledge, this is the first study to leverage the care manager's proactive outreach to and routine follow-ups with patients toward engagement in self-help digital tools.

Trial Registration: ClinicalTrials.gov NCT04689568; https://clinicaltrials.gov/study/NCT04689568

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KEYWORDS

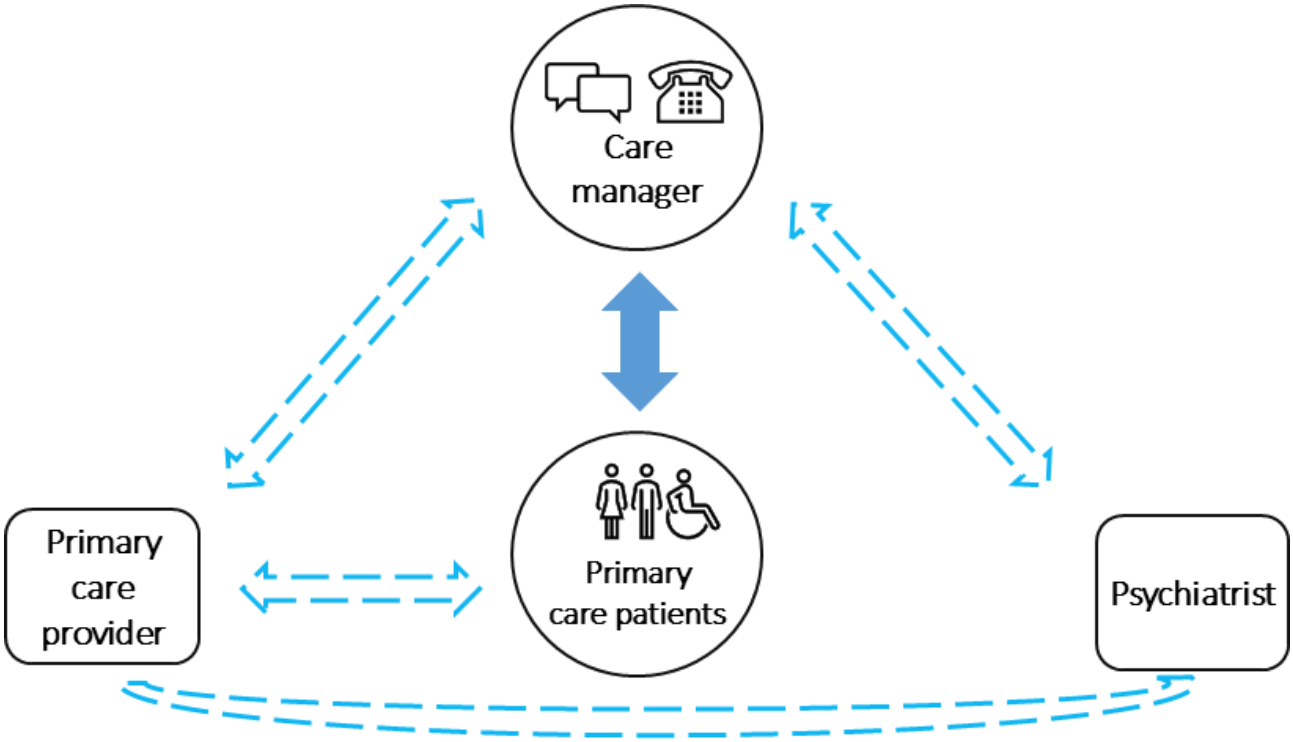
collaborative care model; e-mental health tools; primary care; depression; service delivery models; collaborative care; eHealth; tool; mental health; treatment; e-mental health; health technology; pilot study; self-help; self-care; self-management; self-report; behavioral therapy; female; women; clinic; evidence-based; principle; efficacy; attractiveness; low cost; mobile phone

Introduction

Background

Developed almost 3 decades ago, the collaborative care model (CoCM) is an extensively used evidence-based strategy for prompt access to quality behavioral health care in primary care settings [1-3]. Its positive impact on patient outcomes is supported by more than 80 randomized controlled trials [1] and relies largely on effective communication and teamwork between a primary care provider (PCP), a care manager, and a consulting psychiatrist (Figure 1). In this model, patients occupy a central place as empowered and active participants, making educated decisions about their treatment goals. The care manager, usually a trained social worker or nurse, maintains regular contact with patients through phone calls or secure SMS text messaging from enrollment in the CoCM to discharge. Through individualized care planning, the care manager routinely assesses psychosocial health needs, tracks patient outcomes through symptom measures, shares appropriate resources, discusses psychiatric recommendations, and provides support, as well as brief psychotherapy interventions.

Figure 1. The collaborative care model.



To date, efforts to augment the CoCM with web-based and digital health technology have primarily focused on automated screening, measurement-based care, patient-provider communication, and, to a limited extent, basic psychoeducational information [4,5]. Integration of more active technology-augmented treatment, such as mental health therapy apps and websites, or "e-mental health (e-MH) tools," is needed. These digital tools are self-help resources drawn from evidence-based psychotherapy principles [6] such as cognitive behavioral therapy (CBT) and from general coping strategies. They are accessible and affordable, and their effectiveness has been demonstrated through numerous randomized controlled trials, primarily for major depression [6,7]. While collaborative care clinicians show great enthusiasm and see value in adapting the CoCM for integration of e-MH tools, they also express doubts about clinic readiness [8] and point to similar challenges evidenced in digital health implementation studies, primarily poor user engagement [9-12], clinician's lack of comfort, and perceived clinical burden [8-12].

This pilot study leveraged the dynamic relationship between patient and care manager within the CoCM to introduce three self-help e-MH tools for major depression into a primary care clinic: (1) moodgym, a web-based CBT program [13-15]; (2) MoodKit, a CBT smartphone app [16,17]; and (3) the Depression Center Toolkit, an educational website [18]. Given evidence of adherence challenges, mainly with standalone digital health interventions [5,9-11,19], these tools were added to the care manager's therapeutic toolbox as self-help resources to discuss with patients during routine check-ins while adopting a low-intensity "coaching" style. We hypothesized this approach would enhance uptake and engagement in the e-MH tools, as Gordon et al [19] and Moon et al [5] suggested in their reviews of factors influencing real-world integration of health technology. Such an integration was most successful when operating within existing workflows. Considering the CoCM is designed such that it promotes patients' abilities and confidence to manage their mental health, we encouraged patients to choose and switch their preferred tools based on their needs, a therapeutic method proven to scale up service uptake and engagement in clinical trials [20]. To our knowledge, this is the first study to optimize the unique patient-care manager dyad within the CoCM toward implementation of self-help e-MH tools for depression.

Objectives

The aim of this pilot study was 2-fold. First, to assess user selection, uptake, and engagement style with three self-help e-MH tools. Second, to understand facilitators and barriers to user engagement with these tools, as well as user satisfaction, with and continued use of the intervention.

Method

Study Design

This was a single-center, nonrandomized, preference clinical trial of 3 self-help e-MH tools involving patients with major depression: moodgym, Moodkit, and the Depression Center Toolkit (Clinical Trial Registration number NCT04689568). The length of the intervention was 6 weeks, which was determined by the content of the tools and recommendations provided for their use. Our goal was to conduct the study in as naturalistic and patient-centered a manner as possible. As such, participants could choose the e-MH tools they preferred to try, with the option to switch tools if desired.

Ethical Considerations

The University of Michigan Institutional Review Board approved and monitored the study (HUM00174081), and all procedures followed were in accordance with the ethical standards of the Institutional Review Board. The study complied with all regulations and policies regarding informed consent and the protection of personal information, privacy, and human rights. Participants had the ability to opt out of the study at any time.

Study Setting and Participants

The study was conducted in a primary care clinic serving a catchment area with high needs for increased access and capacity for mental health services. The clinic CoCM program had the capacity to accept up to 100 patients on a rolling basis, managed by one full-time care manager (a licensed social worker), one psychiatrist, and multiple PCPs. The primary care clinic is part of an academic center.

Eligible participants were 18 years or older, English-speaking, newly referred to the clinic's CoCM for major depression with a Patient Health Questionnaire-9 (PHQ-9) score of ≥11, and had access to the internet and a smartphone. Exclusion criteria consisted of already using an e-MH tool, cognitive impairment, substance use, and unstable mental or physical health problems (eg, marked suicidality and active psychosis).

Study Recruitment

Participants were recruited between January 2021 and March 2022. The care manager performed a routine initial mental health evaluation for patients referred to the CoCM by their PCP. She used a script at the end of her assessment to ask pre-eligible patients whether the study coordinator could contact them about the study. A total of 5 months into recruitment, we streamlined the process by having the study coordinator directly contact the patients deemed pre-eligible based on their PHQ-9 scores or diagnosis of major depression at the time of their entry into the CoCM. We used an electronic consent form, which provided a detailed overview of the e-MH tools, including privacy policies.

To describe the sample profile at enrollment, we gathered information about demographics, mental health treatment, and comorbid conditions and assessed the level of impairment in various domains of functioning through the Sheehan Disability Scale. The PHQ-9 was also collected at week 6 as part of the care manager outcome monitoring to assess the sample's clinical progress. Compensation was provided in the form of US $25 gift cards to participants after completing each of the enrollment, study completion (week 6), and postintervention (week 10) questionnaires.

Study Interventions

The 3 self-help e-MH tools were selected based on their use of evidence-based principles, reported efficacy, attractiveness of user interface, and low cost [13-18]. Participants received a descriptive summary of the study interventions, including general recommendations on daily or weekly use (Multimedia Appendix 1).

moodgym is an interactive CBT-based program, accessible on any electronic device, designed to prevent or reduce symptoms of depression and anxiety, and encourage good coping skills [13-15]. moodgym consists of 5 modules that are completed in a prescribed order and through animated demonstrations, mood tracking, homework exercises, and feedback that helps users identify and manage different thinking styles and vulnerabilities and their impact on emotions and outcomes. The study covered the annual subscription cost for moodgym (US $27). The study recommendation for use stated, "Aim to complete one module on this program weekly."

MoodKit is a CBT-based smartphone app, available only through the Apple Store, that provides integrated tools to effectively manage symptoms of depression and anxiety, enhance emotional well-being, and more significantly, coping self-efficacy [16,17]. MoodKit offers four features in an unstructured, unprompted way, comprising a collection of mood-enhancing activities and suggested steps for accomplishing them, a thought checker, a mood tracker, and a variety of therapeutically designed journal templates. The study covered the one-time fee for MoodKit (US $4.99). The study recommendation for use stated, "Aim to complete one individual goal and use two sections of this app once daily."

The Depression Center Toolkit is an informational website developed by academic experts with the help of individuals with lived experience [18]. The Toolkit is divided into 5 sections that focus on different aspects of someone's mental health journey. It includes detailed educational information, strategies to incorporate into a health regimen, steps toward making lasting lifestyle changes, and practical tools such as communication guides, medication tracking journals, and sleep logs. The Toolkit is free and accessible on any device. The study recommendation for use stated, "Focus on one section a week, switch each week."

The care manager incorporated a guided script of low-intensity coaching into her weekly routine check-ins with participants. It was designed to remediate likely mechanisms underlying nonadherence to the e-MH tools [8-11], which included

resolving minor technical questions, supplementing information and suggestions with emotional support, and motivating continued use of the tools (Multimedia Appendix 1).

Study Outcomes

Primary Outcomes

Based on the content of the self-help tools and instructions provided for their use, we conceptualized engagement as the use of the tool three times a week, for approximately 15 minutes at a time. Once a week, for 6 weeks, the care manager gathered frequency and duration of use of the tools through participants' self-reports.

Secondary Outcomes

Facilitators and barriers to user engagement, as well as user satisfaction with the tools, were collected once weekly, for 6 weeks, through participants' self-reports as part of the care manager's scripted low-intensity coaching, which included open-ended questions for discussion (Multimedia Appendix 1). We reviewed all write-in qualitative responses as a team, and using discussion and consensus, identified salient themes. After the study completion at week 10, the care manager surveyed participants on their continued use of their tools.

Data Analysis

The care manager gathered the study outcomes during her routine check-ins with patients. In controlled and real-world settings, the care manager's inability to reach patients for a routine check-in is common and can be as high as 36% [21]. We reviewed the trend of missed check-ins at the study site, and using discussion and consensus as a team, agreed that missingness did not differ during and after the pilot study. The care manager usually explores reasons around missed check-ins as part of the CoCM personalized care plan to ensure patient time is respected. For this real-world pilot, participants were kept in the study regardless of the number of check-ins missed unless they asked to be removed from the study. We deemed it useful not to impute the missing data and kept our observation of the study events unchanged. As a self-report study, there was a risk of social desirability bias, which we tried to minimize through the care manager's weekly monitoring and discussion of patients' progress with homework or activities suggested by their tools or the care manager. We used descriptive statistics to report individual survey responses and their relative percentages. We also provided narrative summaries of participant comments.

Results

Study Recruitment

A total of 121 patients were found pre-eligible for the study, and 115 patients qualified. Among those, 51 patients were unreachable, 32 patients consented to participate in the study, and 32 patients declined and were encouraged to share why they were "not interested" or asked to be recontacted later. About 37% (12/32) had issues with the study design including the lack of focus on anxiety disorders, the lack of diversity of apps (such as meditation-based app), and the length of the consent process; 28% (9/32) were busy with either caregiving duties or work or managing an acute illness; 9% (3/32) pointed to their lack of digital skills; and 25% (8/32) provided no explanation. An additional 495 individuals who saw the study posted on the academic center's health research website expressed interest in participating, but none qualified as they were not part of the study's primary clinic.

Study Participants

The 32 enrolled participants were primarily identified as female (27/32, 84%) and White, non-Hispanic (31/32, 97%), which reflected the racial and ethnic background of the study catchment area. The mean age was 41.8 (SD 16.1; range: 20-78) years. About 60% (19/32) of the sample were in a relationship, 50% (16/32) had children, and 66% (21/32) were employed. The mean PHQ-9 score was 16 (SD 3.7; range: 11 - 23) at the time of enrollment. Based on the participants' clinical presentation, the majority needed psychotherapy (29/32, 91%), and all needed pharmacotherapy interventions. About 88% (28/32) reported comorbid anxiety symptoms, and 66% (21/32) endorsed active pain (Table 1).

Table . Characteristics of the study sample (n=32).

Initial e-MH[a] tool selection	Moodkit (n=17)	moodgym (n=8)	Depression toolkit (n=7)	Sample total (n=32)
Sex, n (%)				
Female	11 (34)	9 (28)	7 (22)	27 (84)
Male	3 (9)	2 (6)	0 (0)	5 (16)
Age (years)				
Mean (SD)	44.6 (18.3)	38 (11.6)	44.2 (15.8)	41.8 (16.1)
Range	20 - 78	24 - 62	20 - 60	20 - 78
Race and ethnicity, n (%)				
Asian	0 (0)	0 (0)	1 (3)	1 (3)
White, non-Hispanic	17 (53)	8 (25)	6 (19)	31 (97)
Marital status, n (%)				
In a relationship	8 (25)	7 (22)	4 (13)	19 (60)
Not in a relationship	6 (19)	4 (12)	3 (9)	10 (40)
Caring for young children, n (%)				
Yes	9 (28)	5 (15)	2 (6)	16 (50)
No	5 (16)	6 (19)	5 (16)	16 (50)
Employment status, n (%)				
Employed full-time or part-time	8 (25)	8 (25)	5 (16)	21 (66)
Unemployed	3 (9)	3 (9)	2 (7)	8 (25)
Retired	3 (9)	0 (0)	0 (0)	3 (9)
PHQ-9[b] severity				
Mean (SD)	16.5 (4.0)	14.8 (3.1)	16.6 (3.6)	16 (3.7)
Range	11 - 23	11 - 21	12 - 22	11 - 23
Need a referral to psychotherapy, n (%)				
Yes	13 (41)	10 (31)	6 (19)	29 (91)
No	1 (3)	1 (3)	1 (3)	3 (9)
Need antidepressant adjustment or initiation, n (%)				
Yes	13 (41)	10 (31)	7 (22)	30 (94)
No	1 (3)	1 (3)	0 (5)	2 (6)

[a]e-MH: e-mental health.

[b]PHQ-9: Patient Health Questionnaire-9.

A total of 29 participants filled out the Sheehan Disability Scale and reported a “markedly impaired to extremely impaired functioning” in social life (17/29, 59%), in family life and home responsibilities (16/29, 55%), and at work and in school activities (10/29, 35%).

Study Interventions

The CBT app, MoodKit, was initially selected by 53% (n=17) of the participants, the CBT web-based program, moodgym, by 25% (n=8) of participants, and the educational website, the Depression Center Toolkit, by 22% (n=7) of participants (Table 1).

In total, 4 (12%) participants requested to switch tools within the first week, including 3 users who could not access MoodKit through their Android operating system and opted to transition to moodgym (n=2) and the Depression Center Toolkit (n=1). Another participant, interested in a “more interactive” tool “with journaling” option, changed from the Depression Center Toolkit to moodgym.

The care manager made 162 calls to participants as part of her routine clinical check-ins and weekly low-intensity coaching of the tools, at which time she also gathered some of the study outcomes. Of these 162 calls, 77% (125/162) were successful, 20% (33/162) were marked “missed” for participants who were unreachable on a given week for various reasons including

illnesses and caregiving responsibilities, and 3% (4/162) were solely made to discharge participants from the study at week 1 (Table 2).

Table . Frequency of use of participants' selected e-MH tools.

Final e-MH[a] tool selection	Moodkit (n=13[b])	moodgym (n=11)	Depression toolkit (n=7)	Sample total (n=31[b])
Participants who withdrew from the study, n (%)	4 (13)	2 (6)	0 (0)	6 (19)
Use of the tools				
Week 1				
Mean (SD)	4.2 (4.3)	2.7 (1.5)	2.0 (1.4)	3.2 (3.2)
Range	0 - 15	1 - 5	0 - 4	0 - 15
Week 2				
Mean (SD)	3.8 (2.2)	2.6 (2.0)	2.2 (1.7)	3.0 (2.1)
Range	0 - 7	1 - 7	0 - 4	0 - 7
Week 3				
Mean (SD)	3.5 (2.6)	1.8 (0.4)	3.6 (2.1)	3.1 (2.2)
Range	0 - 8	1 - 2	1 - 7	0 - 8
Week 4				
Mean (SD)	5.0 (2.1)	2.6 (1.8)	1.4 (1.5)	3.2 (2.4)
Range	2 - 7	0 - 6	0 - 4	0 - 7
Week 5				
Mean (SD)	3.6 (2.2)	1.8 (0.4)	3.3 (1.9)	3.1 (2.0)
Range	0 - 7	1 - 2	1 - 7	0 - 7
Week 6				
Mean (SD)	2.7 (2.1)	1.6 (0.8)	3.4 (2.1)	2.6 (1.9)
Range	0 - 7	0 - 2	1 - 7	0 - 7
Total				
Mean (SD)	3.8 (2.9)	2.3 (1.5)	2.7 (2.0)	3.0 (2.4)
Range	0 - 15	0 - 7	0 - 7	0 - 15
Participants reached, n (%)				
Week 1	11 (85)	7 (64)	6 (86)	24 (77)
Week 2	9 (70)	8 (73)	6 (86)	23 (74)
Week 3	11 (85)	6 (55)	5 (71)	22 (65)
Week 4	7 (54)	7 (64)	5 (71)	19 (61)
Week 5	8 (62)	4 (36)	6 (86)	18 (58)
Week 6	9 (70)	5 (45)	5 (71)	19 (61)

[a]e-MH: e-mental health.

[b]One participant was removed by the study team at week 1, which brought the new sample size to 31 (n=31).

The low-intensity coaching lasted on average 7.9 (SD 3.9; range: 2 - 20) minutes, and 90% (112/125) of the calls varied between 2 and 10 minutes; 9% (11/125) ran for 15 minutes for participants with engagement issues, and 1% (2/162) lasted 20 minutes for one participant who wanted to better understand the concept of cognitive restructuring proposed by the tool. The average time for the brief coaching varies minimally per week whether it was the care manager's first (8.1 min), second (8.1 min), third (7.9 min), fourth (7.8 min), fifth (7.9 min), or sixth (7.8 min) calls to participants to discuss engagement with their selected tools.

Primary Outcomes

A total of 6 of 32 (19%) participants withdrew from the study (Table 1) and did so within the first week (n=3), second week (n=1), and third week (n=2). They were between 30 and 76 years old (n=6), had initially selected MoodKit (n=4) or moodgym (n=2), did not ask to switch tools (n=6), and pointed

primarily to time constraints with family life, home responsibilities, or work as the main reasons for dropout (n=4). One participant deemed not appropriate for the study was discharged at week 1, which brought the sample size to 31.

The care manager reached between 58% (18/31) and 77% (24/31) of the study sample weekly, who reported interacting with their tools on average between 3.0 and 3.2 times the first 5 weeks, and 2.6 times during the last week of monitoring, week 6 (Table 2). Weekly engagement with the tools varied between none to seven times weekly, with one Moodkit user reporting engaging with the app 15 times the first week and 8 times the third week for a more in-depth exploration and practice of the CBT activities. Average utilization was higher for Moodkit, followed by the Depression Center Toolkit, then moodgym (Table 2).

For the most part, participants interacted with their tools "11 to 20 minutes" at a time (52/125, 42%) and "more than 20 minutes" at a time (31/125, 25%). The tools were also used for "6 to 10 minutes" about 19% (24/125) of the time, "1 to 5 minutes" about 3% (4/125) of the time, and none about 11% (14/125) of the time. More time ("11 min or greater") was spent interacting with Moodkit, compared to moodgym and the Depression Center Toolkit (Table 3).

Table . Duration of use of participants' selected e-MH[a] tools.

Final e-MH tool selection	Moodkit (n=13)[b]	moodgym (n=11)	Depression toolkit (n=7)	Sample total (n=31)[b]
Number of times participants were reached, n	55	37	33	125
Number of times participants use the tool for a designated time frame (minutes), n (%)				
0	7 (5.6)	2 (1.6)	5 (4)	14 (11.2)
1-5	3 (2.4)	1 (0.8)	0 (0)	4 (3.2)
6-10	12 (9.6)	4 (3.2)	8 (6.4)	24 (19.2)
11-20	24 (19.2)	14 (11.2)	14 (11.2)	52 (41.6)
More than 20	9 (7.2)	16 (12.8)	6 (4.8)	31 (24.8)

[a]e-MH: e-mental health.

[b]One participant was removed by the study team at week 1 which brought the new sample size to 31 (n=31).

Continuous Engagement at Study Completion and Postintervention

A total of 19 of 31 (61%) participants were reached and surveyed at the end of the study, at week 6. Of these, 16 (52%) participants were still using their tools on average 3.1 (SD 1.8; range: 1 - 7) times for at least 11 minutes at a time for the most part, including 2 users who had switched tools. Compared to the rest of the study sample, they missed fewer check-ins with the care manager (6/96, 6%), reported greater interactions on average with their tools (3.6 times) over a longer period of time (5 or 6 wk), and endorsed a lower depression score at study completion (6.8, SD 5.0; range: 1 - 15) compared to baseline (15.5, SD 3.6; range: 11 - 21). Half (8/16) of these users were between 45 and 78 years old. Four weeks postintervention, at week 10, a total of 12 participants in this subgroup reported continued use of the interventions with no coaching; this represented 39% (12/31) of the study sample.

About half of the study sample (17/31, 55%) completed the PHQ-9 at the end of the study. Their average depression severity score decreased to 8.1 (SD 5.7; range: 1 - 22) compared to 16 (SD 3.7; range: 11 - 23) at enrollment.

Secondary Outcomes

Participants' satisfaction with their selected tools increased with time. Satisfaction with the selected e-MH tools was reported for users (21/31, 68%) who did a moderate amount to a great deal of homework or activities suggested by their tools or the care manager. Dissatisfaction or uncertainty with the e-MH tools was reported for users who did not engage or interacted very little with their tools and put a great focus on difficulties navigating the tool or time constraints.

Participant-reported facilitators consisted of some specific characteristics of each tool, such as organization, convenience, accessibility, and privacy policies. Participant-reported barriers to adherence to the tools included time constraints, depressive symptoms, and uncertainty about the efficacy of the tool.

Participant Engagement With the CoCM

A total of 8 of 31 (25%) study participants minimally engaged with the CoCM during and after the study. They missed the care manager's calls or asked to be recontacted on numerous occasions. They were discharged by the collaborative care team within 3 to 6 months of enrollment in the CoCM. In total, 4 of these 8 patients had requested to be removed from the study within the first 2 weeks, and the other 4 patients remained unreachable for most of the study.

Discussion

Principal Findings

This was a real-world pilot study based in a CoCM primary care program, assessing patients' selection, uptake, and engagement with 2 CBT-based digital tools, Moodkit and moodgym, and an educational website, the Depression Center Toolkit. The study interventions were well-received, with a preference given to the CBT-based tools. All 3 tools were paired with adherence-focused, low-intensity coaching incorporated

into the care manager's routine check-ins with patients. Our study sample consisted primarily of non-Hispanic White, partnered women with childcare or work responsibilities who endorsed moderate to severe major depression (average PHQ-9 score: 16, SD 3.7), comorbid anxiety and pain symptoms, and needed psychotherapy referrals. Participants identified parental duties and acute illnesses as the chief reasons for missing 20% of the care manager's weekly follow-ups and study outcome tracking. However, designed to be a real-world patient-centered intervention, participants were allowed to continue in the study as they would in the CoCM, where missingness is not uncommon [21], and engagement is known to be particularly challenging for caregiver mothers with mental illnesses [22].

The care manager reached 58% (18/31) to 77% (24/31) of the study sample weekly. Participants reported engaging with the interventions on average 3 to 3.2 times per week for the first 5 weeks, and 2.6 times during the last week. Most (67%) did so for 11 minutes or more at a time. Such a decline in frequency of use is expected and has been observed in numerous digital mental health studies [10,11,14,15,19,23-26], including those involving moodgym [[[[[[[[[[14,15]]]]]]]]]] and Moodkit [25]. We selected our engagement target with this in mind and designed the low-intensity coaching to encourage what Zhang et al [24] called the right dose of digital therapy ("not too much or not too little") while promoting three key user behaviors essential to clinically meaningful use of e-MH tools: learning (eg, identifying a coping activity), goal setting, and self-tracking (eg, mood rate and sleep logs). While this pilot did not intend to assess the clinical efficacy of the tools, participants' depression severity scores improved at the end of the study. Such an improvement was greater (16/31, 52%) for those with consistent use of tools until the end of the study, at week 6. This continuous engagement style was comparable to [14,25] or higher than [14,15,26,24] previous digital mental health interventions with moodgym, Moodkit, and self-report pilot trials, some conducted in primary care clinics. Retention rates at 5 and 6 weeks were as low as 26.5% even when these interventions were coupled with a digital health support. Pharmacotherapy management, being an integral part of the CoCM, cannot be ruled out as a contributor to the PHQ-9 score improvement.

Shared Familiarity With the e-MH Tools

The study team's knowledge of available e-MH tools was essential to the intervention selection process. A shared familiarity with the tools facilitated the development of a reasonable and therapeutic engagement target, as well as suggestions for maximization of their use. It also promoted informed decision-making. Patients received a descriptive summary of the tools with recommendations on how to use them before selecting one. Tools with evidence-based principles, reported efficacy, an attractive user interface, low cost, and no embedded clinician support were given priority for inclusion in the study. Overall, participants' satisfaction with the tools increased with time and was observed for those who engaged in homework or activities suggested by their tools or the care manager, who became accustomed to the different modules.

Existing Team-Based Care and Workflows

Capitalizing on the existing infrastructure of the CoCM for integration of the tools allowed for an adjunct care approach with monitoring and follow-ups and saved the cost, time, and clinical burden that may have ensued with a standalone implementation process. For the study duration, the CoCM workflow was adjusted as minimally as possible. As such, the care manager carried out her usual clinical duties in coordinating care with participants' PCPs and their consulting psychiatrist and also shared patients' experiences with their selected tools. The low-intensity "coaching" lasted on average 7.8 to 8.1 minutes, regardless of the study week. Our overall observation is that the care manager perceived no additional burden with the intervention. The latter seemed to have effectively supplemented her brief psychotherapy interventions by offering a collection of activities and tools to which patients might otherwise not have had access, such as mood tracking, journaling, homework exercises, advice for lifestyle changes, medication, and sleep logs.

Flexible and Tailored Approach to Engagement

In contrast to other digital health implementation studies, patients were encouraged to select their preferred tools and switch if desired. In total, 4 participants took advantage of this flexible approach because of phone compatibility issues or a lack of therapeutic functionality with the selected tools. This approach is consistent with centering patient empowerment and shared decision-making in the CoCM and is also more naturalistic, given that in real-life settings, it is unlikely that clinics would require patients to choose particular tools. A potential key determinant to uptake and engagement to consider is the appropriate timing for the introduction of e-MH tools into patient care. Patients with momentary time constraints, due to an acute illness or a specific life event, who did not enroll were asked to be recontacted to enroll, while those already in the study stopped using their tools for 1 or 2 weeks. We accommodated both. Timing should be explored in concert with the patient.

As part of the personalized care planning offered in the CoCM, there is value in inquiring about why patients declined self-help digital health resources. For instance, most patients (12/32, 37%) who turned down participation in the study pointed to a lack of focus on comorbid anxiety disorders and the absence of meditation-based apps, among other issues. Relatedly, about 88% (22/32) of the study sample were found with active anxiety symptoms of various severity in addition to major depression. A more diverse menu of e-MH tools could be beneficial in the future, including apps for pain, another active comorbidity found in 66% (21/32) of the study sample.

Limitations

Due to the small sample size, we were not able to make statistical inferences. In total, 20% of the care manager's check-ins were missed as patients were unreachable for various reasons, resulting in a missed opportunity to deliver the low-intensity coaching and gather the study outcomes. With the self-report design of this pilot study, we faced the possibility of social desirability bias, which we tried to minimize by weekly

monitoring and discussion of patients' progress with homework or activities suggested by their tools or the care manager.

Conclusions

Efforts to augment the CoCM with web-based and digital health technology have been limited. To our knowledge, this is the first study to leverage the unique patient-care manager relationship within the CoCM toward integration of self-help e-MH tools for depression. Such an implementation can be successful when centered around patient empowerment and integrated within existing clinical workflows. These findings may inform digital health intervention efforts in the CoCM with considerations for the barriers that are unique to this model.

Conflicts of Interest

None declared.

Multimedia Appendix 1
Study Outcome Questionnaire.
[PDF File, 75 KB - jopm_v17i1e55349_app1.pdf]

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Abbreviations

CBT: cognitive behavioral therapy
CoCM: collaborative care model
e-MH: e-mental health
PCP: primary care provider
PHQ-9: Patient Health Questionnaire-9

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Original Paper

Using Community Engagement to Create a Telecoaching Intervention to Improve Self-Management in Adolescents and Young Adults With Cystic Fibrosis: Qualitative Study

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Abstract

Background: Adolescents and young adults (AYA) with cystic fibrosis (CF) are at risk for deviating from their daily treatment regimen due to significant time burden, complicated daily therapies, and life stressors. Developing patient-centric, effective, engaging, and practical behavioral interventions is vital to help sustain therapeutically meaningful self-management.

Objective: This study aimed to devise and refine a patient-centered telecoaching intervention to foster self-management in AYA with CF using a combination of intervention development approaches, including an evidence- and theory-based approach (ie, applying existing theories and research evidence for behavior change) and a target population–centered approach (ie, intervention refinement based on the perspectives and actions of those individuals who will use it).

Methods: AYA with CF, their caregivers, and health professionals from their CF care teams were recruited to take part in focus groups (or individual qualitative interviews) through a video call interface to (1) obtain perspectives on the overall structure and logistics of the intervention (ie, Step 1) and (2) refine the overall framework of the intervention and obtain feedback on feasibility, content, materials, and coach training (ie, Step 2). Qualitative data were analyzed using a reflexive thematic analysis process. Results were used to create and then modify the intervention structure and content in response to community partner input.

Results: For Step 1, a total of 31 AYA and 20 clinicians took part in focus groups or interviews, resulting in 2 broad themes: (1) video call experience and (2) logistics and content of intervention. For Step 2, a total of 22 AYA, 18 clinicians, and 11 caregivers completed focus groups or interviews, yielding 3 major themes: (1) intervention structure, (2) intervention materials, and (3) session-specific feedback. Our Step 1 qualitative findings helped inform the structure (eg, telecoaching session frequency and duration) and approach of the telecoaching intervention. Step 2 qualitative results generally suggested that community partners perceived the feasibility and practicality of the proposed telecoaching intervention in promoting self-management in the face of complex treatment regimens. Extensive specific feedback was used to refine our telecoaching intervention before its efficacy

testing in subsequent research. The diverse community partner input was critical in optimizing and tailoring our telecoaching intervention.

Conclusions: This study documents the methods and results for engaging key community partners in creating an evidence-based behavioral intervention to promote self-management in AYA with CF. Incorporating the lived experiences and perspectives of community partners is essential when devising tailored and patient-centered interventions.

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KEYWORDS

cystic fibrosis; telecoaching; self-management; community engagement; community partner; intervention development

Introduction

Cystic fibrosis (CF) is a progressive genetic disorder that impacts many systems in the body, including potentially causing chronic lung infections, gastrointestinal abnormalities that create malabsorption and make it difficult to grow and gain weight [1], impairment of sexual health and reproduction [2,3], and numerous other comorbidities [4]. CF is estimated to affect approximately 40,000 children and adults in the United States and about 105,000 people worldwide [5,6]. Historically, children with CF rarely lived to adulthood. Currently, however, the median expected survival age of a child born with CF in 2023 in the United States is 68 years [7]. Recent improvement in survival is primarily due to the advances in therapeutics, that is, cystic fibrosis transmembrane conductance regulator (CFTR) modulators, or CFTR corrector and potentiator medications, which ameliorate pulmonary disease [8]. Still, the potential to benefit from these new therapeutics is paralleled by the increasing complexity and time required to complete multiple daily treatments.

Adolescents and young adults (AYA) with CF are at particular risk for nonadherence to their treatment regimen, given stressors common to this developmental period, including social pressures and increased academic or work demands [9]. Furthermore, people with CF report a significant time burden (ie, more than 1 hour) in completing their daily therapies [10]. It is not surprising, then, that adherence to prescribed treatment regimens is a common problem in CF, with adherence rates to all CF treatments ranging from 35% to 75%, while CF medication-specific adherence spans 31% to 79% [11-13]. This wide range in adherence rates stems from variability in measurement approach (ie, self-report vs objective measures), age of the individual, differences across treatment components, and other factors [14]. People with CF are unable to benefit from cutting-edge medications and interventions if barriers exist that prevent therapeutically meaningful self-management. As treatments in CF expand to include the groundbreaking use of CFTR modulators, efforts to improve medication and treatment self-management are of paramount importance. Identifying and developing effective behavioral interventions that are patient-centered, engaging, and practical (for both people with CF and care teams) will be critical to successful implementation and subsequent positive impact in helping individuals follow their CF treatment.

Although telecoaching has been used to successfully manage other health conditions [15,16], it has not been adopted to address self-management in people with CF. The flexibility of telecoaching affords the opportunity to take an accessible and patient-centered approach to identify individualized self-management concerns and address them with relevant, efficacious interventions. Indeed, a range of behavioral interventions have been effective or promising in addressing self-management in patients across disease populations [15,17,18]. These interventions include organizational and behavioral strategies, problem-solving around barriers to self-management, motivational interviewing, and educational approaches [19]. Core aspects of these interventions can be woven into brief telecoaching sessions, especially if these strategies are linked specifically to the personal barriers that patients report facing with their daily regimen. In addition, given that fewer outpatient visits and poor follow-up by providers negatively impact self-management [20], brief telecoaching sessions with a trusted and personally known health care clinician offer a pragmatic and accessible way to link clinicians and patients on a more regular basis. Yet, little is known about its clinical effectiveness in improving self-management in people with CF.

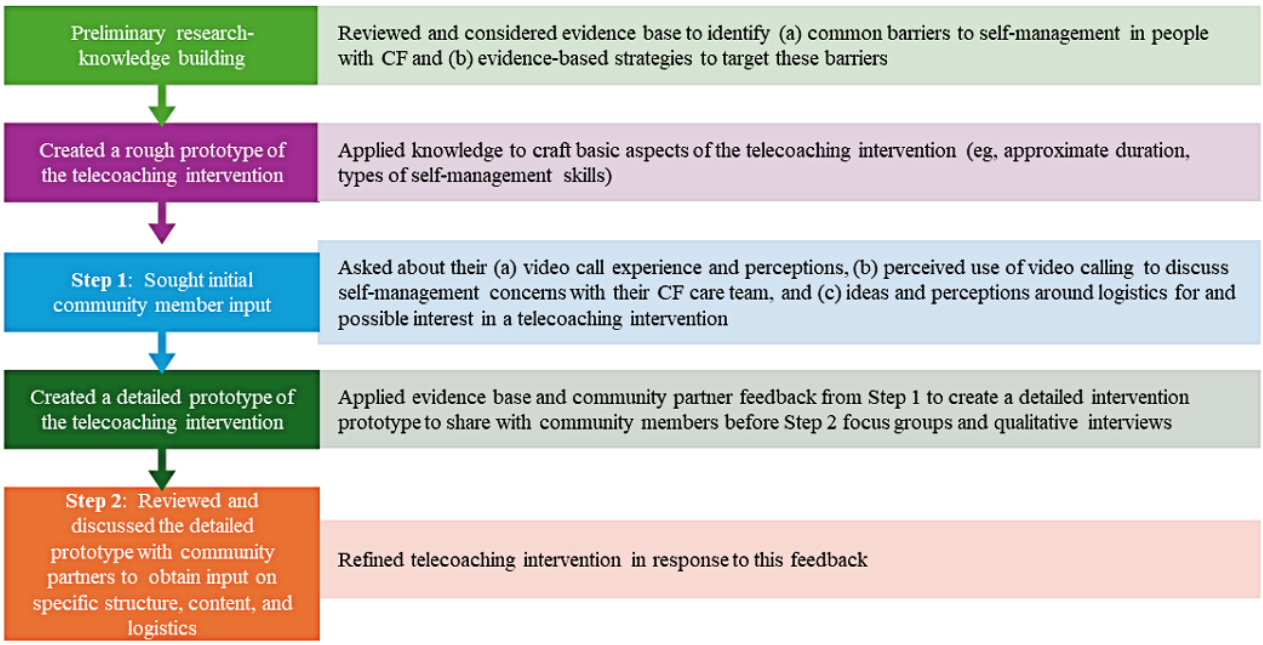
The goal of this study was to obtain and apply community partner feedback to develop (Step 1) and refine (Step 2) a novel and patient-tailored telecoaching intervention to enhance self-management in adolescents and young adults with CF (ages 14-25 years). In our subsequent line of research, the telecoaching intervention will be tested for its feasibility, acceptability, and effectiveness. Our ultimate goal is to establish an accessible, acceptable, and efficacious telecoaching intervention to offer during routine care across CF care centers in the future.

Methods

Study Design

Figure 1 shows the study design, which consisted of a combination of intervention development approaches, including an evidence and theory-based approach (ie, applying existing theories, like social cognitive theory [21], and research evidence for health behavior change) and a target population-centered approach (ie, intervention refinement based on the perspectives and actions of those individuals who will use it [22]). Consistent with guidance from O'Cathain et al [22], Step 1 pertained to key aspects of intervention development, whereas Step 2 focused on intervention design.

Figure 1. Study design. CF: cystic fibrosis.



Sample

Participants included AYA with CF (ie, "patients"), their caregivers, and health care professionals (ie, "clinicians") from their CF care teams. From November 2017 to June 2018, research staff recruited participants from 5 CF centers in the United States (Children's Hospital Colorado, National Jewish Health, Northwestern University, University of Kansas Medical Center, and West Virginia University). Together, these CF centers provided a diverse population from which to draw our sample. Eligible patients were recruited during routine clinic visits and were English-speaking, aged 14 to 25 years, diagnosed with CF, and prescribed at least one respiratory medication (eg, inhaled antibiotic, dornase alfa, hypertonic saline, oral azithromycin, ivacaftor, lumacaftor, and ivacaftor combination), used a vest device with usage monitor (ie, SmartVest [Electromed Inc], Hill-Rom [Baxter International], Afflovest [Rotech Healthcare], or Respirtech [Koninklijke Philips]) for airway clearance, and had access to a device with an internet connection to host a teleconference meeting. Patients were not eligible if they had a history of lung transplant. English-speaking primary caregivers who resided with a patient participant, (and who received permission to participate from a patient who was 18 years or older) were recruited too. Eligible CF care clinicians were English-speaking and employed within a participating accredited Cystic Fibrosis Foundation care center; study staff recruited them to take part in this research.

Study Procedures

Before Step 1, the study team devised a rough prototype of the telecoaching intervention. Step 1 of intervention development involved conducting community partner interviews (February-August 2018), using a semistructured guide, to obtain perspectives and thoughts on the overall intervention structure and logistics—that is, access to the internet and smart devices, experience and perspectives using video calling in general, experience with and potential application of video calling to communicate with the patients or CF care team and the potential application of video calling to the discussion of self-management concerns, preferences for who serves as a coach, some overall intervention feasibility (eg, frequency of sessions) questions, and potential interest in this type of intervention. The study team met to discuss the interview information needed to fully create the intervention prototype (eg, access to the internet, video calling experience, and interest). The first author created the initial draft of the interview guide, which was then jointly edited by the study team. The interview guide generally covered the same topics across informants (more details in Multimedia Appendix 1).

Then, before Step 2, the study team expanded the creation of the telecoaching intervention, using findings from Step 1 and applying the research evidence base regarding specific, efficacious behavioral strategies (eg, problem-solving and behavioral activation) to target various common barriers that people with CF experience when managing their treatments. A detailed overview document of the proposed telecoaching intervention was shared with participants just before the Step 2 focus group or qualitative interviews, which took place from November 2018 to February 2019. This summary was used as a reference during the interviews, with its content reviewed and discussed. The interview guide again was created by the first author and subsequently edited by the study team, with the goal of obtaining specific feedback from community partners to refine the details of the telecoaching intervention structure, logistics, and content (more details in Multimedia Appendix 2).

In addition to AYA with CF and their health care clinicians, caregivers of enrolled AYA with CF also engaged in Step 2 interviews. For patients and clinicians, the overview document included key points (eg, session duration, coach professions, and basic structure), a description of what skill sessions were, sample session activities, an overall intervention timeline and flow of sessions, and a sample intervention timeline and session flow for a hypothetical participant. The caregiver overview

handout was a 2-page intervention summary (as caregivers were not expected to be participants in the intervention). All informants were asked to comment on the overall structure and duration of the telecoaching program; feedback on specific skill sessions, intervention materials, and their format (paper vs digital); and feasibility and preference for session timing (eg, work hours, nights, weekends). Clinicians were also asked what training the coaches might need, and caregivers were asked to share any caregiver-specific considerations the team should keep in mind.

Research Team and Reflexivity

Research staff (ER, EW, KD, CA-N, and MH) carried out the interviews and coding. These individuals were research staff, with KD, CA-N, and MH working in the labs of the lead investigators (CLD and DP). All were trained and experienced in conducting interviews. Although none of the interviewers had previous relationships with the participants, KD and CA-N were advanced doctoral clinical psychology students who had supervised experience in clinical interviewing, including building rapport. At the outset of all interviews, the interviewer introduced themselves, explained the purpose of the research, and began the meeting with an icebreaker activity. The study team was also comprised of 3 licensed and academic clinical psychologists (CLD, EFM, and JL), all with extensive clinical and research experience with people with CF. This experience, coupled with that of a pulmonologist fully dedicated to CF care (DP), provided combined strengths when discussing interpretations of data. Contributions from advanced research staff (EB and AG) ensured proper study management and data integrity, which helped reduce bias and enhance the reliability of our findings. Our entire study team was female; two of our members identified as people of color, and one as Hispanic.

Qualitative Analysis

All interviews were conducted with an experienced coauthor interviewer (ER for Step 1 and EW for Step 2) using a video-conferencing platform. Adolescents (ages <18 years) and young adults (ages 18-25) were interviewed separately. Note that an 18-year-old attending high school was assigned to the adolescent group rather than the young adult group. Clinicians were grouped based on scheduling availability; thus, each focus group had a mix of professionals. Caregivers were grouped separately, depending on whether they were parents of an adolescent or young adult (as per patient cohort grouping above). All participants were encouraged to take part in a focus group; however, individual qualitative interviews (using the same guide) were offered to those not interested in a group format or to those with scheduling constraints. All groups had 1 interviewer, plus 1 staff member behind the scenes to address any potential technology concerns and to take notes. All focus groups and individual qualitative interviews were audio-recorded and transcribed by a paid service. Transcripts were cleansed by contrasting their content with the original recordings. All information also was deidentified.

Thematic analysis was performed for each informant group in an iterative manner using NVivo software (Lumivero) [23]. Experienced qualitative coders (ER, KD, and EW for Step 1; CA-N and MH for Step 2) conducted this analysis as data were obtained. A clear audit trail of notes and decision-making was established with files stored in a secure, shared account. Interviews for Steps 1 and 2 were conducted until saturation of themes was achieved upon iterative review of transcripts.

For both steps, the first author and 2 coders (primary and secondary) read the first transcript of each cohort, recording initial codes using the comment function in Microsoft Word. They discussed and established the initial coding frame and codebook. Then, the primary coder continued coding transcripts, while the secondary coder coded a random sample of each cohort of transcripts until at least 20% of transcripts were double-coded [24]. Initial kappa values between coders ranged from κ=0.61 to κ=0.73, indicating substantial agreement [25]. Throughout this process, discrepancies were discussed, and modifications to the codebook were made, as needed, in an iterative manner. Saturation (ie, no new themes arising) was attained in coding data for both steps. After coding was complete for all cohorts, the first author and 2 coders collaborated to organize the codes into a thematic structure.

After reflexive thematic analysis was complete for Step 1, the study team discussed all findings, considering different participant perspectives, and collectively made decisions regarding plans for creating the telecoaching intervention prototype before Step 2. In addition to the thematic analysis for Step 2, results were detailed in a Microsoft Excel table. This table consisted of the following columns: cohort (ie, patient, provider, and caregiver), target area (ie, intervention, coach training, and scheduling and logistics), specific topic (eg, general intervention, logistics, scheduling, and SMART goals session), relevant transcription excerpts, and action needed (ie, add, modify, and clarify). The study team carefully discussed each item until a decision was made regarding modifying the intervention. Information regarding each decision was recorded in 2 additional columns in the Excel file: (1) whether a change to the intervention prototype would be made based on the feedback (ie, yes or no) and study team response (a tracking system to record responsible parties and steps taken).

Ethical Considerations

Study procedures were reviewed and approved by the Boston Children's Hospital's institutional review board (IRB-P00022531), which served as the Institutional Review Board of Record. Written informed consent was required from all participants (assent from minors, with parental consent). Potential participants were informed that they could opt out of the study, and it would not impact their standard CF care (patients and caregivers) or their standing within the CF care team (clinicians). All data were deidentified and coded with a unique participant number. Upon consenting to the study, patients and caregivers completed surveys as an Enrollment Assessment; each was compensated US $30. Clinicians completed a brief demographic survey upon enrollment, for which no compensation was provided. All participants were compensated US $30 for completing each qualitative interview.

Results

Step 1 Results

Participants

A total of 31 AYA patients with CF (13 adolescents; 18 young adults; more details in Table 1) participated across 9 focus groups (2-4 participants per focus group) and 10 one-on-one interviews. Focus groups lasted a mean of 59 minutes (SD 12; range 47-71), while individual interviews had a mean duration of 37 minutes (SD 13; range 29-61). A total of 20 clinicians (more details in Table 2) were interviewed across 6 groups (2-4 participants each), lasting 64 minutes on average (SD 6; range 51-68).

Table 1. Demographic and medical characteristics of participants (patients).

Patients	Overall (N=38)	Step 1 (N=31)	Step 2 (N=22)
Age, mean (SD)	19.8 (3.8)	19.8 (3.8)	19.9 (3.88)
Female, n (%)	22 (57.9)	20 (65)	16 (73)
White, non-Hispanic, n (%)	31 (81.6)	25 (81)	17 (77)
White, Hispanic, n (%)	4 (10.5)	4 (12.9)	4 (18.2)
Other, unspecified, n (%)	2 (5.3)	1 (3.2)	0 (0)
Other, Hispanic, n (%)	1 (2.6)	1 (3.2)	1 (4.5)
Household income (US $), n (%)			
<60,000	6 (15.8)	3 (10)	2 (9)
60,000 to <120,000	7 (18.4)	6 (19)	4 (18)
≥120,000	7 (18.4)	6 (19)	4 (18)
Do not know or refuse to answer	18 (47.4)	16 (52)	12 (55)
Insurance, n (%)			
Private or military	32 (84.2)	26 (84)	19 (86)
Public or no insurance	6 (15.8)	5 (16)	3 (14)
FEV1[a] percent predicted, mean (SD)	79.8 (22.2)	82.8 (21)	84 (21)
≥70%, n (%)	26 (68.4)	23 (74)	17 (77)
40-69%, n (%)	10 (26.3)	7 (23)	4 (18)
<40%, n (%)	2 (2.3)	1 (3)	1 (5)
BMI percentile, mean (SD)	51.8 (24.6)	56.2 (23.2)	68.1 (10.7)
BMI, mean (SD)	23.2 (3.3)	23.5 (3.2)	23.1 (3.4)
Pseudomonas aeruginosa, n (%)	21 (55.3)	18 (58)	12 (54)
Gastroesophageal reflux disease (GERD), n (%)	16 (42.1)	12 (39)	9 (41)
Cystic fibrosis–related diabetes (CFRD), n (%)	15 (39.5)	12 (39)	9 (41)
Pancreatic insufficiency, n (%)	37 (97.4)	30 (97)	21 (95)
F508del[b], n (%)			
Homozygous	22 (57.9)	16 (52)	12 (55)
Heterozygous	15 (39.5)	14 (45)	10 (45)
Other	1 (2.6)	1 (3)	0 (0)
Treatment complexity score [26], mean (SD)[c]	18.9 (5)	19 (5.5)	19 (5.8)

[a]Forced Expiratory Volume in one second.

[b]Delta F508 mutation, the most common genetic mutation in cystic fibrosis.

[c]Higher scores indicate a more complex regimen (range 0-76).

Table 2. Demographic and medical characteristics of participants (clinicians).

Clinicians	Step 1 (N=20)	Step 2 (N=18)
Female, n (%)	18 (90)	16 (89)
White, non-Hispanic, n (%)	20 (100)	18 (100)
Clinician role, n (%)		
Nurse	2 (10)	2 (11)
Nurse practitioner (advanced practice nurse)	2 (10)	2 (11)
Nutritionist or dietitian	1 (5)	1 (6)
Physical therapist	1 (5)	1 (6)
Physician	2 (10)	1 (6)
Psychologist or psychiatrist	1 (5)	1 (6)
Registered nurse	3 (15)	3 (17)
Respiratory therapist	4 (20)	3 (17)
Social worker	4 (20)	4 (22)
Clinical population, n (%)		
Adult	11 (55)	11 (61)
Pediatric	4 (20)	3 (17)
Both	5 (25)	4 (22)

Thematic Results

Overview

Results yielded two major themes: (1) video call experience and (2) logistics and content of the telecoaching intervention. Tables S1 and S2 in Multimedia Appendices 3 and 4 contain subthemes and descriptive quotes for these 2 themes, respectively. Step 1 thematic content is summarized below.

Video Call Experience

Patients' previous use of video calling varied, with few reporting never having used video calls and the majority frequently using video calls for a range of purposes (eg, medical visits, personal communication with friends and family). Patients reported consistent availability of internet services and typically owned and had no restrictions on a personal device (ie, cell phone, laptop, or tablet). AYA differed somewhat on access, with adolescents having more restrictions (eg, parental settings). Patients identified benefits of video calling including the convenience, ease of use, infrequency of technical issues, ability to connect more with the other person, and their own comfort level. However, patients referenced some practical challenges (eg, video internet connectivity, privacy, and scheduling), as well as lack of motivation and changes in health, as possible concerns when using video calls for intervention delivery.

Clinicians perceived many benefits of conducting video calls with patients. They noted that video calling is convenient and allows for an alternative way to communicate with or reach patients. This method may be helpful to access previously hard-to-reach populations that live far away or have poor attendance to clinic visits. In addition, video calls could minimize missed school and workdays for patients and reduce concerns about infection control in clinics. Clinicians reported video calling allows them to gain new information as compared with discussing over the phone and allows them to see body language and reactions from patients. Video calling facilitates focus and reduces multitasking or distractions on the side of both patient and clinician. Finally, clinicians believed that patients may be more comfortable disclosing information because it is a less intimidating environment than a clinic.

Similarly, clinicians also reported some challenges in using video calls. They noted that patients may not have access to resources such as a device (phone or computer) or internet access to be able to engage in a video call in telecoaching. Access barriers may be financial or situational (eg, the situation at the time of call). Clinicians also reported the potential for issues with the platform itself and internet connection (eg, buffering or loss of connection), which can be distracting to or interrupt the conversation. Clinicians stated that video conferencing would require that both patients and clinicians receive additional training on how to use the platforms. Clinicians also expressed concerns for patient privacy (eg, challenging to find a private space to have the conversation) and felt that this might introduce an aspect of intrusiveness. Furthermore, they questioned whether video conferencing is an appropriate platform for conversations about mental health or other acute or sensitive issues. Concerns about difficulty scheduling calls and billing for services were expressed by many clinicians. Finally, clinicians wondered if video conferencing would impact rapport with patients and clinic attendance.

Regarding their perceptions of patient interest, many clinicians (17/20, 89%) stated they believed that patients would respond positively to the option for teleconferencing, particularly for convenience. They emphasized clinicians would need to be prepared that patients may be uncomfortable discussing self-management due to the calls feeling invasive or like a

lecture instead of supportive. Clinicians had recommendations about subgroups of patients (eg, young, newly diagnosed, or parents) that they believed would benefit most from a telecoaching intervention.

Logistics and Content of Telecoaching Intervention

AYA with CF provided their suggestions about the qualifications of a coach for the proposed telecoaching intervention. Many patients confirmed they would be comfortable speaking with a coach about self-management concerns if the coach was knowledgeable about CF and they knew the person (ie, the coach was a member of their care team). When considering the profession of the coach, participants differed in their recommendations from a nurse, respiratory therapist, or social worker. AYA varied in their opinions of the frequency of video calls and length of the telecoaching intervention. The most common suggestion was that the duration of the intervention should be tailored to personal goals or needs. Other participants' suggestions varied from a few months in length to 6 months to a year. Similarly, some patients with CF believed that the duration of telecoaching calls should vary based on situation and need, while others voiced that a duration of 30-60 minutes would suffice. AYA identified session topics (eg, mental health, changes in treatment regimen) they believed should be included in the intervention and those they thought were not appropriate for telecoaching (eg, sick visits or serious topics, such as surgery) and would require a face-to-face encounter.

While some clinicians recommended that session topics should be tailored to the patient's goals and interests, others suggested a routine agenda for all video calls. They discussed that coaches should focus on emotionally sensitive issues (eg, mental health), identifying and addressing self-management barriers, and adjustment to life transitions (eg, moving to adult care or starting a job) during telecoaching intervention sessions. Several clinicians thought telecoaching would be useful for demonstrating a treatment technique or use of medical equipment. Many clinicians suggested the frequency of video calls should vary based on patient needs. Others voiced a specified frequency of calls (eg, every 1-2 weeks, monthly), more frequent sessions, or tapering sessions as potentially helpful and realistic for some patients. With respect to the length of intervention, many clinicians believed that 6 months was feasible, and the intervention needed to be a specified length for it to be effective. Few clinicians suggested the intervention should vary based on patient needs. Clinicians were mixed in their responses about how easy it would be for them to integrate telecoaching into their current practice. While many said they believe it would be feasible, others cited challenges around workload and scheduling (eg, time and space availability, fitting within the current workload). To integrate telecoaching calls, clinicians noted they would need support in how to allocate time around their own responsibilities and a patient's schedule or activities and would need access to additional resources such as a private space and equipment. When discussing who on the CF care team should serve as a coach, some clinicians suggested a specific care team member (eg, nurse, social worker, respiratory therapist). However, clinicians reported that the coach chosen should depend on individual patient's needs and existing relationships and therefore, identifying the coach may require a team approach. Clinicians suggested using visual or video tools to engage patients in telecoaching intervention sessions. Many clinicians suggested approaching patients with language other than "adherence" to preface intervention discussions as nonjudgmental.

Step 2 Results

Participants

A total of 22 AYA (9 adolescents; 13 young adults), 18 clinicians, and 11 caregivers completed interviews. Table 3 shows the descriptive statistics for the AYA and clinician or caregiver cohorts, respectively. AYA participated in a total of 6 focus groups (2-4 participants each) and 5 individual interviews, lasting an average of 60 (SD 14; range 46-81) minutes and 68 (SD 17; range 50-94) minutes, respectively. Clinicians were interviewed across 6 groups (2-4 participants each), lasting 68 minutes on average (SD 7; range 62-80 minutes). Caregivers participated in 1 of 4 focus groups (2-3 participants per group; mean duration of 84 minutes, SD 17; range 69-106 minutes), with one taking part in a qualitative interview (40 minutes).

Table 3. Demographic and medical characteristics of participants (primary caregivers).

Primary caregivers	Step 2 (N=11)
Female, n (%)	11 (100)
White, non-Hispanic, n (%)	9 (82)
White, Hispanic, n (%)	2 (18)
Marital status, n (%)	
Single or never married	0 (0)
With a partner	0 (0)
Married	10 (91)
Widowed	0 (0)
Separated	0 (0)
Divorced	1 (9)
Education, n (%)	
Some high school or less	0 (0)
High school diploma or certificate equivalent	1 (9)
Vocational or trade school	0 (0)
Some college	1 (9)
Associate degree	0 (0)
College degree (eg, BA, BS)	2 (18)
Graduate or professional degree	7 (64)
Work or school status, n (%)[a]	
Attending school full time	0 (0)
Attending school part time	0 (0)
Working full-time	5 (45)
Working part-time	3 (27)
Full-time homemaker	4 (36)
Volunteer full-time	0 (0)
Volunteer part-time	1 (9)
Unemployed, seeking work	0 (0)
Not attending school or employed due to my child's health	1 (9)
Not attending school or employed due to my health	0 (0)
Not attending school or employed due to other reasons	0 (0)

[a]Work or school status item offers "check all that apply" as a response.

Thematic Results

Overview

Results yielded 3 major themes: (1) intervention structure, (2) intervention materials, and (3) specific session feedback. Tables S3 and S4 in Multimedia Appendices 5 and 6 display sample quotes for subthemes corresponding to the themes for intervention structure and intervention materials, which also are summarized below. Table S5 in Multimedia Appendix 7 reviews the data obtained for specific session feedback. All results were used to subsequently refine the telecoaching intervention.

Intervention Structure

Most AYA reported favorably on their overall perception of the intervention, stating that they thought it was good, unique, structured well, etc. Some young adults noted that the coaching aspect would be supportive in different ways (eg, serve as a reminder) and that the intervention could potentially have a positive, and even transformative, impact on some people with CF. A few adolescents noted concerns that it might be a lot to do, however, and some young adults felt that the program would not be something that they would need or want. Clinicians made some practical recommendations. For example, clinicians noted that if financial concerns or problems using treatment equipment arose as a concern for the participant, the coach would have to ensure that the participant reached out to their care team for this

sort of guidance. Clinicians also emphasized the importance of having "mock" sessions as part of coach training. Some clinicians noted that it will be helpful to have the additional support of the coach reinforcing similar discussions that other clinicians are having around self-management during patient encounters. Caregivers were highly mixed in their perspectives. Some felt less enthusiastic about the intervention because they thought it would be difficult for their adolescent to find time for telecoaching sessions (in addition to existing CF cares) or that their child would not be interested or committed to finishing it. Other caregivers reported that they could see possible benefits and that it was worth trying. Some suggestions were offered by caregivers including perhaps starting younger (before teen years) with patients, offering an introductory session for parents to feel connected, and sharing intervention content with caregivers (eg, as "touch points") so that they can discuss with their child and reinforce their child's efforts.

Regarding session length, most AYA felt that 30 minutes was sufficient time—not too short and not too long. Clinicians generally felt that the half-hour time frame was good, but some recognized that the length of the session might also need to be responsive to the extent of barriers the participant experiences. Caregivers had mixed views—some reported that it was too long, while others thought it was what would be needed, and others suggested having some flexibility to go shorter or longer, as needed. In terms of frequency of sessions, adolescents noted that having 2 weeks between sessions was sufficient for completing tasks and strikes a nice balance between keeping participants engaged but not overwhelming them. Some young adults reported that the frequency was good, while others suggested that once a month might be more reasonable. Clinician and caregiver perspectives aligned well with adolescents, feeling that 2 weeks between sessions keep individuals engaged in the intervention (eg, fosters routine check-ins). AYA reported that scheduling sessions could be challenging, given school or work, activities, and holidays. Many indicated that sessions would need to take place in the evenings or on weekends to be feasible. Caregivers consistently reported a need to use evenings and weekends as well. One caregiver suggested that having a telecoaching session during vest airway clearance would be ideal. Only a few AYA mentioned that day times (eg, early mornings) would be possible. Clinicians consistently recognized that patients likely would prefer evenings and, perhaps more rarely, early mornings; however, they also noted that it would be difficult for coaches to work after-hours if their time is not protected for that schedule. Furthermore, some clinicians emphasized the challenge of putting in long workdays and then having to find the motivation to engage in a telecoaching session in the evening. Nevertheless, many clinicians stated that there could be ways to find some flexibility (eg, looking at their schedules in advance and choosing to stay later if the clinical day is less busy) to address the scheduling challenge. It also was noted that if these services could be billable, it would make flexible scheduling more feasible.

With respect to the overall intervention length, several AYAs indicated that less than 6-7 months would be preferable, but others felt it was a good length to acquire skills and see how they work. Clinicians, for the most part, felt that the intervention length might be too long and could be a deterrent to those who do not want to make that sort of commitment or who might already have low motivation as part of their self-management concerns. Most caregivers felt that the intervention length was appropriate, noting that it would go by fast, and that extended time is needed to build habits; though, some caregivers remarked that it may seem too long. Overall, we obtained mixed views on the proposed length of the telecoaching intervention.

Clinicians and caregivers were asked about their views on who should serve as coach. Clinicians generally reported feeling comfortable serving as a possible coach in this intervention. They felt that the sessions would be feasible to implement with participants and that their preexisting relationship with the patient would likely be an asset to the process. Furthermore, clinicians reported positive views of the proposed monthly supervision meetings, stating that these meetings will provide coaches with feedback and support. Caregivers mentioned that the quality of the coach is essential, with rapport and empathy as central to fostering a good relationship with the participant.

Caregivers specifically were also asked about their potential involvement in the intervention. Most noted that they wanted to at least be aware of what was happening with the intervention, while others stated that such awareness could facilitate their supporting their AYA with skills. Even if not extensive, it was felt that parents being involved were consistent with the overall care approach with CF—that being "teams" working together.

Intervention Materials

Given the importance of the intervention binder as a resource for AYA, participants were queried for their perspectives and feedback on it. Generally, opinions on binder format—printed versus online materials—were highly mixed, but some participants recognized that having both options likely is ideal for meeting anyone's preference. Consistently, AYA and clinicians also reported that the binder, as an intervention tool, and its contents were accessible and helpful. Many caregivers noted that the binder could be particularly useful for parents to stay informed about the intervention, though other caregivers indicated that their child may not use it, especially after the intervention ends. AYA offered a few suggestions for adding to the binder. These included additional resources that participants could access if interested in more information on a topic, as well as contact information and a brief biography (eg, name, hobbies) on their coach so that the participant can get to know them. Furthermore, it was suggested that a chart would be helpful—documenting treatment plans and intervention activities—to keep things organized. Caregivers further felt that including some additional resources (eg, blog sites and websites) would be helpful.

Specific Session Feedback

AYA and clinician feedback on specific sessions within the intervention (eg, overall perception; specific considerations for session activities and worksheets) is reviewed in Table S5 in Multimedia Appendix 7. Overall, perceptions were positive. Participants provided their overall perception but also shared some very helpful recommendations to consider when refining session content and materials.

Discussion

Principal Findings

The results of this 2-step series of focus groups and qualitative interviews with the same cohort demonstrate the perceived feasibility of telecoaching as a practical approach through a video calling interface, to navigate personalized efforts in improving treatment self-management for AYA with CF. After formulating the intervention based on Step 1 interviews, qualitative data from Step 2 reflected a general acceptance of the community partner-informed, telecoaching intervention formulated for future testing. Broadly, the findings from these focus groups and individual interviews provided diverse input to inform and optimize a telecoaching intervention that teaches care team members to address problems in people with CF managing their complex treatment regimens. Community partner input showed a sensitivity to the diversity of technological access across people with CF, including a potential lack of device and internet access, which we observed to be uncommon yet remains an important consideration. Input also included practical considerations of the timing and frequency of calls, privacy policies, and relevant clinician concerns (eg, care team schedules and fatigue). Notably, AYA concerns regarding possible reduced motivation in the context of a remote video call should be considered when evaluating the impact of telecoaching in future research. Finally, scheduling concerns were a prominent theme across informants, with comments specific to challenges in finding time to dedicate to regular sessions, as well as conflicting schedule preferences between care team members (likely prefer work hours) and AYA (likely prefer evenings and weekends). Consequently, flexibility in scheduling will need to be an important consideration when implementing the telecoaching intervention.

Strengths and Limitations

Obtaining community partner input when devising a behavioral intervention is an optimal practice; consequently, our methodological approach is a strength. Individuals with lived experience in having to self-manage CF care on a daily basis (ie, patients) or provide tangible support to individuals managing their CF (ie, caregivers and providers) have key perspectives to share regarding what is feasible, acceptable, and useful to include in a behavioral intervention targeting self-management. They are intimately aware of what areas of self-management are challenging and why, and this information is critical when devising the content and structure of a telecoaching intervention. Furthermore, our 2-phase approach included obtaining community partner perspectives in creating the intervention, as well as critical feedback to help us refine what was initially developed. Confirmability and credibility were enhanced by having the same individuals participate in both Step 1 and Step 2 interviews, thereby providing additional opportunities for feedback. Finally, dependability was assured through an audit trail of detailed notes from coding discussions and decisions, all accessible to the coders throughout the project.

Though these findings provide rich detail and context for finalizing our telecoaching intervention content and structure, and in planning for its overall implementation in a clinical trial, our results also have some limitations. First, although participants were recruited from multiple CF care centers, each different in size and region of the United States, there may be some concerns regarding the transferability of study findings. Our AYA and caregiver sample was primarily White and non-Hispanic. Although these demographics are characteristic of much of the CF population (ie, 90.9% of the CF population in 2023 identified as White [7]), our findings may not capture important perspectives and experiences of individuals with CF who come from minoritized backgrounds. Similarly, our CF clinicians were all White and non-Hispanic, which likely does not reflect the demographic distribution for care team members across the United States. In addition, all caregivers and most patients and clinicians identified as female. As the telecoaching intervention continues to be evaluated and implemented, sensitivity to diversity factors will be critical in ensuring that the intervention is relevant and applicable across CF populations.

Second, key historical events arose following the completion of our focus groups. Although these events did not impact our qualitative data, they still should be considered as we move forward with our intervention. The first historical event was the United States Food and Drug Administration's approval of the Elexacaftor, Tezacaftor, and Ivacaftor combination (ETI) in October 2019, for people with CF aged 12 years and older with at least one F508del mutation. This was a landmark event in the history of treatments for people with CF, given the profound positive health impact of ETI. Indeed, the advent of ETI as a highly effective therapy for the majority of the US CF population spurned further research on the need for continuing multiple airway-clearing treatments in CF (eg, SIMPLIFY clinical trial) [27]. This factor alone shifted treatment regimens (and complexity) for many people with CF as self-driven or care team-informed decision-making began to decrease the number of treatments for some people with CF. For others, the improvements in lung and overall health positively shifted treatment self-management due to increased motivation and energy. This highly effective CFTR modulator has had marked impacts on CF quality of life [28,29]; the associated impact on the overall prescribed treatment regimen and self-management remains an important point of future investigation—one that will clearly be relevant to the implementation and use of our telecoaching intervention.

The second historical event was the COVID-19 pandemic that began in November 2019 and rapidly changed care practices in outpatient US health care delivery, including CF, to use telehealth visits. To protect people with CF who are vulnerable to the spread of respiratory pathogens (including SARS-CoV-2), many CF centers adopted telehealth visits to provide safe access to continued outpatient care. Care team members familiarity with telehealth thus vastly increased in almost all medical fields. Furthermore, patient and family familiarity with the use of video-conferencing technology also increased rapidly across health care, work, and social contexts. The feasibility of videoconferencing for patients and families with CF for use in telecoaching will likely be enhanced given experiences with teleconferencing as a mainstay of communication during the pandemic. Nevertheless, the impact of the COVID-19 pandemic on telehealth services and delivery remains in evolution.

Reimbursement for telehealth visits and adjusting licensure for providing telehealth across expanding geographic areas are just two aspects of how the behavioral health field has incorporated the use of teleconferencing to optimize health care delivery within multidisciplinary health care teams. Findings on the feasibility or acceptability of telecoaching, which may closely mirror some aspects of mental health care to lay persons, may be improved after the widespread use of these technologies during the COVID-19 pandemic.

Future Directions

Telecoaching is gaining applications in the treatment of chronic disease in many areas but remains nascent in CF. To our knowledge, this is the first study in CF to explore and describe the integrated perspectives of patients, family members, and health care clinicians on telecoaching as an intervention in CF to improve treatment self-management. The results of this study informed the structure and content of the telecoaching intervention, which recently was implemented in a feasibility pilot investigation addressing treatment self-management in AYA with CF [30]. In addition, an ongoing European multicenter trial of people with CF aged 12 years and older is integrating telemedicine along with telecoaching to address treatment self-management [31]. This investigation will evaluate the impact of these approaches on CF health outcomes, measuring a primary outcome of time to pulmonary exacerbation [31] while additionally studying impacts on treatment self-management and other features of CF health. The findings of studies such as these will become foundational knowledge for future health care practices to promote disease self-management in CF. In other chronic muco-obstructive disease processes, such as chronic obstructive pulmonary disease, telecoaching has already shown feasibility and acceptability for both patients and coaches in a 3-month intervention to improve physical activity [32]. Usage of the telemonitoring (a step counter) was excellent, although engagement with smartphone tasks was overall lower and decreased with time [32]. The phenomenon of initial uptake followed by declining use of any new technology is not unique. These types of trends may, in fact, support the importance of integrating interactive and interpersonal exchange, like telecoaching, in concert with the use of new technologies to improve treatment self-management significantly and sustainably.

Conclusions

The results of this 2-part series of focus groups support that the CF community is interested in applying the technology of video conferencing with an interactive coaching intervention as a method to address the challenges of chronic treatment self-management and self-management in CF. While people with CF, family members, and health care clinicians voice unique considerations that are valuable in informing a telecoaching intervention for the CF community, the overall enthusiasm reflected for video calling as part of CF care is an important factor when developing future care models in CF. These findings, which were established in a pre-pandemic era of CF, will be of both contemporary and historic value when studying the feasibility and acceptability of telecoaching and remote monitoring of treatment self-management in a post-pandemic landscape of CF treatment.

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Data Availability

All data generated or analyzed during this study are included in this published article.

Authors' Contributions

CLD, DP, EFM, and JL were responsible for study design and execution. CLD, DP, EFM, JL, and KD contributed to the manuscript writing. KD, ER, EW, CA-N, and MH conducted qualitative interviews and coding. CLD and KD summarized qualitative results. EB and AG assisted with project and data management. All authors reviewed and edited the final manuscript.

Conflicts of Interest

None declared.

Multimedia Appendix 1
Step 1 focus group and qualitative interview guides.
[DOCX File , 27 KB - jopm_v17i1e49941_app1.docx]

Multimedia Appendix 2
Step 2 focus group and qualitative interview guides.
[DOCX File , 34 KB - jopm_v17i1e49941_app2.docx]

Multimedia Appendix 3
Table S1: Step 1 video call experience theme and subthemes.
[DOCX File , 53 KB - jopm_v17i1e49941_app3.docx]

Multimedia Appendix 4
Table S2: Step 1 logistics and content of telecoaching intervention theme and subthemes.
[DOCX File , 55 KB - jopm_v17i1e49941_app4.docx]

Multimedia Appendix 5
Table S3: Step 2 overall intervention structure theme and subtheme.
[DOCX File , 55 KB - jopm_v17i1e49941_app5.docx]

Multimedia Appendix 6
Table S4: Step 2 intervention materials theme and subthemes.
[DOCX File , 53 KB - jopm_v17i1e49941_app6.docx]

Multimedia Appendix 7
Table S5: Summary of specific session feedback (across informants).
[DOCX File , 55 KB - jopm_v17i1e49941_app7.docx]

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Abbreviations

AYA: adolescents and young adults
CF: cystic fibrosis
CFTR: cystic fibrosis transmembrane conductance regulator
ETI: Elexacaftor, Tezacaftor, and Ivacaftor combination

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Original Paper

Developing a Smart Sensing Sock to Prevent Diabetic Foot Ulcers: Qualitative Focus Group and Interview Study

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Abstract

Background: Diabetic foot ulcers are common and costly. Most cases are preventable, although few interventions exist to reliably support patients in performing self-care. Emerging technologies are showing promise in this domain, although patient and health care provider perspectives are rarely incorporated into digital intervention designs.

Objective: This study explored patient and health care provider feedback on a smart sensing sock to detect shear strain and alert the wearer to change their behavior (ie, pause activity and check their feet) and considered how patient experience and attitudes toward self-care are likely to impact uptake and long-term effective engagement with the device to curate guiding principles for successful future intervention development.

Methods: This qualitative study combined semistructured interviews and a focus group alongside a participant advisory group that was consulted throughout the study. In total, 20 people with diabetic neuropathy (n=16, 80% with history of diabetic foot ulcers) and 2 carers were recruited directly from podiatry clinics as well as via a recruitment network and national health mobile app for one-to-one interviews either in person or via landline or video call. A total of 6 podiatrists were recruited via professional networks for 1 virtual focus group. Participants were asked about their experience of diabetic foot health and for feedback on the proposed device, including how it might work for them in daily life or clinical practice. The data were analyzed thematically.

Results: Three main themes were generated, each raising a barrier to the use of the sock complemented by potential solutions: (1) patient buy-in—challenged by lack of awareness of risk and potentially addressed through using the device to collect and record evidence to enhance clinical messaging; (2) effective engagement—challenged by difficulties accepting and actioning information and requiring simple, specific, and supportive instructions in line with podiatrist advice; and (3) sustained use—challenged by difficulties coping, with the possibility to gain control through an early warning system.

Conclusions: While both patients and podiatrists were interested in the concept, it would need to be packaged as part of a wider health intervention to overcome barriers to uptake and longer-term effective engagement. This study recommends specific considerations for the framing of feedback messages and instructions as well as provision of support for health care providers to

integrate the use of such smart devices into practice. The guiding principles generated by this study can orient future research and development of smart sensing devices for diabetic foot care to help optimize patient engagement and improve health outcomes.

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KEYWORDS

diabetes; diabetic neuropathy; diabetic foot ulcer; podiatry; prevention; health technology; behavior change

Introduction

Background

Foot ulceration is a common and debilitating problem for people with diabetes and is costly to the health care system. Up to one-third of individuals with diabetes will develop a foot ulcer in their lifetime [1], and amputation or death is likely in up to half of those individuals within 5 years [2]. These adverse outcomes understandably impact patient mental health, and it is reported that one-third of people experience clinical depression with their first diabetic foot ulcer [3]. In the United Kingdom, for the year 2014 to 2015, diabetic foot disease cost the National Health Service (NHS) 1% of its entire budget [4]. Indirect costs include impacts on individual earnings, costs of carers, and absenteeism for employers [5]. Despite many ulcers being preventable [6], only a fraction of health care spending is on prevention [7,8]. It is estimated that preventing one-third of ulcers in England would save the UK NHS >£250 million (US $325 million) [4].

Digital interventions show promise for supporting foot ulcer prevention. Emerging technologies include wearable devices such as smart insoles or smart socks that can be worn daily to provide constant monitoring of the feet and alert the wearer to at-risk foot loading [9-12]. Tests of these technologies show that regular use could be effective in predicting ulceration [9] and that participants find smart socks comfortable, yielding a good compliance rate [13,14]. Socks may be preferable to insoles as they can be worn with any type of footwear (or indeed on their own) [15]. Current smart wearable devices (socks and insoles) monitor temperature and plantar pressure, but research suggests that results would be improved by measuring shear strain, which reflects the “rubbing” across the foot [16,17]. Technology that measures shear strain has only been developed bespoke for research purposes, and application to wearables in this population is currently unavailable [18,19]. Recently, insoles capable of measuring shear safely have been developed and laboratory tested [20-22], but no studies have yet been found to measure shear strain via socks.

Objectives

A recent systematic review of smart wearable technology in diabetic foot ulcer prevention highlighted the limited involvement of patient and health care provider perspectives in device design and evaluation [23]. It is not surprising, then, that there is a lack and urgent need of interventions addressing patient barriers to adherence [24], and this requires patients and health care providers involved in diabetic foot health care to be consulted throughout the design process [25]. If the aim is to support effective engagement with a device [26] and improve health outcomes, interventions should carefully consider not only usability of features but whether the technologies are likely to change critical behaviors [27]. For example, it is important that users are supported not only in wearing the device but also in responding to it appropriately (ie, offloading the foot or seeking medical help if an ulcer has developed). This study used qualitative data to facilitate the co-design of a novel solution for daily monitoring and prevention of diabetic foot ulcers (a smart sock to detect shear strain and an associated feedback system). The aim of this study was to better understand the needs and preferences of those who would use or support the use of the technology to inform decisions about what would be needed to make a shear-sensing smart sock most likely to be adopted and adhered to in the long term and maximize the potential patient benefit. This included exploring lived experiences of diabetic foot ulcers as well as direct feedback on the proposed technology. This paper summarizes our findings thematically and includes a related set of guiding principles for future research and practice in smart sensing devices for diabetic foot care.

Methods

Study Design

Qualitative data were collected via semistructured interviews and a focus group in parallel to the technology development and used to iteratively inform its progress. In addition to participant input, regular patient and public inclusion and engagement (PPIE) opportunities with a patient advisory group of 8 people living with diabetes and presenting with diversity in severity of diabetic neuropathy (and consequent risk of diabetic foot ulcers) were held at regular intervals throughout the study period.

The role of the PPIE group was to provide lived experience input and early advice to the research team to help shape the study in the early phases (eg, co-designing and piloting the interview schedule) and throughout the data collection and analysis phases for credibility checking and feedback. Finally, they reviewed and provided input on the authorship of this publication. Members were recruited via professional networks and snowballing during the grant and ethics application phases of the study. The group met 5 times over 12 months.

Ethical Considerations

Ethics approval for this study was obtained from the University of Southampton (Ethics and Research Governance Online 78959), the UK Health Research Authority (Integrated Research Application System 323631), and the local research ethics committee (South Central – Hampshire B Ethics Committee; 23/SC/0098). The procedures followed were in accordance with the ethical standards of the responsible committee on human experimentation and with the Helsinki Declaration of 1975 as

revised in 2000. All participants took part after completing an informed consent procedure, with the possibility to opt out of the study at any time. All references to participants and their data have been anonymized to protect their privacy. The participation of the PPIE group was voluntary, with no contractual obligations, and they were paid £25 (US $31.25) per hour of involvement. Participants were offered a £25 (US $31.25) gift voucher as a thank you.

Participants

Potential users of the technology were identified to be people with diabetes and neuropathy and, therefore, at risk of developing diabetic foot ulcers who might use the sock and feedback system on a daily basis; their carers who might facilitate this daily use; and podiatrists (although various health care providers may be involved in diabetic foot care, podiatrists are most likely to implement the technology in clinical practice and have the most specialized knowledge in the area for device feedback). Recruitment began in May 2023 (month 7 of the study) and was completed in December 2023 (month 13 of the study).

Patients and Carers (for Interviews)

People with diabetes were recruited via postal mail-out from NHS podiatry clinics. Although the invitations were targeted to patients, carers were also invited to participate. Invitation packages included a cover letter with a brief summary of the study and contact information and a full participant information sheet detailing potential risks and data governance. Patient participants were included if they had diabetes and reported changes in sensation in their feet. Interested participants contacted the research team directly to ask questions, find out more about the study, and provide contact details for participation.

In addition to invitations from the clinic, the study was also posted on the NHS app, and an additional recruitment stream was set up using a consent-for-approach recruitment service (National Institute for Health and Care Research Clinical Research Network, Research for the Future).

With an aim to understand barriers to equitable engagement with the technology and mitigate them through its design, participants were selected purposively to include a range of ages, gender identities, ethnicities, and relative deprivation levels (based on the Index of Multiple Deprivation score [28] from their address), with an aim to oversample from underserved groups (eg, groups of a lower socioeconomic status and non-White ethnicity).

Those who were eligible were invited to be interviewed either in person in their homes or remotely via teleconferencing software or via landline telephone. On the basis of previous similar projects, a sample size of 20 to 30 patients and carers was estimated to provide sufficient information power [29]. Diversity of perspectives, depth of insight through strong dialogue, and rich data collection were prioritized over achieving a specific sample size.

Podiatry Group (for Focus Group)

Podiatrists working with people with diabetes were recruited via professional networks. Information about the study was made available via the clinics that were recruiting patients and via emails to colleagues. Interested participants contacted the research team directly to ask questions, express interest, and indicate availability to participate.

Data Collection

One-to-one interviews were conducted by JC (a qualitative researcher and lead author) in person in the participants' homes (6/22, 27%) or via teleconferencing (11/22, 50%) or phone (5/22, 23%) where preferred. Each participant was interviewed once. Before recording, the researcher reviewed the purpose of the study. Participants were given the opportunity to ask questions and then asked to complete the consent form followed by a demographic questionnaire including questions about their age, gender identity, living arrangements, and medical history. Participants were advised that specific questions about the technology were asked in terms of co-design, as if they were designing it for their own personal needs, and there were no right or wrong answers. "Shear strain" was described as "rubbing," and the researcher demonstrated this concept by rubbing the back of her hand and showing how the skin "stretches."

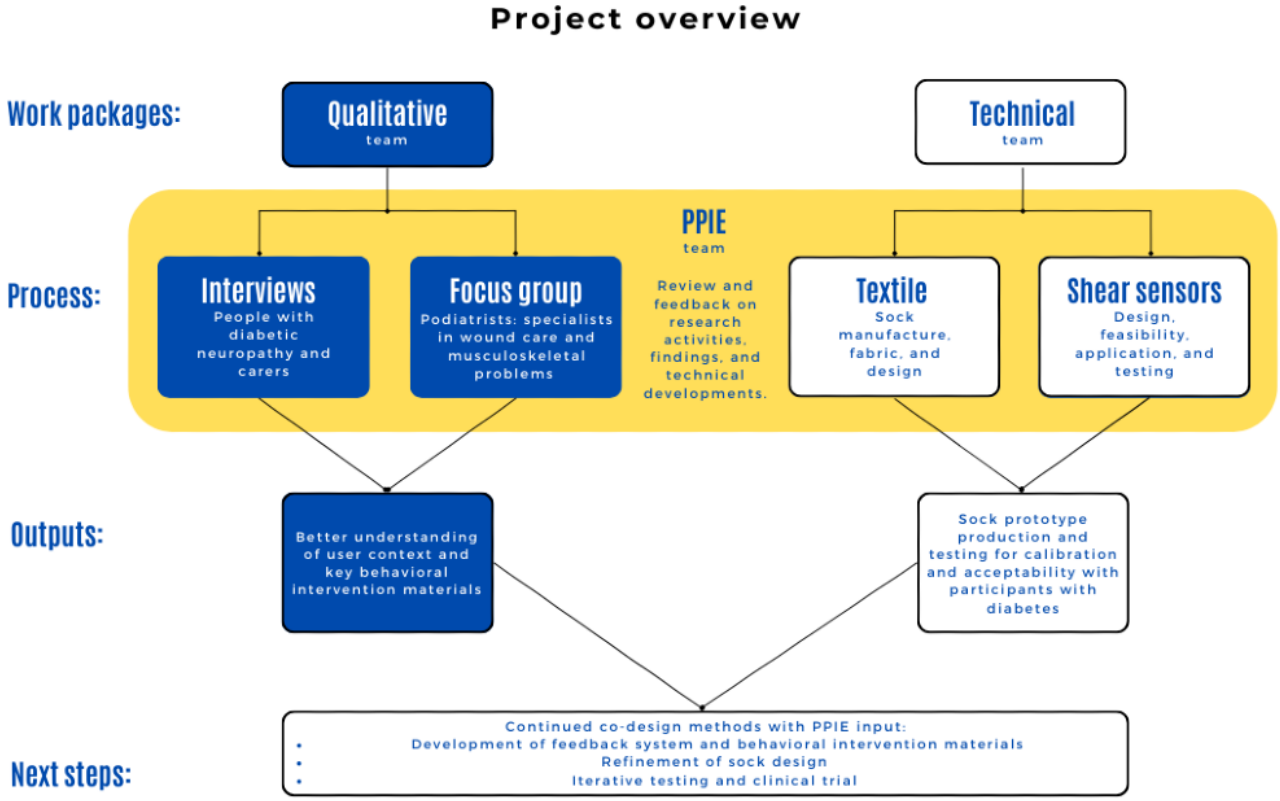
A semistructured interview guide with main questions and prompts was used and initially piloted and refined with the PPIE group (Multimedia Appendix 1). The interviews began by asking about the participants' experience with their foot care—previous issues, how they managed their foot care, and what they understood about diabetic foot health. The researcher then provided a standardized lay summary of the concept of the sock and feedback system (also developed with the PPIE group) with sock samples where available. The participants were encouraged to ask questions freely during and after the description. Participants were asked about their first impressions, whether the technology might fit into their daily life, how they would respond to alerts, and whether there were any concerns they had about the design or elements they would like to change. The interviews lasted an average of 52.5 (SD 11.0) minutes and were audio recorded and transcribed verbatim.

One focus group with podiatrists was conducted at month 12 of the study via the Microsoft Teams (Microsoft Corp) teleconferencing platform and facilitated by JC. Participants were sent 4 different sock samples and 1 sample of sensor material in the post before the discussion. The discussion began with a review of socks currently marketed for patients with diabetes and what the participants thought were important features for a sock designed for patients at high risk of diabetic foot ulcers. The concept of the sock and feedback system was presented orally using visual presentation slides. Participants were encouraged to speak freely about their first impressions of the technology in general, specific features, and implications for practice. The focus group lasted 70 minutes and was audio recorded and transcribed verbatim. Field notes and a reflective diary were kept throughout the data collection period.

Data Analysis

Data were collected over 5 months and were initially coded by the main author as positive and negative comments about the socks. These comments were presented to the PPIE group and the wider research team, including engineers of the sensors and manufacturers of the socks, for feedback. A brief summary of these findings is presented in Multimedia Appendix 2, and Figure 1 illustrates the parallel nature of this qualitative data collection and central role of PPIE input alongside the technical development of the sock by the wider research team. This ongoing process allowed for new data to be compared with previously collected data to identify similarities and deviances that were relevant and helpful to consider in the technology development process. Once all data had been collected, an overview and in-depth reflexive thematic analysis was conducted by JC guided by the principles of Braun and Clarke [30].

Figure 1. Division of work streams within the Socksess project and their interactions. PPIE: patient and public inclusion and engagement.



As JC collected and transcribed the data and had reviewed each case for feedback and discussion with the PPIE group, she was already familiar with the data by the stage of full analysis when attentional focus turned to the transcripts and field notes as a corpus. Codes were generated inductively using the NVivo software (QSR International) [31]. As the podiatrist data were more technical than the interview data and focused more on elements of the technology rather than on patient context, these data were assessed in parallel as a unique perspective separate from but related to the patient perspective. Throughout the coding process, the researcher made reflective notes.

Once generated, the codes and researcher notes were assessed together as a corpus. Throughout the process of data collection, JC learned about the experience of diabetic foot ulcers and developed empathy for the participants regarding the challenges of peripheral neuropathy and self-management of ulcer treatment and prevention. JC drew on the personal impact of these stories while analyzing the data to generate themes describing salient aspects of the experience of diabetic foot disease and how a novel technology such as this one may work in the everyday lives of people managing it. Initial themes were drafted and presented to the PPIE group and the larger research team for discussion and were reviewed and refined iteratively. PPIE engagement was essential to this refinement process, developing the themes in a way that presented a credible and relevant narrative.

To ensure the quality of data reporting, the COREQ (Consolidated Criteria for Reporting Qualitative Research) guidelines were followed [32]. A copy of the checklist, including a reflexivity statement, can be found in Multimedia Appendix 3.

Results

Recruitment

A total of 22 participants were recruited for the interviews, including 20 (91%) participants with diabetic peripheral neuropathy (n=13, 59% identified as male; n=8, 36% identified as female; and n=1, 5% identified as transgender), of whom 5 (23%) had type 1 diabetes and 17 (77%) had type 2 diabetes. Participants had a mean age of 66.0 (SD 10.5) years and a mean diabetes duration of 21.6 (SD 12.1) years. Of these participants, 73% (16/22) had a previous history of ulceration, 27% (6/22) had a previous history of amputation, and 14% (3/22) had a diagnosis of Charcot neuroarthropathy. Participant characteristics are summarized in Table 1.

Table 1. Interview participants (N=22)[a].

Characteristic	Values
Participant type, n (%)	
Patient	20 (91)
Carer	2 (9)
Gender identity, n (%)	
Man	13 (59)
Woman	8 (36)
Transgender	1 (5)
Patient age (years; n=20), n (%)	
36-45	1 (5)
46-55	3 (15)
56-65	2 (10)
66-75	8 (40)
76-85	6 (30)
Ethnicity, n (%)	
Asian (Indian, Pakistani, Bangladeshi, Chinese, or any other Asian background)	3 (14)
Black, African, or Caribbean	2 (9)
Mixed (2 or more ethnic groups)	1 (5)
White British	16 (73)
IMD[b] score, n (%)	
1	3 (14)
2	2 (9)
3	5 (23)
4	2 (9)
5	1 (5)
6	1 (5)
7	2 (9)
8	0 (0)
9	2 (9)
10	4 (18)
Housing, n (%)	
Living alone	9 (41)
Living with at least one other family member	13 (59)
Diabetes	
Type 1, n (%)	5 (23)
Type 2, n (%)	17 (77)
Duration (years), mean (SD)	21.6 (12.1)
Years since diabetes diagnosis (n=20), n (%)	
1-10	3 (15)
11-20	4 (20)
21-30	6 (30)
31-40	7 (35)

Characteristic	Values
Years since neuropathy diagnosis (n=20), n (%)	
1-10	11 (55)
11-20	4 (20)
21-30	3 (15)
Not sure	2 (10)
DFU[c], n (%)	
Previous ulcers	16 (73)
Amputation	6 (27)
Charcot neuroarthropathy	3 (14)
Perceived risk versus actual risk[d], n (%)	
Underestimation	7 (32)
Accurate estimation	9 (41)
Overestimation	3 (14)

[a]The demographics listed include those of the patients and carers except for the health-related data, which are only provided for patients.

[b]IMD: Index of Multiple Deprivation score—a relative measure of deprivation for a small geographic area (single postcode) in the United Kingdom. Scores range between 1 (most deprived) and 10 (least deprived).

[c]DFU: diabetic foot ulcer.

[d]Participants were asked whether they thought their risk of another ulcer was low, medium, or high, and this was compared with the risk levels on the National Institute for Health and Care Excellence guidelines informed by their self-reported presence of neuropathy and history of ulcers. Self-report of symptoms usually exceeds diagnosis, and participants were often unsure or in denial. Responses were vague. Where a range was given, an average was used; where the response was "at least x years," x was used.

A total of 6 Health and Care Professions Council–registered podiatrists were recruited. All currently worked in England (5/6, 83%) or Scotland (1/6, 17%), in the NHS (5/6, 83%), and academia (1/6, 17%). Participants had previous experience working in public and private health care systems as well as working overseas. Participants specialized in wound care (5/6, 83%) and musculoskeletal problems (1/6, 17%).

Thematic Analysis Findings

Overview

This section presents a thematic analysis of participant feedback on the design concept of this device. In total, 3 themes were developed: patient buy-in, effective engagement, and sustained use. Each theme is split into 2 subthemes, the first highlighting a contextual challenge and the second presenting participant preferences for the intervention related to that challenge.

On presentation of the design concept, many participants appeared surprised that such a technology might exist, with comments such as "it would be a revolution, if it could work" (P17). The subsequent disbelief yielded questions and doubts about the sensitivity of the device:

> *...you know, a beep every five minutes you're just gonna get plain fed up with it aren't you? And then if you don't find anything, you know your faith in the product is just going to diminish.* [P16]

This concern was understandably a pivotal factor for acceptability. As such, participants were asked to imagine using a device that was perfectly calibrated to them. The remainder of this section describes the themes in detail with quotations from participants.

Patient Buy-In

Lack of Awareness of Risk

Although most participants considered the idea of the sock to be interesting, participants who judged themselves to be at lower risk of ulceration or doubted that rubbing was a cause of foot injury for them needed more persuading:

> *Would I say I would go out and buy a pair of those socks? Not necessarily, because I don't think I need to.* [P8]

The device is designed to target loss of sensation caused by diabetic neuropathy, and yet this was a particularly challenging symptom for participants to make sense of and describe. In cases in which participants believed that they had sensation in their feet, the diagnosis of neuropathy could be more challenging to accept cognitively, whereas the association with loss or inadequacy could also be difficult to accept emotionally:

> *You lose sensitivity in your feet to different degrees, I mean as far as I'm concerned, I fail the medical test where they put a hair across your feet to designate if there's any feeling there, so I fail that, and I failed it for a long time, however in terms of if I stood on something, or if can I feel the pedals in the car, yes, I can.* [P8]

The podiatrist group also noted challenges with limited patient awareness and acceptance of risk—"they're in denial about a lot of things" (podiatrist 3)—and consequent issues engaging

these patients to actively participate in their foot health management:

> *...it's a cohort of patients who don't even do the basic kind of self-care stuff.* [Podiatrist 1]

Despite efforts to educate their patients in the clinic, they were aware that many of their patients struggled to follow the self-care instructions at home:

> *Essentially we're there to help them heal, but at the end of the day their foot is at the end of their leg and that goes home with them. And what happens in between appointments is obviously based on what they do.* [Podiatrist 4]

Ability to Collect and Record Evidence

Without the ability to physically perceive shear strain occurring, people with neuropathy would not normally have the information to understand and detect how, when, or why damage occurred. This created confusion and doubt in some participants, who were unsure of how to make sense of their ulcers. Participants from both groups (interviews and focus group) thought that the sock could help elucidate issues regarding shear strain, thus clarifying misconceptions and reinforcing clinical messaging. The following quote is one participant's response to being asked why their ulcers may have occurred:

> *I haven't got a clue. I feel that there hasn't been a common reason I've had these ulcers...There's no plausible reason for why it's happened. Anything that investigates that would be nice to know the results.* [P19]

Podiatrists thought that the sock could be useful in creating awareness and collecting information surrounding the time of alerts that would otherwise not be possible to obtain. Importantly, they felt that becoming aware of when the shear strain occurred might help patients (and clinicians) identify factors that could be controlled (eg, if it only happens at work when wearing steel-toe boots) and, ultimately, help the patient mitigate these risks themselves:

> *I would be thinking straight away what activity are they doing? Are they stationary? Are they, you know, walking along somewhere? Are they pottering around indoors? Because when is it rubbing? That's because that's the type of thing that I would ask in clinic, you know, with footwear. What were you doing?* [Podiatrist 6]

Lack of sensation limits not only the ability of patients to know what is happening with their feet in real time but also how they can communicate issues to others. Consequently, information that patients report in the clinic or at home is often not complete or reliable for the podiatrists or the carer to know how and when to proceed with treatment. Participants saw the sock as a tool that might improve care by providing objective, real-time information for feedback and reassurance to the wearer or health care provider. In this way, it could be used to raise awareness of safety as well as risk. At home, it could help with choosing new footwear or checking that they have effectively resolved a previous alert, and similarly, in clinical practice, it could be potentially useful when prescribing custom footwear or other offloading devices:

> *For me, I think it would be useful as an early warning and actually checking is my [clinical offloading] device doing what I think it's doing.* [Podiatrist 4]

Effective Engagement

Challenges Accepting and Actioning Information

While the idea of a smart sensing sock was generally accessible and acceptable to participants, when questioned further about how they would use the sock, more practical questions arose, particularly about how to respond to the alert, what to look for on the affected foot, and how to find and correct the cause of the shear strain:

> *What can you do? You're getting this information that's telling you there is rubbing taking place, and is likely to cause you a problem. So, guidance or suggestions is what has to come.* [P20; carer]

This reaction was fueled by limited understanding of foot ulcers, associated risk factors, or what could be done to prevent them. Even when there was adequate understanding, many participants faced multiple competing demands of family, community, or employment responsibilities and reflected on how this deprioritized their self-care:

> *It's difficult to prioritise yourself when you've got two children, you're working, you're trying to keep all the balls in the air. I don't think I prioritised my health enough.* [P7]

Sometimes, this competition for attention was exacerbated by the sheer amount of information that needed to be absorbed after their diabetes diagnosis. The seriousness of diabetic foot ulcers and their own risk of developing them might only have come to light at the time of a foot emergency, resulting in a steep learning curve and information overload:

> *It was a period in our lives where I'd got so much information. Trying to compartmentalise it all.* [P20; carer]

Participants noted that information about foot ulcers, and especially associated risk of amputation and threat to life, could be frightening. While some participants actively sought information and felt that it reinforced the importance and practice of self-care, others appeared to be more vulnerable to the information and preferred not to know:

> *...don't read up on it because it'll scare you to death.* [P4]

These participants recalled the loss of close family members because of foot problems or reflected on the fact that it was information that they could not identify with, assuming that it was something that happened to other people and would not affect them. Whether it was trauma, naivety, bravado, or turning a blind eye, the reality of their own susceptibility was difficult for them to accept:

> *It was the worst time of my life. It took me 18 months to go to hospital to get it done in the first place. I was an ex-footballer. I was a man who was proud, if you*

> *know what I mean. I shouldn't be losing my toe, even though what had happened. I just couldn't get it in my head.* [P17]

Simple, Specific, and Supportive Guides

Given the importance of underestimation of risk, lack of information, and social and emotional distractions to carrying out instructions, podiatrists recommended a clear and simple decision-making tool to accompany the device. They suggested step-by-step prompts to guide the patient to safely respond to an alert; assess damage; and, critically, know when to contact their foot health team:

> *It sounds like you're spoon feeding them, but sometimes it ends up being the case that you have to do that to prevent this...The time between a problem arising and how long something is done about it, within hours, diabetic feet can deteriorate, you can get a foot attack. So if that prompt is there like, "you need to check it right now" that would be really useful.* [Podiatrist 4]

In addition, lack of sensory information should also be addressed and supported. Both interview and focus group participants called for information in the feedback system to indicate the location of the shear strain as well as instructions on how to respond to rubbing in different areas:

> *You have to put yourself in their shoes. They don't actually feel, so if you or I were to get a bit of rubbing, we'd stop what we're doing and alternate our foot, or fix our shoe, tie our lace, because they can't feel they haven't a clue.* [Podiatrist 3]

Sustained Use

Difficulties Coping

While some were comfortable with monitoring their own health and reassured by taking measurements or recording data, others preferred to wait until clinic appointments, feeling that constant management created more, not less, anxiety. One participant who was skeptical about using the sock referred to health-monitoring devices as "worry-meters" (P5). This was a concern for the podiatrist group as well, who worried that challenges with patient engagement could be due to being overwhelmed and were hesitant to add more burden:

> *You just know there'll be patients that probably wouldn't want to have another thing to check—got to check the blood sugars, insulin like everything else. This is just another tool, but it's another thing to do as well, and sometimes people get kind of overwhelmed.* [Podiatrist 1]

As we can see from the previous subthemes, participants could start their diabetic neuropathy journey without awareness, acceptance, or understanding of their foot health risk. When they experienced foot ulcers, they were understandably unprepared, challenging their ability to cope. Narratives ranged from hopelessness, including misusing their insulin in attempts to die, to emphasizing their luck in life and downplaying the misfortune of their experiences. While the fortunate few who were happy with their medical care, confident in their own abilities to self-manage their condition, and supported by family felt that their symptoms did not dominate their lives, other participants felt that they had less control:

> *...it's [my foot health] totally entwined with the diabetes that really controls me, controls my feet, my eyes, all the other diabetic symptoms.* [P3]

Diabetic foot ulcers can escalate rapidly, and participants reported that the progression of their wounds was shocking. One participant did not even know he had diabetes until 5 days after he noticed a "small sore," when he was admitted to hospital for emergency amputation:

> *I was whisked up to some theatre or other, fully conscious—because I'd eaten. I couldn't have an epidural, so they put a needle down my leg. I was lying there, conscious—compos mentis. There was a screen up, so I couldn't see what he was doing, but I could hear it. He took four toes off, and a little bit of the foot. I signed up to the knee, because they keep going until they run out of the bad.* [P12]

Where there was pain associated with the ulcer and more obvious threat to life, amputation appeared easier to understand and accept; there could even be a sense of relief after treatment. Conversely, where neuropathy masked any pain, it was more difficult to perceive the severity of the wound, and consequently, amputation could be harder to cope with. Participants described having part of their body taken away with a sense of loss and grief:

> *The first one I was in pain and I wanted to get rid of it. The second one, I was in no pain, and it was unexpected. It's like someone dropping down dead; or someone dying slowly of cancer or something. That's the difference. That one was painful, and I wanted to get rid of it. I know it was for the better. That one, I was in no pain, and it was unexpected.* [P1]

Participants reported lasting emotional impacts of ulceration. This could be paranoia or hypervigilance, checking their feet multiple times a day. There could be feelings of guilt or regret for not taking better care beforehand. Where there was deformity or amputation, some participants noted shame in the appearance of their feet or in being classified as disabled. One of the hardest things to deal with for participants was a lack of independence:

> *I'm aware people make concessions for me...and psychologically that's horrible...I don't like it. I don't like being needy really.* [P16]

Participants reported doing what they could to manage their foot health based on their understanding and acceptance of risk factors and preventative measures. Even then, some still experienced repeated wounds and infections, often from what they considered an innocent cause, such as a small cut, a new shoe, or getting sand in between their toes on holiday. For some, there was a feeling of frustration that, whatever they tried, they could not stop it happening:

> *You get to the end of your tether and you think, "what? what? what can I do?"* [P4]

Gaining Control Through an Early Warning System

When speaking to participants, concerns about calibration and sensitivity were undermined by the positive possibilities of the sock. For those who recognized the risk of shear strain for themselves, if the sock was easy to use and provided reliable information, they felt that it would be more of a support than a burden. One participant said that it could be "another best friend" (P6) in the same way that she described other valued tools in her life, such as her mobile phone and well-fitted walking shoes.

Participants who reported using health devices such as continuous glucose monitors were already used to responding to alerts and appreciated the real-time feedback and prompt to take corrective action in the moment. They felt that the devices gave them more control over their health and related the sock to this same concept:

> *I guess I'm used to sort of reacting to information that I've received on, on the sort of shape of things during the course of the day. So this would just be another thing.* [P16]

One participant referred to the idea of an early warning system as providing "a level playing field" (P23) by compensating for lost sensation. Others felt that it could help in social situations, empowering them to speak up for themselves and take the breaks they needed rather than pushing on to keep up with others:

> *Especially being on your feet all day and you get busy, you get distracted. They would be great because then it would give me a bit of an alarm, so to speak, to say something's not right, and then I need to sit out.* [P4]

If these benefits outweighed the burden of using the sock as well as the burden of not using it, then it would help patients manage their foot health more easily:

> *Well, I think it's a good positive idea, but I don't think it's a game changer for diabetes. I think it's a useful addition, like fingerprinting is a useful addition. It doesn't make me better. It doesn't change my life. It just helps me manage the situation better...if they were available and they work and I'm not sending them off for dry cleaning every day or, you know, that sort of thing, if the process was hard in living terms, then that would put you off. I'm sorry to give you the extra problem, but they need to fit into an ordinary sort of life, you know.* [P16]

Discussion

Summary and Comparison With Other Work

This is the first qualitative study to explore patient and podiatrist perceptions of a smart sensing device to measure shear strain for the prevention of diabetic foot ulcers. The findings suggest that potential users welcome the idea of such a device but that the experience of living with diabetic neuropathy presents several barriers to uptake and sustained effective engagement, namely, limited awareness of risk among patients and family caregivers, psychosocial challenges accepting health information and actioning health behaviors, and the emotional burdens of living with diabetic neuropathy. These barriers suggest that, for the device to be effective in improving health outcomes for this population, it should be implemented alongside a behavioral intervention.

There is limited research in this area, and our findings confirm those of the few other qualitative studies looking at patient experience of diabetic foot ulcers [33], treatment burden in long-term conditions [34], patient and podiatrist perspectives of other smart sensing wearable devices for diabetic foot ulcers [35-37], and behavioral understandings of the impacts of emotional burden on self-care behaviors [38,39]. A key novel finding of this study was that, unlike plantar pressure, which is often caused by inactivity (eg, the foot being in a single loading position for an extended period), participants considered alerts for shear strain to be associated with a different cause (ie, from a certain activity or incorrectly fitting footwear) and, consequently, that alerts would signal the need to assess and address the cause rather than simply to offload. It was not always obvious to patients how to appropriately respond to an alert for shear strain, and therefore, any future device would need to clarify the responses required. Research into smart sensing wearables for plantar pressure has found that a minimum number of alerts (1 every 2 hours) is required for optimum response [40], whereas this study suggests that, for shear strain, if the alerts are perceived as too frequent and there is no clear resolvable issue in the footwear or visible indication of rubbing on the foot (eg, redness), there is a risk that participants will assume the device to be faulty.

In addition to identifying barriers to uptake of and engagement with a smart sensing device, the findings also present potential solutions to these barriers through participant-identified adaptations to the device and its implementation. These highlight novel patient and podiatrist priorities and include using the sock to collect evidence to support clinical messaging and patient understanding of shear strain and ulceration, providing a simple decision-making tool to guide safe self-care and response to alerts, and supporting the normalization of health-monitoring behaviors to increase self-efficacy and self-advocacy regarding foot health. To further these learnings, we curated a set of guiding principles [27] derived from the outcomes of this study to support the future development of smart sensing devices for diabetic foot ulcers (Multimedia Appendix 4 [6,8,16,35-55]). These guiding principles draw on data-driven findings supported by evidence from the wider literature on this patient population and similar devices to identify key intervention features to address identified psychosocial barriers to uptake and engagement. This provision of principles addresses an urgent need to provide behaviorally informed guidance to this emerging field of smart sensing technology for diabetic foot ulcers [24]. These findings may apply to other devices that measure shear strain and be relevant to smart sensing devices for diabetic foot health more generally, and it is hoped that publishing these principles will help guide further optimization of diabetic foot health devices and the implementation of devices into standard care.

Strengths and Limitations

The impacts of social determinants of health on individuals with diabetic neuropathy are acknowledged but not well understood [56,57] and should be considered from the outset of the research process to maximize inclusivity [58]. The strengths of this study include that people with diabetes were involved in all stages of the study, patient and podiatrist participants were purposively sampled to ensure heterogeneity of perspectives (good representation was achieved in terms of gender identity, race, age, professional experience, and patient risk factors), data collection explored feedback on the technology in the context of lived experience of diabetic foot health, and the analysis was led by a multidisciplinary team of researchers. This approach, using multidisciplinary co-design for device development and implementation and acknowledgment of contextual influences, is critical to facilitate a device to function as a clinically integrated self-care tool for prevention of diabetic foot ulcers [55]. Future research can build on the findings and guiding principles presented in this study to develop a prototype for the device and wider intervention, including supportive materials for patients, carers, and health care professionals. These supportive materials can be tested, iterated, and optimized alongside the development of the device itself. It is critical that this process continues with a focus on diversity and inclusion.

Future research can also learn from the limitations of this study. As is typical of qualitative research, participants were self-selected and, therefore, represent a portion of the population who, by their interest in taking part in research, may be more engaged in health care than those who did not respond to the invitation. Several of these patients did reflect on the fact that they had not always been so engaged and, thus, provided insights into issues that might otherwise not have been included. Participants recruited through NHS clinics were prescreened as being at high risk of diabetic foot ulcers, whereas another recruitment stream used could only prescreen by diagnosis of diabetes. All interested participants were further screened by a nonclinical research member using questions guided by author IY, who is a podiatrist. Therefore, inclusion in the study was ultimately based on their self-report of diabetic neuropathy, which is likely less reliable than clinical screening, but their diagnosis was confirmed through clinically informed screening and the narratives of their interviews, and using different recruitment streams actually helped achieve a broad sample of patients with a range of ulcer histories and experiences.

Conclusions

This qualitative study explored patient and health care provider feedback on a novel smart sensing wearable technology (a sock and feedback system to detect and alert to shear strain) for the prevention of diabetic foot ulcers. The findings suggest that potential users welcome the idea of such a device but that the experience of living with diabetic neuropathy presents several barriers to uptake and sustained effective engagement, namely, limited awareness of risk among patients and family caregivers, psychosocial challenges accepting health information and actioning health behaviors, and the emotional burdens of living with diabetic neuropathy. This study also identified potential solutions to these barriers to improve device uptake, engagement, and sustained use. These include using the sock to collect evidence to support clinical messaging and patient understanding of shear strain and ulceration, providing a simple decision-making tool to guide safe self-care and response to alerts, and supporting the normalization of health-monitoring behaviors to increase self-efficacy and self-advocacy regarding foot health. These suggest that the device should be considered as a tool within a wider behavioral intervention designed to support self-management behaviors, for example, through specific framing of feedback messages and instructions to improve risk appraisal and build self-efficacy and by supporting health care professionals to introduce and use the device as part of their practice. A set of guiding principles was presented to support future research on device design that addresses the contextual barriers to successful uptake and long-term effective engagement identified in this study.

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Data Availability

The datasets generated during this study are not publicly available to protect the identities of the participants but are available from the corresponding author on reasonable request.

Authors' Contributions

NDR, KB, PC, and IY contributed to the conceptualization of and funding acquisition for this study. This study was visualized by JC, KB, and IY. Methodology was designed by JC and KB. Project administration, formal analysis, and original write-up were conducted by JC with supervision from KB and IY. The findings were validated by PB, EW, RL, and GP, and all authors contributed to reviewing and editing the manuscript.

Conflicts of Interest

None declared.

Multimedia Appendix 1
Semistructured interview guide.
[DOCX File , 17 KB - jopm_v17i1e59608_app1.docx]

Multimedia Appendix 2
Sock design features.
[DOCX File , 711 KB - jopm_v17i1e59608_app2.docx]

Multimedia Appendix 3
COREQ (Consolidated Criteria for Reporting Qualitative Research) checklist.
[DOCX File , 22 KB - jopm_v17i1e59608_app3.docx]

Multimedia Appendix 4
Guiding principles.
[DOCX File , 28 KB - jopm_v17i1e59608_app4.docx]

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Abbreviations

COREQ: Consolidated Criteria for Reporting Qualitative Research
NHS: National Health Service
PPIE: patient and public inclusion and engagement

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Original Paper

Development of an Online Scenario-Based Tool to Enable Research Participation and Public Engagement in Cystic Fibrosis Newborn Screening: Mixed Methods Study

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Abstract

Background: Newborn screening aims to identify babies affected by rare but serious genetic conditions. As technology advances, there is the potential to expand the newborn screening program following evaluation of the likely benefits and drawbacks. To inform these decisions, it is important to consider the family experience of screening and the views of the public. Engaging in public dialogue can be difficult. The conditions, screening processes, and associated moral and ethical considerations are complex.

Objective: This study aims to develop a stand-alone online resource to enable a range of stakeholders to understand whether and how next-generation sequencing should be incorporated into the CF screening algorithm.

Methods: Around 4 development workshops with policymakers, parents, and other stakeholders informed the design of an interactive activity, including the structure, content, and questions posed. Stakeholders were recruited to take part in the development workshops via purposeful and snowball sampling methods to achieve a diversity of views across roles and organizations, with email invitations sent to representative individuals with lived, clinical, and academic experience related to CF and screening. Ten stakeholders informed the development process including those with lived experience of CF (2/10, 20%), clinicians (2/10, 20%), and representatives from relevant government, charity, and research organizations (6/10, 60%). Vignettes constructed using interview data and translated into scripts were recorded to provide short films to represent and provoke consideration of families' experiences. Participants were recruited (n=6, adults older than 18 years) to test the resulting resource. Study advertisements were circulated via physical posters and digital newsletters to recruit participants who self-identified as having a reading difficulty or having English as a second language.

Results: An open access online resource, "Cystic Fibrosis Newborn Screening: You Decide," was developed and usability and acceptability tested to provide the "user" (eg, a parent, the general public, or a health care professional) with an interactive scenario-based presentation of the potential outcomes of extended genetic testing, allowing them to visualize the impact on families. This included a learning workbook that explains key concepts and processes. The resulting tool facilitates public engagement with and understanding of complex genetic and screening concepts.

Conclusions: Online resources such as the one developed during this work have the potential to help people form considered views and facilitate access to the perspectives of parents and the wider public on genetic testing. These may be otherwise difficult to obtain but are of importance to health care professionals and policymakers.

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KEYWORDS

extended genetic testing; next-generation sequencing; cystic fibrosis; decision-making; engagement

Introduction

Background

In the United Kingdom, every baby aged 5 days is offered newborn screening (the "heel-prick" test) for 10 rare but serious conditions [1,2]. The screening program aims to identify babies affected by genetic or congenital conditions before symptoms emerge in order to achieve the best outcomes through early treatment [1]. Screening in the United Kingdom is encouraged as a public health initiative [3], but it is an informed choice by parents who can decline it for their baby [1].

Newborn Screening in the United Kingdom for Cystic Fibrosis

Overview

Each year in the United Kingdom, around 1 in every 200 babies will receive a positive newborn screening result for cystic fibrosis (CF) using first-tier biochemical testing. This result will initiate further diagnostic testing, including genetic testing, and around 250 will be found to have CF, 200 will be identified as "probable carriers" (which means they have one variant of the CF transmembrane conductance regulator gene responsible for CF), and approximately 25 children will receive an inconclusive outcome. This inconclusive outcome has been termed CF transmembrane conductance regulator (CFTR) related metabolic syndrome (CRMS) or CF screen positive, inconclusive diagnosis (CRMS or CFSPID) [4]. Children with CRMS or CFSPID have either a normal sweat chloride (<30 mmol/L) and two CFTR variants (at least one of which has unclear phenotypic consequences) or an intermediate sweat chloride value (30-59 mmol/L) and one or no CFTR variants [5,6]. Some of these children will go on to develop CF or a CFTR-related disorder, but most will remain well.

The current CF screening algorithm includes up to 50 of the most common gene variants associated with CF in the United Kingdom [7] and this detects most cases (about 97%) of CF. However, wider genetic testing of the CFTR gene would potentially allow more (several hundred) CF-causing CFTR gene variants to be identified [8,9]. Therefore, the use of extended genetic testing (next-generation sequencing [NGS]) is currently under consideration in the United Kingdom.

Potential Harms and Benefits of Incorporating Next-Generation Sequencing Into the CF Newborn Screening Algorithm

NGS could potentially increase the correct identification of CF (true positives) and therefore the number of children who would benefit from early treatment [10,11] and reduce the number of repeated bloodspot tests required compared with the current diagnostic pathway [12]. However, depending on how the testing is implemented, it could also have an impact on the number of inconclusive (CRMS or CFSPID) or missed results. Inconclusive results may lead to more diagnostic uncertainty; parents may be left unclear of how their child may be affected, and this may present interpretive dilemmas for clinicians [13]. A missed result is where the condition is missed through screening but later emerges through the presentation of symptoms (also termed a false negative) [14].

Specificity Versus Sensitivity

The United Kingdom National Screening Committee uses measures of "specificity" and "sensitivity" to help them decide how well screening works in a population [15]. Sensitivity refers to the test's ability to correctly identify a baby with CF. A sensitive test will rarely miss babies with CF. Specificity is the test's ability to correctly exclude a baby without CF. A highly specific test is more selective for variants that are known to cause CF, which means that there are few false positives (where babies are incorrectly thought to have the condition) or inconclusive results.

A specific approach to NGS for CF may mean missing a small number of babies with true CF (up to 10 per year in the United Kingdom; this includes those already missed [5 or 6 per year]). It would also reduce the number of babies given a designation of CRMS or CFSPID from 25 to around 5 per year. If a sensitive approach to NGS for CF were used, it might avoid missing additional babies with true CF but lead to the detection of more cases of CRMS or CFSPID (from 25 to 80 per year).

Decision-Making Around NGS

The parental experience of the screening process and receiving results is a particular concern for the development and operation of screening programs [16,17]. Parental confusion or anxiety about the implementation of NGS could lead to a reduction in newborn screening participation, resulting in treatable conditions going undetected. Parents need to have adequate information and understanding to consent to screening and understand the potential long-term implications of the results [10]. As well as the implications of positive results, the period of confirmatory testing following a positive screen can cause significant anxiety for the families as they wait for results [18,19] with potential impact upon family relationships, parental depression, and ongoing relationships with health care professionals (HCPs) [18-20]. The adoption of NGS could lead to knowledge that causes additional anxiety and has implications for the wider family's health and reproductive decision-making [10]. Therefore, the use of NGS has prompted a range of concerns [21] and before the implementation of such advances, the impact on families should be considered [22]. Support from the public, and especially parents, is critical if extended genetic testing is to be successfully integrated into newborn screening [10].

Decision-making in the context of expanded screening and the use of genetic testing is complex. There are a range of considerations for policymakers weighing the advantages and disadvantages. Stakeholders engaging in the consideration of

new screening programs have a range of technical, medical, legal, economic, ethical, psychological, and sociological concerns [21] to consider alongside the families' experiences of screening, as well as the views of the public. Similarly, HCPs supporting the delivery of screening programs and interacting with parents as they reach a screening decision for their child also have complex information to relay and process. It is argued here that it is important to further explore and develop the ways in which screening information, including the benefits and potential disbenefits, is communicated to and understood by families and the wider public.

Developing Online Tools

The use of online tools may offer a solution to relaying complex genetic information to families to aid their decision-making. There has been a global proliferation of digital health and online applications to address a range of health-related needs including training and education, condition management, health care records, disease screening, diagnosis, and monitoring [23]. As well as technology designed for specific conditions and condition management, users expect to access health information online to inform their understanding and decision-making, predict a prognosis, and cope with illness [24-26]. Parents are no different in their use of the internet to search for information about their child's health and guide their health-related decisions [26]. There are limited online tools related to newborn screening, with the most comprehensive and reliable sources being those provided by the National Health Service (NHS) to support parental decision-making about screening for their child, rather than considering wider policy questions.

The research team has led and delivered a range of research projects exploring parental experiences of newborn screening, as well as research considering stakeholder perspectives on the potential expansion of screening programs [27-37]. We have found that due to the nature of the inherited conditions and the complexity of the screening process, communicating the potential outcomes of screening and their implications during the research process, consultation, and public engagement activity is challenging [38]. However, within the context of newborn screening, without end-user engagement, we may constrain the desired outcomes of the screening programs as well as the information sources developed to support them [39-41].

Understanding the benefits and potential disbenefits of different approaches to screening can be complex for several reasons. The way screening programs are evaluated is complex and involves measuring concepts some stakeholders are unlikely to have engaged with before. Also, the conditions screened for are rare, meaning the general public may not have heard of them. This makes them less likely to engage in research or stakeholder engagement around them [42,43]. Finally, newborn screening consent processes are often less than desirable and not recognized as a choice [44], which can mean the general public does not see the relevance or engage in research around it.

It is argued here that to make the information accessible and understandable, there are elements and techniques from storytelling and aspects of game design that can be applied. For example, scenario-based approaches and storytelling, and encouraging game-like behaviors (such as interaction and learning) in order to build engagement and motivate the user [45,46]. A previous project demonstrated the difficulties of engaging the public with research exploring the views and experiences of people with genetic conditions and highlighted the need for innovation and creativity in this area [47]. The approach taken here seeks to develop knowledge, facilitate critical thinking, and build empathy with the experiences of families, as well as interest and confidence in complex concepts and scenarios [48-51]. The study, therefore, adopted a game-based intervention development process [52] and a storytelling approach using scenario-based narratives [51] to encourage interaction and sufficient understanding to inform decision-making.

Goal of the Work

We aimed to consider a new approach to engage and consult with stakeholders. We sought to develop a stand-alone resource to enable a range of stakeholders to understand and consider the question "How should NGS be incorporated into the CF screening algorithm?"

Methods

Overview

We sought to develop an online tool to facilitate clinical and stakeholder consultations related to newborn screening. To develop an effective tool, an iterative user-centered development process was adopted, informed by principles from games research and interdisciplinary approaches to building an online narrative interaction [51]. User-centered design draws on research and understanding across a range of disciplines to center the design of innovation (eg, products, software systems, educational resources, service delivery, and so on) around the knowledge and understanding of those that will use it, in order to optimize ease of use, effectiveness, efficiency, and satisfaction [53-55]. The development of the tool was informed by collaboration with a range of stakeholders and built upon previous research undertaken with parents and HCPs [27,38,56,57].

Recruitment

Stakeholder Group

Stakeholders were recruited via purposeful and snowball sampling methods to achieve a diversity of views across roles and organizations. Email invitations were sent to representatives from the European CF Society, newborn screening laboratories, NHS England, consultant pediatricians specializing in CF, the NHS Newborn Blood Spot Screening Program, Genomics England, CF Clinical Nurse Specialists, the Cystic Fibrosis Trust, individuals with lived experience of CF either personally or as a parent, and academic experts in newborn bloodspot screening (NBS) and medical ethics. This approach ensured that the development of the tool was informed by both direct and indirect knowledge of a range of different family experiences of NBS. Members formed an oversight group that provided input and feedback on development.

Testers as Potential Users

In addition to the stakeholder groups, participants were recruited to test the resulting tool. Study advertisements were circulated via physical posters and digital newsletters, as well as via a social enterprise and Coventry University support structures for academic writing and English as a second language. Participants were offered a US $25 shopping voucher to thank them for their time.

Iterative Codevelopment of the Online Scenario-Based Tool

The stages through which stakeholders were involved in the codevelopment of the tool are given in Table 1. Initially, concept development workshops were undertaken to scope out the purpose of the tool and the requirements of the various stakeholders. This was followed by the development of filmed scenarios, written content within an interactive workbook, and an online tool. These were further developed and refined based on feedback from stakeholders and the group of user testers.

Table 1. Stages of stakeholder involvement and codevelopment.

Stages of development	Roles and involvement in the development process	Purpose of the development activities
About 2 concept development workshops	• Research team plus stakeholder group members from the CF Trust • Research team with 6 members of the stakeholder group (3 from NHS England, 1 pediatrician, and 1 pediatric nurse)	• Determine the scope of the system and decisions to enable via the system • Define stakeholder requirements for the system • Highlight any challenging concepts that may need support with additional information
Initial ideas and content development	• Research team activity	• Based on the scope defined in the workshops, the academic team selected suitable interviews to illustrate the scenarios and form vignettes
Development of the site structure	• Research and technical team activity • Workshop session with academic team	• Refine system requirements • Develop the structure of the system on paper • Test structure with the research team
Script and workbook development	• Research and video production team	• Iteratively developed vignettes into scripts • Develop supporting workbook content to provide additional information • Review and revise the full draft of scripts and workbook by the research and production team • Further drafts reviewed through 1:1 meetings with pediatric nurses and meetings with National Health Service - England
Script and website structure review	• Research team and stakeholder group (2 National Health Service - England, pediatric consultant, pediatric nurses, and 3 academic specialists)	• Review the script in advance of a facilitated workshop session to identify issues, refine the messaging, and add contextual details
Script and workbook finalized and signed off	• The research and production team revised the script based on the feedback • Script signed off by the • stakeholder group	• Final script reviewed by a wider stakeholder group by email and agreement sought that filming could commence
Filming	• Research and production team • A health care professional (child nurse) was present to guide the accuracy of the clinical experience and interactions	• Actors receive the scripts • Around 4 days before recording, a read through was held via an online meeting • The scenes were recorded with professional actors in health and home simulation facilities
Film production	• Production team	• Films were recorded, edited, and produced • Films were edited following feedback from the research team
Development of the digital tool and interactive activity	• Technical team	• Creation of structure of the digital tool within WordPress • Developed interactive workbook • Several iterations based on feedback from the research team to improve structure and usability • Test sheets logged the usability issues and agreed actions to resolve
Oversight group review of the films	• Workshop with stakeholder group	• Review of the videos to ensure clinical accuracy and appropriate representation within an NHS context via a workshop • Revisions to the videos based on the feedback • Videos inserted into the digital tool
Final review of the digital tool and interactive activity	• Stakeholder consultation	• Stakeholder group reviewed the digital tool, particularly the questions being asked via the polls or survey element
Launch of the digital tool	• Technical team	• Digital tool and interactive activity made available as open access
Review of digital tool accessibility	• Research team with testers as potential users	• Readability and acceptability testing by potential users to improve accessibility

Development Workshops

As outlined in Table 1, a series of 4 workshops were undertaken to inform the iterative development. The number of participants varied per workshop, but across the 4 workshops, there was representation from the European CF Society, newborn screening laboratories, NHS England, a consultant pediatrician specializing in CF, NHS Newborn Blood Spot Screening Program, Genomics England, a Clinical Nurse Specialist, the Cystic Fibrosis Trust, individuals with lived experience of CF either personally or as a parent, and academic experts in NBS and medical ethics. The workshops aimed to ensure that the tool remained focused on the key issues and questions we wished to ask, provided suitable messaging, represented NHS best practices, and also reflected parents' actual experiences with newborn screening.

Development of the Tool

Acknowledging the development challenges of creating an effective digital tool, production guidance was applied from the transdisciplinary methodology of game-based intervention design [52], and the development process was managed over 3 cycles: preproduction, production, and postproduction. Technical development quality considerations were observed from the standards outlined in the CISQ Quality Characteristic Measures of Software Coding Standards [58]. As outlined in Table 1, the structure of the digital tool and interactive workbook was initially developed by the technical team and iterated based on feedback from the research team. The stakeholder group tested and provided feedback on the individual elements (eg, videos and other interactive elements) during both workshop sessions and 1:1 reviews. They also provided a final review and approved the digital tool and interactive activity.

Usability and Acceptability Testing

The final prototype was usability and acceptability tested via walkthroughs of the tool. Data collection involved either an online or face-to-face session that lasted between one and two hours. Participants walked through the website at their own pace and navigated through it "naturally." After exploring each page, participants were encouraged to give both positive and critical feedback. They were guided by a series of usability and readability prompts based on readability assessment tools (Suitability Assessment of Materials, Comprehensibility Assessment of Materials [59], the Health Literacy Index [60], and key usability principles [61]). The sessions were recorded (video and audio) and transcribed.

Ethical Considerations

The research was approved by the Coventry University Ethics Committee (P149430 and P133880). All participants consented to their involvement. Data were pseudonymised. Participants did not receive compensation for their involvement.

Results

Sample

A total of 10 (N) stakeholders took part in the development process, including those with lived experience of CF (2/10, 20%), clinicians (2/10, 20%), and representatives from relevant government, charity, and research organizations (6/10, 60%). Everyone that was approached agreed to take part.

A total of 16 people responded to the call for participation, who self-identified as having a reading difficulty or having English as a second language to test the resulting tool. Among them, 9 adults either dropped out or did not respond to follow-up emails, and 1 did not meet the inclusion criteria as they had significant previous knowledge or experience of CF. In the end, 6 adults (older than 18 years of age) were recruited to test the resulting tool.

The Concept and Focus

The development process enabled the definition of an online tool that would (1) explain to the general public 2 different ways NGS could be incorporated into the CF screening algorithm in the future (sensitive or specific approaches), (2) allow us to collect public and stakeholder views on these 2 different ways of implementing NGS to inform policy decisions and research, and (3) demonstrate that the public can engage and contribute to very specific and complex issues in health care when given appropriate information and tools.

The 4 development workshops enabled the exploration of the implications of NGS [38,56,57]. It was decided that the interactive tool would focus on the question: "How should NGS be used when screening babies for cystic fibrosis?"

It was agreed that the online format would enable wider and more geographically distributed public views to be considered. In previous research, the team developed short PowerPoint presentations to explain newborn screening concepts to participants and collected views through interviews and workshops [38,56,57]. An online tool would enable the team to explain complex concepts more effectively and potentially enable data collection on a larger scale.

The tool focused on understanding public views on whether a "sensitive" or "specific" approach should be adopted if NGS were to be incorporated into the CF screening algorithm. An outcome of the workshops (and informed by the games-based approach) was the decision that the potential impact of the 2 different approaches (sensitive and specific) would be explored through the use of video-based storytelling to bring the concepts to life and build empathy with family experiences.

Having established the potential implications of the specific and sensitive tests we sought to represent and tell the family experience through 4 scenarios:

- Scenario 1: A "not suspected" or "normal screening result": In this scenario, it is unlikely that the baby has CF. The screening outcome is normal and no additional follow-up is required. The vast majority of babies will have a "not suspected" or "normal newborn screening result" and these families will be notified about their baby's normal test results by 6 weeks of age.
- Scenario 2: CFSPID: Sometimes, newborn screening results suggest that a baby could have CF, but the baby is healthy and follow-up tests do not confirm CF but rather indicate an inconclusive sweat test result and the baby is described by a designation CRMS or CFSPID. Most children with

CRMS or CFSPID will remain well, and their health will not be affected by this result, while a small number may go on to develop CF or a CF-related disorder.

- Scenario 3: Missed CF: Babies with a normal NBS result sometimes turn out to have CF. This is known as a "false negative" or "missed" CF result. These cases are usually identified after a baby or child presents with physical symptoms of the condition and further investigations are carried out. All screening programs can produce false negative results, although efforts are made to minimize them and ensure babies are identified and treated as soon as possible.
- Scenario 4: True positive, CF confirmed: A small number of babies will have a positive screening result for CF (about 1 in every 3000 babies screened). These results are communicated to parents by a specialist HCP within a few days of becoming available so that the baby can be assessed quickly and, if needed, start treatment. Follow-up tests (such as a sweat test) will be performed to determine if the baby has CF.

Representing the Family Experience

To ensure accurate representation of family experiences, it was agreed to use anonymized data previously collected from parents about their screening experiences [27,62]. Vignettes were constructed using interview data based on interviews with 16 participants (parents) who had experienced a positive CF NBS result; 6 were parents to a child with CF, 3 were carrier parents, and 7 were parents to a child with CFSPID to represent each different scenario. We also sought to show varying emotions over time as the diagnoses unfolded for families. These were then formed into scripts by the research team guided by a producer. The interview transcripts were iteratively developed by the research team and the media producer into production scripts. We brought together stakeholders with different perspectives (ie, from different roles and organizations) who have worked with families with a wide range of experiences to inform the development of the scenarios. Stakeholder feedback was sought after each iteration, and this led to changes that ensured accuracy in terms of the screening pathway and clinical information as well as portraying an authentic parent experience in the media content.

Filming and Production

Once approved the scripts were translated into a production plan for the 4 scenarios, and research into location, casting, costume, and clinical props was undertaken. The main roles for each film were cast through a talent management agency. Actors' profiles were screened and selected in light of their past acting experience as well as their age and image for their suitability within each role. The actors playing the parental roles were selected in line with our interview sample and data [27] and the 2023 UK CF Registry Annual Data Report [63], which indicates only 5.4% of the UK CF population are of non-White or mixed ethnicity. Diversity of representation was considered through the casting of non-White actors to portray HCP roles and variation in the presented family dynamics (eg, inclusion of an older father, regional accents, and a single-parent family). Additional clinical roles with little to no dialogue were assigned to stakeholders, colleagues, and crew due to budget limitations.

Costumes and the relevant clinical props were sourced through the lead university and from clinical stakeholders. The locations for the filming were chosen to not only provide a suitable range of clinical settings that would reflect those used throughout the screening process but also to cater to each family's home setting. The Faculty of Health and Life Sciences Facility at Coventry University incorporates a range of simulation facilities including hospital wards and consulting rooms, as well as 2 mock houses built for student training that could be repurposed for each of the family homes.

The 4 scenarios were filmed within a 3-day period to meet constraints around actor, stakeholder (on set as advisors), and location availability. This approach required 2 film crews totaling 8 production operatives to work in parallel during the first day of production and a single film crew of 4 production operatives on the second day. The filmed scenarios were edited into a reflective narrative for each short film. Many hours of filmed content were reduced into short narrative dialogues of no more than 5 minutes in length to allow for online delivery within the interactive activity.

During the rough-cut stages of postproduction, the initially edited sequences were reviewed by the stakeholder community and were assessed based on the realism of the actor's delivery, focusing on their emotional journey as well as the clinical accuracy portrayed. Several iterations were produced and reviewed during the processes until the content was approved for use in the interactive activity, at which point a final cut was produced for each of the 3 films where the audio was enhanced and the images were color graded to reflect the emotion of each parent's journey through newborn screening.

In parallel to the production of the films, the development of the online digital tool commenced.

Preproduction Considerations

The hosting service "Domain of One's Own" [52,58,64] was chosen as a cost-effective and easily accessible web hosting platform with access to more than 100 open-source applications. WordPress [65] was chosen from the open-source applications as it provides a number of built-in tools and features, such as prebuilt website themes, infrastructure security, automatic backup, and a large catalog of free-to-use plugins for customization and user-experience design. The Elementor (Elementor Ltd) plugin, for example, supports a "drag and drop" responsive approach to creating and editing websites. This add-on supported customization of the website layout, theme, and structure, and minimized development time. With minimum coding required, the development team could quickly build and test content sections to test the user journey and flow through the website. This supported an iterative design and development cycle, in which both the website infrastructure and delivery of the content could be modified quickly. Due to the complexity of the proposed content, it could be packaged into sections and appointed pages, allowing the user autonomy in deciding what content and information was relevant to their needs.

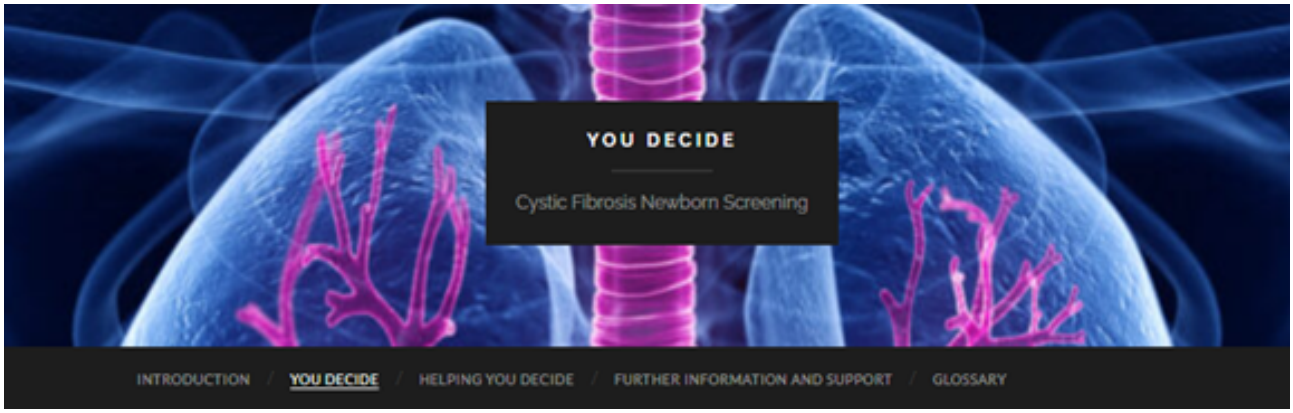
Production Considerations

An architectural map of the website structure was codeveloped with the stakeholder group. The mapping activity aided an analog approach to planning the user's interaction and experience. It helped prioritize content, which was ordered into either essential or supplementary information, informing the design, layout, naming, and signposting within the website's structure.

Layout and Content

The layout of the online tool is available on the CF Newborn Screening: You Decide website [66]. It is comprised of 5 sections as given in Figure 1. An introduction section explains the purpose of the site. The "You Decide" section contains the question for the user to consider alongside the 4 filmed experience scenarios, as well as a survey link enabling the capture of the user's view on the question: "How should NGS be used when screening newborn babies for cystic fibrosis?" An interactive workbook is provided on the "Helping You Decide" page. It is recommended that the user reads the information and plays through all of the videos before sharing their views via the survey link. The activity takes approximately 40 minutes to complete.

Figure 1. Cystic fibrosis newborn screening: you decide site structure.



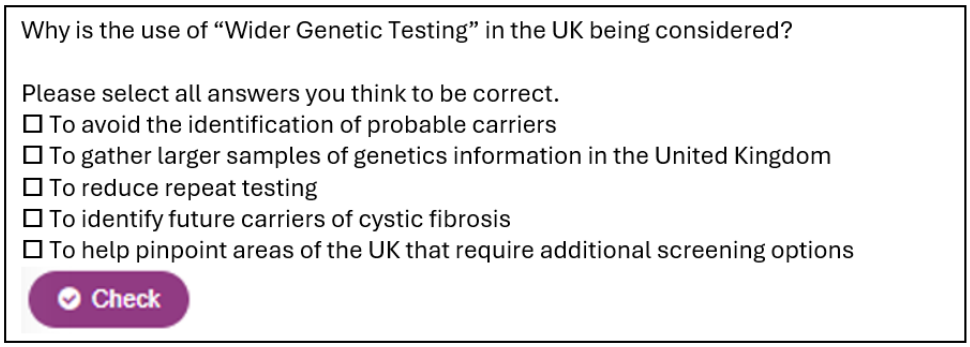
Presentation of Filmed Scenarios

Using the Elementor plugin, each video scenario was laid out in an order to view. The video scenarios were labeled and displayed using a visual template to show the viewing order and progression to the next scenario. Audio, caption support, and control features (such as pause, fast forward, backward, skip, and replay) were added to each video playback template for user access and control over the information being presented.

Interactive Workbook

During the development, stakeholders agreed that, as well as the filmed scenarios, further information would be beneficial for users. The resulting "Helping You Decide" section contains background information about CF, newborn screening, screening test outcomes, genetic testing, and specific versus sensitive tests. The user is encouraged to familiarize themselves with the interactive workbook content to enable an informed decision, but it is possible to skip through the sections depending on what the user may already know or choose to explore. There is also a glossary of key terms for reference. The interactive workbook was developed using the HTML 5 package plugin to present information in selectable and skippable sections. To encourage user engagement and interaction with the workbook content, gamified interactive elements were used, including multiple-choice quiz formats, memory games, flashcards, drag-and-drop elements, and interactive images (Figure 2).

Figure 2. Example of a question to encourage user engagement with the workbook content.



Capturing Views

With the aim of facilitating public engagement and capturing their views, polls and a survey were embedded within the tool. As the user works through the filmed scenarios, they are asked to complete the polls prompting their immediate responses to each of the filmed scenarios (Figure 3). The "Poll Maker" plugin was embedded to create these online polls. It was recognized

the user's view may change as they go through the experiences, and assimilate more information.

Once the user has watched all 4 experiences, they are asked to share their final decision via the "My Decision" survey (Figure 4). This final decision question is situated within an online survey software (JISC Online Surveys). Currently, the polls, surveys, and interactive elements are anonymous and do not collect any identifying data from those responding, but the use of online survey software enables the addition of informed consent processes, if required, for data retention, analysis, and use, as well as the collection of additional demographic information (if required).

Figure 3. Example of a question to prompt immediate reflections after watching a filmed scenario. CFSPID: cystic fibrosis screen positive, inconclusive diagnosis.

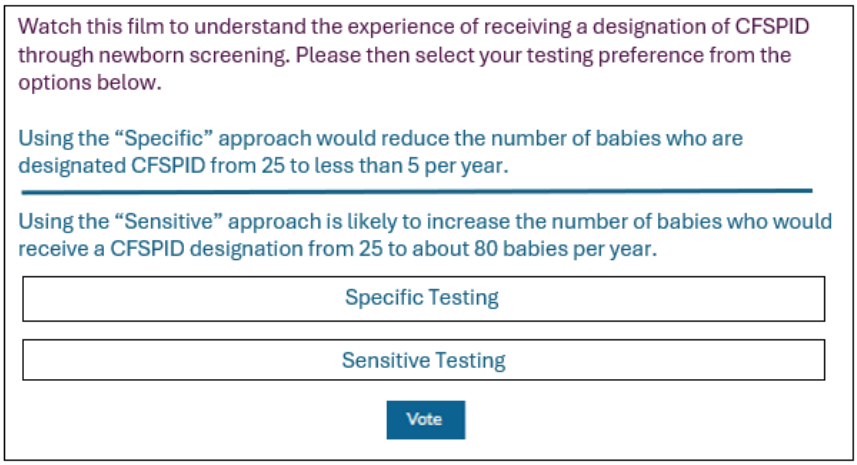
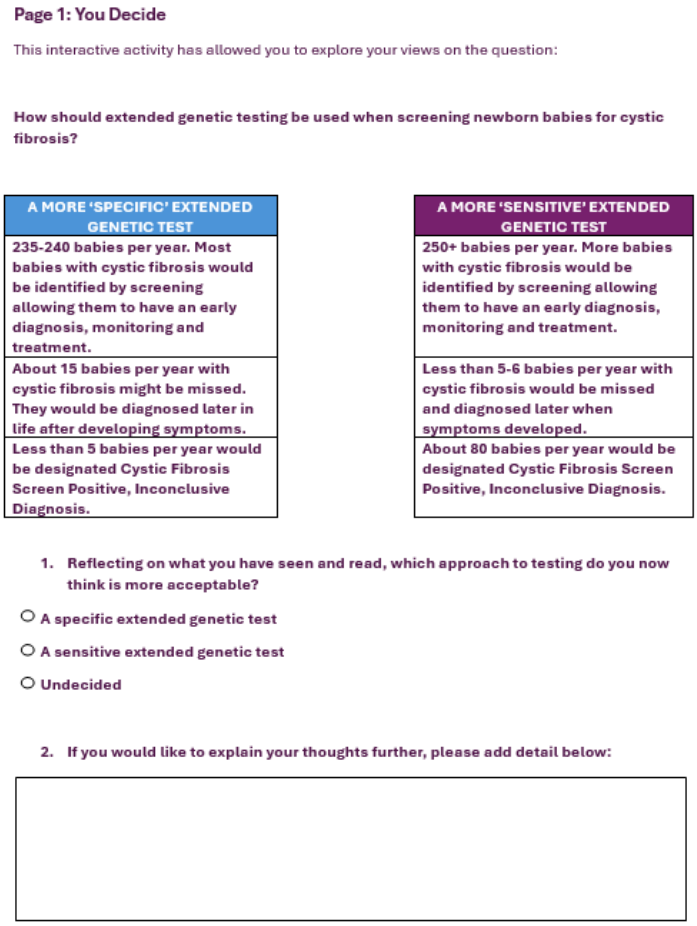


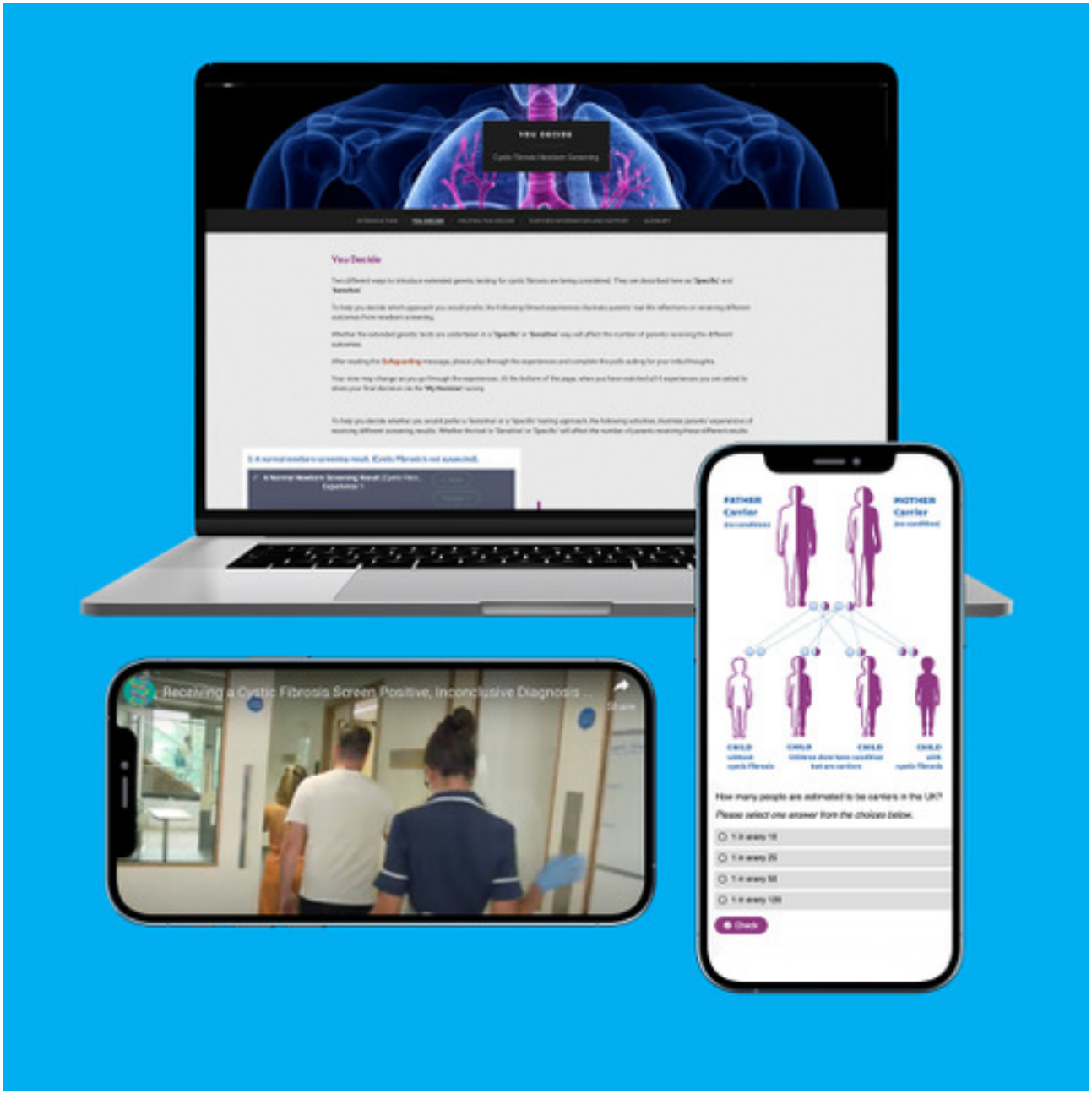
Figure 4. Question to gather a final view of the user on the question: "How should extended genetic testing be used when screening newborn babies for cystic fibrosis?" CFSPID: cystic fibrosis screen positive, inconclusive diagnosis.



Thematic Design

The color stylization of the website (Figure 5) was designed to match the purple CF awareness ribbon and the NHS blue logo to reinforce end-user recognition, acceptance, and clinical validity of the website content. Presentation of text was standardized to aid visual identification of links to information sources as well as key information or terminology. Images used were either under a Creative Commons license or purchased with an educational use license.

Figure 5. Thematic style.



Safeguarding

Due to the potentially sensitive nature of the content (eg, experiences of receiving a diagnosis of a long-term condition and discussions of reproductive outcomes), it was agreed among the stakeholders that a safeguarding message should be displayed. Further guidance and sources of urgent and nonurgent support were also signposted.

Postproduction Considerations

Overview

As part of the iterative design and development process, the tool was tested by users. A "test sheet" template was first created to guide the stakeholder group on how to log technical flaws, and editing needs, and highlight areas for reassessment. The site went through 3 iterations of testing with stakeholders before being tested with new users.

Usability and Acceptability

Usability and acceptability were tested through walkthroughs by 6 novice users. They found the tool easy to use and did not struggle when interacting with or navigating the site or the interactive workbook. Participants liked the colors and design of the site, feeling that it conveyed the right tone.

They reported that the videos were engaging, elicited empathy, and helped to form an understanding of the parents' experiences. One participant commented, "It gets more interesting, I just want to keep going on and on."

They felt the videos elicited empathy for the parents and helped build their experiences of the test results. Several of the participants commented on how the emotional storytelling and representation of the family experience helped them to understand that "experience is the best teacher" and "…you learn more through people's experience. That's the fact of life."

There were some usability issues identified with the videos, specifically their size on different devices and the number of interactions or clicks needed to access and progress through the videos. The interactive workbook element was mostly considered easy to understand, and it helped users to form an understanding of the differences between the specific and sensitive approaches to testing. One participant noted, "It gives me a lot of information about this, which I really like."

Multiple participants stated they liked the engagement and interactive elements, specifically that the questions helped their understanding by drawing attention to the main points and encouraging them to reread if they had not understood.

To further improve readability, participants suggested reducing the amount of text, shortening the length of individual pages, adding a read-aloud function, and supplementing text with additional images and diagrams. One participant shared, "I love graphics. I love pictures, so I'm seeing this will give me more interest to go through it."

They found the pictures and diagrams to be an engaging and accessible way to summarize information, drawing attention to a comparison table graphic that helped them to understand the difference between "sensitive" and "specific" testing.

Discussion

Principal Findings

The "CF Newborn Screening: You Decide" tool was conceived as a novel approach to engage the public and stakeholders in addressing the complex issues and debates around newborn screening. Through an iterative design process, in collaboration with key policymakers (eg, NHS England) and stakeholders (eg, parents and clinicians), a stand-alone resource has been developed to enable the public to understand and consider the question: How should NGS be used when screening babies for cystic fibrosis? It is intended that the tool will help people to form considered views and facilitate access to the perspectives of parents and the wider public on genetic testing that are otherwise difficult to obtain but are of importance to HCPs and policymakers.

As an open-access online resource, the "user" (eg, a parent, a member of the general public, or an HCP) is provided with an interactive presentation of the potential outcomes of NGS, allowing them to visualize the impact upon families through storytelling. The initial feedback suggests that the stories or filmed scenarios, based on real-life experiences, are engaging and enable a deeper level of understanding. Previous research has shown that the public's views can change when exposed to different viewpoints and sources of information [8]. This tool prompts considered views through the presentation of different viewpoints and experiences, while offering users time to reflect on the provided information.

In addition to enabling the provision of considered views to inform policy as an innovative approach, this tool could support a range of activities to inform screening and genomics research, including engagement, consultation, coproduction, and research. The tool and its approach could be applied to other screening scenarios, for example, when public consultation is required, or indeed other scenarios where decision-making needs to be based on a complex set of scientific and experience-based data that may otherwise be hard to access. Future research could include an analysis of tool usage with the potential for interviews with users afterward to explore their understanding and decision-making. This is timely, given the current interest in the use of extended genetic screening techniques to enhance existing newborn screening programs internationally [14,67,68].

Limitations

Due to project resource constraints, the initial design and development have focused on a web application suitable for access via a PC. The site structure and content require further optimization for viewing on smaller screens or touch-based interaction, as well as consideration of accessibility features to include, for instance, non-English speakers, people with learning differences, and those without access to technologies. In addition to considering mobile access, ongoing development is addressing several recommendations from the testing, including simplification of some of the text, the design of more graphical elements, and the incorporation of voice-over elements.

Through the tool and filmed scenarios, we sought to provide common experiences and emotional responses based on our previous interview findings. However, we recognize that family experiences do vary. We sought to address bias by drawing on previously published research [27] but do acknowledge the potential bias introduced through the researchers' choice of vignettes and the stakeholders' lived experiences in reviewing the films and supporting material.

The tool has been developed for consideration of incorporating NGS into the CF newborn screening algorithm. While it is acknowledged that screening programs include many different conditions, it is felt that this work could be used as an exemplar for the development of future tools that could be used to assist parents and professionals with decision-making during the NBS process. The tool is still in development and evaluation. While the process of usability and acceptability testing outcomes are promising, further work is needed, including piloting with parents who are considering CF screening for their child.

Comparison With Previous Work

As changes are introduced to screening programs to maximize their benefits and reduce their harms, the results produced and how they are interpreted are becoming increasingly complex. The challenge of reaching informed decisions about the nature and content of screening programs is correspondingly also increasing [21]. For parents and stakeholders to understand the implications of introducing expanded newborn screening and extended genetic testing, they need to consider some of the arising ethical questions, including the possible harms (eg, parental anxiety, overdiagnosis, and uncertain results) and the balance of these against potential benefits (eg, early intervention) [10]. These can be complex ideas to communicate to stakeholders and for them to evaluate [10,21,69]. Here, we propose a novel approach to achieving that communication and engagement through using a storytelling approach and scenario-based narratives.

Conclusions

The online scenario-based tool facilitates access to the considered views of parents and the wider public on genetic testing using storytelling and interactive elements. These views are otherwise difficult to elicit and obtain but are of critical importance to policymakers and stakeholders. Initial feedback on the tool has been positive. Development and further testing continue. It has been identified through the development process that the tool, with its highly interactive nature, will also be of value to those delivering medical training and public health outreach. It allows participants to explore challenging and emotive scenarios in an environment that gives them the opportunity to develop knowledge and empathy. In addition, it has the potential to be used for future research, engagement, consultation, training, outreach, and coproduction. There is also the potential for this sort of online activity to be used as a decision tool for parents deciding whether to have their child screened.

Acknowledgments

The datasets generated or analyzed during this study are available from the corresponding author on reasonable request.

Data Availability

Data presented in this study are available on request from the corresponding author. Data are not publicly available due to ethical constraints.

Authors' Contributions

LM, SC, MC, RHG, JRB, FB, and JC contributed to the conceptualization. LM, SC, MC, RHG, JRB, FB, PH, CC, and JC were involved in the methodology. LM, SC, MC, RHG, FB, PH, CC, and JC conducted the formal analysis. LM, FB, PH, CC, and JC were responsible for data curation. LM and JC prepared the original draft. LM, SC, MC, RHG, JRB, FB, PH, CC, and JC contributed to the writing–review and editing. SC and MC contributed to the software development. LM, JC, and PH managed the project administration. LM, JC, and FB were in charge of funding acquisition.

Conflicts of Interest

None declared.

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Abbreviations

CF: cystic fibrosis
CFSPID: CF screen positive, inconclusive diagnosis
CFTR: CF transmembrane conductance regulator
CRMS: CF transmembrane conductance regulator-related metabolic syndrome
HCP: health care professional
NBS: newborn bloodspot screening
NGS: next-generation sequencing
NHS: National Health Service

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Original Paper

Engagement Methods in Brain Tumor Genomic Research: Multimethod Comparative Study

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Abstract

Background: Engaging patients, care partners, and others in research planning and conduct is increasingly valued. However, identifying the most effective ways to do so remains a challenge.

Objective: This study aimed to evaluate participation and participant experience using 3 engagement methods with the Low-Grade Glioma (LGG) Registry's Optimizing Engagement in Discovery of Molecular Evolution of Low-Grade Glioma (OPTIMUM) project, part of the National Cancer Institute's Participant Engagement and Cancer Genome Sequencing Network.

Methods: We evaluated LGG Registry research advisory council (RAC) meetings, Twitter (now known as X), and Facebook discussions across 4 engagement activities with each group. Researchers recorded discussions and performed qualitative content analysis to evaluate differences in the nature of interactions and recommendations for promoting trust and participation in LGG Registry research. Participants completed experience surveys after engagements 1 and 4 (Public and Patient Engagement Evaluation Tool, Research Engagement Survey Tool, Trust in Medical Researchers Scale, and Patient Engagement in Research Scale).

Results: RAC engagements involved 25 unique participants representing diverse backgrounds; tweet chats and Facebook discussions had 197 and 133 participants, respectively. Qualitative findings highlighted differences in the nature of interactions (eg, communication styles and types of information shared) across groups, but there was general agreement around recommendations

for promoting participation in genomic research. Postengagement surveys (n=52 in ipostengagement activity 1; n=40 in postengagement activity 4) showed patterns suggesting a more positive experience overall for the RAC.

Conclusions: Advisory councils and social media engagement methods have advantages and disadvantages. Advisory councils provide consistent interactions with the same individuals and clear procedures. Despite theoretically broader reach, social media engagement may yield less diverse perspectives. The LGG Registry aims to use RAC and social media engagement methods to promote diverse perspectives and maintain consistent interactions.

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KEYWORDS

engagement; brain cancer; brain tumor; low-grade glioma; research advisory council; social media

Introduction

Background

Engagement of patients, families, and others has become essential to research, from study conception to dissemination [1-6]. An increasing body of evidence shows that engagement can positively influence the research process—shaping the research questions asked, improving research conduct (eg, recruitment, retention, and data collection), guiding the return of results, and more—all in ways that center patient and community perspectives [7-12]. Cancer and cancer genomics research are no exception [13]. Patients have a long history of advocacy and engagement in cancer research [14,15]. Engagement is thought to be critical to promoting representativeness, recruitment, retention, and trust (understood broadly to mean participants can rely on the research enterprise to protect their interests) in genomics research [16]. For instance, engagement has the potential to improve research relevance, promote recruitment and retention, enhance dissemination, and increase diversity among research participants [17].

A recent review involving major cancer research and cancer genomics programs (such as the National Cancer Institute [NCI] Cancer Moonshot Initiative's Participant Engagement and Cancer Genome Sequencing [PE-CGS] Network) called for measuring effectiveness and comparing methods of engagement in cancer genomics research [18]. Despite progress in the measurement of engagement effectiveness [9,19-25], comparative effectiveness research on discrete engagement methods (eg, advisory panel methods, social media–based engagement discussions, and community engagement studios) is sparse and tends to focus on a single aspect of a method (eg, group composition or online vs in-person modalities) [26,27].

Understanding the most effective, efficient, and patient-centered methods of engagement may be particularly important for rare cancers, including adult lower-grade gliomas [28]. Although rare (affecting <1 per 100,000 people in the United States), they represent up to 20% of malignant brain tumors, affect relatively young adults, and are associated with high morbidity and mortality. Genomics research promises to provide new insights into low-grade glioma (LGG) diagnosis and treatment, including understanding the many potential genomic variations in tumor types [29-31]. Because lower-grade gliomas are rare, research must often recruit from multiple geographic locations, with variability in social, economic, technological, and clinical contexts [32]. This geographically dispersed community creates challenges for research—yet presents an opportunity for studying engagement methods.

The International Low-Grade Glioma Registry (LGG Registry) was established in 2016 at Yale University to conduct genomic and epidemiological research into risk factors and outcomes for LGG. Recently, a study of the molecular evolution of LGG, termed Optimizing Engagement in Discovery of Molecular Evolution of Low-Grade Glioma (OPTIMUM) and focused on persons with recurrent LGG in the LGG Registry, was funded by the NCI as part of the Cancer Moonshot Effort and PE-CGS network [33].

To date, the LGG Registry includes more than 700 registrants from around the world. Most participants define themselves as White, of non-Hispanic ancestry, and of relatively high educational and economic status. To reduce disparities in access or willingness to engage in LGG research, the LGG Registry has developed partnerships with people living with LGG, care partners, and experts [34,35]. As it remains unclear which engagement methods are the most effective, the LGG Registry explored 3 methods for engagement of the LGG community in genomic research: a research advisory council (RAC) and online discussions via Facebook (Meta Platforms, Inc) and Twitter (X Corp) social media.

Objectives

The purpose of this study was to compare engagement processes and outcomes among 3 methods of engaging people living with LGG, their care partners, clinicians, researchers, and others in the planning, conduct, and dissemination of genomic research.

Methods

Study Design and Context

Funded as part of the NCI's PE-CGS Network, OPTIMUM aims to enroll into the LGG Registry people diagnosed with LGG who have had 2 or more surgeries for glioma. OPTIMUM's Engagement Optimization Unit—a required PE-CGS center component—aims to identify effective and feasible strategies for engaging people with LGG and others in the planning, conduct, and dissemination of genomic research. The OPTIMUM engagement optimization unit's primary goal is to identify effective strategies for engaging the LGG community in LGG genomics research to inform LGG Registry recruitment, data collection procedures, and the return of results. We conducted an exploratory quasi-experimental multimethod study to compare 3 engagement methods; participants were not

randomly assigned to the engagement method (but instead had voluntarily chosen their assignment), but we did structure engagement activities to be as similar as possible. Our level of assessment was the engagement method itself. We used project tracking documents, audio recordings, data gathered from social media platforms, and surveys to evaluate reach, engagement experience, and trust in research. Permission was requested and granted for publishing direct quotes reported in this paper from identifiable individuals.

Comparator Engagement Methods

An engagement method refers to "a set of tools, techniques, and processes that are used to enact all of the 'high-level' purposes of engagement: identify and convene partners, create reciprocal relationships (level the playing field), engage in bi-directional communication, elicit perspectives, and make decisions over time and in partnership" [36]. We compared 3 engagement methods for building relationships and gathering community input to inform research [37-40]. Engagement methods included facilitated discussions with the LGG Registry's RAC; "tweet chats" in collaboration with the #BTSM (brain tumor social media) community (established in 2012; monthly tweet chats started in 2013) on Twitter; and interactive Facebook posts with the Oligodendroglioma/LGG Warriors (henceforth "Warriors") private Facebook group (established in 2013), which includes primarily people living with LGG. Each engagement method involved 4 parallel engagement activities with each group, in the form of interactive discussions facilitated by the research team about topics relevant to the conduct of LGG genomics research.

Both social media groups existed before this project and were established by members of the brain tumor community, not the research team (Table 1). The RAC was established by the research team as part of the OPTIMUM project to inform optimization of LGG Registry recruitment, enrollment, and return of results strategies. RAC members were originally recruited in early 2022 from research team personal contacts, the LGG Registry contact list, and social media. The RAC consists of 25 people (including 19 people with LGG) purposefully selected to represent a range of community and scientific perspectives and to be demographically diverse (Multimedia Appendix 1). The RAC met once for an introductory call in February 2022 before the structured engagement activities described in the subsequent sections. Our overall goal was to minimize differences in how each parallel engagement activity was conducted across groups. All 3 methods were established at the time of our study; that is, the RAC, "tweet chats" with #BTSM, and Facebook "topic of the day" discussions were existing methods of engagement. First, for each engagement method, we held facilitated discussions on the same four topics: (1) trust and benefits of genomic research, (2) registry recruitment, (3) registry data collection, and (4) return of results. All engagement activities occurred during March through September 2022. Second, for each topic, we developed a facilitator's agenda with near-identical prompts tailored to the engagement modality and population (Multimedia Appendix 2). There were typically 3 to 4 discussion prompts for each topic, aligned with 4 orienting research ethics concepts: autonomy, privacy, ownership, and relevance.

It is important to note the differences that may exist between these 3 methods that may create differences in the experience of participating in a given engagement activity. For instance, the Facebook Warriors group responded to prompts asynchronously, whereas the RAC and Twitter engagement activities occurred synchronously; this was done to respect the existing structure of the Warriors group, which included a "topic of the day" with most responses written within 24 to 48 hours. In addition, the free-flowing, unpredictable nature of these semistructured group discussions meant that impromptu prompts occurred in response to the discussion and were thus not the same across methods (as would be the case if we had used rigidly structured engagement activities). To facilitate the discussion, facilitators for each engagement activity prompted participants to clarify in their answers which prompt they were addressing in their answer.

RAC members consented to audio recording to allow for analysis. Tweet chats and Facebook posts included "transparency notices" indicating that the content of the discussions would be used to inform research priorities for the LGG Registry and that anyone who did not wish to be included in the analysis should not participate.

Table 1. Distinguishing features of comparator engagement methods.

Engagement features	Research advisory council virtual meetings	Facebook O/LGG[a] Warriors group chats	#BTSM[b] Twitter community tweet chats
Description of engagement activities	• Synchronous 1-hour video conference meetings over Zoom (Zoom Communications, Inc). • Brief presentation of the topic or issues, followed by 3-4 breakout rooms with moderated live discussion using group facilitation techniques following a structured agenda with prompts.	• A series of 4 Facebook posts from the LGG team, 1 per day over the course of a week, in a private Facebook group. • Posts included brief prompts, polls, links to external content, or graphics inviting commentary. • Group members react asynchronously, typically in the 24-48 hours after the post is made.	• Publicly available, 1-hour–long synchronous discussions on Twitter, promoted in advance and hosted by existing social media community leaders with the #BTSM community • Participants introduced themselves, and every 15 minutes, a new topic was introduced by a host. • Participants tweet in response during the 1-hour chat.
Participants	• 25 members: 19 people with LGG, 1 care partner, 1 clinician, 2 regulatory experts, 1 advocacy organization representative, and 1 genetics expert	• Open invitation to members of the O/LGG Warriors group • 133 unique participants (58, 17, and 88 participants in Facebook posts 1, 2, and 4c, respectively)	• Open invitation to Twitter users; #BTSM, @gliomaregistry, and @NBTStweets followers • 197 unique participants (72, 37, 81, and 77 participants in tweet chats 1-4, respectively)
Platform	• Zoom web conferencing	• Facebook social media platform	• Twitter social media platform
Recruitment	• Email with a link to an interest form sent to 447 people living with LGG, care partners, clinicians, researchers, and others involved in the LGG Registry	• Group administrator for the O/LGG Warriors group (>3100 members) shared posts explaining the process and inviting group members to participate.	• Partnership with the #BTSM community. • To advertise tweet chats, the #BTSM community leaders posted from their accounts and the @BTSMchat Twitter account (with >3200 followers). These posts included details about the chat topics, dates and times, and special guests.
Leaders	• Brain cancer expert patient (LS) and researchers	• O/LGG Warriors group administrator (NG) and researchers	• #BTSM social media organizers (LS and others) and researchers
Duration and frequency	• Monthly 1-hour meetings (March to June 2022)	• Semimonthly series of 4 "Topic of the Day" posts over 1 week (April, June, and September 2022)	• Semimonthly 1-hour tweet chats following promotional tweets leading up to the chat (March, May, July, and September 2022)
Data source	• Detailed meeting notes and recordings	• PDFs of posts and comments	• Symplur transcripts

[a]O/LGG: Oligodendroglioma/Low-Grade Glioma.

[b]#BTSM: brain tumor social media.

[c]"Engagement 3" on Facebook was not included in our analysis, as it was not intended to be part of the study. Engagement 3 used different procedures designed to assess whether mentioning research was decreasing willingness to participate, and participants were not alerted to the potential for their responses to be included in research analyses. Therefore, results present data from engagements 1, 2, and 4.

Engagement Activity Participation

We manually tracked attendance in RAC meetings. Tweet chat participation data were generated using Symplur, a health care social media analytics company. Symplur provides downloadable spreadsheets with the total number of Twitter accounts that tweeted a particular hashtag in a given time frame, the number of tweets and mentions for each account, user-reported location, and Symplur-identified stakeholder category for each participating account. We manually counted the number of unique individuals participating (commenting or reacting to a Facebook "topic of the day" post) in each Facebook activity.

To describe the general characteristics of engagement activity participants, we used several data sources. RAC members completed a survey as part of the application process in which they self-reported race, ethnicity, gender, income, education, stakeholder type, type of LGG diagnosis, insurance type, and US geographic location. For the #BTSM community, we used Symplur data (which include stakeholder type, eg, patient, clinician, and care partner) and self-reported geographic location for all Twitter accounts that participated in @BTSMchat-hosted

tweet chats on March 6, 2022, April 3, 2022, June 5, 2022, and August 7, 2022. Each "live" chat lasted 60 minutes in length, although due to the asynchronous nature of Twitter, participation data include tweets posted using the #BTSM hashtag during the chat and up to 12 hours after each live event; for the first chat only, we also included chats in the 12 hours before the live event. For Facebook group members, the administrator for the Warriors group provided group-level demographics (age, gender, and US-based) generated using Facebook's Page Admin interface.

Generation and Analysis of Qualitative Data

We used qualitative content analysis to compare the 3 engagement methods in terms of (1) the nature of the interactions between community members and the research team during engagement activities and (2) recommendations to the LGG Registry. All RAC meeting discussions were audio recorded and then professionally transcribed by a professional transcription service. Twitter transcripts were generated by Symplur, which included all tweet content, the associated Twitter account, time and date of the tweet, and data about participant demographics and stakeholder type (eg, patient, clinician, and care partner). Facebook transcripts were created through screenshot and PDF creation of all comments and reactions to the "topic of the day" posts. All transcripts were uploaded to the qualitative data management software, ATLAS.ti (version 23; ATLAS.ti GmbH).

Qualitative analysis was conducted by a team experienced in qualitative data analysis. Coding and analysis were conducted by 2 data analysts (CR and SGH) and 1 qualitative methodologist (JGB). The analysis was immersive and iterative, beginning with data collection and involving multiple passes through the data to identify deductive and inductive codes to represent the discussion topics (experiences, concerns, and interests of participants). To create the codebook, an inductive approach allowed ideas to emerge [41,42], and deductive codes were added based upon the discussion prompts. Content analysis was completed within and across engagement methods. Preliminary findings were identified for each method, followed by a comparison of the results to identify themes. In detail, rounds of team-based coding were completed by engagement method (in order: RAC, Twitter, and then Facebook) until all 3 engagement methods were fully analyzed across all of their engagement activities. Coders only coded data as linked to a prompt if it were clearly a response to it; data that were not clearly in response to a prompt were coded inductively. Then, the qualitative team compared the preliminary results by engagement method to identify similarities and differences between methods to determine the qualitative results (themes).

The qualitative team met regularly to debrief, refine the codebook, and ensure the codes were applied similarly across coders, thus helping in establishing trustworthiness of the analysis and results [43]. After initial coding calibration, team members double coded 80% of the transcripts to maintain calibration. To further ensure analytic rigor and reliability, the research team engaged in member checking by sharing findings back with participants to see if initial results reflected their experience and capture any missing important discussion points [44]. A reflexive framework guided all aspects of analyses (framing of the analysis, assigning codes, and emerging interpretations of data into themes) [45]. In the final analytic stage, we assessed similarities and differences in the nature of interactions and recommendations for building trust in genomic research and enhancing participation in the LGG Registry among the 3 engagement methods [35,36,38,40,44].

Engagement Experience Surveys

We chose to evaluate the engagement methods as both a "state" and a "process" [46]. This meant evaluating engagement activities (by having participants fill out surveys after an engagement activity and being specifically told to evaluate that activity) and the overall process of engagement after all 4 activities for each method (in this case, using the Patient Engagement in Research Scale [PEIRS-22]). To do so, at the end of the first and last engagement, participants were invited to complete an online survey evaluating their experience via Qualtrics (Qualtrics International Inc), with a target sample size of 20 survey respondents per method per administration (Multimedia Appendices 3 and 4). Surveys are reported in a manner consistent with the CHERRIES (Checklist for Reporting Results of Internet E-Surveys) checklist for web-based surveys [47] (Multimedia Appendix 5). RAC members received an email invitation via Qualtrics. For Facebook and Twitter, the group administrators posted an announcement about the opportunity to participate in a survey, indicating interested participants should direct message the study lead to receive a link to the survey. Engagement participants also received direct messages from the study lead or group administrator inviting them to complete the survey. Participants received a US $20 gift card for each survey they completed (earning up to US $40 if they completed both surveys).

The postengagement surveys included measures of engagement experience, trust in medical researchers, recollections of which LGG Registry team members were involved, self-reported costs to participate, and demographics. Engagement experience was assessed using 3 established survey measures and some de novo items. The Public and Patient Engagement Evaluation Tool (PPEET) [48] assesses engagement experience, processes, and perceived outcomes of engagement. The 9-item condensed Research Engagement Survey Tool (REST) [49,50] assesses 8 engagement principles based in community-based participatory research, including partner input, capacity building, equity, and trust among partners. The PEIRS [21] is a 22-item survey that has been validated, shortened [51], and even translated into other languages [52,53]. We chose the PEIRS-22 additionally because its items appear capable of evaluating discrete engagement activities (in contrast to the REST, which assesses more long-term, community-based partnerships). PEIRS-22 assesses the overall meaningfulness of engagement on a scale of from 0 to 100 and includes 7 subscales. These subscales include procedural requirements (ie, 7 items assessing team introductions, opportunities to contribute, ability to perform tasks, participation in decisions, receipt of updates, clear communication, and participants' assessment of time, all on 5-point Likert scales), convenience (ie, 3 items assessing convenience in participating), contributions (ie, 3 items assessing engagement activity and participants' perceptions of their

contributions), team environment and interaction (ie, 2 items assessing perceptions of the team), support (ie, 2 items assessing support to participate), feeling valued (ie, 2 items assessing how participants thought they were valued), and benefits (ie, 3 items assessing how engagement activity participants benefitted from the experience). The 4-item Trust in Medical Researchers Scale was used to assess trust [54].

Statistical Analysis

Given the low expected sample size for the surveys, these analyses were considered exploratory. Participation data and survey demographic data were analyzed using descriptive statistics (counts, frequencies, and percentages). To our knowledge, no standardized scoring system exists for the PPEET items, which range from "strongly disagree" to "strongly agree" on a 5-point Likert scale; consistent with standard survey practice, these were dichotomized, and the percentage of participants who strongly agreed or agreed with each item was presented. PEIRS-22 subscales were dichotomized using the cutoff values used by the scale's designers during its validation [51], with respondents with scores indicating low meaningfulness contrasted with those reporting the engagement was moderately, very, or extremely meaningful. For categorical data, tests between groups within each time point were performed using the chi-square test; Fisher exact test was used in cases of low expected cell counts. Continuous survey responses were described using medians and IQRs when the distribution was highly skewed (ie, PEIRS-22 overall scale and REST) and using means and SDs when normally distributed (ie, Trust in Medical Researchers Scale). Comparisons between the 3 engagement methods at each time point were made using Kruskal-Wallis test and 1-way ANOVA. All statistical analyses were performed using SAS (version 9.4; SAS Institute), and $P<.05$ was considered significant.

Ethical Considerations

This study was approved as exempt human participants research by the Colorado Multiple Institutional Review Board (protocol 20-1001). Participation in engagement activities and analysis of engagement discussion transcripts was not considered human participants research and did not require informed consent. Nonetheless, social media posts included transparency notices, indicating that the activity was being led by a group of researchers and the discussions held may be used to inform research. Only engagement experience surveys were considered human participants research. Survey participants received an information consent before completing the surveys. They were compensated with gift cards worth US $20 for survey completion. All survey data were stored in secure folders accessible only to the research team to protect privacy and confidentiality. Documentation of consent was waived.

Results

Engagement Activity Participants

All 25 RAC members participated in at least 1 of the 4 engagement activities reported here (n=24, 96%; n=21, 84%; n=21, 84%; and n=22, 88% participants in RAC meetings 1-4 respectively). There were 197 unique people who participated in tweet chats (n=72; n=37; n=81; n=77 participants in chats 1-4, respectively). Tweet chat participants were a mixture of community representatives, with 45% identified by Symplur, a social media analytics platform, as people with brain tumors (including, but not limited to, LGG). There were 133 unique people who participated in Facebook Warriors page discussions (58, 17, and 88, participants in Facebook post series 1, 2, and 4, respectively [post series #3 excluded; refer to the footnotes in Table 1]). On the basis of Facebook Page Admin statistics, 76% of the group members are aged between 25 and 54 years, 73% identify as women, and 65% live in the United States. Among those people who participated in the engagement activities, there were 92 completed postengagement experience surveys (52 postengagement 1; 40 postengagement 4; refer to Table 2 for survey respondent characteristics). As surveys were anonymous, it is not known how many of the survey respondents were the same across administrations. While not statistically significant due to the small "n" involved, the RAC appeared to have greater representation of those of Black or African American race and Hispanic ethnicity, as well as a more equal self-identified gender balance.

Table 2. Characteristics of the engagement survey respondent sample.

	RAC[a], n (%)		Facebook, n (%)		Twitter, n (%)	
	Post 1 (n=19)	Post 4 (n=17)	Post 1 (n=12)	Post 4 (n=6)	Post 1 (n=21)	Post 4 (n=16[b])
Age (y)						
18-29	4 (21)	3 (18)	0 (0)	0 (0)	2 (10)	2 (13)
30-49	9 (47)	9 (53)	9 (75)	4 (67)	18 (86)	8 (50)
50-69	6 (32)	5 (29)	3 (25)	2 (33)	1 (5)	6 (38)
Gender						
Men	10 (53)	8 (47)	1 (8)	1 (17)	5 (24)	7 (44)
Women	9 (47)	9 (53)	11 (92)	5 (83)	16 (76)	7 (44)
Nonbinary or prefer to self-describe	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	2 (13)
Race						
Black or African American	1 (5)	1 (6)	0 (0)	0 (0)	0 (0)	0 (0)
Hispanic or Latino ethnicity	2 (11)	3 (18)	0 (0)	1 (17)	0 (0)	0 (0)
White	15 (79)	13 (77)	12 (100)	5 (83)	18 (86)	14 (88)
Other or unknown[c]	3 (16)	3 (18)	0 (0)	1 (17)	3 (14)	2 (13)
Education						
High school	1 (5)	1 (6)	1 (8)	1 (17)	2 (10)	1 (6)
Some college or associate degree	1 (5)	2 (12)	1 (8)	2 (33)	1 (5)	1 (6)
Bachelor’s degree	6 (32)	5 (29)	2 (17)	1 (17)	6 (29)	4 (25)
Master’s degree	8 (42)	5 (29)	7 (58)	1 (17)	5 (24)	3 (19)
Doctoral or professional degree	3 (16)	4 (24)	1 (8)	1 (17)	7 (33)	7 (44)
Household income (US $)						
Unknown or prefer not to answer	2 (11)	4 (24)	4 (33)	0 (0)	5 (24)	3 (19)
<50,000	5 (26)	4 (24)	2 (17)	2 (33)	2 (10)	0 (0)
50,000-99,999	1 (5)	4 (24)	1 (8)	4 (67)	9 (43)	7 (44)
≥100,000	11 (58)	5 (29)	5 (42)	0 (0)	5 (24)	6 (38)
Participant perspective [d]						
I have personally been diagnosed with a brain tumor.	15 (79)	14 (82)	12 (100)	6 (100)	12 (57)	10 (63)
I am a care partner (such as a family member or friend) for someone who has been diagnosed with a brain tumor.	2 (11)	1 (6)	0 (0)	0 (0)	4 (19)	2 (13)
I am a researcher who studies brain tumors or topics related to brain tumors.	2 (11)	3 (18)	0 (0)	0 (0)	3 (14)	1 (6)
I am a health care provider who cares for people with brain tumors.	2 (11)	1 (6)	0 (0)	0 (0)	3 (14)	4 (25)
I am a representative of an advocacy organization or other service organization that addresses issues important to people with brain tumors.	3 (16)	1 (6)	0 (0)	0 (0)	4 (19)	0 (0)
I am a community member with a general interest in brain tumors and genomic research.	2 (11)	2 (12)	1 (8)	1 (17)	4 (19)	1 (6)

[a]RAC: research advisory council.

[b]A total of 17 participants in this group were analyzed for other outcomes, but one chose not to provide any demographic information and was excluded from this table.

[c]Includes participants who identify as Asian (4 respondents), White and Asian (2 respondents), White and Black (2 respondents), American Indian or Alaska Native (1 respondent), and those who did not respond (3 respondents).

[d]Responses may add to >100% as participants were able to select all options that applied.

Nature of the Engagement Activity Interactions

Overview

Qualitative analyses revealed differences in the nature of the interactions among engagement activity participants for each engagement method (Table 3 provides additional illustrative quotes).

Table 3. Additional supportive quotations about the differences in the nature of interaction themes by engagement method.

Similar and dissimilar themes	Illustrative quotations from engagement activity participants
Style of communicating: extent of 2-way communication	
Similar—2-way communication	RAC[a] engagement activity 4: patient, about their views on returning genomic results to patients: "Is he [a research scientist] mostly looking at the genetic material from the tumor itself, or are we also looking at the genetic factors of just the person or the kind of people that tumors occur in for the first place, or where they recur? Then, also, are we also looking at environmental factors or things like that?"; researcher: "Yes, all of those. They are characterizing the tumor, and then they're doing a whole genome sequencing. Not only can they look at genetic factors for brain tumors, they also will have results for do you have the gene for Huntington's disease? Do you have the gene for such and such? The results that get returned to individuals could potentially have all of those things in one report."
Dissimilar—posts with limited back-and-forth communication	Facebook engagement activities 3 and 4: in response to a question posted to the Facebook page: "After surgery did you all get a pathology report with your tumor's IDH mutations and co-deletion status"; patient: "No the dr kept it. Not sure why. He read it to me." (No other reply or comments posted in response during the Facebook engagement)
Sharing of personal challenges with LGG [b]	
Similar—personal challenges with LGG shared	Facebook engagement activity 2: patient: "When I was first diagnosed they didn't know what I had, the only thing they could tell me was it was slow growing tumor that I've had for 10 yrs [years] or more. But then I did what everyone isn't supposed to do, I went to Google. I put in 'what do I ask when I see the doctors- oncologist' and 'what supplements should I take.' I found a page that is no longer in use, but that really helped me start the process." RAC engagement activity 4: patient: "For me, at least there was a roller coaster. Surgery was like, 'Ah, yes. This was completely successful. I don't have to worry about this anymore.' Then a kind of downhill slide of, 'Oh, I know this is gonna come back.' Then kind of warring between the two of those, just a mental gymnastics, trying to figure out, 'Am I going to let myself live my life and trust this is never gonna come back and deal with it if it comes back? Am I going to mentally prepare and kind of live in a semi-state of anxiety?'...Finding that balance has been my biggest hurdle so far."
Dissimilar—direct calls for change in LGG research	Tweet chat engagement activity 4: other advocate: "[researchers should, for] any new drug approved, publish in the Journal of Neuro-Oncology the mutations/pathology report of every GBM/AA/Olglio [sic] patient anonymously etc and how they reacted to that medecine [sic] or combination [of medicines]."
Specificity of scientific concepts	
Similar—described LGG science and its uncertainties	Tweet chat engagement activity 1: doctor: "I find it hard in #braintumors to be able to explain much about many genetic tests because we still need to learn so much on the implications of a particular mutation in #braintumors vs others." RAC engagement activity 4: "All I got handed [after surgery] was the 1p19q codeletion with the IDH2 mutation...I was between grade II and grade III. Some oncologists were hesitant about calling it grade II. Some others were hesitant about calling it grade III, because I had seven percent of my tumor cells that were solid grade III. The other 93 percent was grade II...Depending on the doctor or the institution, they would call it either a solid II or a solid III. I asked for it just to be considered a solid III, just out of precaution."
Dissimilar—extent of LGG details differed by engagement method	Facebook engagement activity 1: patient: "I'm so confused on what my low grade glioma actually is. I don't have the mutations to clearly categorize it."

[a]RAC: research advisory council.

[b]LGG: low-grade glioma.

Style of Communicating

The groups showed differences in their styles of communicating during engagement activities. Twitter participants and RAC members were more likely than Facebook participants to be involved in 2-way communication with other engagement activity participants, such as through replies to each others' comments. As an example, a person who identified themselves as a person with LGG, in response to what causes them concern if seen in advertisements about an LGG medical treatment or study, posted the following:

> *I take it more seriously if it says something about improvements instead. But a cure seems a bit much. I also get suspicious when more than 3 cancers are mentioned. #btsm.* [Tweet chat 2]

A reply to this tweet posted by a person who identified themselves as a medical provider stated the following:

> *Instead of promising results, I try to go into the science of why I think a given clinical trial *could* be better than standard of care, based on the available data, but I always, always say that I cannot promise better results, because we're still figuring that out.*

There are multiple examples of a back-and-forth discussion occurring between participants during tweets and RAC engagement activities. This was in contrast to a paucity of back-and-forth exchanges during Facebook engagement activities.

Another similarity in communication style between 2 engagement methods was the sharing of stories about personal challenges. This communication style occurred similarly among members of Facebook and RAC engagement activities and did not occur nearly as often among participants on Twitter. For instance, a Facebook discussion participant with LGG posted the following (Table 3 provides an additional supportive quotation):

> *When I was first diagnosed they didn't know what I had, the only thing they could tell me was it was slow growing tumor that I've had for 10 yrs or more...I went to Google. I put in "what do I ask when I see the doctors- oncologist" and "what supplements should I take."* [Facebook engagement 2]

In comparison, Twitter partners tended to post short and direct calls for change in research process standards for record and specimen acquisition and returning research results to participants with fewer expressions of personal stories. For instance, a person who identified themselves as having LGG posted the following (without sharing any information about their experiences with LGG diagnosis or treatment):

> *Are there targetable mutations? How might we attempt to stop them? Are there repurposed drugs that could be tried?* [Tweet chat 4]

Specificity of Scientific Concepts

There were qualitative differences across engagement methods in the level of detail and specificity of scientific concepts participants used to express themselves. Twitter and RAC discussions included clinicians and researchers responding directly to questions raised by community members about uncertainty in the current science associated with LGG, the etiology of LGG, or its prognosis:

> *I find it hard in #braintumors to be able to explain much about many genetic tests because we still need to learn so much on the implications of a particular mutation in #braintumors vs others.* [Doctor, tweet chat 1]

Similarly, during a RAC engagement, a person with LGG stated the following:

> *...I had a biopsy for possible recurrence or radiation necrosis...I believe it was the T2-FLAIR that kept growing, that kept getting bigger and bigger...I have the low-grade astrocytoma grade two with the IDH1 mutation, and I would really like to know what the rhyme or reason is [that may cause LGG recurrence].* [RAC engagement 4]

Conversely, Facebook discussion participants—who tend to be largely people with LGG glioma or care partners, not clinicians or researchers—detailed their desires to better understand their LGG clinical information:

> *I basically check the internet every day for news on cancer trials/treatments/etc. Of course, it'd be nice to feel like my doctor was doing that for me, especially because she's better equipped to understand the info & figure out what's actually pertinent to me.* [Patient, Facebook]

Recommendations for Building Trust and Promoting Participation in the LGG Registry

Overview

We examined whether the 3 comparator engagement methods would lead to similar recommendations for enhancing trust in genomic research and participation in the LGG Registry. Due to limited volume and details in Facebook comments, recommendations largely reflect input from RAC and tweet chat participants (Table 4). To illustrate, there were 8654 transcribed words in the transcripts across the Facebook engagement activities, whereas the Twitter engagement activities had 35,471 transcribed words and the RAC engagement activities had 127,691 transcribed words. Overall, we found no major qualitative differences in the content of recommendations for the LGG research team generated by each engagement method.

Table 4. Additional supportive quotations about trust in genomic research and participation in the Low-Grade Glioma (LGG) Registry.

Trust and participation themes	Illustrative quotations from engagement activity participants
Trust in genomic research and researchers transparently sharing information	RAC[a] engagement activity 1: patient said the following about the question "Would you want to know before deciding to participate in research that studies LGG genes?": "I would wanna know, what is the point? What is the end goal? What are we looking for? What do we hope to accomplish with this?...I think a general overview just to know that nothing nefarious is being planned. [With this information,] I think—for the most part-- if folks sign up to participate, there's an implicit trust implied there." Tweet chat engagement activity 1: other advocate: "Breaking it [information about research] down and putting it into terms that the patient and care partner could easily understand and grasp would be crucial in my opinion. I think it would also help in strengthening the partnership between patient and researcher." Facebook engagement activity 2: patient and researcher: "Sharing results in a transparent way is key. As a patient, if you tell me the results aren't promising, that honesty goes a long way in instilling trust and recruiting participants."
Support for participation in LGG genomic research and the LGG Registry	RAC engagement activity 1: patient and researcher: "When I got my brain tumor diagnosis—now like 14 years ago—some of like the subpopulations of brain tumors didn't exist. It was before the reclassification of the different brain tumor stuff. I just decided to share all of my health information because I felt like—to participate in any study because there weren't any people specifically studying low-grade glioma 14 years ago. That led me to this path to wanna see how I could get involved in as many things as I possibly could, just thinking that the more information is out there, the better..." Tweet chat engagement activity 1: other advocate: "I would want to know how they (researchers) predict the results of this study could help future patients and their care partners." Facebook engagement activity 1: patient: "I don't care at all they can have access to every facet of my tumors genetics, my lifestyle, family history, location I grew up, I am more than willing to give up any and all privacy if it helps researchers find a cure for future generations. They can have my brain when I die someday too!"
Data collection and enrollment processes	RAC engagement activity 3: patient: "...if instead of me gathering all the records, I just sign a HIPAA release form...Then you (researchers) go fly off and reach out to those institutions and say, 'Here's the HIPAA. We need access to this.' That's the easiest thing...Instead of me feeding you the fish, I tell you where the fish is..." Tweet chat engagement activity 3: patient family member and advocate: "When [name] was sick he shuffled between so many institutions, none of whom communicated with each other. It was a nightmare." Facebook engagement activity 1: patient: "...working with a researcher who is directly introduced to me by my team of doctors really increases my comfortably with everything [sharing specimens and records for research]."
Return of results	RAC engagement activity 3: patient: "...we all are brain-tumor—brain cancer patients. Sometimes we lose a little bit of the understanding of how things work. Having that broke down to where—like I'm a five-year-old is very easy for me to be able to do...I think [that approach] would be very beneficial." Tweet chat engagement activity 1: patient: "I would want updates on what is being studied and what is being learned, how it is being used. I am a huge research proponent but not if the patients and their care partners get kept in the dark since the research wouldn't happen without their participation." Facebook engagement activities 3 and 4: patient said the following about their views returning individual results to patients: "Please let us know what treatments are successful and when they are going to update the survival rate for IDH1 grade 2. There's IDH1 inhibitors and we need to know if these are working?"

[a]RAC: research advisory council.

Trust in Genomic Research and Researchers Transparently Sharing Information

Participants in all 3 engagement groups expressed widespread trust in research and researchers. This trust appeared to be related to positive prior experiences or personal connections with researchers and research institutions. One participant reported the following:

> *I have worked with researchers. I don't feel that same sense of detachment from the research environment 'cause I'm working day in and day out with these folks who I think are outstanding...I don't feel inclined to have a distrust of the [research] process and I've actually participated in some studies and I haven't had a bad experience.* [RAC engagement activity 1]

To help build trust in genomic research in general and for participants in the LGG Registry in particular, recommendations included transparent, regular, and clear communication about (1) what is happening with participants' data and (2) research findings that can help individuals with personal decision-making and improve community health outcomes. Participants emphasized that researchers might build trust by highlighting personal connections with the community and demonstrating affiliation with trusted institutions.

Support for Participation in LGG Genomic Research and the LGG Registry

Participants across all 3 engagement methods generally supported LGG Registry participation because it provided an opportunity to help find answers for people with LGG and their families. For instance, 1 participant with LGG emphasized the following:

> *I don't care at all they can have access to every facet of my tumors [sic] genetics, my lifestyle, family history, location I grew up, I am more than willing to give up any and all privacy if it helps researchers find a cure for future generations. They can have my brain when I die someday too!* [Facebook engagement activity 1]

Recommendations for LGG Registry recruitment messages included highlighting the trusted institutions involved, the opportunity to find answers that people with LGG and families

care about (such as planning for their futures and about familial risk associated with LGG), and how participant medical records data and genomic information will be kept private and secure. One participant highlighted this last point by recommending a secure place for patients to send their data:

> *I think also having the repository of where we know we're sending it. Having assurances on how they're protecting our privacy as to where we're sending it to, I think, provides some reassurance to patients if they know that the portal that they're sending to has certain security in play.* [RAC engagement activity 3]

Data Collection and Enrollment Processes

Participants expressed the need to minimize the burden of obtaining patient health records and specimens; many individuals detailed challenges they had experienced collecting their medical records and specimens. A patient family member and advocate said the following:

> *When [name] was sick he shuffled between so many institutions, none of whom communicated with each other. It was a nightmare.* [Tweet chat 3]

Burdens that were described by these participants included both cognitive (eg, remembering or tracking institutional requirements) and physical (eg, traveling to request and receive paper copies and radiography films). Participants emphasized this in part because people with LGG can experience cognitive and other disabilities.

Return of Results

If someone agrees to participate in genomic research, they expect to receive their own individual results showing biomarkers and genomics reports and overall research findings in plain language. For instance, 1 person with LGG shared the following:

> *[W]e all are brain-tumor—brain cancer patients. Sometimes we lose a little bit of the understanding of how things work. Having that [individual genomics results] broke down to where—like I'm a five-year-old...I think [that approach] would be very beneficial.* [RAC engagement activity 3]

Informing participants of new genomic findings or updates in general for LGG brain tumors was also recommended. While participants want to use individual results for personal and family decision-making, clinicians, researchers, and institutional review board representatives clarified that participants needed to understand that research results might not be validated genomic tests, which they believed are the only results that should inform clinical care or personal or family decisions.

Engagement Experience Survey Results

Results of the engagement experience surveys (n=52, postengagement 1; n=40, postengagement 4) are shown in Table 5 (PPEET), Table 6 (REST and Trust in Medical Researchers Scale), and Table 7 (PEIRS-22; postengagement 4 only). The PPEET items showed positive ratings of engagement experience overall for RAC participants, where all items were endorsed by at least 70% of respondents; ratings for social media methods were more variable, with the lowest ratings reported by Facebook engagement activity participants, where several items were endorsed by only 50% to 70% of participants. As shown in Table 5, there were statistically significant differences in engagement experience for several PPEET items: belief that participation was diverse (eg, at time point postengagement activity 1: RAC: 100%, Twitter: 91%, and Facebook: 58%; P=.004), belief that a wide range of views were expressed in engagement 1 (RAC: 84%, Twitter: 91%, and Facebook: 50%; *P*=.02), and belief that the activity achieved the stated objectives (RAC: 100%, Twitter: 81%, and Facebook: 67%; *P*=.03).

P values obtained from the Kruskal-Wallis test for REST and 1-way ANOVA for TMR. *P* value considered statistically significant at <.05.

There were no statistically significant differences between engagement approaches in the overall meaningfulness of engagement, as assessed by the REST or PEIRS-22 (Figure 1A). However, RAC members rated PEIRS-22 procedural requirements more positively (Figure 1B) and reported recalling a wider range of expressed views than social media participants (Table 5); only 6% (1/16) of RAC members assessed the procedural requirements as "low" in terms of meaningfulness, compared to 55% (6/11) of Twitter participants and 50% (1/2) of Facebook participants (*P*=.01).

Table 5. Public and Patient Engagement Evaluation Tool (PPEET) engagement experience survey results.

PPEET item	Research advisory council, n (%) (agree/strongly agree)		Facebook, n (%) (agree/strongly agree)		Twitter, n (%) (agree/strongly agree)		Group comparison *P* values[a]	
	Post 1 (n=19)	Post 4 (n=17)	Post 1 (n=12)	Post 4 (n=6)	Post 1 (n=21)	Post 4 (n=17)	Post 1	Post 4
Overall, I was satisfied with this activity	18 (95)	15 (88)	11 (92)	5 (83)	21 (100)	17 (100)	.51	.36
The purpose of the activity was clearly explained	18 (95)	16 (94)	11 (92)	5 (83)	20 (95)	16 (94)	>.99	.53
I had enough information to contribute to the topic being discussed	19 (100)	15 (88)	12 (100)	5 (83)	19 (91)	16 (94)	.34	.80
I feel that my views were heard	19 (100)	15 (88)	11 (92)	5 (83)	19 (91)	17 (100)	.44	.36
This activity was a good use of my time	19 (100)[b]	14 (82)	10 (83)	5 (83)	21 (100)	17 (100)	.05	.19
I was able to express my views freely	19 (100)	16 (88)	10 (83)	5 (83)	20 (95)	17 (100)	.23	.36
I feel that the input provided through this activity will be considered by the organizers	19 (100)	17 (100)	12 (100)	4 (67)	18 (86)	16 (94)	.17	.05
This activity included diverse participants from different backgrounds and walks of life	19 (100)	12 (71)	7 (58)	3 (50)	19 (91)	16 (94)	.004	.05
A wide range of views on the topic were expressed	16 (84)	14 (82)	6 (50)	5 (83)	19 (91)	17 (100)	.02	.19
The activity achieved its stated objectives	19 (100)	12 (71)	8 (67)	4 (67)	17 (81)	16 (94)	.03	.12
The supports I needed to participate were available (eg, travel, child care, technology)	16 (84)	17 (94)	8 (67)	4 (67)	15 (71)	16 (94)	.50	.24
As a result of my participation in this activity, I have greater trust in the researchers who are leading the Low Grade Glioma Registry	18 (95)	15 (88)	9 (75)	3 (50)	14 (67)	13 (77)	.08	.14
I think this activity will make a difference	18 (95)	13 (77)	9 (75)	4 (67)	16 (76)	10 (59)	.23	.55
I understand how the input from this activity will be used.	15 (79)	14 (82)	10 (83)	4 (67)	16 (76)	11 (65)	>.99	.56
As a result of my participation in this activity, I am better informed about the Low Grade Glioma Registry	16 (84)	14 (82)	8 (67)	4 (67)	14 (67)	11 (65)	.39	.56

[a]*P* values obtained from chi-squared tests or Fisher exact test. *P* value considered statistically significant at <.05.

Table 6. Research Engagement Survey Tool (REST) and Trust in Medical Researchers (TMR) engagement experience survey results. REST: mean score of items scored 1 to 5, poor to excellent. TMR: scored 1 to 5, strongly disagree to strongly agree, with negative items reverse-coded so that higher score indicates more trust. Theoretical range was 4 to 20.

	RAC[a] post 1 (n=19), median (IQR)	RAC post 4 (n=17), median (IQR)	Facebook post 1 (n=12[b]), median (IQR)	Facebook post 4 (n=6), median (IQR)	Twitter post 1 (n=21), median (IQR)	Twitter post 4 (n=17), median (IQR)	Post 1, *P* value	Post 4, *P* value
REST	4.1 (4.0-4.6)	4.0 (3.6-4.3)	3.9 (3.2-4.8)	3.3 (3.0-4.7)	4.3 (3.3-4.5)	4.2 (3.8-4.5)	.71	.33
TMR	14.2 (3.3)	13.6 (2.6)	14.8 (2.5)	13.2 (2.8)	13.6 (2.0)	14.9 (2.4)	.48	.24

[a]RAC: research advisory council.

[b]A total of 12 participants had values for TMR and 11 participants had values for REST.

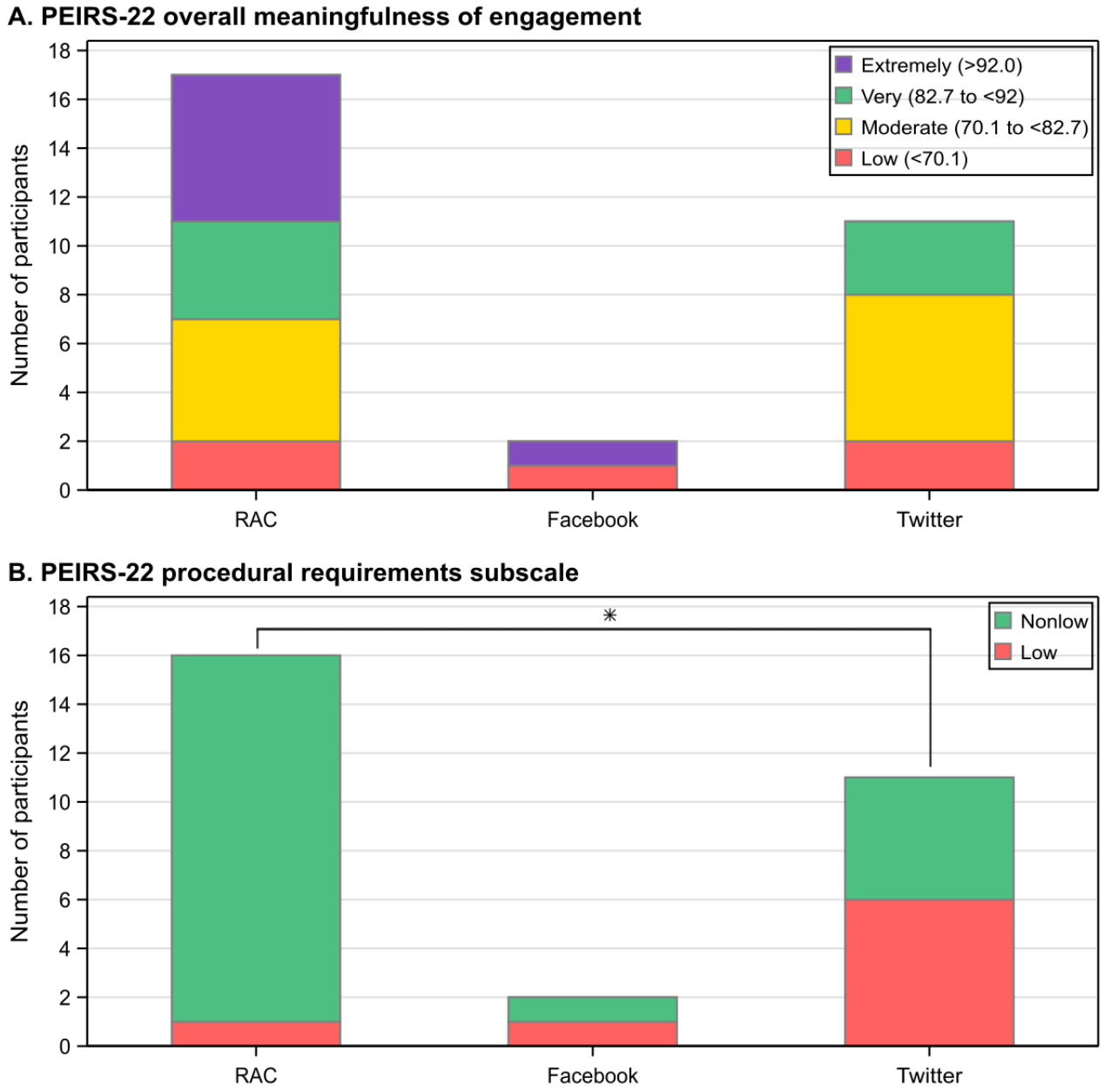
Table 7. Postengagement 4 Patient Engagement in Research Scale (PEIRS-22) responses overall and by domain across engagement methods.

	RAC[a] post 4 (n=17)	Facebook post 4 (n=6)	Twitter post 4 (n=16)	Differences among groups, *P* value[b]
PEIRS-22 (range 0-100), median (IQR)	87.5 (75.0-94.3)	78.9 (59.1-98.7)	77.3 (71.2-85.2)	.24
PEIRS degree of meaningfulness				.12
Low (<70.1), n (%)	2 (12)	1 (50)	2 (18)	
Moderately (70.1 to <82.7), n (%)	5 (29)	0 (0)	6 (55)	
Very (82.7 to <92.0), n (%)	4 (24)	0 (0)	3 (27)	
Extremely (>92.0-100), n (%)	6 (35)	1 (50)	0 (0)	
PEIRS degree of meaningfulness				.40
Low (<70.1), n (%)	2 (12)	1 (50)	2 (18)	
Moderately, very, and extremely (≥70.1), n (%)	15 (88)	1 (50)	9 (82)	
Missing, n	0	4	5	
Procedural requirements (range 0-31.8)				.01
Low (<22.3), n (%)	1 (6)	1 (50)	6 (55)	
Moderately, very, and extremely (≥22.3), n (%)	15 (94)	1 (50)	5 (46)	
Missing, n	1	4	5	
Convenience (range 0-13.6)				.23
Low (<9.6), n (%)	3 (18)	3 (50)	2 (13)	
Moderately, very, and extremely (≥9.6), n (%)	14 (82)	3 (50)	13 (87)	
Missing, n	0	0	1	
Contributions (range 0-13.6)				.14
Low (<9.6), n (%)	1 (6)	2 (40)	2 (13)	
Moderately, very, and extremely (≥9.6), n (%)	16 (94)	3 (60)	14 (88)	
Missing, n	0	1	0	
Team environment and interaction (range 0-9.1)				.72
Low (<6.4), n (%)	4 (24)	0 (0)	3 (23)	
Moderately, very, and extremely (≥6.4), n (%)	13 (77)	4 (100)	10 (77)	
Missing, n	0	2	2	
Support (range 0-9.1)				.67
Low (<6.4), n (%)	1 (6)	0 (0)	2 (18)	
Moderately, very, and extremely (≥6.4), n (%)	16 (94)	3 (100)	9 (82)	
Missing, n	0	3	5	
Feel valued (range 0-9.1)				>.99
Low (<6.4), n (%)	2 (13)	0 (0)	1 (8)	
Moderately, very, and extremely (≥6.4), n (%)	14 (88)	3 (100)	12 (92)	
Missing, n	1	3	3	
Benefits (range 0-13.6)				.27
Low (<9.6), n (%)	1 (6)	1 (33)	2 (13)	
Moderately, very, and extremely (≥9.6), n (%)	16 (94)	2 (67)	13 (87)	
Missing, n	0	3	1	

[a]RAC: research advisory council.

[b]*P* values obtained from the Kruskal-Wallis test for the continuous overall scale. *P* values obtained from chi-square tests or Fisher exact test for categorical comparisons. *P* value considered statistically significant at <.05.

Figure 1. Patient Engagement in Research Scale (PEIRS-22) survey results. RAC: research advisory council.



Discussion

Principal Findings

This study was designed to compare advisory council versus social media–based methods for engaging patients and other community representatives in the planning and conduct of LGG genomic research. To our knowledge, this was the first study designed prospectively to evaluate differences between advisory council and social media–based research engagement methods. Qualitative analyses revealed minimal content differences in the insights generated by each engagement method; recommendations for how the OPTIMUM project may improve trust, promote participation in LGG genomic research, manage data collection, and return individual and research results were similar across engagement methods. However, the 3 methods exhibited differences in the number and types of people engaged, the nature of interactions between researchers and engagement activity participants, and how participants experienced the engagement process.

We observed differences in the PEIRS-22 procedural subscale between the 3 engagement methods, with the RAC rating engagement procedures more favorably; no differences were found in the other subscales. For the other subscales, this may be because the participating members of the research team were consistent across engagement methods (meaning differences in the team and environment were mitigated), all methods were considered convenient for individual participants (who volunteered to participate), and so on. For the procedural subscale, the fact that a RAC comes with an expectation of a standing advisory committee over time could mean that participants are more likely to feel introduced to the research team, have opportunities to contribute, and participate in decisions—all core elements of that subscale.

Importantly, we do not conclude that a RAC is inherently "better" than other methods; instead, we aim to highlight relevant differences. A RAC may provide consistent engagement with the same individuals, a relatively simple structure, and the ability to purposively select members for diversity. However, a RAC may not have the reach of social media engagement, which can engage more diverse individuals, and social media engagement may be less labor or resource intensive for learning important insights (as our study found similar qualitative themes). However, our findings suggest this is not a given; social media did not necessarily yield more diverse participants, and additional efforts may be needed to promote diversity and inclusivity for those methods of engagement. These relevant differences inform selecting the type of engagement activity based on the research question and population. For instance, a research topic that requires a higher level of scientific understanding may best plan to engage Twitter and RAC communities, as the quantity and quality of Facebook data may be limited. Likewise, Facebook and RAC engagement may better suit a research question best understood through narrative interaction between participants, as these engagements were where we observed participants organically responding to one another.

As expected, the advisory council method represented fewer total individuals than those engaged through social media. We had aimed to broaden both total numbers and the representativeness of those participating by using social media methods. Contrary to expectations, our results show that the RAC was more diverse in terms of race and ethnicity than those engaged through social media. The OPTIMUM project team translated findings from this study into several types of decisions. First, the results informed how we would continue to engage the LGG community throughout the remaining conduct and dissemination of the research, with both RAC and social media engagement continuing throughout the project period, although the RAC meets more regularly and is more involved in all aspects of study conduct and dissemination. Second, the results informed content for recruitment messages and channels (eg, an emphasis on recruitment via clinical settings rather than through online channels), content for the LGG Registry website and social media pages, and decisions to allocate more project resources to partnerships with additional clinical sites. The need for mitigating data and specimen collection burden—especially regarding access to electronic health records, pathology reports, and tumor samples—was a key insight.

Our study adds to the literature on the science of engagement in important ways. Although research shows that engagement can influence which questions are asked, how studies are conducted, and how findings are shared with relevant communities [1-12], few studies examine which specific engagement methods are most effective for particular purposes or populations. Prior studies have examined the effect of panel composition (eg, Delphi panels [55]) and compared the experience of patients versus researchers within a single method [26]. One previous study used surveys to examine online versus in-person focus group engagement regarding rural health care (not research); it found greater satisfaction among in-person participants and a lack of representativeness [27]. Others compared online voting, in-person focus groups, and mailed surveys in a low back pain data registry; using a qualitative evaluation, results showed that all methods generated similar research priorities but a better experience among in-person focus groups [56].

Unlike these previous studies, we used both qualitative and quantitative data (validated surveys and scales) prospectively to compare the 3 methods of engagement. Similar to these previous studies, we found few differences in the content of recommendations, but we did find differences in communication styles and how recommendations were expressed. Importantly, we found few quantitative differences in participants' overall assessment of engagement methods or their overall trust in research. Together, these findings suggest that all 3 methods may have a place in OPTIMUM LGG genomic research engagement. Experience may be optimized when participants are able to choose methods with which they are comfortable.

Our results have implications for how to engage community in research more effectively and hypotheses for future research. Participants in the advisory council rated the procedural elements of engagement (eg, proper introductions, opportunities to contribute, bilateral communication, and whether the activity is worth one's time) more highly. If social media engagement included more informal or unstructured time, these findings might change. Unexpected results showed that our RAC members were less likely to report feeling their views were heard. This finding could reflect the opinions of council members who felt uncomfortable speaking, the existence of more outgoing and outspoken personalities in a group, or different expectations among social media participants about what it means to feel heard. Third, despite the arguably broader reach of social media, advisory council participants perceived greater diversity of views. This could reflect the intentional recruitment efforts that RACs often involve, as ours did, or the persistence of a digital divide.

As a pilot exploratory study of the comparative effectiveness of engagement methods, we interpret our findings cautiously but can still offer several recommendations for researchers. First, our study demonstrates the feasibility of conducting an evaluation of engagement processes alongside engagement activities and the ability to detect differences even with relatively small numbers. Related to this, we found the engagement survey tools and items we used to be appropriate for these methods and this context, although adapted tools and items may be needed for other communities. Second, although qualitatively we found no differences in the content of recommendations among groups, we do not suggest they are therefore equal. Issues of cost, time, and expertise, for example, are likely to matter; a researcher already familiar with advisory panel methods is likely to do a better job with that method compared to social media formats, for example, and not all communities have active online communities.

Third, our findings suggest that the presumed advantages and disadvantages of each method are not fixed or guaranteed. Engagement via online social media sites did not inherently appear to increase reach or diversity; researchers may need to

take extra steps to identify and recruit for diversity or use other methods to fill these gaps. Likewise, an advisory panel—despite engaging a small number of individuals—did not necessarily mean all voices were heard; a researcher will still need to use techniques within meetings (eg, use of a talking object that is passed around a real or virtual room) to allow all individuals an opportunity to contribute. Finally, a robust, comprehensive, and comparative assessment of engagement methods in different contexts and for different purposes is still an unmet need, particularly for underrepresented research groups and groups considered marginalized. Further research is needed to improve and validate engagement measures used (eg, in languages other than English). Patient partners (coauthors of this paper) emphasize that the results of this study highlight opportunities to engage the brain tumor community not only in genomic research but also in a wide range of other priority areas, such as quality of life research.

Limitations

The principal limitation of this study was that this analysis was secondary to the primary purpose of the engagement activities—which was to establish bidirectional communication and build relationships with the LGG community. The fact that we used existing engagement structures via the RAC, Twitter, and Facebook meant that participants self-selected into engagement methods that may have matched their preferred style of communication. This approach is respectful of engagement principles; that we observed statistically significant differences and meaningful qualitative differences between groups is thus still important, and future research should explore the possibility and permissibility of randomized designs. Moreover, although we sought to evaluate the engagement state after specific activities in engagements 1 and 4 as well as the process from beginning to end using the PEIRS-22, the wording of items and participants' own perceptions of them can be subject to interpretation. This too requires further research.

In addition, the data used for qualitative analysis were not gathered using standard qualitative research methods, such that the usual ability to follow up with a respondent to ask for clarification or more information about a statement was not present. The high degree of trust in medical research reported in postengagement surveys suggested that we failed to engage community members with less trust in research. The resulting recruitment messages may therefore underemphasize key points needed to enhance trust. For instance, those engaged suggested that noting the involvement of respected research institutions and naming scientists involved would enhance trust in the LGG Registry, but that might not be the opinion of those without previous good experiences with academic institutions. Although we partnered with the community in engaging Facebook participants, other strategies—different Facebook groups, different social media platforms, or nonsocial media–based engagement—may be required to gather more diverse perspectives.

Conclusions

Engagement of patients, families, and other community partners in research is an ethical imperative. To do so with authenticity requires that we evaluate engagement methods for their effectiveness across diverse contexts, and we must hold our engagement methods to the same rigorous standard of evidence as our research methods. Our study demonstrates the feasibility of comparative evaluation of engagement methods that can further inform engagement approaches. Future research should examine additional methods comparatively in different research settings and communities and for different purposes.

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Data Availability

The datasets generated or analyzed during this study are not publicly available due to identifiability concerns but are available from the corresponding author on reasonable request.

Conflicts of Interest

RV is a cofounder and has equity interest in Boundless Bio. LS reports speaking honoraria from Medscape Oncology. All other authors declare no other conflicts of interest.

Multimedia Appendix 1
Research advisory council descriptive characteristics.
[DOCX File , 19 KB - jopm_v17i1e68852_app1.docx]

Multimedia Appendix 2
Engagement discussion prompts.
[DOCX File , 28 KB - jopm_v17i1e68852_app2.docx]

Multimedia Appendix 3
Postengagement survey 1.
[DOCX File , 41 KB - jopm_v17i1e68852_app3.docx]

Multimedia Appendix 4
Postengagement survey 4.
[DOCX File , 49 KB - jopm_v17i1e68852_app4.docx]

Multimedia Appendix 5
CHERRIES (Checklist for Reporting Results of Internet E-Surveys) checklist.
[PDF File (Adobe PDF File), 138 KB - jopm_v17i1e68852_app5.pdf]

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Abbreviations

#BTSM: brain tumor social media
CHERRIES: Checklist for Reporting Results of Internet E-Surveys
LGG: low-grade glioma
NCI: National Cancer Institute
PE-CGS: Participant Engagement and Cancer Genome Sequencing
PEIRS: Patient Engagement in Research Scale
PPEET: Public and Patient Engagement Evaluation Tool

RAC: research advisory council
REST: Research Engagement Survey Tool

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SPAN@DEM (SingHealth Patient Advocacy Network @ Department of Emergency Medicine)—A Pioneer in Emergency Department-Specific Patient Advocacy: Development Study

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Abstract

Background: Launched in January 2022, the SingHealth Patient Advocacy Network at the Department of Emergency Medicine (SPAN@DEM) represents the first emergency department-specific advocacy group in Singapore. This initiative marks a significant advancement in local patient advocacy efforts because it employs a shared collaborative model to address the needs and concerns of patients within the unique context of the emergency department environment. SPAN@DEM emerged in recognition of the limitations of existing cluster-level advocacy groups, which are inadequate to address specific challenges inherent to the fast-paced, high-pressure nature of the emergency department.

Objective: In this article, we describe the establishment of SPAN@DEM, discuss the challenges and considerations encountered, and reflect on lessons gleaned through this journey.

Methods: A start-up committee, comprising two emergency physicians and four patient advocates, was convened to delineate the processes required to form a new patient advocacy group. Key features of SPAN@DEM include co-leadership by an emergency physician and a patient advocate, and diverse membership composition with equal representation from health care professionals and patient advocates. SPAN@DEM convenes quarterly with informal luncheons during meetings to foster open communication between advocates and health care staff. Membership is voluntary and motivated solely by altruism, and all members are required to participate in mandatory advocacy training to empower them to provide more actionable insights.

Results: Since its inception, SPAN@DEM has implemented several initiatives such as *PIKACHU* (Project to Improve next-of-Kin Advice, Communications and Helpful Updates)—a suite of quality improvement measures that resulted in improved patient and next-of-kin satisfaction rates and reduced formal communication-related complaints—and Digital FAQ—an online web-based resource designed to clarify emergency department processes for patients. SPAN@DEM advocates have also contributed to the planning, design, and transition to the new Emergency Medicine Building. More importantly, SPAN@DEM has fostered a cultural shift towards patient-centered care, with the department now routinely engaging patient advocates in decisions affecting patient and next-of-kin experience.

Conclusions: SPAN@DEM exemplifies the value of specialized emergency department-specific advocacy groups in advancing patient-centered emergency care. This model may serve as an exemplar for other health care institutions seeking to enhance patient advocacy efforts.

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KEYWORDS

patient advocacy; emergency department; patient-centred care; emergency physician; start-up committee; patient-centered care

Introduction

The evolution of patient advocacy can be traced to its origins as disease-specific cancer support groups, which primarily focused on connecting survivors and fostering mutual support among patients. Over time, this movement has expanded to encompass critical domains such as patient safety, patient empowerment, and patient-centered care [1]. Health care institutions globally have increasingly acknowledged the importance of establishing dedicated liaisons between patients and care providers, recognizing their role as vital stakeholders who can contribute patient perspectives to formulate health care policies and provide feedback on health care processes as part of broader organizational improvement strategies [2]. This concerted effort to integrate patient advocacy across all settings

within the health care delivery system [3] has led to the emergence of patient advocacy groups and organizations that are dedicated to supporting and promoting patients' rights and interests within the health care system [4].

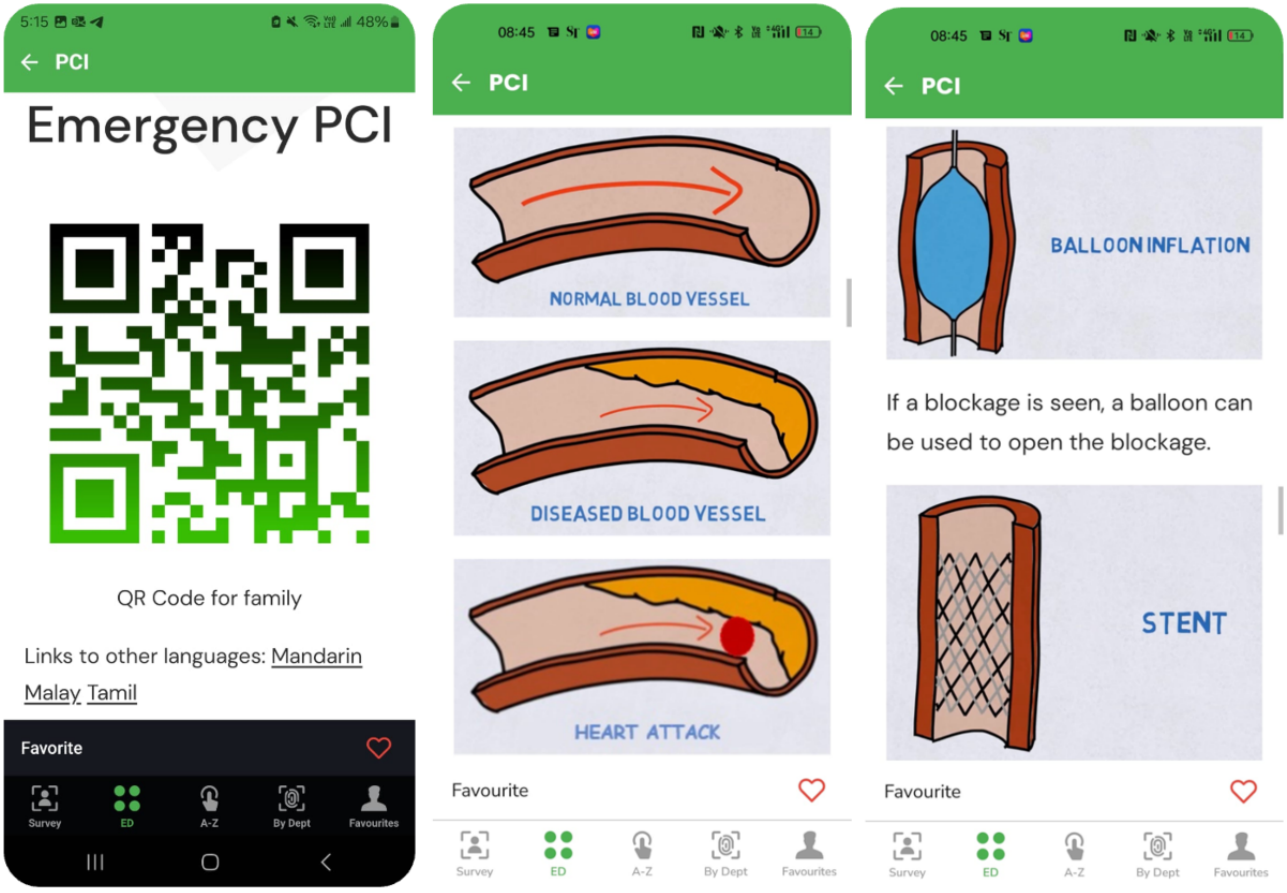
Emergency medicine, with its fast pace and high-acuity environment, presents unique challenges for effective patient advocacy. The emergency department functions as a critical entry point for many individuals into the hospital, frequently during times of acute distress, profound vulnerability, and heightened uncertainty. Under such stress, health care professionals may encounter difficulties in delivering compassionate care and fostering collaborative relationships with patients and their families, particularly given the overcrowded and demanding nature of the emergency department setting [5]. These factors are further complicated by the usage patterns of the emergency department. Frequent attendees may not be suitable candidates to serve as patient advocates given potential biases, while infrequent users lack insight into department operations. Moreover, the demographics of emergency department patients are notably heterogeneous, encompassing diverse cultural backgrounds, health literacy levels, and clinical needs. The absence of longitudinal follow-up further limits the continuity of physician–patient interactions as the emergency department often represents a single encounter along the patient's broader health care journey.

Within this context, the inception of the SingHealth Patient Advocacy Network at the Department of Emergency Medicine (SPAN@DEM) in January 2022 signifies a major effort in the advancement of local patient advocacy initiatives. As the first emergency department-specific patient advocacy group in Singapore, SPAN@DEM represents a novel approach of using a shared collaborative model to address patient needs and concerns within the unique and challenging environment of the emergency department. By examining the journey that SPAN@DEM took through its conceptualization, implementation, and impact, this paper seeks to offer meaningful insights into the role that specialized emergency department-specific advocacy groups can play in shaping the future landscape of emergency care delivery.

The seeds for SPAN@DEM were sowed when a team of emergency physicians at the Singapore General Hospital (SGH) Department of Emergency Medicine (DEM) created *CommunicAid*. Emergency physicians frequently encountered difficulties in effectively communicating and obtaining informed consent for invasive procedures (such as percutaneous coronary angioplasty) from critically ill patients in high-stress, time-sensitive conditions. To address this challenge, *CommunicAid* was developed as a mobile phone application that featured standardized pictorial representations and simplified scripts to facilitate the explanation of complex medical terminology such as "stent" and "angioplasty" (Figure 1). However, the team faced challenges in selecting the appropriate communication medium and choice of terminology, which underscored the importance of incorporating the perspectives of non-medically trained laypersons to represent patient understanding more accurately. This realization resulted in a focus group discussion with patient advocates where it became apparent that the inclusion of the patient voice in department matters can be valuable. The concept of an emergency department-specific patient advocacy group was thus conceived, with *CommunicAid* serving as the impetus and foundational project for launching SPAN@DEM in January 2022.

During the development process, various models of patient advocacy were systematically evaluated, with particular attention given to successful exemplars implemented in other leading health care institutions. The emergency departments in leading hospitals like Johns Hopkins [6,7], Brigham and Women's Faulkner Hospital [8], and UCLA Health [9] had collaborated with patients and family members to form Patient and Family Advocacy Councils. Indeed, the widespread adoption of Patient and Family Advocacy Councils internationally had prompted the Institute for Patient and Family Centered Care in the United States to create starter packs to provide structured guidance and advance such initiatives [10].

Figure 1. CommunicAid: a web-app to enhance patient communication. PCI: percutaneous coronary intervention.



Locally, departments (like the emergency department) serve as the foundational building blocks. Several departments make up a division (like the Division of Medicine), several of which in turn make up an institution (such as SGH). These institutions collectively form a health care cluster, like SingHealth, which is responsible for overseeing one-third of the nation's population health needs and comprises a network of four restructured public hospitals, two community hospitals, and a network of polyclinics. At the cluster level, SingHealth has embraced several patient advocacy initiatives at the macro cluster level, most notably the SingHealth Patient Advocacy Network (SPAN or SPAN@SingHealth) that launched in 2017 [3].

SPAN@SingHealth adopts a consultative model, whereby individual departments may submit requests for feedback from patient advocates on specific projects on an ad-hoc basis. Despite the positive and meaningful outcomes associated with these cluster-level initiatives, SGH DEM identified the need for a more integrated and sustained partnership with patient advocates that was grounded in a collaborative, rather than consultative, approach. SGH DEM was keen to embrace the inclusion of patient perspectives into all aspects of planning and implementation within the department, with the ultimate objective of fostering a shift towards a patient and family-centric departmental culture. In recognition of the need to bridge this mismatch between the broader, macro-level focus of cluster-level organizations like SPAN@SingHealth and the specific micro-level needs of the emergency department, SPAN@DEM was conceived as a distinct organization to better address the unique requirements of the emergency department.

As the first-ever department-level patient advocacy group locally, the principal strength of SPAN@DEM lies in its capability to deliver focused, contextually appropriate support that directly addresses the unique challenges encountered by patients in the emergency department. Operating at the department level allows SPAN@DEM to leverage intimate knowledge of emergency medicine processes and deeply integrate its advocacy efforts into routine clinical practice. In this article, we describe the process of establishing our patient advocacy group, discuss the challenges and considerations involved, and reflect on lessons learnt through this journey.

Methods

Ethical Considerations

As this is a descriptive paper that involves no patient recruitment or data, it did not require any ethical review.

Start-Up Committee

A "start-up committee," comprising two emergency physicians and four senior patient advocates from SPAN@SingHealth, was first formed to explore the processes required to create an emergency department-centric patient advocacy group. Involving SPAN@SingHealth in the initial start-up process proved valuable as it allowed the committee to avoid duplication of efforts and leverage on the parent organization's extensive experiences and wealth of resources. This committee also engaged the SingHealth Office of Patient Experience and SingHealth Duke-National University of Singapore (NUS)

Institute for Patient Safety and Quality in the discussion to provide critical insights on how to bring SPAN@DEM into fruition.

Leadership

The start-up committee grappled with selecting an appropriate leadership model for SPAN@DEM early on. Two prevalent forms in Patient and Family Advocacy Councils were considered: one where the committee is headed solely by an advocate, and another with co-leadership shared between a health care worker and a patient advocate. While SPAN@SingHealth is headed solely by patient advocates, the decision was made to adopt the latter approach. This decision was driven by the goal of having SPAN@DEM integrate its advocacy efforts deeply within routine department practices. The dual co-leadership model leverages the unique perspectives and strengths of both health care professionals and patient advocates as the health care worker co-chair is better positioned to spearhead projects within the DEM. As most projects were initiated and implemented by the committee, it was found that proposing and following through on the projects (rather than simply consulting on projects) also gave SPAN@DEM members a strong sense of ownership and purpose in the work done.

In addition to its co-chairs, SPAN@DEM benefits from the guidance of several advisors, including the Head of Department of SGH DEM as well as representatives from the SingHealth Office of Patient Experience and the SingHealth Duke-NUS Institute for Patient Safety and Quality. These advisors are experts and are able to draw on practices implemented in other institutions to offer valuable recommendations regarding patient experience and service improvement initiatives. Securing the endorsement of senior leadership has also been critical to the success of SPAN@DEM. The initiative consistently received strong and unwavering support from the current SGH DEM Head of Department, who in his capacity as advisor to SPAN@DEM, moderated the majority of SPAN@DEM meetings alongside the Senior Nurse Manager of the department. Their regular attendance underscored the department's strong commitment to the work and objectives of SPAN@DEM.

Composition

To ensure diverse representation in the committee, it was decided that the committee should have a mix of specialist emergency physicians, junior doctors, emergency nurses, and department administrators. This brought the total number of 11, which was evenly split between six health care workers and five patient advocates who are patients or caregivers of patients who have previously received care from SGH DEM. Department administrative staff also served as secretariats and assisted in organizing meetings and documenting minutes. Each member was appointed for a year with an official letter and terms of reference presented at the start of each work year.

The selection process for new SPAN@DEM members was also deliberately evaluated. One approach considered was to introduce objective criteria such as frequency of emergency department visits or history of providing feedback. Members were also purposively selected to ensure sufficient representation across key demographic characteristics such as age group, gender, and underlying health conditions to better reflect the heterogeneous nature of the patient population in the emergency department. However, this presented challenges because it proved difficult to distinguish between patients with complex medical conditions requiring frequent care for legitimate clinical indications, from frequent attenders who struggle with predominantly social or mental health issues instead and contribute to disproportionate use of emergency department resources. Furthermore, the subjective and emotional nature of patient feedback resulted in much difficulty differentiating between substantive, constructive, and actionable feedback from expressions of frustration stemming from divergent worldviews that could not be realistically addressed.

The co-chairs consequently implemented a screening process and conducted interviews with prospective members to better understand their prior health care experiences and determine their suitability for membership prior to admission. This approach aimed to ensure a balanced representation of patient perspectives while maintaining the group's focus on achievable improvements within the department's resource constraints.

Remuneration

Various models of remuneration were carefully considered due to the importance and sensitivity of the issue. To preserve objectivity and credibility of SPAN@DEM, it was decided that participation would be voluntary and all work would be done on an altruistic basis with no gratuities provided. Advocates would also be required to declare any potential or perceived conflict of interests (for instance, if they are affiliated to pharmaceutical organizations) and any gifts received in the course of their work for SPAN@DEM.

While advocates would not be compensated for time in monetary terms, it was decided that advocates ought to be compensated for transport and parking costs should they wish to make claims. It was also stressed in the terms of reference that advocates must respect the religious beliefs and faiths of others and strictly refrain from using SPAN@DEM as a platform to proselytize or conduct evangelism. In addition, a luncheon was organized before every meeting using department funding in recognition of the time and commitment put in by the patient advocates and health care professionals. The informal and social nature of the luncheon before each meeting (as well as the year-end parties) allowed closer friendships and bonds to be forged, which proved integral to the success of SPAN@DEM because open conversations and honest discussions can be carried out more easily.

Meeting Frequency

The group decided on meeting quarterly. During each meeting, the committee would discuss ongoing projects as well as new ideas. While the very first meeting was conducted over video conference due to COVID-19 restrictions, subsequent meetings were conducted in-person every 3 months.

Training

Patient advocacy involves more than just voicing personal grievances and complaints—it requires maturity for non-medical laypersons to structure and deliver feedback to health care staff

in an effective manner to improve patient care. In recognition of this, SPAN@SingHealth mandated comprehensive patient advocacy training for advocates to equip them with the necessary skills to provide constructive feedback, engage in meaningful dialog, and effectively represent patient interests. It was decided that all advocates joining SPAN@DEM should undergo the same training under the Patient Advocate Communication Training program as part of the SPAN training package within the first 6 months of appointment to empower them to offer more actionable insights [2]. These workshops focus on an array of relevant topics ranging from design thinking, story-telling, to quality improvement methodology in health care and can better aid new patient advocates to work together with health care staff and achieve constructive collaboration.

Confidentiality and Media Policy

While patient complaints and feedback that are shared during SPAN@DEM meetings are anonymized, patient advocates are allowed to do walkabouts within the department to grant them better understanding of the patient and next-of-kin (NOK) experience in the department. A non-disclosure clause was written into the terms of reference for SPAN@DEM patient advocates. This mandated that they agree to maintain the strictest confidentiality on sensitive information that they become privy to in the course of their work for SPAN@DEM. In addition, advocates are also required to inform the secretariat before engaging with media if they are approached to contribute their views in published articles or interviews in their capacity as a representative of SPAN@DEM.

Results

Thus far, SPAN@DEM has embarked on several projects in our department. Projects were either initiated by SPAN@DEM itself, or advocates were recruited for projects initiated by the department.

Project to Improve next-of-Kin Advice, Communications and Helpful Updates: PIKACHU

Patients and families in the emergency department often face anxiety, pain, and uncertainty, making effective communication and support critical. The rapid pace of emergency care can further limit opportunities for in-depth discussions and shared decision-making. An analysis of the complaints received by the department led to the recognition that most of these could be distilled to the lack of adequate communications with the NOK. It was in this vein that *PIKACHU* (Project to Improve next-of-Kin Advice, Communications and Helpful Updates) was started. This project sought to improve NOK satisfaction with communications within the SGH DEM and reduce communication-related complaints using systemic quality improvement methodology by introducing a bundle of quality improvement initiatives that are targeted at the root causes of patient and NOK frustration with communications ("pain points") within the department.

Surveys were conducted to better understand the problem before several key interventions were conceptualized and implemented using a Plan-Do-Study-Act (PDSA) cycle approach [11]. Posters were put up to manage NOK expectations about likely waiting times, a patient service associate was designated as the official point-of-contact for NOK enquiries, and SMSes (short message service) were used as means to close the loop and communicate updates with NOK without compromising clinical care. *PIKACHU* demonstrated an increase in satisfaction rate among NOKs on survey scores (35% to 58%) and a significant sustained decrease in formal complaints on DEM communication matters from a monthly average of 11.3 cases pre-intervention (October to December 2022) to 0.66 cases post-intervention (July to September 2023). Nonetheless, the qualitative feedback generated from this exercise showed the team that there were still areas for improvement, especially during surge periods with lean manpower.

Communications Workshop

Patient advocates and DEM staff analyzed actual complaints received by the department to gain insights into the nature of patient feedback. These complaints were categorized, and the most common complaints revolved around long waiting time (for consultation or for admission bed), inadequate communication (lack of updates or unclear explanation of condition or treatment instituted), and mismatched expectations. Based on these findings, the team designed four realistic scenarios to train junior doctors in managing challenging communications with the advocates portraying simulated patients to preserve authenticity.

As part of this biannual communications workshop, patient advocates also freely shared their perspectives and personal experiences with the junior doctors alongside guest speakers from the Office of Patient Experience. These light-hearted and engaging sessions aimed to foster greater empathy among the junior doctors and highlight the importance of empathy and compassionate communication amidst the stresses at work. A particularly thought-provoking observation was shared by one patient advocate: oftentimes, non-medical laypersons lack the medical knowledge to evaluate the quality of care, so they can only evaluate the quality of the communication and bedside manners and use this as a proxy in their perception of the medical care that they receive.

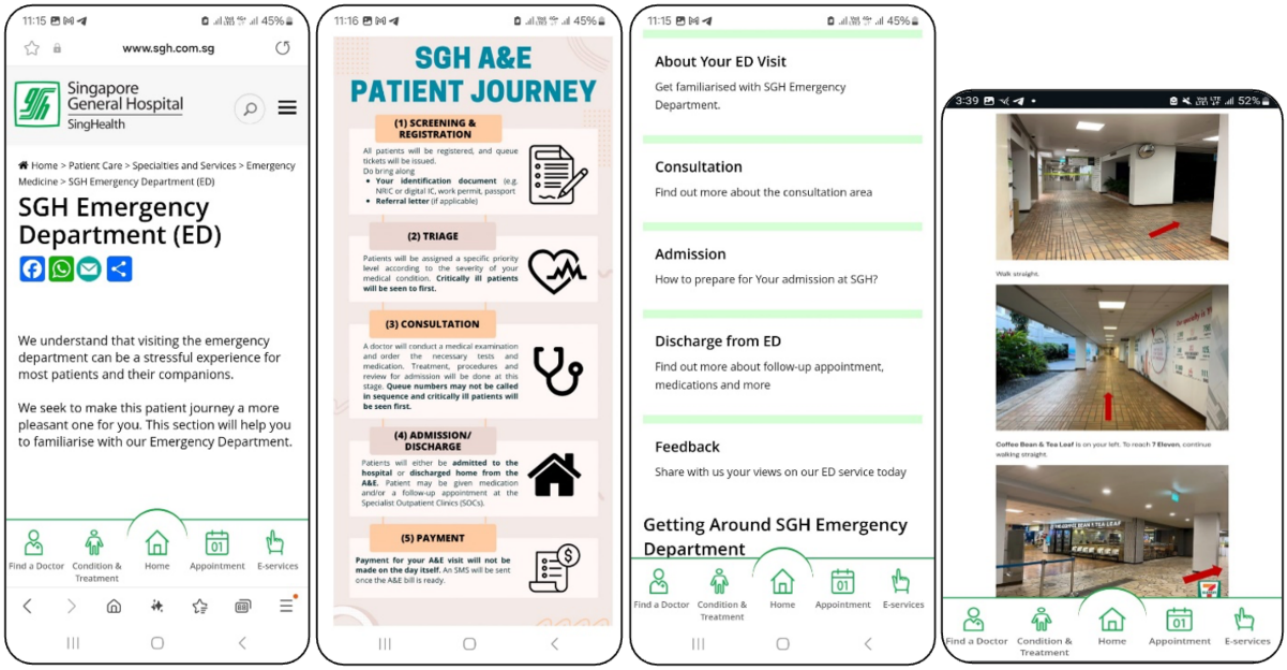
Digital FAQ

Most visitors to the emergency department would be familiar with the processes in Specialist Outpatient Clinics that follow a first-come-first-served system but often feel a sense of injustice when patients who came after them are attended to first in the emergency department. In addition, unlike the relatively linear workflow of the Specialist Outpatient Clinics, a patient's journey in the emergency department varies significantly depending on the chief complaint and complexity of the condition that the patient presents for. Some patients could get asked to have blood laboratory investigations or X-ray imaging done first or even have treatment started before consultation ("care initiated at triage"), while others may require referral to a specialist following their emergency physician consult, which results in a much lengthier wait. Other non-medical issues contribute to the overall caregiver and patient experience in the emergency department; for example, "Where can I get a meal at 2am in the morning?" or "Should I stay or should I go home?" or "Can I

feed or stay with my mother?" are questions that the DEM staff frequently encounter.

Patient advocates collaborated with the DEM staff to jointly create a series of web pages to answer these frequently encountered questions and explain the rationale behind some of the SGH DEM work processes [12].This Digital FAQ resource (Figure 2) can be accessed by patients and NOK by scanning a Quick Response code on their mobile phones and can provide patients and NOK with guidance on their journey in the emergency department.

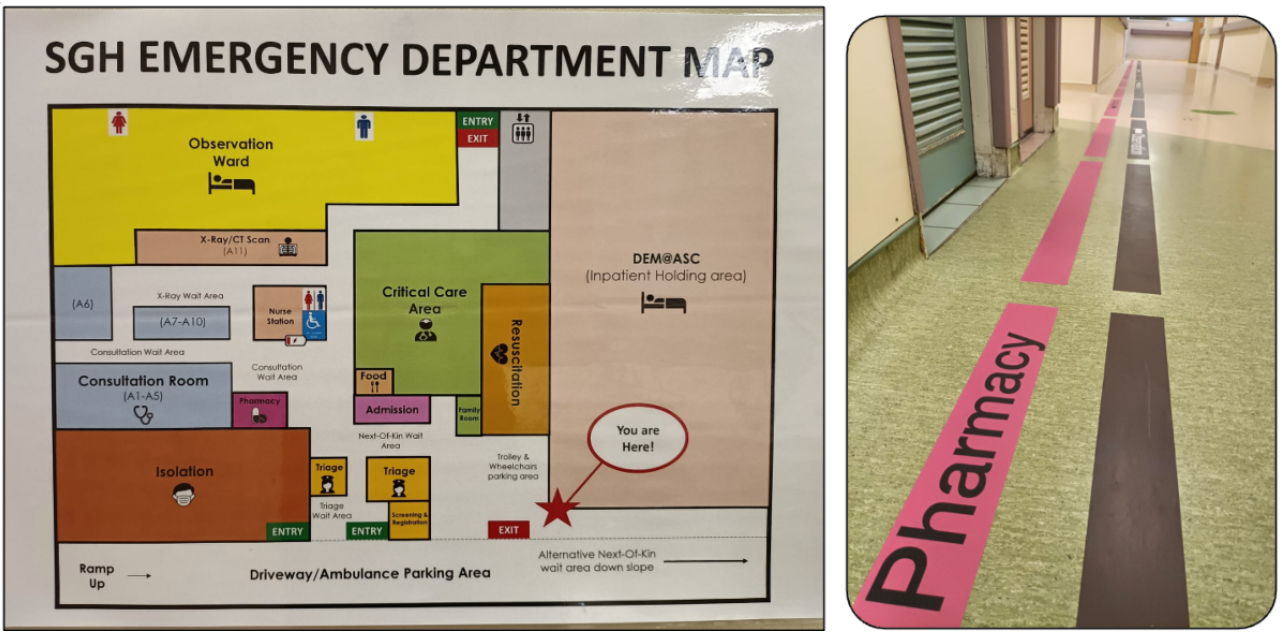
Figure 2. Digital FAQ resource. FAQ: frequently asked questions.



Department Wayfinding

Patient advocates from SPAN@DEM did a walkthrough of the department (with a simulated patient navigating in a wheelchair) to identify confusing signage. Several signage were amended for clarity, some were lowered to improve visualization, and loud posters were removed as they drew attention away from important signage. Directional floor stickers were also introduced (Figure 3). A new simplified map of the department layout was also created with valuable feedback from SPAN@DEM advocates (Figure 3). This did away with as many words as possible and used universal symbols to transcend language barriers and ensure that patients can understand the map more easily.

Figure 3. Department wayfinding.



Planning for the New Emergency Medicine Building

As SGH DEM would be moving to a new building in 2026, the patient advocates with SPAN@DEM have also been actively contributing to this endeavor by participating in various rehearsals and exercises as simulated patients, giving feedback on wayfinding and signages at the new premises. In addition, SPAN@DEM advocates have also been involved in designing and creating media material to smoothen the transition to the new building. These efforts include public education on what conditions should (or should not) be a cause to seek medical attention at the emergency department as well as how to get to the new department via various modes of transport.

Department Culture

Beyond large-scale initiatives like *PIKACHU*, the inception of SPAN@DEM has fostered more nuanced and intangible changes within the department. SGH DEM has increasingly integrated patient advocates into routine department decision-making. During the development of the department's sedation protocol, patient advocates highlighted their preference for the use of neutral terminology like "sedative" and "relaxant" over technical terms like "chemical restraint," resulting in a corresponding adjustment to the wording of the protocol.

Furthermore, the close collaboration within SPAN@DEM allows the health care professionals to poll the advocates immediately and opportunistically. This facilitated rapid and prompt resolution of patient experience-related queries, such as whether patients would prefer self-registration booths at triage versus staffed counters or which patient-facing interface to display wait times was best. Emergency physicians outside of the core committee also increasingly appreciated the ability to leverage on this new-found resource and found it useful to consult the patient advocates on other matters. In some cases, SPAN@DEM advocates played "kingmaker" when the department was evenly split between several options and could not arrive at a unanimous decision. One such instance was when deciding on the naming convention within the new Emergency Medicine Building—the advocates recognized that patients and NOK may be unfamiliar with clinical jargon and proposed a zonal approach (for example, "Zone A (Critical Care)" rather than simply "Critical Care"). These developments collectively bear testimony to the subtle but significant shift in department culture towards the consistent incorporation of patient and caregiver perspectives in everyday decision-making (Table 1).

Table . Projects done by SPAN@DEM[a] since its launch in January 2022.

Project name	Project time period	Project aim
CommunicAid	January 2022	Created pictorial diagrams to aid explanation and consent-taking of time-critical emergency department interventions
Department Wayfinding	March 2022 - June 2022	Redesigned navigational aids like maps and floor stickers to aid wayfinding within the emergency department
Patient Journey Feedback Analysis	September 2022	Conducted thematic analysis of patient feedback/complaints at various stages of the patient journey leading to a renewed focus on communication issues
Queue Viewer system	September 2022	Provided feedback to the implementation of a new queue display system in Consultation Area to improve how emergency department wait times are communicated to patients and next-of-kins
Digital FAQ	July 2022-September 2023	Created a virtual guide to address frequently asked questions for next-of-kins in the emergency department
Managing Effective Communications (I)	September 2022	Designed curriculum for communications workshop for junior doctors; participated as simulated patients to increase realism of simulation scenarios
GovTech	November 2022	Provided feedback on GovTech app-based solutions to divert cases to general practitioners as part of the GPFirst project
Surge Solutions	January-May 2023	Collectively brainstormed ideas on potential ways to alleviate stress on the ground during high patient load and emergency department lodger conditions
Managing Effective Communications (II)	March 2023	Shared patient and next-of-kin perspectives for junior doctors during communications workshops
Complex and Rare Diseases Card	September 2023 – Current	Provided feedback on creation of a medical alert card meant to improve the emergency department experience and outcomes of patients with complex and rare diseases
Managing Effective Communications (III)	October 2023	Shared patient and next-of-kin perspectives for junior doctors during communications workshops
Emergency Medicine Building	April 2024 – Current	Provided feedback about clarity of navigational aids and wayfinding signs for new emergency medicine building; filmed educational videos on which conditions should/ should not seek attendance to emergency department; actively participated as simulated patients in mock simulation rehearsals

[a]SPAN@DEM: the SingHealth Patient Advocacy Network at the Department of Emergency Medicine.

Discussion

Challenges

Assessing and demonstrating the impact of advocacy work remains challenging due to the inherently subjective nature of patient experience. Standard patient satisfaction metrics are not routinely collected in the emergency department, and developing qualitative metrics to capture less tangible benefits, such as enhanced patient dignity or emotional support, has proven complex. A mixed-methods analysis incorporating both qualitative and quantitative methodology was necessary for *PIKACHU* but was resource-intensive.

A key challenge for SPAN@DEM and similar advocacy groups face is to avoid tokenistic engagement. It is essential that health care staff refrain from engaging advocates solely for the appearance of “inclusivity” or soliciting input from advocates on matters where decisions have already been predetermined. Genuine commitment to valuing patient experiences and perspectives is essential for SPAN@DEM to be meaningful. SPAN@DEM must ensure that activities are substantive and

not perfunctory; senior patient advocates have played a critical role in maintaining this standard by rigorously questioning the rationale behind proposed projects during meetings to ensure that the purpose aligned with the broader mission of SPAN@DEM.

Patient advocates, on the other hand, must adopt a broad perspective and recognize the operational constraints and limitations of the public health care system. They must understand that not all recommendations can be successfully implemented. Emotional detachment from personal experiences is important to facilitate constructive dialog. Training programs, such as the Patient Advocacy Communication Training organized by SPAN@SingHealth in collaboration with the SingHealth-Duke NUS Institute for Patient Safety and Quality, are instrumental in equipping new advocates with the skills needed to communicate their perspectives effectively and empathetically and a better appreciation of the broader public health care landscape.

Sustaining a diverse and representative membership remains an ongoing challenge that SPAN@DEM faces. Without renewal to introduce a diversity of ideas that reflect the heterogenous nature of emergency department patients, SPAN@DEM risks becoming characterized by groupthink and losing its ability to represent and remain relevant. The episodic, unscheduled, and infrequent nature of most emergency department attendances complicates membership selection, as it is inevitable that most advocates may not have recent and immediate firsthand experience of emergency department care. They thus may not fully understand the realities and frustrations faced by other patients in the emergency department. Conversely, the small group of patients with disproportionately frequent emergency department reattendances, and who therefore ironically know the department "best," typically have a high prevalence of mental health disorders and substance or alcohol misuse and are therefore less suitable to be recruited as patient advocates.

Other more specialized departments may yield limited benefit from establishing department-specific patient advocacy groups, as existing condition-specific organizations may already have addressed these patient advocacy needs. For instance, the Department of Colorectal Surgery can work together with groups dedicated to Crohn disease, colorectal cancer, or stoma care rather than duplicate work undertaken by them. Similarly, patients managed by the Department of Neurology may already be supported by advocacy groups representing conditions such as epilepsy, Parkinson disease, or myasthenia gravis. In contrast, SPAN@DEM advocates are heterogeneous in demographic characteristics (disease type or severity, age, or socioeconomic background) and are primarily unified by their shared experiences during their emergency department visits and their desire to enhance this experience for other patients. This motivation for organizational improvement might arguably be less cohesive a bond that that of some condition-specific advocacy groups like cancer support groups, where members share common lifelong advocacy needs that extend beyond the initial emergency department encounter to inpatient care, rehabilitation, and the pursuit of resuming normalcy in life following discharge.

Despite these limitations, SPAN@DEM remains well-positioned to address the immediate and transitional needs of patients in the emergency department. The emergency department often represents patients' first interactions with the health care system and, for many individuals, the emergency department environment remains overwhelming and stressful. SPAN@DEM plays a vital role in supporting patients and their loved ones in this regard, facilitating effective communications with the health care team and helping them navigate this critical phase of their health care journey.

Future Directions

SPAN@DEM has served as an exemplar for others to emulate, with SPAN@DEM chairpersons having given talks and presentations at various platforms such as the Singapore Patient Advocacy Connection and the Singapore Healthcare Management Conference. SPAN@DEM co-chairs were also invited to share their experiences as a successful case study of patient advocacy to participants of the Duke-NUS Medical School Graduate Diploma in the Patient Safety and Healthcare Quality course.

As SPAN@DEM continues to evolve, the future offers exciting possibilities for enhancing patient advocacy in health care. By expanding the model to other disciplines, integrating and aligning with broader cluster-level initiatives, pursuing rigorous qualitative research and longitudinal studies on patient experience, and influencing and shaping policy, the impact of department-level patient advocacy could extend far beyond its original emergency medicine setting, potentially transforming patient experiences across the health care system.

Conclusion

The success of SPAN@DEM underscores the value of adapting and tailoring advocacy efforts to the specific needs and challenges of individual departments. The close collaboration between advocates and clinical staff has fostered a more holistic approach to patient care in the emergency setting. SPAN@DEM marks step forward in patient-centered care within emergency medicine, potentially serving as a model for other departments and health care institutions seeking to enhance their patient advocacy efforts.

Conflicts of Interest

None declared.

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Abbreviations

DEM: Department of Medicine
NOK: next-of-kin
NUS: National University of Singapore
PDSA: Plan-Do-Study-Act
PIKACHU: Project to Improve next-of-Kin Advice, Communications and Helpful Updates
SGH: Singapore General Hospital
SPAN@DEM: SingHealth Patient Advocacy Network at the Department of Medicine

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Feasibility and Effectiveness of an Urgent Care–Community Partnership to Reduce Disparities in Patient Portal Uptake: Quality Improvement Project

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Abstract

Background: Patient portals demonstrate significant potential for improving health care engagement but face critical adoption challenges. Disparities persist across different demographic groups, creating a digital divide in health care access. Targeted training strategies, particularly personalized and one-on-one approaches, show promise in increasing portal utilization. Innovative solutions, like community health workers specializing in digital navigation, offer a potential pathway to reduce enrollment barriers. The key challenge remains developing a scalable, cost-effective training model.

Objective: Our quality improvement (QI) project aimed to assess the feasibility and effectiveness of a collaborative effort between a free community-based digital navigation program and an urgent care clinic in facilitating patient access to their portal.

Methods: We created the Digital Health Equity Navigation Training (DHENT) program to improve patient portal access and usage. The program used a train-the-trainer model to scale up patient portal training across the community. DHENT trainers partnered with urgent care physicians to enroll patients in the portal. Physicians briefly explained portal benefits and referred interested patients for DHENT assistance. Trainers then contacted patients by phone to help with enrollment and navigation. We employed 3 Plan-Do-Study-Act cycles to understand the feasibility of the collaboration. We used descriptive statistics to describe participant characteristics and referral processes.

Results: The collaboration was marginally successful, exceeding referral targets by 27.7% (115/90). Most patients were under 60 years old (94/115, 81.7%) and White (78/115, 67.8%). There was a significant delay in contact, averaging 37 days. While 4.8% (5/104) of patients accessed the portal with DHENT trainer assistance, 9.6% (10/104) had already signed up independently after their urgent care visit.

Conclusions: Overall, we found our partnership had a moderate impact, and only a low dose of intervention and resources were needed.

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KEYWORDS

patient portal; urgent care; digital divide; navigation; equity; disparities

Introduction

Problem

Physicians in one of the University of Rochester's urgent care clinics identified the need to increase patient portal access and use in their practice. They believed portal use would be beneficial for reducing time spent outside the clinical encounter, making patients aware of nonemergent updates to their health information that was readily available in their patient portal (eg, lab results). The problem was that they did not have a systematic way to remind patients to sign up, flag, or support those who needed help accessing their portal outside the clinical encounter.

Available Knowledge

A systematic review found patient portal interventions to be overall effective in improving medication adherence, some psychological outcomes, and preventive service use [1]. Varady et al [2] determined that portal use was independently associated

with lower no-show rates, which they estimated corresponded to US $218,225 in yearly savings for their health system. Unfortunately, disparities in patient portal use persist by sex, age, morbidity, and health literacy [3].

Patient training can address nonuse. One-on-one interventions have the most evidence for increasing portal use in vulnerable populations [4]. However, training can vary in how it is delivered (eg, live or in person, via videos) and by whom it is delivered (eg, physician, nurse, navigator). In a randomized controlled trial, in-person patient portal training delivered by a trained study team member for hospitalized patients led to increased portal use and improved patient satisfaction and engagement. Patients who received personalized training accessed the portal more often and used more portal functions compared to those who only watched training videos [5]. Digital navigators (DNs) are a potentially cost-saving, individually delivered training strategy that shows promise for reducing patient portal disparities. DNs are lay professionals, like community health workers, who tend to work closely with the health care system and focus on patients' use of digital health tools while addressing barriers such as digital literacy. A pilot DN program designed to reduce racial and ethnic disparities in patient portal uptake in a primary care setting increased portal enrollment among Black and Hispanic patients who had low enrollment rates prior to the program [6].

Rationale

The optimal training approach remains unclear, both in terms of who the trainers should be and how to implement collaborative training strategies. Research has revealed differences in portal uptake based on who engaged them about it. One study found disparities in portal utilization patterns between patients trained by residents versus attending primary care providers, with residents' patients demonstrating lower engagement [7]. These findings have significant implications for intervention delivery costs. For example, the time an attending physician dedicates to training a patient may be nonbillable and detract from other patient care. Conversely, DNs may offer a more cost-effective alternative, but patient uptake may be lower, thereby negating any cost savings.

A hybrid training approach between physicians and lower-cost trainers may therefore be best. As the race to close the digital divide in patient portal use persists, a comprehensive evaluation of factors influencing adoption and long-term sustainability is crucial [7].

Specific Aims

Our quality improvement (QI) project aimed to assess the feasibility and effectiveness of a collaborative effort between a free community-based DN program and an urgent care clinic in facilitating patient access to their portal.

Methods

Context

The University of Rochester Department of Family Medicine and Health Equity Program Support Office partnered with local community leaders to create a Digital Health Equity Navigation Training (DHENT) program. The goal of the program was to improve access and use of the health system's patient portal (MyChart), increase the community's awareness of no or low-cost internet services, and gather data on the community's digital health needs.

DHENT employed a train-the-trainer model, offering free training to individuals who agreed to train others within their respective communities and organizations that provided direct care (especially community health workers, peer navigators, promotores, etc). This approach allows for a more efficient and scalable way to implement patient portal training across larger communities. Among our initial trainees were 3 undergraduate students and a Public Health AmeriCorps Service Member summer volunteer.

Intervention

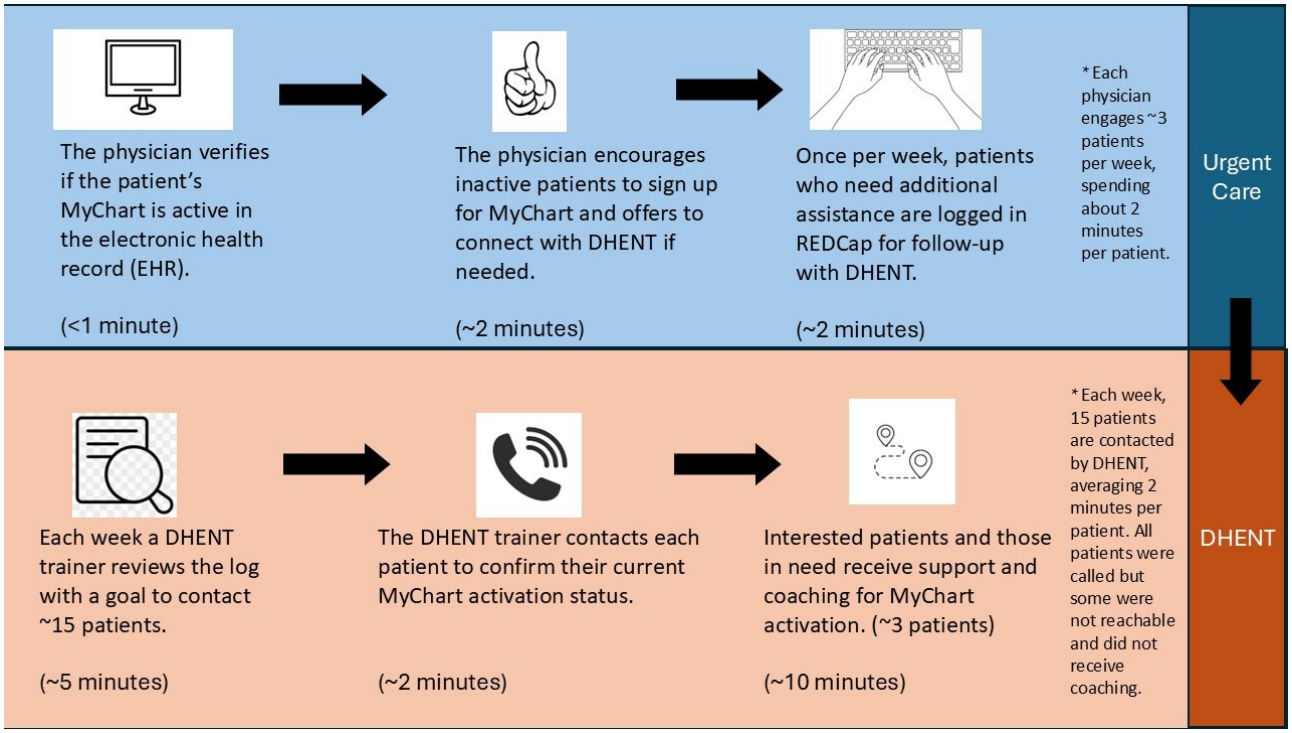
The DHENT curriculum was originally designed for working with patients face-to-face. We later tailored it to be appropriate for the telephone navigation [6]. For example, rather than using the "show-me" method ("Can you show me how you would find your recent lab test results?"), the trainers asked patients to explain in detail what they saw on their screens and used verbal cues to confirm the patient's progress through each step ("Tell me what words, shapes, or colors you see on your screen"). We conducted two 90-minute training sessions with the trainers. We charged them with three primary goals for their patients: (1) educate them on the benefits of MyChart for their care, (2) identify and overcome any barriers to accessing MyChart (eg, recovering an email password or linking them to free resources in the community), and (3) help them navigate key functions within the portal on their own.

The DHENT trainers partnered with an urgent care practice within our health care system to support 6 physicians in enrolling their patients in the portal. DHENT trainers and urgent care physicians were not colocated. At the end of an urgent care visit for adult patients who were not actively using the portal, each physician agreed to spend 2 - 3 minutes explaining the benefits of the portal and encouraging the patient to enroll. When warranted, physicians asked patients for consent to be contacted by DHENT via telephone for further assistance with sign-up.

Participants

Six physicians were trained by a practice champion (an urgent care physician) during a team meeting. The practice champion told them about the purpose of the project and demonstrated how to refer patients. Specifically, the physicians learned how to complete a brief 8-item survey in Research Electronic Data Capture (REDCap; a secure and web-based platform for data collection) to (1) provide the contact information for each patient they referred (eg, name; phone number; email address, if available) and (2) inform the DHENT team about any known barriers the patient had to signing up (eg, requests for an access code) (Figure 1).

Figure 1. Flow diagram illustrating the weekly process for identifying and logging patients who require additional assistance for follow-up with DHENT. DHENT: Digital Health Equity Navigation Training; REDCap: Research Electronic Data Capture.



Measures and Analysis

We used descriptive statistics to describe participant characteristics and referral processes. Feasibility was based on reach (number of referred patients divided by number of anticipated referrals per physician), time (length of time between physician referral and DHENT trainer contact with the patient), and participation rates (number of referred patients per number of contacted patients). Effectiveness was defined as the percent of patients who accessed their portal during the phone call.

Ethical Considerations

This project was undertaken as a quality improvement (QI) initiative and, according to the University of Rochester's Guideline for Determining Human Subject Research (Human Subject Research Determination Checklist) [8], did not meet the definition of human participant research as outlined in the US Health & Human Services Common Rule 45 CFR 46 [9]. No compensation was provided to participants. Data were shared on a secure database accessible only to the study team, and patients provided verbal consent to clinicians prior to inclusion. Because the project did not meet the definition of human participant research, formal written informed consent was not required.

Study of the Intervention

We employed 3 Plan-Do-Study-Act (PDSA) cycles to understand the feasibility of the collaboration.

PDSA Cycle 1

The goal was for each physician to engage 3 patients per week and log them in the REDCap database. For the first 2 weeks, only 2 physicians had logged 8 patients. The practice champion determined that some of the physicians had engaged patients but did not have time to log them in REDCap. Given that, the practice champion volunteered to offer support to those who needed help with data entry and entered their data at the end of each week. As a result, the DHENT trainers reviewed the updated list once per week and made phone calls.

PDSA Cycle 2

The practice champion checked in with the DHENT trainers each week to assess emergent needs. The team added a data field to REDCap so a physician could indicate when a patient spoke a language other than English or was deaf or hard of hearing. By the end of week 4, five physicians had logged 38 patients.

PDSA Cycle 3

Continuity of care with urgent care patients and their physicians is challenging because there is no long-term patient-provider relationship. This makes it difficult to verify information (such as phone numbers) during future visits. This, combined with lagged data entry and DHENT contact, left many patients unreachable by the DHENT team. At the end of cycle 3, the phone-based DHENT support ended. However, the physicians continued to remind patients to sign up for their portal and provided brief in-house support (eg, resetting access codes or verifying login information) to patients at the end of the visit.

Results

The program was piloted with a sample of 125 adult patients who visited the urgent care practice from May 2024 to July 2024. DHENT trainers made phone calls to patients one day per week from June 2024 to August 2024. The trainers completed a brief survey after they attempted to contact each patient. Questions included the outcome of the attempt (eg,

unable to contact, helped a patient sign up, left a message) and any open-ended notes about their experience during the telephone encounter.

The collaboration was feasible with marginal success. We exceeded our target number of referrals by 27.7% (115/90). Of the 125 patients who were engaged by their urgent care physician, 115 were then referred to DHENT, and 104 had complete contact information. Physician referrals ranged from 1 to 46 patients. The average time between referral and DHENT contact (including at least 2 attempts via voice message) was 37 days (median 43, range 16-70 days). Most patients were less than 60 years old (94/115, 81.7%) and White (78/115, 67.8%).

DHENT trainers were unable to speak to 51.9% (54/104) of the patients and left them a voicemail message. They were unable to contact 17.3% (18/104) due to a wrong phone number, the phone not being in service, or an inability to leave a voicemail message. While 4.8% (5/104) of patients accessed the portal with the DHENT trainers, 9.6% (10/104) had already signed up on their own since leaving their urgent care appointment (Table 1). Finally, 1.9% (2/104) of patients told the DHENT trainer they were no longer interested in accessing their portal.

Table . Digital Health Equity Navigation Training (DHENT) trainers phone call outcomes.

DHENT phone call outcomes	Value (n=104), n (%)
Left patient a message	54 (51.9)
Assisted patient in accessing MyChart	5 (4.8)
Provided patient with MyChart education	1 (1.0)
Patient unwilling to sign-up for MyChart	2 (1.9)
Patient unable to sign-up for MyChart	2 (1.9)
Patient's phone not in service	4 (3.8)
Rescheduled (patient currently unavailable)	10 (9.6)
Wrong phone number	5 (4.8)
Voicemail box full, unable to leave patient a message	8 (7.7)
Patient already signed-up for MyChart	11 (10.6)
Patient hung up the phone	2 (1.9)

Discussion

Summary

Our DHENT trainers were unable to contact more than half of the patients that were referred to the program. However, for those that were contacted, they were able to leverage physician endorsement and DHENT trainer experience to engage patients. We found large variation in referrals per physician. We are unsure if this indicates problems with the referral process for some physicians or if there needs to be more done to increase physician interest and awareness of the program.

A few patients enrolled in their portal on their own before they were contacted by DHENT. This may mean that not all the patients that were identified by the urgent care physicians genuinely needed help. Better strategies for identifying patients in need can reduce resource inefficiency and divert DHENT time to those who truly need it. However, we cannot discount the possibility that some patients may have reported they enrolled in the portal but did not actually do so. The DHENT trainers were unable to validate the patients' self-report. Second, there was a significant lag between physician referral and first contact. DHENT trainers only made telephone calls once per week. This low-dose intervention and the delay in contacting patients may have reduced their interest in accessing their portal. Our findings align with those of Rodriguez et al [6], which show that DNs struggle to reach and enroll all patients that are referred to digital navigation services. Nonetheless, their rates were still higher than ours; they reached 74% of their referrals compared to 48% for DHENT. However, it is important to note their program had more resources. Their navigator was employed and colocated, worked closely with the health care team, and sent information to patients via postal mail about the portal. The demographics of patients in our study differed from what we anticipated. Our sample was predominantly White and somewhat younger than the populations typically reported in previous studies as less likely to enroll in the patient portal (i.e., individuals aged 65 years and older). [3,10,11]. This may signal sampling bias but may also underscore the impact of the location of the urgent care centers and demographics of patients that are most likely to use them [12,13].

Lessons and Limitations

The findings from this QI project have important implications for future practice and research in health interventions. The potential for scalability through partnerships with volunteer programs such as DHENT presents an opportunity to extend the reach of digital support for patients. Undergraduate students receive real-world patient experience to support future endeavors, and patients receive support. This model serves as a viable framework for health care practices with limited or no resources. Overall, our findings underscore the importance of community involvement, teamwork, and resourcefulness in developing effective interventions for patients.

Patient portals are becoming an increasingly used communication tool. Patients unable to access them may face

significant barriers to digitally engaging their care unless efforts are made to provide support from alternative means outside the clinical encounter. Our project highlights the need for more robust evidence to show whether low-cost or low-resource approaches such as volunteer phone outreach can be better tailored to meet patient needs over more resource-intensive approaches such as face-to-face, point-of-care interventions. Although less robust, approaches such as this may better align with resource availability in safety-net practices and with the preferences and time availability of patients and their families.

Despite the successful implementation of the partnership, there were some notable limitations. First, this was designed as a QI project. Future studies should rigorously test our approach and its impact on patient health-related outcomes. Second, we did not collect any information on patient or physician satisfaction. These types of information are necessary for understanding long-term sustainability. Future studies should look to include a more diverse and representative sample of patients, thereby enhancing the applicability of our findings.

Conclusions

Overall, we found our partnership had a marginal impact, and only a low dose of intervention and resources was needed.

Acknowledgments

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Conflicts of Interest

None declared.

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Abbreviations

DHENT: Digital Health Equity Navigation Training

DN: digital navigator
PDSA: Plan-Do-Study-Act
QI: quality improvement
REDCap: Research Electronic Data Capture

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Assessment of Mental and Chronic Health Conditions as Determinants of Health Care Needs and Digital Innovations for Women With Sexual Dysfunction: Cross-Sectional Population-Based Survey Study in Germany

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Abstract

Background: A chronic health condition (CHC) is a recognized risk factor for experiencing problems in sexual function (PSF). According to the *International Classification of Diseases, 11th Revision* (*ICD-11*), the development of severe symptoms of sexual distress is the defining criterion for clinically relevant sexual dysfunction. Data on the contribution of specific CHCs to clinically relevant sexual dysfunction symptoms and related health care needs are limited, hindering targeted interventions.

Objective: This study examines the prevalence of PSF, sexual dysfunction, and sexual distress; assesses associations with CHC status; evaluates sexual dysfunction diagnoses; and explores health care preferences.

Methods: Data collection in this cross-sectional population-based survey study was based on a questionnaire developed with patient and public involvement and administered by YouGov to a representative sample of adults in Germany. Analyses included 1970 women with and without CHCs and different CHC subgroups (mental health–related, gynecological, cardiovascular and metabolic, infectious and inflammatory, cancer, pain-related, and neurological). The outcomes measured were PSF, clinically relevant sexual dysfunction symptoms, sexual distress (Female Sexual Distress Scale-Desire/Arousal/Orgasm [FSDS-DAO]), and self-reported sexual dysfunction diagnoses. Multivariable regression and network analysis explored associations among CHC subgroups, PSF, sexual dysfunction, and FSDS-DAO scores.

Results: Among 1970 cisgender women (mean age 49.6, SD 16.0 years), 1186 (60.2%) reported CHCs. The 6-month PSF prevalence was 75.2% (820/1090) in women with CHCs and 62.5% (399/638) in women without CHCs. Clinically relevant sexual dysfunction symptoms were less prevalent (CHC: 202/1046, 19.3% vs no CHC: 68/601, 11.3%). Multivariable regression models showed an association between sexual dysfunction and CHCs (odds ratio [OR] 2.56, 95% CI 1.90 - 3.49), which was the strongest for women with mental health–related CHCs (OR 2.31, 95% CI 1.70 - 3.13) and cancer CHCs (OR 2.00, 95% CI 1.45 - 2.78). Being in a relationship was a protective factor for clinically relevant distress among women with CHCs. Network analysis showed positive associations of PSF with gynecological and mental health–related CHCs and of sexual dysfunction with mental health–related, gynecological, and cancer CHCs. Women with sexual dysfunction symptoms reported low rates of sexual dysfunction diagnosis (CHC: 39/200, 19.4% vs no CHC: 6/55, 10.7%) and treatment (CHC: 16/146, 11.0% vs no CHC: 3/40, 7.0%). Gynecologists were the preferred health care providers for sexual dysfunction. The most commonly reported unmet need was a lack of information. Digital solutions, such as apps and websites with exercises, were desired as health care innovations.

Conclusions: The burden of CHCs on women's sexual health extends beyond functional sexual impairment, with high rates of clinically relevant sexual distress. Cancer and mental health conditions are the strongest predictors of sexual dysfunction. Despite the high prevalence of sexual dysfunction in women with CHCs, access to diagnosis and treatment is limited. Digital offerings could help address these unmet needs.

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KEYWORDS

sexual health; chronic health conditions; mental health; female sexual dysfunction; sexual pain disorders; sexual distress; diagnosis; ICD-11; network analysis; International Classification of Diseases, 11th Revision

Introduction

Background

Problems in sexual function (PSF), including problems with sexual desire, arousal, orgasm, or pain during sex, are common among adult women. In Germany, the 12-month self-reported prevalence rate of these problems in the general female population is 45.7% [1]. According to the *International Classification of Diseases, 11th Revision* (*ICD-11*), the presence of distress associated with PSF is the defining criterion for the diagnosis of any sexual dysfunction and sexual pain disorder [2]. The 12-month prevalence of sexual dysfunction, including clinically relevant distress, is estimated at 16.5% in the general population [1]. Previous literature has identified several well-established biopsychosocial risk factors for sexual dysfunction. These include relationship-related issues, history of abuse, religious affiliation, poor physical or mental health, and chronic diseases [3-5]. Chronic health conditions (CHCs) affect more than 60% of the general population in Germany [6]. CHCs, along with treatment side effects and complications, often affect other physical functions beyond the specific impairments caused by the conditions themselves. The impact of the inability to participate in social activities can cause emotional distress and reduce quality of life [7-10]. The elevated rates of sexual complaints among women with CHCs, such as 66.0% in patients with cancer [11], 61.4% in patients with diabetes [12], and 61.4% in patients with inflammatory bowel disease [13], highlight the strong association between physical conditions and sexual dysfunction. Moreover, mental health conditions, such as affective disorders, have been shown to be associated with higher rates of sexual dysfunction [3-5,14]. Specifically, the rates of sexual dysfunction range from 45% to 95% in individuals with major depression and 33% to 75% in those with anxiety disorders, based on sexual functioning assessments [15]. The underlying causes are multifaceted and may include somatic changes such as altered blood flow, pelvic floor dysfunction, hormonal imbalances, neuropathy, and neurobiological factors [16-22]. Various explanatory models suggested that the high prevalence of sexual dysfunction in mental health conditions is driven by similar underlying cognitive and emotional processes, such as internalization and negative self-schema [23-26]. For instance, the symptoms of depression, such as lack of drive and reduced attention, can also manifest in sexual behavior [27]. Meta-analysis results derived from longitudinal studies have suggested the association between depression and sexual dysfunction to be bidirectional [28].

Despite the recognized importance of sexuality as a supporting resource for patients with CHCs, most studies and meta-analyses concerning the prevalence of sexual impairments among women with CHCs have relied on measures that assess impairments in sexual functioning irrespective of distress [11-13,15]. However, beyond its relevance for physical satisfaction and reproduction, sexuality serves as a source of attachment and intimacy [29], and thus comprises a fundamental aspect of well-being [30]. Therefore, clinically relevant symptoms of sexual dysfunction can have profound consequences for quality of life and relationships [14,31-35] and may elicit substantial sexual distress. While sexual distress serves as a recognized indicator of the clinical relevance of sexual dysfunction [2], it is frequently disregarded in studies on sexuality in patients with CHCs. Social relationships represent a well-established protective factor against mortality and morbidity [36,37]. Despite the recognized importance of sexuality as a supporting resource for patients with CHCs, studies that consider sexual distress as an indicator of the clinical relevance of sexual dysfunction symptoms remain scarce in this population.

Scientific societies emphasize the importance of tailoring multimodal treatments to the biopsychosocial factors involved in sexual dysfunction, including the assessment and treatment recommendations for sexual dysfunction [16,17,38]. Despite these guidelines and the prevailing need for information among patients, underdiagnosis and undertreatment of sexual dysfunction remain pervasive issues [39-44]. Contributing factors include limited time and insufficient training among health care providers (ie, psychotherapists, gynecologists, urologists, general practitioners, and nurses) to adequately address sexual health concerns. In response, scientific societies have implemented certified training curricula [45]. However, in Germany, as in many other countries, sex and couples therapy are often not reimbursed, leaving psychotherapy as the only reimbursed option for patients with sexual dysfunction [46,47]. Additionally, patients face barriers such as a lack of awareness regarding where to seek help [48] and shame in communicating needs related to sexual health concerns [49]. These barriers may explain why a plethora of studies have shown that patients prefer their health care providers to initiate discussions about sexuality [32,39]. The resulting obstacles to accessing treatment underscore the urgent need for research on necessary services and treatment goals to identify the most pressing unmet needs. Simultaneously, there is a growing preference for online information and treatment services [39,48,50,51], which have been shown to improve sexual function and reduce sexual distress in meta-analyses [52,53]. However, to meet the most urgent needs of women with CHCs and sexual dysfunction, these services must be carefully tailored to improve health care access.

Objective

The aim of this study is to (1) assess and compare the prevalence of self-reported PSF, sexual dysfunction, and sexual distress among women without CHCs, among women with CHCs, and within CHC subgroups (mental health–related, gynecological, cardiovascular and metabolic, infectious and inflammatory, cancer, pain-related, and neurological conditions); (2) model the associations between sexual dysfunction and CHC status, including CHC subgroups; (3) evaluate the rates of diagnoses and compare them with self-reported sexual dysfunction symptoms; and (4) identify help-seeking behaviors and health care preferences among women with sexual dysfunction, based

on their CHC status and the presence or absence of mental health conditions.

Methods

Study Design and Setting

This cross-sectional study used data from cisgender women drawn from a representative sample of the German population. The data collection was part of a research project funded by the patient and stakeholder engagement grant. Patient and public involvement (PPI) representatives were actively engaged in the development of a questionnaire on help-seeking behaviors and health care needs regarding sexual problems in Germany. This study followed the STROBE (Strengthening the Reporting of Observational Studies in Epidemiology) statement for cross-sectional studies [54] and the CHERRIES (Checklist for Reporting Results of Internet E-Surveys) [55] to ensure comprehensive and transparent reporting. The completed STROBE checklist is provided in Checklist 1.

PPI Information

PPI participants comprised representatives advocating for topics or groups at risk for sexual health issues. The process adhered to PPI recommendations [56-58]. Representatives were required to have sufficient knowledge of the German language. Recruitment took place via email in July 2021. As there are no dedicated organizations for sexual dysfunction in Germany, major nonprofit organizations representing marginalized groups and others at increased risk of sexual dysfunction were approached and informed about the study. These included Vulvodynie Netzwerk, Verein Lichen Sclerosus, Deutsche Endometriose Vereinigung, PSSD Deutschland, Intergeschlechtliche Menschen e.V., and Aktionsbündnis Muslimischer Frauen, as well as key opinion leaders in the areas of female genital mutilation or cutting and sexual violence. Individuals interested in participating were encouraged to contact the respective organizations directly. After signing short-term contracts, 8 patient and public representatives with personal or professional experience in conditions, such as lichen sclerosus, vulvodynia, endometriosis, sexual violence, post-SSRI sexual dysfunction, female genital mutilation or cutting, sex development variations, and psychotherapy with Muslim women, were involved. Based on personal preference, 5 representatives joined the advisory group and 3 representatives served as co-researchers, with compensations of €150 (US $174) and €400 (US $464), respectively. PPI representatives were onboarded by imparting basic knowledge on sexual dysfunction (eg, etiology and treatment options) and the research methods. For all subsequent meetings, 2 internal researchers provided documents with background information and working materials and were available to answer questions at any time during the meetings. From July to December 2021, the co-researchers collaboratively developed and reviewed the questionnaire item set within 10 online meetings. The advisory group participated in 4 online sessions, making key contributions to decisions throughout the development process.

Participants

Recruitment and data collection were conducted by YouGov Deutschland, an independent polling institute and research data and analytics group, from December 8 to 13, 2021. Participants had to be at least 18 years old and provide informed consent to YouGov in order to be eligible for participation. A random sample was drawn from the entire YouGov Germany panel of over 800,000 individuals. Sampling was conducted using YouGov's proprietary "turbo sampling" method, which draws approximately 24 random subsamples per day across all active studies based on real-time completion rates within predefined quota cells (ie, age, sex, and federal state). These quotas are dynamically updated to ensure representativeness over the field period. Panel members received generic email invitations and were routed via a survey router to the most appropriate live survey based on their profile and current quotas, enabling efficient and unbiased quota fulfillment. To ensure data quality, participants with inconsistent responses to key demographics (eg, discrepancies between personal and household income) were excluded. Survey questions followed a fixed order. Participation was limited to 1 completion per person via a personal login to the survey and cookies. Statistical weights were applied to make the sample representative of the German adult population by age, sex, and federal state [59]. Panel members were recruited through advertising and website partnerships [60]. The survey link was provided to adult panelists until the sample size reached 4000 participants. The sample size was chosen based on practicality and feasibility considerations.

Measures

Questionnaire Development

The questionnaire was developed through an iterative process in collaboration with PPI representatives. The final draft was submitted to YouGov, who provided feedback on item formulation, clarity, and technical implementation. To enhance clarity and feasibility, adjustments were made to the wording and length of items. YouGov also contributed recommendations regarding the use of filter questions. Based on their input, final adjustments were discussed and agreed upon jointly with the PPI representatives. Before launching the survey, internal and external pretests were conducted with 19 participants via YouGov. Survey items were typically presented 1 per page.

The finalized PPI-developed questionnaire, which required approximately 20 minutes to complete, comprised a total of 51 items for women. Of these, 23 items were newly developed through the PPI process, while 28 were selected from validated instruments assessing sexual distress (15 items), pain-related distress (1 item), and sexual dysfunction (8 items for women or 10 items for men), as detailed below. The Relationships Questionnaire-2 (RQ-2; 4 items) was also administered but has not been included in the present analyses [61]. Validated measures were initially proposed by the research team and subsequently reviewed and selected in collaboration with the PPI representatives. The PPI-developed items were organized into six thematic sections: (1) sociodemographic characteristics relevant for quota-based sampling (4 items; eg, sex, age, and federal state); (2) sexual health (2 items; eg, awareness for PSF

and awareness for help); (3) self-reported received diagnosis (1 item; presence of CHC and sexual dysfunction diagnosis); (4) biopsychosocial protective and risk factors (2 items; eg, life events, general health status, and interpersonal experience); (5) help-seeking behavior (6 items; eg, source of information and received treatment); and (6) health care needs (8 items; eg, treatment goals and preferred offerings). The PSF awareness item in the sexual health section served as a filter for questions about past help-seeking behavior. In addition, 12 sociodemographic and health items (eg, religious affiliation and relationship status) from YouGov's existing registration dataset were purchased and incorporated to align with recommendations on overall survey length. The full codebook is available in Multimedia Appendix 1.

Sociodemographic, Behavioral, and Sexual Factors

Total items regarding sociodemographic variables included age (in years), education level (>12 years), monthly net income, employment status, religious affiliation, relationship status, heterosexual orientation, migration background (ie, self or parental immigration after 1949), presence of ≥1 child in the household, history of pregnancy and child birth, current breastfeeding status, household size (≥2 individuals), responsibility for the majority of housework, primary caregiver status, and urban residence. Behavioral factors included current medication use, alcohol consumption (>1 drink per week), smoking status (ie, all respondents who did not select "I am a nonsmoker"), and low physical activity (ie, less than once per week). Sexual factors included experiences of sexual discrimination, masturbation, and partnered sexual activity within the past 12 months; a history of sexual trauma; and time spent in emotionally meaningful relationships. Operationalization and measurement details are provided in the codebook available in Multimedia Appendix 1.

ICD-11 Screener for Sexual Dysfunction and Pain Disorders

Sexual dysfunction was assessed according to *ICD-11* using an early version of the Screening for Sexual Problems in Women (SSP-F) by Velten and Zarski [62], which included 8 questions. Four questions addressed the occurrence of PSF in the 4 domains of desire, arousal, orgasm, and pain on a 5-point Likert scale (1, not at all; 2, episodically; 3, sometimes; 4, often (75%); 5, always). If applicable, a further question assessed the related sexual distress level with the following response: not at all (1), a bit (2), partly (3), severe (4), or very severe (5). Sexual dysfunction was defined as a sexual problem in any of the 4 domains occurring at least episodically with severe or very severe distress, resulting in a binary sexual dysfunction variable (yes/no). PSF was defined as having any reported sexual problem, regardless of frequency or distress, resulting in a binary PSF variable (yes/no).

Female Sexual Distress Scale

The Female Sexual Distress Scale-Desire/Arousal/Orgasm (FSDS-DAO) from Derogatis et al [63] consists of 15 items capturing the level of distress associated with sexuality within the last 30 days on a 5-point Likert scale ranging from 0 (never) to 4 (always). The German translation was established according to the linguistic validation guidance by the Mapi Group [64]. A total sexual distress sum score was calculated, ranging from 0 to 60, with higher scores indicating greater sexual distress.

Definition of CHC and Mental Health Status

Chronic conditions were grouped into mental health–related CHCs (MH; eg, depression, anxiety disorders, posttraumatic stress disorder, premenstrual dysphoric disorder, autism, and other mental health conditions), cardiovascular and metabolic CHCs (CV; eg, cardiovascular disease, atherosclerosis, hypertension, diabetes, dyslipidemia, and osteoporosis), gynecological CHCs (GY; eg, vulvodynia, vestibulodynia, lichen sclerosus, urinary tract problems, incontinence, endometriosis, dysmenorrhea, pelvic floor dysfunction, polycystic ovary syndrome, and infertility for more than 6 months), infectious and inflammatory CHCs (IN; eg, psoriasis, joint inflammation, rheumatoid arthritis, rheumatism, sexually transmitted infection, and HIV/AIDS), cancer CHCs (CA; eg, breast, cervical, uterine, vulvar, ovarian, and other cancers), pain-related CHCs (PA; eg, chronic pain, chronic pelvic pain, and bladder pain syndrome), and neurological CHCs (NE; eg, Alzheimer disease, dementia, epilepsy, multiple sclerosis, Parkinson disease, stroke, and cerebral palsy). Overall, participants were compared regarding the presence of CHCs (CHC vs no CHC). Among those with CHCs, an additional classification was made based on the presence of at least one MH among CHCs versus the presence of only somatic CHCs without any mental health conditions (MH+ vs CHC MH−).

Definition of Comorbid and Distinct CHC Subgroups

The 7 CHC subgroups consisted of participants affected by at least one of the CHCs, ie, MH+, CV+, GY+, IN+, CA+, PA+, or NE+, referred to as "comorbid CHC" subgroups to highlight that women of these subgroups might not exclusively be affected by 1 CHC.

For the descriptive statistics of the prevalence estimates, participants with more than one CHC were excluded from the MH, CV, GY, IN, CA, PA, and NE subgroups. In analyses, subgroups excluding comorbid individuals have been referred to as "distinct CHC" subgroups to highlight that women in these subgroups are exclusively affected by a specific CHC.

Efforts to Reduce Bias

Experts with personal or professional experience in PSF were included within the PPI process to reduce nonresponse bias and ensure the relevance of the study design.

Statistical Methods

Statistical analyses were conducted using R, version 4.3.2, with the packages UpSetR [65] and IsingFit [66]. The dataset provided by YouGov included a weight variable aligning the data with the Microcensus 2014 regarding age, sex, and federal state. For descriptive analyses, weights were applied (weighted mean, SD, and frequency). Unweighted frequencies have been reported for main group sizes. A comorbidity analysis visualized the overlap of CHC subgroups. For descriptive analyses, such as the prevalence of PSF and sexual dysfunction, and the summary of FSDS-DAO, distinct subgroups were used. FSDS-DAO scores were compared between participants with

and without CHCs, as well as across CHC groups, using linear regression models adjusted for age, sexual activity, and relationship status. Given the skewed distribution and discrete nature of FSDS-DAO as a summed score, a negative binomial regression model was additionally fitted as a sensitivity analysis to account for potential overdispersion and nonnormality of residuals. Multivariable logistic regression assessed the association between sexual dysfunction and CHCs, using (1) a binary variable for CHC status, (2) a binary variable for MH status, or (3) binary variables for comorbid CHC subgroups (MH+, CV+, GY+, IN+, CA+, PA+, and NE+), adjusting for age, sexual activity, and relationship status. Odds ratios (ORs) and 95% CIs have been reported. For ordinal variables with ≥4 categories, median and IQR were estimated. To explore the interrelationships among the CHC subgroups and 4 sexual dysfunction domains, a network analysis was conducted using the methodology proposed by Epskamp and Fried [67] for binary data. Therefore, the Ising model with regularized estimation nodewise logistic regression was applied using the IsingFit R package by van Borkulo et al [66], with the OR rule and an EBIC hyperparameter of γ=0.25. Interaction parameters (β), representing the strength of the interaction between 2 variables, and threshold parameters, indicating the probability of occurrence within the sample, have been reported. Results have been reported by subgroup, including CHC, no CHC, MH+, CHC MH−, and comorbid CHC subgroups, except for the descriptive statistics of the prevalence analysis, which used the distinct CHC subgroups. Missing values were not imputed, and "not specified" and "not answered" responses were treated as missing. All analyses were considered exploratory, with no significance level or adjustment for multiple comparisons.

Ethical Considerations

This human participant study was approved by Charité – Universitätsmedizin Berlin (EA4/221/21). YouGov obtained informed consent from its panelists for data collection and transmitted pseudonymized data to Charité for analysis. Participants were compensated with 500 YouGov points (equivalent to €1 or US $1.16) for completing the questionnaire. Participants could opt out of any item and skip questions without providing a response.

Results

Characteristics of the Study Population

Of 4430 panelists invited to participate, 4122 started and completed the survey, resulting in a 93.0% completion rate. Of those, 99 panelists (2.4%) were excluded due to contradictory demographic data, leaving a total of 4023 data records. After further exclusion of 2007 noneligible participants (unweighted: $n_{cis\text{-}men}$=1787, n_{noncis}=220) and 46 participants not responding to the question regarding CHCs, 1970 participants were included in the analysis (mean age 49.6, SD 16.0 years). For the flow of participants, see Figure 1. Women with CHCs but no MH (CHC MH−; 613/1935, 31.9%) were older than women with MH+ (538/1935, 27.8%), with mean ages of 54.3 (SD 15.5) years and 49.0 (SD 14.3) years, respectively (Table 1 and Table S1 in Multimedia Appendix 2 for CHC subgroups). Women with sexual dysfunction were younger than those without sexual dysfunction, both among those with CHCs (mean age: 46.1, SD 15.6 years vs 53.3, SD 14.2 years) and without CHCs (mean age: 32.8, SD 12.7 years vs 47.4, SD 15.8 years). Among all participants, the majority reported being in a relationship (1157/1929, 60.0%). In the last 12 months, 18.1% (331/1829) were sexually active with another person, and 34.3% (628/1829) were sexually active with themselves. Multiple CHCs were present in 32.6% (633/1939) of participants, with mental health and gynecological conditions being the most frequent comorbidities (Figure 2).

Figure 1. Flowchart of participants with unweighted numbers. CHC: chronic health condition; CHC MH−: chronic health conditions excluding mental health conditions; MH: mental health–related chronic health conditions; MH+: comorbid mental health–related chronic health conditions.

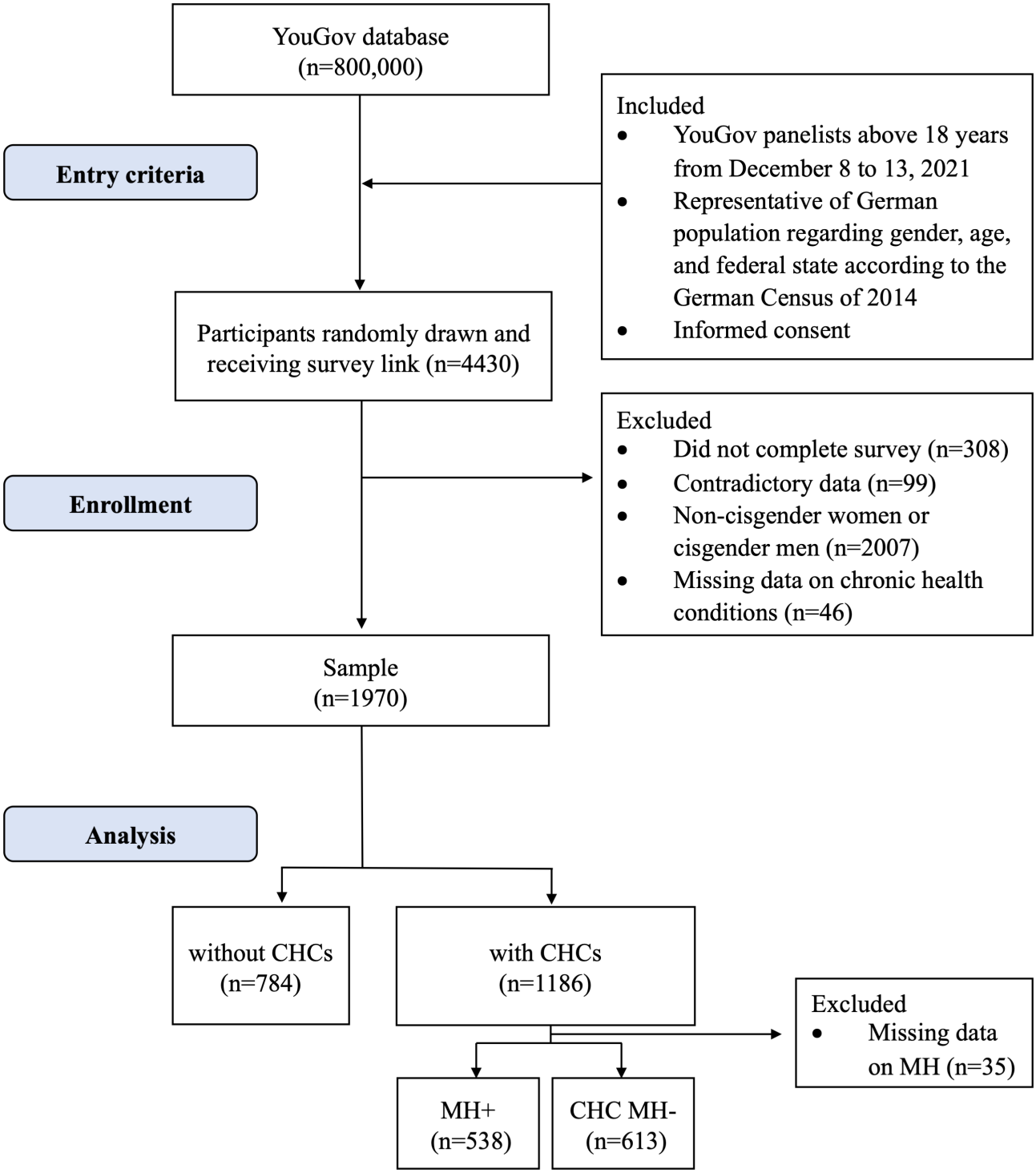


Figure 2. Intersection of chronic conditions visualized using an UpSet plot. The plot displays co-occurrence patterns among 7 chronic health conditions (CHCs). The left bar plot indicates the overall prevalence of each individual condition across the sample, regardless of whether it co-occurs with other conditions. The upper bar plot represents the frequency of specific intersection sets, showing how many individuals are affected by particular combinations of conditions. Each intersection set is denoted by connected dots in the matrix below the upper bar plot, where filled dots indicate the presence of a condition in the corresponding combination. This visualization facilitates the identification of common comorbidity patterns within the dataset. CA: cancer chronic health conditions; CV: cardiovascular and metabolic chronic health conditions; GY: gynecological chronic health conditions; IN: infectious and inflammatory chronic health conditions; MH: mental health–related chronic health conditions; NE: neurological chronic health conditions; PA: pain-related chronic health conditions.

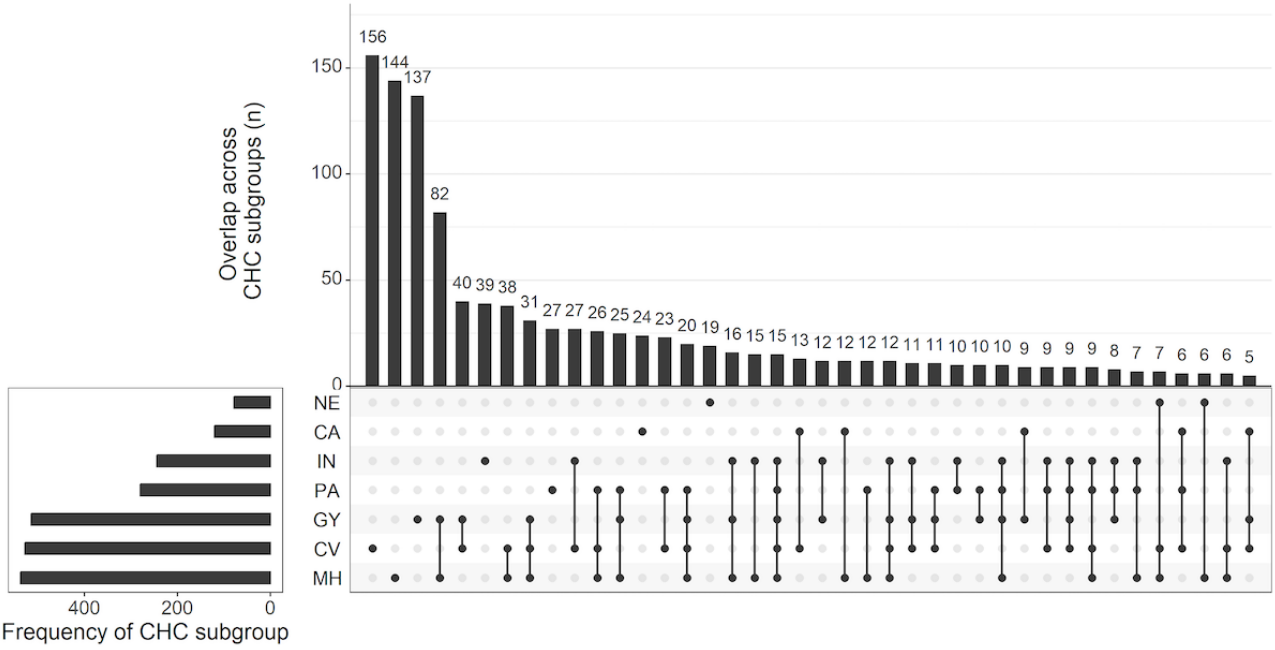


Table . Characteristics of the study population stratified by CHC[a] and mental health–related CHC status (weighted frequencies; group sizes are unweighted).

Characteristic	No CHC (n=784)	CHC		
		All (n=1186)	MH+[b] (n=538)	CHC MH−[c] (n=613)
Age (years), mean (SD)	46.0 (16.6)	52.0 (15.1)	49.0 (14.3)	54.3 (15.5)
Age groups (years), n (%)				
18 - 30	172 (22.4)	137 (11.7)	77 (14.6)	59 (9.8)
31 - 40	147 (19.2)	137 (11.7)	67 (12.6)	70 (11.4)
41 - 50	124 (16.1)	188 (16.0)	104 (19.7)	78 (12.8)
51 - 65	213 (27.8)	484 (41.3)	228 (43.1)	237 (39.1)
>65	111 (14.5)	225 (19.2)	53 (10.1)	163 (26.9)
Education (>12 years), n (%)	348 (45.4)	469 (40.0)	227 (43.0)	231 (38.0)
Monthly net income (€), n (%)				
<2500 (US $2900)	494 (78.8)	854 (82.6)	402 (85.4)	430 (80.2)
2500 - 5000 (US $2900-5800)	118 (18.9)	165 (16.0)	66 (13.9)	96 (17.8)
>5000 (US $5800)	15 (2.3)	14 (1.4)	3 (0.6)	11 (2.0)
Employed, n (%)	430 (62.1)	490 (43.9)	219 (44.3)	260 (44.3)
Religious, n (%)	437 (61.3)	674 (59.9)	278 (54.4)	376 (64.8)
Relationship, n (%)	461 (60.5)	696 (59.6)	295 (56.1)	380 (62.7)
Heterosexual, n (%)	662 (93.7)	1004 (91.2)	449 (89.3)	523 (92.5)
Migration background, n (%)	147 (19.6)	172 (14.7)	77 (14.6)	92 (15.2)
Children (≥1) in same household, n (%)	205 (26.7)	223 (19.0)	96 (18.3)	119 (19.5)
Pregnancy or child birth[d], n (%)	33 (4.8)	62 (5.5)	24 (4.7)	37 (6.2)
Breastfeeding[d], n (%)	23 (3.3)	17 (1.5)	8 (1.6)	9 (1.6)
Household size ≥2, n (%)	562 (73.2)	800 (68.3)	341 (64.6)	437 (71.9)
Majority of housework, n (%)	347 (50.8)	627 (55.7)	285 (55.8)	330 (55.8)
Primary caregiver, n (%)	88 (13.0)	146 (12.9)	63 (12.4)	77 (13.1)
Urban area, n (%)	290 (37.8)	475 (40.6)	229 (43.3)	229 (37.8)
Behavioral risk factors, n (%)				
Medication for CHCs	85 (12.2)	538 (47.3)	269 (52.0)	256 (43.1)
Alcohol consumption[e]	554 (80.2)	878 (77.2)	394 (76.1)	462 (77.8)
Smoking	345 (49.9)	567 (49.8)	262 (50.6)	289 (48.7)
Low physical activity[e]	525 (68.5)	779 (66.5)	347 (65.6)	401 (65.9)
Sexual discrimination	0 (0.0)	15 (1.3)	7 (1.4)	8 (1.3)
Sexual behavior, n (%)				
Masturbation[d]	422 (37.1)	206 (29.8)	231 (44.7)	186 (31.3)
Partnered sexual activity[d]	132 (19.0)	199 (17.5)	120 (23.3)	77 (13.0)
Sexual trauma[d]	18 (2.7)	78 (6.9)	54 (10.4)	24 (4.1)

Characteristic	No CHC (n=784)	CHC		
		All (n=1186)	MH+[b] (n=538)	CHC MH−[c] (n=613)
Spending time in relationships[d]	284 (41.7)	484 (43.0)	193 (37.7)	283 (47.8)

[a]CHC: chronic health condition.

[b]MH+: comorbid mental health–related chronic health conditions.

[c]CHC MH−: chronic health conditions excluding mental health conditions.

[d]In the past 12 months.

[e]Less than once per week.

Sample Representativeness and Comparison With Microcensus Data

The full unweighted sample from YouGov (n=4023) was compared with the 2014 official German Microcensus data [59]. Key demographic characteristics, including sex, age distribution, and federal state, showed comparable distributions (see Tables S3 and S4 in Multimedia Appendix 2).

Prevalence of PSF and Sexual Dysfunction Symptoms and Sexual Distress in Distinct CHC Subgroups

Prevalence

Overall, women with CHCs had a higher prevalence of PSF symptoms (CHC: 820/1090, 75.2% vs no CHC: 399/638, 62.5%; OR 1.82, 95% CI 1.48 - 2.24) and sexual dysfunction symptoms with clinical relevance (CHC: 202/1046, 19.3% vs no CHC: 68/601, 11.3%; OR 1.87, 95% CI 1.40 - 2.53) (Table 2). Low sexual desire was the most frequently experienced PSF in women with and without CHCs. In contrast, sexual dysfunction symptoms with clinical relevance were reported most frequently in the domain of orgasm, independent from CHC status, and in all distinct CHC subgroups, except for CA and IN, which most frequently had sexual pain disorders. For an illustration of PSF and sexual dysfunction prevalence, see Figure 3.

Figure 3. Prevalence of problems in sexual function (PSF) and sexual dysfunction. Panel A shows the prevalence of PSF stratified by overall chronic health condition (CHC) status, mental health–related CHC (MH) status, and distinct CHC subgroups. Panel B presents the corresponding prevalence of sexual dysfunction. For both PSF and sexual dysfunction, prevalence estimates are further broken down by individual PSF or sexual dysfunction domains. CA: cancer chronic health conditions; CHC MH−: chronic health conditions excluding mental health conditions; CV: cardiovascular and metabolic chronic health conditions; GY: gynecological chronic health conditions; IN: infectious and inflammatory chronic health conditions; MH+: comorbid mental health–related chronic health conditions; NE: neurological chronic health conditions; PA: pain-related chronic health conditions.

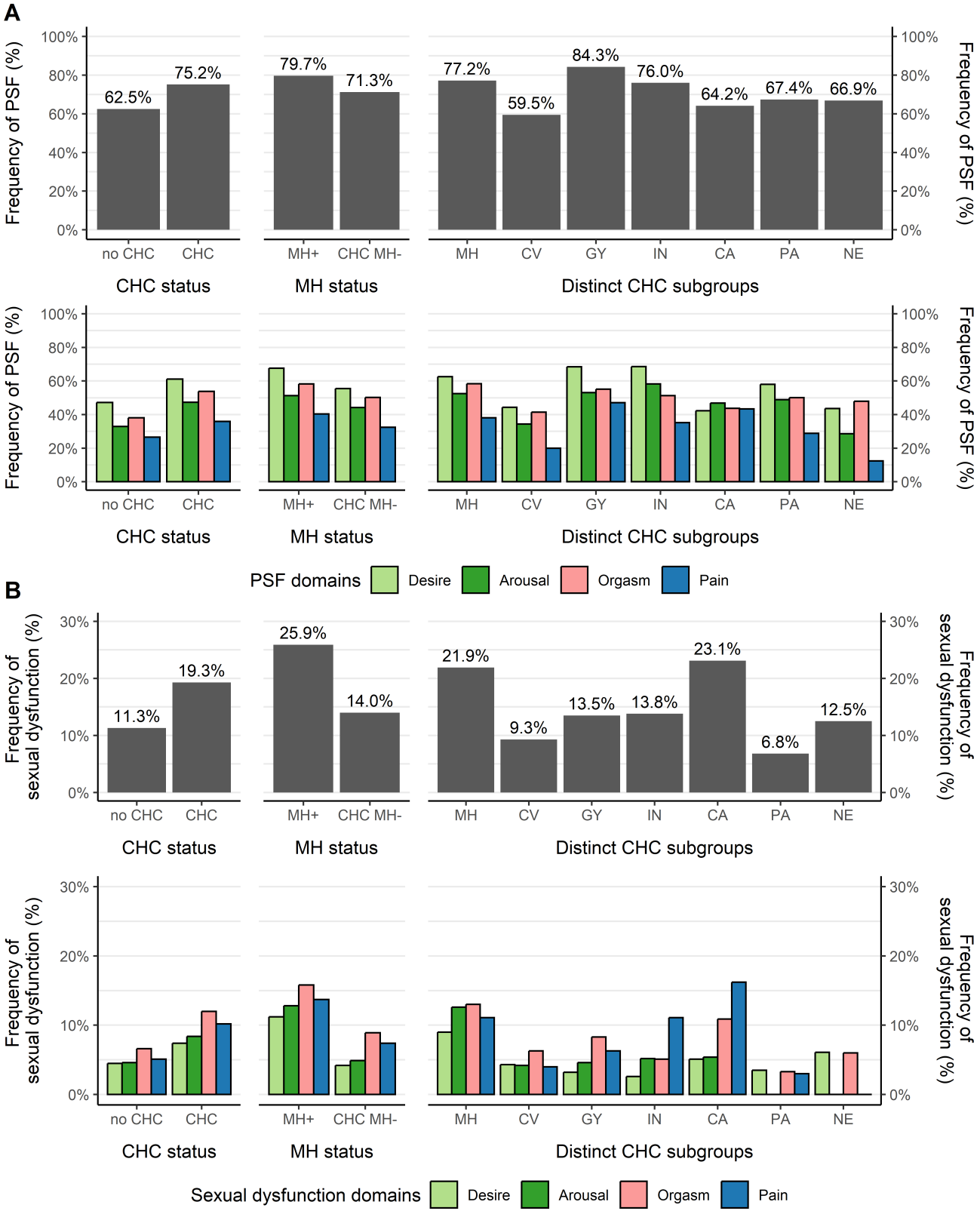


Table . Prevalence of problems in sexual function and sexual dysfunction, and descriptive summary of Female Sexual Distress Scale-Desire/Arousal/Orgasm findings by CHC[a] status and distinct CHC subgroups (weighted frequencies; group sizes are unweighted).

Variable	No CHC (n=768)	CHC (n=1172)	OR[b] (95% CI)	MH[c] (n=144)	CV[d] (n=156)	GY[e] (n=137)	IN[f] (n=39)	CA[g] (n=24)	PA[h] (n=27)	NE[i] (n=19)
PSF[j], n (%)										
≥Domain	399 (62.5)	820 (75.2)	1.82 (1.48 - 2.24)	397 (79.7)	84 (59.5)	109 (84.3)	26 (76.0)	13 (64.2)	17 (67.4)	11 (66.9)
Desire	318 (47.2)	674 (61.1)	1.76 (1.45 - 2.14)	82 (62.6)	64 (44.3)	89 (68.4)	24 (68.5)	9 (42.3)	14 (58.0)	7 (43.6)
Arousal	212 (32.9)	518 (47.3)	1.83 (1.50 - 2.24)	68 (52.5)	49 (34.3)	69 (53.1)	20 (58.2)	10 (46.8)	12 (48.9)	5 (28.6)
Orgasm	240 (38.1)	582 (53.8)	1.90 (1.56 - 2.31)	76 (58.4)	58 (41.4)	72 (55.1)	17 (51.3)	8 (43.7)	12 (50.1)	8 (47.9)
Pain	169 (26.6)	387 (35.9)	1.54 (1.25 - 1.91)	50 (38.1)	28 (20.0)	61 (47.1)	12 (35.2)	8 (43.4)	7 (28.8)	2 (12.4)
Sexual dysfunction, n (%)										
≥Domain	68 (11.3)	202 (19.3)	1.87 (1.40 - 2.53)	124 (25.9)	13 (9.3)	17 (13.5)	5 (13.8)	4 (23.1)	2 (6.8)	2 (12.5)
Desire	30 (4.5)	81 (7.4)	1.69 (1.11 - 2.63)	12 (9.0)	6 (4.3)	4 (3.2)	1 (2.6)	1 (5.1)	1 (3.5)	1 (6.1)
Arousal	29 (4.6)	91 (8.4)	1.91 (1.26 - 2.96)	16 (12.6)	6 (4.2)	6 (4.6)	2 (5.2)	1 (5.4)	0 (0)	0 (0)
Orgasm	42 (6.6)	129 (12.0)	1.91 (1.34 - 2.77)	17 (13.0)	9 (6.3)	11 (8.3)	2 (5.1)	2 (10.9)	1 (3.3)	1 (6.0)
Pain	32 (5.1)	109 (10.2)	2.10 (1.42 - 3.18)	14 (11.1)	6 (4.0)	8 (6.3)	4 (11.1)	3 (16.2)	1 (3.0)	0 (0)
FSDS-DAO[k] (score 0 - 60), median (IQR)										
All	3 (0.0 - 13.0)	9 (1.0 - 21.0)	—[l]	13 (3-23)	4 (0 - 11)	10 (4-19)	6 (1-19)	3 (3-23)	4 (1-14)	1 (0 - 2)
Women with PSF	9 (2.0 - 19.0)	14 (5.0 - 25.0)	—	16 (7-25)	9 (3-16)	13 (5-21)	14 (4-24)	23 (3-25)	8 (3-17)	0 (0 - 2)
FSDS-DAO (score 0 - 60), mean (SD)										
All	8.4 (11.1)	12.9 (12.9)	—	14.7 (13.1)	7.8 (10.6)	12.3 (10.4)	10.6 (10.6)	12.3 (13.8)	8.1 (9.3)	3.2 (6.2)
Women with PSF	12.5 (12.3)	16.2 (13.2)	—	17.5 (13.1)	12.2 (11.9)	14.2 (10.4)	12.9 (10.5)	15.9 (15.3)	10.0 (9.4)	2.5 (5.1)

[a]CHC: chronic health condition.

[b]Odds ratios (ORs) are reported for the comparison of women with and those without chronic health conditions.

[c]MH: mental health–related chronic health conditions.

[d]CV: cardiovascular and metabolic chronic health conditions.

[e]GY: gynecological chronic health conditions.

[f]IN: infectious and inflammatory chronic health conditions.

[g]CA: cancer chronic health conditions.

[h]PA: pain-related chronic health conditions.

[i]NE: neurological chronic health conditions.

[j]PSF: problems in sexual function.

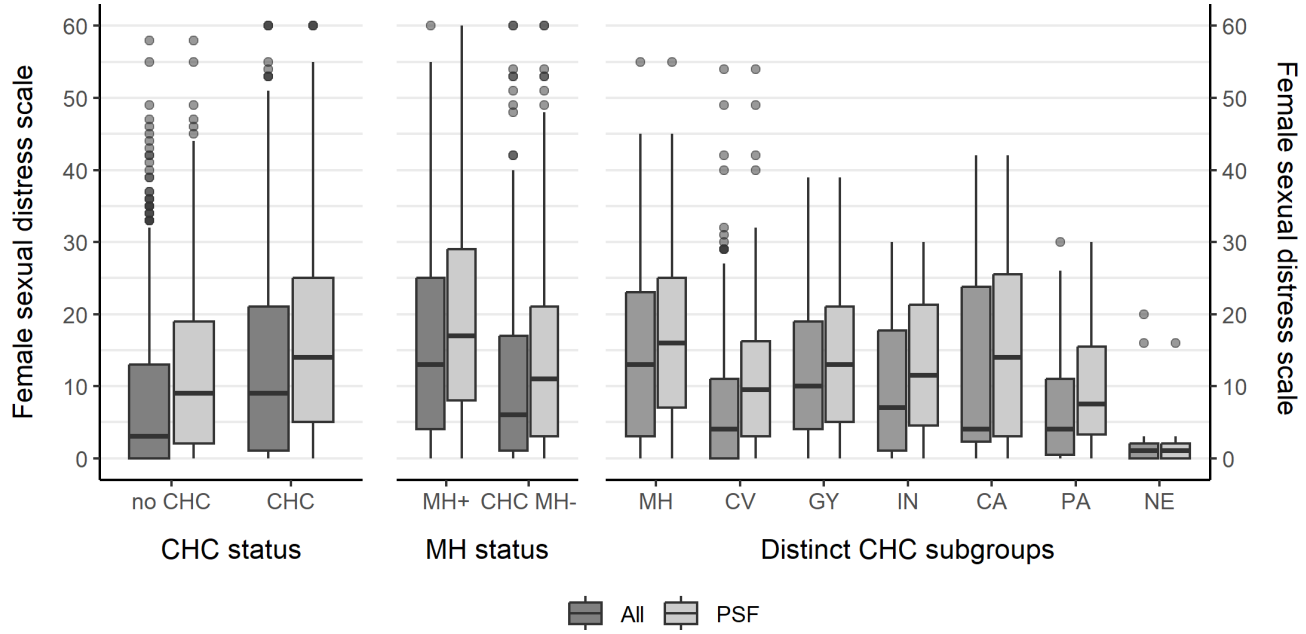
[k]FSDS-DAO: Female Sexual Distress Scale-Desire/Arousal/Orgasm.

[l]Not applicable.

Sexual Distress

As assessed by the FSDS-DAO, participants with CHCs reported higher sexual distress (mean 12.9, SD 12.9) than those without CHCs (mean 8.4, SD 11.1). Among women with CHCs, women with MH reported higher mean scores (mean 16.0, SD 13.6) than those without MH (mean 10.2, SD 11.6). Among participants with PSF, the highest FSDS-DAO scores were noted in women with cancer (n=11; median 23, IQR 3 - 25) and those with MH (n=92; median 16, IQR 7 - 25) (Figure 4).

Figure 4. Sexual distress measured by the Female Sexual Distress Scale-Desire/Arousal/Orgasm by chronic health condition (CHC) status, mental health–related CHC (MH) status, and distinct CHC subgroups. CA: cancer chronic health conditions; CHC MH−: chronic health conditions excluding mental health conditions; CV: cardiovascular and metabolic chronic health conditions; GY: gynecological chronic health conditions; IN: infectious and inflammatory chronic health conditions; MH+: comorbid mental health–related chronic health conditions; NE: neurological chronic health conditions; PA: pain-related chronic health conditions; PSF: problems in sexual function.



Association of CHC Status and CHC Subgroups With PSF, Sexual Dysfunction, and Sexual Distress

Multivariable Regression Models

For the analysis of a CHC as a risk factor for sexual dysfunction, logistic regression models were adjusted for age, sexual activity, and relationship status. Being sexually active was a protective factor, while being in a relationship increased the risk for sexual dysfunction in all models. Having any CHC was considerably associated with sexual dysfunction (adjusted OR 2.56, 95% CI 1.90 - 3.49; *P*<.001) (see Model 1 in Table 3). Model 2 showed that the odds of sexual dysfunction symptoms were twice as high in the MH+ group compared to the CHC MH− group (adjusted OR 2.00, 95% CI 1.45 - 2.78; *P*<.001). Model 3 revealed the strongest associations between CHCs and sexual dysfunction for participants with MH+ (adjusted OR 2.31, 95% CI 1.70 - 3.13; *P*<.001) and those with cancer (adjusted OR 1.98, 95% CI 1.18 - 3.25; *P*=.008). A subgroup analysis for the relationship status revealed that the association between CHCs and sexual dysfunction was lower in women who were in a relationship (OR 2.06) than in those who were not (OR 4.18) (Table S2 in Multimedia Appendix 2).

Table . Multivariable logistic regression models for sexual dysfunction using binary CHC[a] status (model 1), mental health–related CHC (MH) status (model 2), and comorbid CHC subgroups (model 3).

Variable	Model 1 (n=1675)		Model 2 (n=1675)		Model 3 (n=1491)	
	OR[b] (95% CI)	*P* value	OR (95% CI)	*P* value	OR (95% CI)	*P* value
CHC (yes)	2.56 (1.90 - 3.49)	<.001	—[c]	—	—	—
Age	0.96 (0.95 - 0.97)	<.001	0.97 (0.96 - 0.98)	<.001	0.96 (0.95 - 0.97)	<.001
Sexual activity[d]	0.90 (0.65 - 1.25)	.55	0.79 (0.52 - 1.18)	.25	0.80 (0.55 - 1.15)	.24
Relationship	1.34 (1.01 - 1.77)	.04	1.27 (0.92 - 2.78)	.16	1.56 (1.15 - 2.13)	.005
MH+[e]/CHC MH−[f] (MH)	—	—	2.00 (1.45 - 2.78)	<.001	—	—
CHC						
MH+	—	—	—	—	2.31 (1.70 - 3.13)	<.001
CV+[g]	—	—	—	—	1.35 (0.95 - 1.91)	.09
GY+[h]	—	—	—	—	1.40 (1.03 - 1.90)	.03
IN+[i]	—	—	—	—	1.21 (0.85 - 1.89)	.34
CA+[j]	—	—	—	—	1.98 (1.18 - 3.25)	.008
PA+[k]	—	—	—	—	1.28 (0.85 - 1.89)	.23
NE+[l]	—	—	—	—	1.16 (0.57 - 2.19)	.67

[a]CHC: chronic health condition.

[b]OR: odds ratio.

[c]Not applicable.

[d]Partnered sexual activity in the last 12 months.

[e]MH+: comorbid mental health–related chronic health conditions.

[f]CHC MH−: chronic health conditions excluding mental health conditions.

[g]CV+: comorbid cardiovascular and metabolic chronic health conditions.

[h]GY+: comorbid gynecological chronic health conditions.

[i]IN+: comorbid infectious and inflammatory chronic health conditions.

[j]CA+: comorbid cancer chronic health conditions.

[k]PA+: comorbid pain-related chronic health conditions.

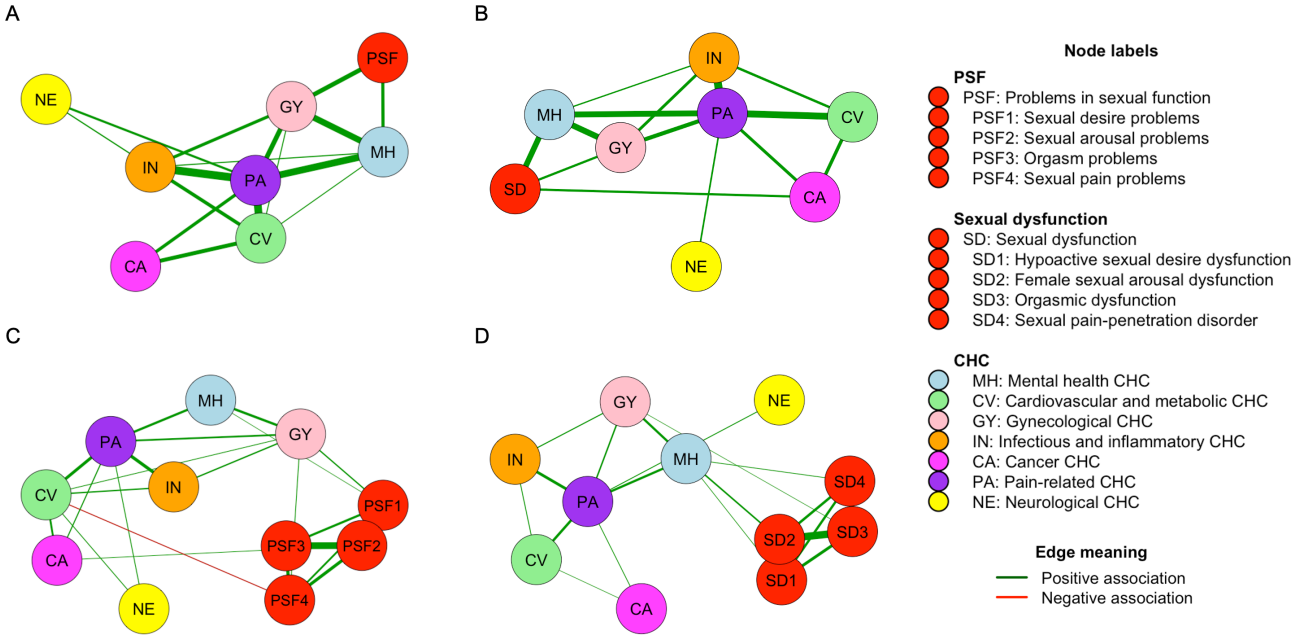
[l]NE+: comorbid neurological chronic health conditions.

For the analysis of a CHC as a risk factor for sexual distress, linear models revealed an average increase in the FSDS-DAO score by 6 points for CHC vs no CHC (Table S5 in Multimedia Appendix 2). In addition, a negative binomial regression was applied owing to 25% zero inflation and a poor fit with linear regression, confirming the presence of a CHC as a risk factor for sexual distress (data not shown).

Network Analyses

The network analyses of the comorbidity structure of CHC subgroups with PSF and CHC subgroups with sexual dysfunction are presented visually in Figure 5. With a hyperparameter value of 0.25, associations were observed between PSF and GY (β_{PSFGY}=.59) and between PSF and MH (β_{PSFMH}=.42). The PSF domains showed strong intercorrelations, most pronounced between desire and arousal ($\beta_{PSF1PSF2}$=2.45) and arousal and orgasm ($\beta_{PSF2PSF3}$=2.45). Sexual dysfunction had moderate positive associations with MH (β_{SDMH}=.75) and weak associations with GY (β_{SDGY}=.32) and CA (β_{SDCA}=.32). As with the PSF domains, the sexual dysfunction domains were also strongly intercorrelated. For further information on interaction parameter β, see Tables S6-S9 in Multimedia Appendix 2. Using the spring layout, PA was centrally located in all networks and showed high regression coefficients across different conditions, especially with IN and CV. CV had the highest thresholds in all networks, except for PSF in network A, indicating its high probability of presence (Table S10 in Multimedia Appendix 2).

Figure 5. Network analyses of chronic health condition (CHC) subgroups and (A) total problems in sexual function (PSF), (B) total sexual dysfunction (SD), (C) individual domains of PSF, and (D) individual domains of SD. Nodes represent outcome variables, and edges represent interaction parameters (β), with thickness indicating the strength of the association.



Received Diagnoses in Women With Sexual Dysfunction

The prevalence of self-reported sexual dysfunction diagnoses in the female study population was 7.4% (129/1749) for any sexual dysfunction diagnosis, 4.8% (83/1750) for hypoactive sexual desire disorder, 2.0% (35/1750) for orgasmic disorder, and 1.7% (30/1749) for sexual pain-penetration disorder. When compared to the prevalence rates of clinically relevant sexual dysfunction symptoms according to *ICD-11*, substantial gaps were observed in all sexual dysfunction domains. Assessment of diagnosis rates among women reporting sexual dysfunction symptoms revealed large gaps between sexual dysfunction prevalence based on *ICD-11* criteria and actual diagnosis rates, with differences depending on CHC status and sexual dysfunction domains. Although underdiagnosis could be shown for all groups, higher rates of sexual dysfunction diagnosis were found among women with CHC (CHC: 39/200, 19.4% vs no CHC: 6/55, 10.7%; OR 2.00, 95% CI 0.85 - 5.53), in particular among those with MH+ (MH+: 29/124, 23.5% vs CHC MH−: 10/76, 12.8%; OR 2.10, 95% CI 0.99 - 4.81). However, within sexual dysfunction domains, higher diagnosis rates for women with CHCs were detected only for hypoactive sexual desire disorder (CHC: 23/200, 11.7% vs no CHC: 2/55, 3.6%; OR 3.54, 95% CI 1.01 - 22.45) and sexual pain-penetration disorder (CHC: 10/200, 4.9% vs no CHC: 1/55, 1.6%; OR 3.11, 95% CI 0.55 - 70.20). In contrast, women with CHCs had slightly lower rates of diagnosis when they had orgasmic disorder (CHC: 12/200, 6.2% vs no CHC: 4/55, 7.5%; OR 0.82, 95% CI 0.28 - 2.94).

Health Care Needs

Help-Seeking Behavior

The most reported primary sources of information about sexual problems were the internet (CHC: 63/150, 42.1% vs no CHC: 23/39, 59.7%; MH+: 45/102, 44.8% vs CHC MH−: 18/48, 37.2%) and gynecological visits (CHC: 61/150, 40.5% vs no CHC: 15/39, 38.0%; MH+: 39/102, 38.2% vs CHC MH−: 21/48, 44.2%). Access to therapy for women with sexual dysfunction was limited (CHC: 16/145, 11.0% vs no CHC: 2/39, 7.0%). The median duration to start treatment after symptom onset was shorter for women with CHCs (CHC: 3 - 4 months vs no CHC: 5 - 6 months). Access to psychotherapy was rare. However, it was slightly higher for women with CHC (CHC: 18/149, 11.8% vs no CHC: 1/38, 2.5%; OR 5.30, 95% CI 1.01 - 106.69) but lower for those without MH (MH+: 14/101, 14.4% vs CHC MH−: 3/48, 6.6%). The most reported barriers for women with sexual dysfunction and CHCs were shame (CHC: 81/197, 41.1% vs no CHC: 28/65, 43.0%), fear of not being taken seriously (CHC: 56/197, 28.4% vs no CHC: 25/65, 38.3%), and a lack of information about who to contact (CHC: 54/197, 27.5% vs no CHC: 19/65, 28.8%). For complete data on the help-seeking behavior of women with sexual dysfunction, see Table S11 in Multimedia Appendix 2.

Preferred Access to Care and Treatment

Women with sexual dysfunction preferred gynecological visits for information, regardless of CHC status (CHC: 113/197, 57.4% vs no CHC: 42/66, 63.5%) and the presence or absence of MH (MH+: 71/120, 59.1% vs CHC MH−: 42/75, 56.1%). Favoring psychotherapy as a treatment for sexual dysfunction was only marginally different between CHC groups (CHC: 51/202, 25.5% vs no CHC: 14/68, 21.2%) but more frequent in women with MH (MH+: 42/124, 34.0% vs CHC MH−: 9/76, 12.4%). In contrast to women without CHC, more women with CHC preferred the sexual dysfunction treatment options of specialized clinics (CHC: 46/202, 22.6% vs no CHC: 9/68, 13.2%; OR 1.94, 95% CI 0.93 - 4.45), drugs (CHC: 48/202, 23.9% vs no CHC: 6/68, 9.2%; OR 3.09, 95% CI 1.37 - 8.15), and surgery (CHC: 14/202, 6.8% vs no CHC: 1/68, 1.5%; OR 4.71, 95% CI 0.95 - 77.33). For women with sexual dysfunction and CHCs, the most important treatment goals were increases in body and sexual self-esteem (CHC: 82/196, 42.0%; MH+: 57/121, 46.9%

vs CHC MH−: 26/73, 35.2%), relationship satisfaction (CHC: 76/196, 38.7%; MH+: 44/121, 36.6% vs CHC MH−: 31/73, 42.1%), and sexual satisfaction (CHC: 75/196, 38.5%; MH+: 46/121, 37.9% vs CHC MH−: 29/73, 39.4%). Regarding functional domains, improvement in desire was more often rated as important by women with MH (MH+: 43/121, 35.8% vs CHC MH−: 20/73, 27.6%) and pain by women without MH (MH+: 32/121, 26.4% vs CHC MH−: 24/73, 32.2%). For complete data on preferred access to care and treatment, see Table S12 in Multimedia Appendix 2.

Preferred Future Developments

Improved access to information was the most frequently desired development (60/179, 33.6%). Regarding the ratings of digital offers (10-point Likert scales), reimbursement by health insurance (mean 8.3, SD 2.4) and contact with sexual medicine experts (mean 7.5, SD 2.4) were considered most relevant by all women with sexual dysfunction. Women with sexual dysfunction and MH more often reported a need for direct contact per video call (MH+: 21/111, 19.0% vs CHC MH−: 5/70, 7.1%). For an overview of favored future developments and digital expert contact, see Table 4.

Table . Health care needs of women with sexual dysfunction by chronic health condition (CHC) and mental health–related CHC status.

Variable	Without CHC[a] (n=69)	With CHC (n=207)	OR[b] (95% CI)	MH+[c] (n=127)	CHC MH−[d] (n=78)
Favored future developments, n	59	179	—[e]	106	71
New drugs, n (%)	6 (10.2)	29 (16.2)	1.71 (0.72 - 4.72)	13 (12.5)	16 (22.2)
New surgery, n (%)	3 (5.5)	15 (8.6)	1.60 (0.53 - 6.53)	10 (9.2)	6 (7.9)
Better information, n (%)	12 (20.3)	60 (33.6)	1.99 (1.01 - 4.14)	33 (30.8)	27 (37.8)
Digital offers, n (%)					
Apps	13 (21.9)	43 (23.9)	1.12 (0.57 - 2.32)	24 (22.5)	19 (26.8)
Websites	9 (16.0)	41 (23.2)	1.59 (0.76 - 3.61)	27 (25.4)	15 (20.4)
Home aids	10 (16.9)	39 (21.7)	1.37 (0.66 - 3.06)	22 (20.6)	16 (22.2)
With physical face-to-face treatments	5 (9.2)	20 (11.2)	1.25 (0.49 - 3.69)	12 (11.0)	8 (11.7)
Contact with experts	11 (18.1)	38 (21.0)	1.20 (0.59 - 2.64)	26 (24.7)	12 (16.2)
Training					
Physicians	10 (16.3)	29 (16.3)	1.00 (0.47 - 2.30)	17 (16.3)	12 (16.9)
Psychologists	16 (27.7)	32 (17.8)	0.57 (0.29 - 1.13)	25 (23.4)	7 (10.1)
Diversity and trauma[f]	5 (8.6)	29 (16.5)	2.09 (0.84 - 6.25)	18 (17.2)	11 (15.9)
Expert contact in digital offers, n	61	183	—	111	70
Medical experts, n (%)	27 (45.2)	107 (58.5)	1.71 (0.96 - 3.06)	69 (62.4)	37 (52.8)
Psychological experts, n (%)	21 (35.2)	90 (49.1)	1.77 (0.98 - 3.25)	62 (56.3)	27 (39.2)
Video call, n (%)	13 (21.2)	27 (14.9)	0.65 (0.32 - 1.39)	21 (19.0)	5 (7.1)
Chat, n (%)	18 (29.1)	56 (30.5)	1.07 (0.58 - 2.04)	40 (36.5)	15 (20.7)
Email feedback, n (%)	14 (23.3)	46 (24.9)	1.09 (0.56 - 2.20)	26 (23.6)	19 (27.7)

[a]CHC: chronic health condition.

[b]OR: odds ratio. ORs are reported for the comparison of women with and those without chronic health conditions.

[c]MH+: comorbid mental health–related chronic health conditions.

[d]CHC MH−: chronic health conditions excluding mental health conditions.

[e]Not applicable.

[f]Sensitivity training, for example, culture, religion, trauma, gender identity, and sexual orientation.

Discussion

Principal Findings

The objectives of this study were to assess and compare the prevalence of PSF, sexual dysfunction, and sexual distress among women with and without CHCs and in CHC subgroups, to model associations between sexual dysfunction and CHC subgroups, evaluate self-reported diagnosis rates versus self-reported symptoms, and identify help-seeking behaviors associated with CHCs and mental health status. Beyond confirming that the prevalence of sexual dysfunction is higher in women with CHCs compared to those without CHCs when applying *ICD-11* criteria, this representative study provides valuable evidence on the extent to which specific CHC subgroups are affected by the burden of sexual dysfunction. The prevalence of sexual dysfunction in women with MH or CA was twice that in women without CHCs. Network analyses revealed positive associations for PSF with GY and MH and for sexual dysfunction with CA. Notably, specific disorders, such as hypoactive sexual desire disorder, female sexual arousal dysfunction, and sexual pain-penetration disorder, were associated with MH, whereas orgasmic disorder was associated with GY. Although the prevalence of diagnosed sexual dysfunction was generally low among those with a positive *ICD-11* screening, women with MH had a higher prevalence of diagnosed sexual dysfunction compared to women with CHCs, excluding MH. Women with CHCs had higher odds of receiving a diagnosis of sexual dysfunction for hypoactive sexual desire disorder and sexual pain-penetration disorder, but not for orgasmic disorder. Previous help-seeking behavior had mainly occurred online and through gynecological visits, with low therapy initiation rates in all subgroups. In terms of health care needs, women with sexual dysfunction mostly preferred gynecological visits. Women with CHCs sought treatment goals related to body and sexual self-esteem, while those without CHCs prioritized sexual and relationship satisfaction. Most women indicated their interest in better information and digital health services, especially apps with information and exercises, with reimbursement being an important aspect for digital solutions. These findings allow for more accurate quantitative estimates of the need for sexual dysfunction interventions in women's health care.

Sexual Dysfunction Prevalence and Associations With CHCs

The sexual dysfunction prevalence of 16.4% for the general female population in our data is consistent with previous representative surveys in Germany reporting a prevalence of 16.5% [1]. Additionally, the frequency of experienced PSF in women with CHCs (59.5% - 84.3%) in our study sample is comparable to the findings in other studies, which have primarily used functional assessments to detect sexual dysfunction [11-13,15]. Besides applying functional measures, research on sexual health in patients with CHCs is often limited to specific groups of certain disciplines or conditions [3-5,27,32], giving rise to a gap in the literature regarding differences in prevalence rates of PSF and sexual dysfunction in women with and without CHCs and women with different CHCs. The discrepancy between PSF and sexual dysfunction rates, as well as FSDS-DAO scores, suggests that the presence of PSF does not necessarily imply clinically relevant distress. However, some CHCs seem to be more potent than others in increasing vulnerability for the development of sexual distress. In particular, while 5 out of 6 women (84%) with only GY experienced PSF, only a small proportion (13.5%) met the criteria for sexual dysfunction. In contrast, women with only CA had the second lowest prevalence of reported PSF (64%) but the highest prevalence of sexual dysfunction (23.4%). Women with only MH reported high prevalences of PSF (77.2%) and sexual dysfunction (21.9%) compared to all other subgroups.

Consistent with the highest prevalence of sexual dysfunction in our sample, the highest levels of sexual distress were reported by women with a history of only CA and MH, with median FSDS-DAO scores of 14.7 and 12.3, respectively.

In line with these findings, the network with sexual dysfunction and CHC subgroups found positive associations of sexual dysfunction with MH, GY, and CA. This was partly reflected in the multiple logistic regression analysis, which showed that a CHC was a risk factor for reporting sexual dysfunction in this population. In women with CHCs, those with MH showed stronger associations with sexual dysfunction than women with physical conditions, and the strongest associations for sexual dysfunction were with CA and MH. The strong links of MH with sexual dysfunction might be explained by similar underlying cognitive and emotional factors, such as internalizing behaviors, as discussed previously by Forbes et al [15,23-28]. Patients with cancer have also been shown to experience high levels of distress when faced with a life-threatening disease, which may also increase vulnerability to sexual distress [10,11,32]. This study highlights that female cancer survivors with sexual dysfunction face the most severe impact on their sexual health. The high rate of reported willingness to pay substantial amounts for effective therapy by women with cancer further supports this conclusion. In contrast, women with gynecological conditions often have questions about sexual health, but only a few are willing to pursue sex therapy [44]. This suggests a high need for information, but not necessarily for therapy, which is consistent with the lower prevalence of distress in our data. Overall, PSF may primarily reflect questions and informational needs, whereas meeting sexual dysfunction criteria may indicate a need for a targeted therapeutic intervention.

Interestingly, there was a difference in the frequency of symptoms regarding domains of sexual function. Low sexual desire was the most common sexual problem experienced, but orgasmic disorder was the most prevalent sexual dysfunction for all groups, except women with inflammatory conditions and cancer.

Partnered women with CHCs had a reduced risk of sexual dysfunction compared to single women. Partnered women may benefit from more support and understanding from their partners, which may mitigate the impact of CHCs on sexual dysfunction. Studies have provided conflicting results about whether being in a relationship is a risk or protective factor for sexual

dysfunction [4]. Relationship quality has been suggested as a mediator for the effect of relationships on sexual dysfunction [4,5,34]. However, bidirectional links need to be considered, as sexual dysfunction has been shown to be a risk factor for relationship conflict [35]. Our data indicate that being in a relationship is a risk factor for sexual dysfunction, but this may be due to detection bias.

Health Care Preference

Our study found that the internet was the most commonly reported source for information help-seeking, which, on the one hand, underscores the importance of online resources in enhancing access to evidence-based information and treatment, as claimed by previous studies [50,52]. On the other hand, challenging barriers, such as low awareness of sexuality as a health issue, need to be addressed to link women to appropriate treatment effectively. The most important motivations for seeking treatment among all women with sexual dysfunction were to enhance body and sexual self-esteem and improve relationship and sexual satisfaction. This underpins the importance of focusing sexual health interventions on reframing the meaning of sexuality rather than solely targeting sexual functioning.

Challenges in Health Care

The present data show that only a minority of women with sexual dysfunction received therapy (CHC: 10% vs no CHC: 7%). Previous studies have consistently highlighted a lack of treatment [39-44], a trend consistent with our findings of low diagnosis rates. Notably, our figures are lower than those reported in other recent cross-sectional studies in Germany, such as the study by Velten and Margraf [48], which reported a treatment rate of 47.7% for women. This discrepancy may stem from nonrepresentative study samples, likely drawing participants with greater awareness of sexual health concerns (ie, greater health literacy). Furthermore, this study aimed to examine diagnosis rates as an indicator of how aware health care providers are of sexual health as a medical need for women. We found a large gap between the symptoms of sexual dysfunction and the diagnoses received, with 82.4% of sexual dysfunction cases remaining undiagnosed. This would result in a falsely low sexual dysfunction diagnosis prevalence of 7.4% in the general population (CHC: 10.5% vs no CHC: 1.7%).

Gynecologists, identified as the preferred source for information and dialog partners in our study, have also been reported as the first point of contact in previous studies [48]. In our data, women without MH had lower rates of diagnosis and access to treatment than women with sexual dysfunction and MH. Despite this, sexual health concerns are still rarely recognized by health care providers. In outpatient psychotherapy clinics, sexual dysfunction diagnosis rates are as low as 0.2% - 1.2% [43], which contrasts sharply with the 25.9% prevalence of sexual dysfunction symptoms among women with only MH in our study. In line with these findings, women with MH in our study particularly highlighted the need for better training for psychologists. While MH, along with cancer, may carry the highest risk of developing sexual dysfunction, that is, clinically relevant sexual distress requiring treatment, the unmet medical need for sexual health support may be even greater among women without mental health issues.

Furthermore, our data indicate that reimbursement greatly affects therapy access for women with sexual dysfunction in Germany. Most women are willing to pay only small sums, which is insufficient for effective evidence-based interventions, with only 19.7% willing to pay more than €300 (US $348). This highlights the potential impact of a lack of reimbursement options for sex therapy and may explain why initiatives for nationally accredited sexual medicine training may reach only a small proportion of women with sexual dysfunction. Short-term psychotherapy (12 sessions) costs about €1200 (US $1392) [46]. Studies on the efficacy of treatments for sexual dysfunction usually suggest a reduced number of sessions compared to psychotherapy [47]. Assuming that of the 35.7 million adult women in Germany, about 5 million (14%) have sexual dysfunction but no MH, and given that 94.5% have not received therapy for sexual dysfunction and only psychotherapy is reimbursed, the socioeconomic burden would be €5.67 billion (US $6.59 billion) [46,68-70].

Implications for Health Care and Research

The differences in priorities between groups support the need for tailored solutions to address individuals' specific needs, as recommended by scientific societies [16,17,38]. Health care providers with certified training could play a critical role in addressing the significant gap in sexual health care for women with sexual dysfunction. However, it is important to address the limited time and training available to health care providers in this area, particularly among physicians, who may face greater challenges than psychotherapists [41-43]. Given the high prevalence of mental health problems among patients, addressing the needs and reimbursement challenges of those without MH is also critical. In addition, preventive programs that meet reimbursement criteria within the German health care system could provide valuable opportunities to improve relationships and promote sexuality as a resource, particularly for women with CHCs. These programs should also include single women to ensure that their specific needs are addressed.

Quality of Representative Data

Comparison with the 2014 German Microcensus data indicated that the sample was representative of the selected criteria, including age, sex, and federal state [59]. This was reflected in the prevalence of CHCs, which was 60.0% in our study compared to 62.1% reported previously [6]. The completion rate was high (93.0%) relative to other sexuality studies [71]. However, descriptive characteristics revealed that the sample does not fully represent the general German population (eg, the smoking proportion) [72], indicating selection bias or limitations in item design and visibility. Additionally, certain CHCs may have been underreported despite a comprehensive item list, as indicated by non-CHC participants reporting CHC-related medication use. These factors may have contributed to minor deviations in sexual dysfunction prevalence estimates.

Limitations

Our study has several limitations that should be considered. First, we observed notable demographic differences between

women with and those without CHCs. Women with CHCs were generally older, less likely to be employed, and more likely to be retired, leading to disparities in monthly net household income. Additionally, the sexual dysfunction status was unknown for approximately 15% of participants due to missing data in the *ICD-11* screener. The diagnosis of female sexual arousal dysfunction could not be reported in this study, which might lead to an underestimation of sexual dysfunction prevalence. Furthermore, the data are based on a German and German-speaking survey sample, which limits the generalizability of our findings to other German subpopulations.

Conclusions

The contribution of CHCs to the risk of sexual dysfunction appears to vary among different CHCs, with CA and MH showing the strongest association. The finding of limited access to sexual dysfunction diagnosis and treatment supports the contention of previous research that women's sexual health is neglected in the health care system. The data also suggest that gaps in care are unevenly distributed across different CHCs. Women with only physical CHCs, particularly those with cancer, appear to be most affected by gaps in care. The interest in digital solutions, the need for reimbursement, or the specific needs of different target groups can serve as a basis for tailoring future health care innovations for women's sexual health.

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Data Availability

The datasets analyzed during this study are not publicly available due to restrictions imposed by the ethics approval.

Authors' Contributions

Conceptualization: LH, SMK
Data curation: TT-D, SMK
Formal analysis: TT-D, SMK
Funding acquisition: LH, SMK
Methodology: LH, SMK, TT-D
Project administration: SMK, LH
Resources: KMB, LH
Supervision: LH, KMB, MMK, JUB
Validation: TT-D, LH
Visualization: TTD, SMK
Writing – original draft: SMK, LH
Writing – review & editing: SMK, LH, TTD, KMB, MMK, JUB

Conflicts of Interest

None declared.

Multimedia Appendix 1
Codebook.
[PDF File, 628 KB - jopm_v17i1e71301_app1.pdf]

Multimedia Appendix 2
Supplementary data including study population characteristics, multivariable logistic regression models, weighted adjacency matrices, threshold parameters, and more.
[PDF File, 551 KB - jopm_v17i1e71301_app2.pdf]

Checklist 1
STROBE checklist.
[PDF File, 182 KB - jopm_v17i1e71301_app3.pdf]

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Abbreviations

CA: cancer chronic health conditions
CHC: chronic health condition

CHC MH−: chronic health conditions excluding mental health conditions
CV: cardiovascular and metabolic chronic health conditions
FSDS-DAO: Female Sexual Distress Scale-Desire/Arousal/Orgasm
GY: gynecological chronic health conditions
***ICD-11*:** *International Classification of Diseases, 11th Revision*
IN: infectious and inflammatory chronic health conditions
MH: mental health–related chronic health conditions
NE: neurological chronic health conditions
OR: odds ratio
PA: pain-related chronic health conditions
PPI: patient and public involvement
PSF: problems in sexual function
STROBE: Strengthening the Reporting of Observational Studies in Epidemiology

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Understanding the Experiences of Patients With Pancreatic Cancer: Quantitative Analysis of the Pancreatic Cancer Action Network Patient Registry

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Abstract

Background: The Pancreatic Cancer Action Network (PanCAN) established its Patient Registry to gather real-world data from patients with pancreatic cancer and their caregivers, related to their diagnosis, symptoms and symptom management, treatments, and more. Results from version 2 of the PanCAN Registry are presented here.

Objective: We sought to gather and evaluate patient-reported outcomes data inputted into the PanCAN Patient Registry from December 2020 to January 2024. Statistical analyses were used to identify findings from a relatively small sample size (271 participants, as defined by people who filled out the Basics survey of the PanCAN Registry).

Methods: Participation in the PanCAN Patient Registry was voluntary, and participants filled out an electronic consent form before joining the registry. Participants were identified through the PanCAN Patient Services Help Line or navigated to the registry directly via the PanCAN website. Data analysis took place via bivariate analysis using the chi-square test for categorical variables. Statistical significance was defined as a *P* value of <.05, with *P* values between .05 and .1 considered marginally significant, and *P* values >.1 considered insignificant.

Results: Pain was reported by 186 out of the 207 (89.9%) PanCAN Patient Registry participants who filled out the pain-related questions in the General Assessment survey. We observed a marginally significant (*P*=.06) difference between the reporting of pain by patients aged younger than 65 years (86/92, 93.5%) and those aged 65 years or older (66/78, 84.6%). Depression was also a common condition experienced by patients with pancreatic cancer, with 64/103 (62.1%) indicating that they were experiencing or had experienced depression during the course of their illness. A trend suggested that depression was more frequently reported among the subset of patients who also reported pain (53/80, 66.3%) compared with those who did not report pain (5/13, 38.5%*; P*=.07).

Conclusions: The use of patient-reported outcomes and real-world data for patients with pancreatic cancer has the potential to have direct impact on clinical practice. Through a relatively small sampling of patients, trends were identified that suggest a higher reporting of pain amongst patients in a younger age group as well as concurrence of pain and depression. These findings underscore the importance of a multidisciplinary team of health care professionals addressing patients' needs beyond the treatment of their cancer.

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KEYWORDS

pancreatic cancer; patient-reported outcomes; patient registry; pain; depression; cancer; patient outcomes; pancreatic; statistical analyses; survey; cancer patient; patient experience; registry; data collection; health status; well-being

Introduction

Cancer registries play a pivotal role in collecting comprehensive data about patients with cancer, which is essential for advancing research and improving patient outcomes. Patient-reported outcomes (PROs) are crucial in this context as they provide direct insights from patients regarding their health status, encompassing physical, mental, and social well-being. Electronic PROs offer an efficient and standardized way to gather this data electronically, enhancing the accuracy and depth of patient information without interpretation by a clinician [1]. Previous studies of patients with advanced cancer suggest that patient-reported symptom monitoring is associated with prolonged survival [2].

The Pancreatic Cancer Action Network (PanCAN) Patient Registry is an online, pancreatic cancer-specific, global registry enabling patients to self-report sociodemographics, characteristics of the disease and its management, and PROs. There have been 2 versions of PanCAN's Patient Registry, which has been in operation since 2015. Gupta et al [3] explored the usability and usefulness of PROs through data in the PanCAN Patient Registry version 1. This paper [3], which served as a precursor to this study, described the development of the PanCAN Registry and its questions and flow, the user experience, and the application of data generated, emphasizing the value of leveraging PROs to identify trends in diagnosis, treatment, and management of people with pancreatic cancer. The results reported in this analysis are based on the PanCAN Registry version 2. A transition in the vendor managing the PanCAN Registry database technology from the PEER (Platform for Engaging Everyone Responsibly) to LunaDNA as the host occurred in 2020. The LunaDNA platform was built upon the premise that patients owned and had control of their data while having an economic incentive to share it to drive medical research through cryptocurrency [4]. LunaDNA made the decision to close the platform in January 2024 [5].

Both versions of the PanCAN Patient Registry were designed to assist the pancreatic cancer community in understanding the "Right Track" for any patient with pancreatic cancer: right team, right tests, right treatment, and the opportunity to share their data [6]. The primary aims of the PanCAN Patient Registry include: (1) identifying differences between treatment practices and symptom management in community and center-of-excellence settings, (2) identifying hypothesis-generating associations between answers given in survey questionnaires, including molecular data, treatments, family history, care team choices, and patient outcomes, (3) facilitating the gathering of information on the use, effectiveness, and side effects of treatments and remedies, and (4) providing a platform for researchers to add customized modules to answer specific research questions and recruit participants for research. From our experience with the first PanCAN Registry, we learned that many patients and their caregivers are interested in sharing information with researchers that can potentially contribute to better outcomes in the future.

Several scientific meeting abstracts and publications have resulted from the information collected from more than 2000 patients or caregivers who participated in the PanCAN Registry, version 1. Through registry data, we have observed that a concerning proportion of patients (69/205, approximately 34%) were not correctly prescribed pancreatic enzyme replacement therapy based on the recommended dosage and administration of the medication [7]. Even more alarmingly, only 89/205, or about 43% of patients, fully complied with the recommended administration, leading to poorer relief of symptoms and difficulty gaining weight. Another publication explored prediagnosis pain and symptom management, with data suggesting that patients who experience pain before their pancreatic cancer diagnosis had a higher likelihood of being diagnosed with metastatic disease, had more frequent and more intense symptoms, and faced more challenges with pain management throughout their experience with pancreatic cancer [8].

Pancreatic cancer is one of the deadliest cancer diagnoses. Most patients diagnosed with this disease are diagnosed at an advanced stage where cancer has spread from the pancreas to distant parts of the body, resulting in poor survival [9]. The 5-year survival for all stages of disease is currently 13%, the lowest of the major cancers. The aggressive nature of the disease poses a challenge for the collection of survey and PRO information, yet the unmet need demands that all avenues are used, and the patient experience is known and incorporated in the best practices for treatment and care of people with pancreatic cancer. Participation in the PanCAN Registry not only empowers patients and caregivers by involving them directly in research but also enriches the registry with real-world data crucial for understanding the disease and identifying trends that may provide insights into the diagnosis, treatment, and management of pancreatic cancer. PanCAN intends for our Patient Registry to continue to provide valuable information to inform PanCAN and the scientific community of ways to overcome challenges and improve survival for patients with pancreatic cancer for many years to come.

Methods

Participants and Enrollment

Participants in the PanCAN Patient Registry were patients with pancreatic cancer or their caregivers, identified through PanCAN's Patient Services Help Line. Participation was voluntary and required informed consent for the use of their data in research. Patients and caregivers could independently enroll in the PanCAN Registry through the PanCAN website. Upon creating a profile and signing an online informed consent form, participants completed surveys that documented their experiences with pancreatic cancer. Participants completed surveys providing detailed information on diagnosis, symptoms, treatments, complementary medicine regimens, health care decisions, and more.

Registry Versions and Platform

There have been 2 versions of PanCAN's Patient Registry. The results reported in this analysis are based on PanCAN Registry version 2, which was open for enrollment from December 2020 through January 2024. The data collected were facilitated by an online data vendor platform called LunaDNA, which housed the PanCAN Registry survey questions for participants to access. The change to version 2 was due to a transition in the vendor managing the PanCAN Registry database technology. Both registry version 1 and version 2 received institutional review board (IRB) approval through Genetic Alliance, and PanCAN updates the IRB annually to maintain registry study protocol compliance. Although PanCAN Registry version 1 and version 2 used different technology platforms, both functioned similarly as patient-facing databases and adhered to PEER requirements determined by Genetic Alliance.

We provide a Checklist for Reporting Results of Internet E-Surveys (CHERRIES) (Checklist 1) that further describes

the platform, the development and testing of questions, marketing, data protection, and more [10].

Survey Development and Data Collection

PanCAN staff worked with LunaDNA, the platform vendor, to transpose the surveys into the proper platform formatting, including branching logic and data extraction. The surveys used in version 2 of the PanCAN Registry were previously developed in version 1 of PanCAN's Patient Registry and used with occasional changes or updates. These pancreatic cancer-specific surveys were developed and reviewed by experts in the domain and patients affected by pancreatic cancer. The experts included PanCAN staff, oncologists, gastroenterologists, scientists, a dietitian, and a radiation oncologist. The General Assessment survey, previously the Health Assessment survey in PanCAN Registry version 1, included questions derived from the Patient-Reported Outcomes Measurement Information System (PROMIS)-29 validated survey [11,12].

Data Analysis

Data were extracted from the online LunaDNA-hosted registry (PanCAN Patient Registry version 2). Bivariate analysis was conducted using the chi-square test for categorical variables.Statistical significance was defined as a *P* value of <.05, with *P* values between .05 and .1 considered marginally significant, and *P* values >.1 considered insignificant. Due to the relatively small sample size of this study, a significance level of .1 was used to draw conclusions. While a *P* value of <.05 is a conventional threshold in biomedical research, the use of a .1 threshold is sometimes used in social science research, where increasing sample sizes is not always feasible. The Social Science Statistics calculator includes significance level options of .01, .05, and .10 [13]. While a *P* value of <.05 is a conventional threshold in biomedical research, in this context, the 10-fold difference between a *P* value of .06 and .6 is considered meaningful, and we optimized the significance level for this study as per Mudge et al [14].

Efforts to increase the sample size were not possible due to the unexpected closure of the LunaDNA platform, limiting further recruitment. In addition, publication of results from the PanCAN Registry version 2 is necessary to fulfill patient consent requirements and facilitate further analysis of the data. All user response data collected was deduplicated by identifying unique subject IDs within the deidentified data set. This information was organized in tables to display responses such as demographics, interest in joining the registry, sex, age, and more. All data were manually reviewed and validated by PanCAN staff.

Survey Participation

Participants could complete up to 7 unique surveys on the PanCAN Registry website, totaling approximately 175 questions if all surveys were completed. Participants were required to complete the Basics survey before accessing additional surveys. The Basics survey gathered information about the person filling out the survey, the patient's diagnosis and experiences with pancreatic cancer, and high-level information about symptoms, treatments, and reasons for participation. For this study, we defined users as PanCAN Registry participants who had completed at least the Basics survey.

Technological and Regulatory Framework

The technology, user interface, regulatory requirements, and IRB compliance for the PanCAN Registry platform technology have been previously described [3]. The adherence to IRB requirements for the PanCAN Registry platform technology and the collaboration with LunaDNA to ensure the confidentiality and integrity of the data were described in Gupta et al [3]. All patients that joined the platform to participate in the study had the opportunity to remove their data if they chose. This is why LunaDNA reinforced the use of a sandbox workbench when the protocol was active, and participants were enrolling. However, it was explained to participants that they were not able to remove data that was part of a downloaded research set for publication purposes.

Ethical Considerations

The Patient Registry received approval for Protocol PCAN001 from the Genetic Alliance IRB on January 19, 2024, as part of its annual review process. Since its launch in 2015, the registry consistently maintained compliance with IRB requirements as determined by the Genetic Alliance.

As described in the informed consent, data privacy and security were central to the registry's operations. In this agreement with LunaDNA, genomic data (ie, data about an individual's genes or DNA) and medical or health data (eg, medications, allergies, surveys, health records, and information collected by integrated apps and devices) were referred to as Shared Data. To protect participant privacy, Shared Data were separated from Personal Data, a process referred to as deidentification. Once deidentified, Shared Data were aggregated with data from other participants to create a searchable database designed to support research and discovery while protecting individual privacy.

As outlined in the participation and enrollment section, individuals who wished to join the registry had to create a profile and electronically sign an informed consent form before completing surveys about their pancreatic cancer experiences. Those who chose not to sign the informed consent were not eligible to participate.

Participants may revoke their consent or request deletion of their account at any time, in which case their data will be permanently removed or purged from the database. However, any research already conducted or published using the participant's data before revocation of consent or data deletion will remain unaffected. Participants did not receive compensation for participation in the patient registry.

Results

Demographics of Participants

The demographics of the patient population who participated in version 2 of the PanCAN Patient Registry are shown in Table 1. During the time period analyzed, 272 individuals filled out the basics survey in the LunaDNA-based PanCAN Patient Registry. Of the 191 participants who indicated their age, 1 participant (0.5%) was 11 - 15 years old, 13 (6.8%) were aged

25 - 44 years, 89 (46.6%) were aged 45 - 64 years, and 88 (46.1%) were aged 65 years and above. For the purpose of the analyses described below, we stratified patients as under 65 years (53.9%) or 65 years and older (46.1%).

Table . Demographics of participants.

Characteristics	Number of participants
Number completing "Basic Survey"[a]	272
Age, years (n=191), n (%)	
<65	103 (53.9%)
11-15	1 (0.5%)
25-44	13 (6.8%)
45-64	89 (46.6%)
≥65	88 (46.1%)
Sex (n=191), n (%)	
Female	96 (50.3%)
Male	95 (49.7%)
Race (multiple options allowed; n=191, responses=210), n (%)	
White	171 (81.4%)
Hispanic, Latino, or Spanish origin	11 (5.2%)
Black or African American	7 (3.3%)
Asian	6 (2.9%)
Middle Eastern or North African	5 (2.4%)
American Indian or Alaskan Native	3 (1.4%)
Central or Southern American Indian	2 (1.0%)
None of these describe me	5 (2.4%)
Stage of cancer at diagnosis (n=272)	
Metastatic	102 (37.5%)
Resectable	75 (27.6%)
Locally advanced	38 (14.0%)
Borderline resectable	35 (12.9%)
I am not sure	22 (8.1%)
Reason for joining the Registry (multiple options allowed, percentage who strongly agree or agree) (n=272 for each question)	
To provide information for researchers and other patients	255 (93.8%)
To learn more about pancreatic cancer	231 (84.9%)
To share information with friends, family, or a doctor	162 (59.6%)
To organize medical records	107 (39.3%)
Someone (eg, family member, doctor) asked me to	44 (16.2%)

[a] this formed the baseline population of "Users."

These 191 participants were evenly distributed by sex, with equal numbers identified as female and male at birth. The population had minimal racial and ethnic diversity, with 191 respondents providing 210 answers (multiple options were allowed). The majority (171/210, 81.4%) identified as White, and 11/210 (5.2%) of participants identified as being of Hispanic, Latino, or Spanish origin, and 7/210 (3.3%) identified as Black or African American.

Of the 272 total participants, 102 (37.5%) were initially diagnosed with metastatic pancreatic cancer, 38 (14%) with locally advanced disease, 35 (12.9%) borderline resectable, and 75 (27.6%) had resectable pancreatic cancer at diagnosis. The remaining 22/272 (8.1%) of respondents were unsure of their stage of disease at diagnosis. It is worth noting that the average distribution of disease stage at diagnosis is 51% metastatic and 14% localized [15], so the patient population in this study was

skewed toward earlier stage disease compared with the overall patient population with pancreatic cancer.

Participants were also asked to indicate their reasons for joining the PanCAN Patient Registry. Multiple answers could be selected, and all 272 participants responded to this question. The majority (255, 93.8%) of responses indicated that the participant joined the registry "to provide information for researchers and other patients," showing a deep sense of altruism. The next most common answer (231, 84.9%) was "to learn more about pancreatic cancer." A majority (162, 59.6%) of responses indicated that the participant felt the registry would help them "to share information with friends, family, or a doctor."

Participants Reporting Pain

Pancreatic cancer and its treatments are known to cause significant pain, typically of the abdominal area and lower back. Participants in the PanCAN Patient Registry were asked several questions pertaining to their experience with pain within the 7 days before their responding to the survey. A total of 7 questions addressed the presence and intensity of pain as well as its interference with day-to-day activities (Supplementary table in Multimedia Appendix 1). For the purpose of this analysis, we stratified the responses to a yes or no response in regard to the participants experiencing pain over the week before filling out the survey (Table 2).

Table . Responses to pain and depression questions.

Survey item	Number of responses, n (%)	*P* value
Pain		
Reporting pain (n=207)		
Yes	186 (89.9%)	
No	21 (10.1%)	
Reporting pain by sex (n=170)		.58
Male		
Yes	78 (90.7%)	
No	8 (9.3%)	
Female		
Yes	74 (88.1%)	
No	10 (11.9%)	
Reporting pain by age (years; n=170)		.06
<65		
Yes	86 (93.5%)	
No	6 (6.5%)	
≥65		
Yes	66 (84.6%)	
No	12 (15.4%)	
Depression		
Reporting depression (n=103)		
Yes	64 (62.1%)	
No	35 (34%)	
Not sure	4 (3.9%)	
Reporting depression by sex (n=98)		.19
Male		
Yes	26 (56.5%)	
No	18 (39.1%)	
Not sure	2 (4.3%)	
Female		
Yes	36 (69.2%)	
No	14 (26.9%)	
Not sure	2 (3.8%)	
Reporting depression by age (n=91)		.90
<65		
Yes	35 (63.6%)	
No	18 (32.7%)	
Not sure	2 (3.6%)	
≥65		
Yes	22 (61.1%)	
No	12 (33.3%)	
Not sure	2 (5.6%)	
Pain and depression (n=93)		

Survey item	Number of responses, n (%)	*P* value
Those who experienced pain		.07
Depressed		
Yes	53 (66.3%)	
No	24 (30%)	
Not sure	3 (3.8%)	
Those that experienced no pain		
Depressed		
Yes	5 (38.5%)	
No	7 (53.8%)	
Not sure	1 (7.7%)	

Using this methodology, we found that out of 207 respondents, 186 (89.9%) reported pain within the previous 7 days. There was no difference based on sex; approximately 90% of both male and female respondents reported pain.

There was, however, a marginally statistically significant ($P<.1$) difference found in the reporting of pain by age groups, with pain more frequently reported by younger patients. In those aged younger than 65 years, 86/92 (93.5%) reported experiencing some pain over the previous 7 days. A lower percentage (66/78, 84.6%) of individuals aged 65 years and above reported experiencing pain ($P=.06$).

Participants Reporting Depression

Depression is also frequently experienced by people with pancreatic cancer, as shown in Table 2. For this standalone survey, participants were asked whether they were feeling or had felt "depressed at any time throughout the course of the disease." There were 103 respondents to this question, and 64 (62.1%) indicated that they were feeling or had felt depressed, 35 (34%) indicated no depression, and 4 (3.9%) were unsure. There were no statistically significant differences in the responses to feeling or had felt depression by sex or by age.

Concurrence of Pain and Depression

Finally, we were interested in determining the concurrence of pain and depression experienced by individuals who filled out the PanCAN Patient Registry. We hypothesized that those experiencing pain would be more likely to indicate feelings of depression. Indeed, a majority (53/80, 66.3%) of individuals who indicated that they felt pain within 7 days of filling out the survey also said they were experiencing or had experienced feelings of depression. Among individuals who reported no pain, 5/13 (38.5%) answered that they experienced depression. This difference approached statistical significance, with a *P* value of .07.

Discussion

This study is the first to use data gathered through version 2 of the PanCAN Patient Registry. Although a relatively small dataset, our findings further emphasize the value of PROs in identifying trends in the patient experience and seeking new ways to improve outcomes and quality of life for those facing an extremely challenging diagnosis like pancreatic cancer.

Pain is a well-established frequent symptom experienced by people with pancreatic cancer [8,16,17], and our results showed that nearly 90% of respondents had experienced pain within the previous 7 days of responding to the survey in the PanCAN Registry. Furthermore, we observed a higher frequency of pain reported by younger patients as compared with those aged 65 years and older. Previous analysis of the PanCAN Patient Registry version 1 had shown a higher frequency of prediagnosis pain in younger patients, leading to worse symptom burdens throughout the disease [8]. Other groups have shown a higher prevalence of cancer-related pain being reported by younger versus older patients, across cancer types [18-20]. These results suggest that health care providers pay particular attention to discussing and managing pain experienced by patients who have a younger onset of pancreatic cancer. At the same time, other reports show that patients in an older age group may still experience pain but not report it as frequently as their younger counterparts, showing the need for specialized pain management for all people with cancer [19,21].

Patients with pancreatic cancer tend to experience depression at a higher rate than other cancer types, likely due to physiological changes as well as significant distress caused by diagnosis with an especially deadly type of cancer [22-24]. The concurrence of pain and depression in people with pancreatic cancer [25,26] or other types of cancer and chronic illnesses [27-29] is well-established in the literature and consistent with our findings. This result further emphasizes the urgency of pain management to improve quality of life and mood, as well as the need for routine psychosocial care for people with pancreatic cancer.

The study's limitations include a small number of participants, limited racial and ethnic diversity, and patients skewed toward an earlier stage of disease compared with the typical distribution of pancreatic cancer diagnoses. Intrinsic to registry-based studies is a bias toward patients with better overall health as well as internet savviness [30]. The answers to the surveys, particularly those specifying the previous 7-day time period rather than the entire course of disease, lead to a bias based upon the timing of the patient's participation. Finally, we recognize that combining the pain-related questions into yes or no answers removes the

granularity of the data, and the full range of patient experiences are not captured.

Overall, our data using version 2 of the PanCAN Patient Registry validate previous findings that pain is more frequently reported in those experiencing pancreatic cancer at a younger age, and that there is a correlation between pain and depression. These results underscore the value of hearing directly from the patients' perspective and pooling data from patients treated at multiple institutions with varying life and disease experiences. Subsequent research efforts by PanCAN will seek to engage patients of diverse racial and ethnic backgrounds in order to learn more about individual patient experiences and any barriers to high quality and equitable care. Data from both versions of the PanCAN Registry will be made available to the research community by request through a data use agreement [31].

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Conflicts of Interest

None declared.

Multimedia Appendix 1
Supplemental table. Questions pertaining to pain.
[DOCX File, 16 KB - jopm_v17i1e65046_app1.docx]

Checklist 1
Checklist for reporting results of the internet e-surveys: PanCAN patient registry.
[DOCX File, 28 KB - jopm_v17i1e65046_app2.docx]

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ABBREVIATIONS

IRB: institutional review board
PanCAN: Pancreatic Cancer Action Network
PEER: Platform for Engaging Everyone Responsibly
PROMIS: Patient-Reported Outcomes Measurement Information System
PROs: patient-reported outcomes

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Patient and Practitioner Perspectives on the Definition and Measurement of Therapeutic Empathy: Qualitative Study

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Abstract

Background: Most definitions of therapeutic empathy are based on practitioners' perspectives, and few account for patients' views. Therefore, we do not understand what therapeutic empathy means to patients. Given that therapeutic empathy involves a relationship between patients and practitioners, the underrepresentation of the patient voice threatens to undermine the validity of therapeutic empathy definitions and subsequently, how the concept is measured, taught, and practiced.

Objective: The aim of the study is to explore the perspectives of patients and practitioners on the definition of therapeutic empathy and how it should therefore be measured.

Methods: A qualitative study, underpinned by a social constructivist stance, was conducted. Patients and practitioners were purposively sampled from a medical school and a school of health care to represent a diversity of lived experiences and health care professions. In-depth, semistructured interviews were undertaken, and the data were analyzed using reflexive thematic analysis. Data collection ceased upon reaching meaning saturation.

Results: In total, 16 participants (8 patients and 8 practitioners) were interviewed in June and July 2024. Reflexive thematic analysis generated three overarching themes that synthesize the views of patients and practitioners on therapeutic empathy and how it should be measured: (1) therapeutic empathy involves the practitioner showing the patient (that they are interested in the patient as a person, that they are actively listening, that they understand, that they are emotionally engaged, and that they are responding to their needs), (2) context matters (eg, the clinical scenario, time, and the patient), and (3) short, simple scales are a pragmatic approach to measurement.

Conclusions: Patients and practitioners have similar views about what empathy is and define therapeutic empathy as involving the practitioner demonstrating specific attitudes and behaviors to their patients. These attitudes and behaviors should be included in interventions to enhance therapeutic empathy and in measures of the concept. However, contextual factors may influence the expression of therapeutic empathy in practice. The findings highlight the need for, and can inform the development of, a short therapeutic empathy scale that allows the comparison of scores between patients, practitioners, students, and observers.

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KEYWORDS

therapeutic empathy; empathy; patient-practitioner communication; definition; measurement

Introduction

Rationale

Over recent decades, therapeutic empathy (sometimes called "clinical empathy") has become a central tenet of health care practice, research, and education [1-3]. This is unsurprising, given the growing body of research demonstrating its benefits for patients (reduced pain and anxiety and improved satisfaction) [4,5] and practitioners (reduced burnout and improved job satisfaction) [6,7]. Alongside the increasing interest in therapeutic empathy, there has been ongoing controversy surrounding its definition [8]. In particular, authors have debated whether therapeutic empathy is a cognitive (requiring understanding) [9] or affective (requiring feeling) concept [10] or indeed whether it includes both cognitive and affective components [1,11]. A recent review of 39 definitions found that definitions of therapeutic empathy share 6 common components: *exploring* and *understanding* the patient's perspective, reaching a *shared understanding* with the patient, *feeling* in response to understanding, and taking *therapeutic action*, all while *maintaining boundaries*—both personal and professional [11].

This review highlighted that most therapeutic empathy definitions have been developed by and for practitioners and rarely account for patients' perspectives [11]. To wit, a recent scoping review [12] identified only 4 studies [13-17] that

explored patients' experiences of therapeutic empathy. Even these studies were limited to specific patient groups (patients with cancer [13,15,17] or comorbid pain and depression [16]), so the scope of patient representation was limited. A related problem is the near absence of research exploring how patients' perspectives on therapeutic empathy align with practitioners' perspectives and the similarities between them [13,17]. Those who do, position empathy as paying empathic attention to the patient, emotional engagement, and putting oneself in the patient's shoes [13,17]. One study highlighted that the views of patients and practitioners on therapeutic empathy differed greatly [17]. However, in the same way that these studies are limited to particular patient groups, they are limited to specific practitioner populations, including nurses [13] and oncologists [17].

The paucity of patients' perspectives on the definition of therapeutic empathy is problematic for 2 reasons. First, there could be a mismatch between what practitioners believe to be empathic care and what patients perceive as empathic care. This, in turn, is likely to lead to worse patient outcomes [4,5]. Indeed, teaching therapeutic empathy currently focuses on communication skills training, such as active listening and perspective-taking [2]. However, it is unclear whether these educational interventions include all of the necessary elements to successfully train practitioners to be perceived as empathic by their patients [15]. This could explain the great variation in the extent to which patients rate practitioners' empathy levels [18] and the discrepancy between practitioners' self-ratings of empathy and patients' ratings of practitioners' empathy [19-21]. Second, and relatedly, failure to adequately consider patient views threatens to violate standards of good practice for patient involvement in the development and delivery of health care services and interventions [22,23].

Underrepresentation of the patient voice in the definition of therapeutic empathy also creates problems for research, particularly with regard to measurement of the concept. Of the many measures purporting to assess therapeutic empathy [24-31], few are directly informed by patients' perspectives [15,32]. This is problematic because the measurement of any concept should account for the lived experiences of all stakeholders [33,34]. Measures that are not informed by all stakeholders risk having poor content validity (the adequacy with which a measure assesses the intended concept) and poor user-friendliness [33,34]. Indeed, widely used measures of therapeutic empathy, such as the Jefferson Scale of Empathy [31], have been criticized for excluding important components of the concept (such as emotion or therapeutic action) [35] and for being long and unwieldy [24-31,36]. These problems, in turn, threaten the integrity of the conclusions drawn from empirical studies measuring therapeutic empathy and its relationship to other variables.

As such, there is a need for research exploring the views of patients and practitioners on the definition and measurement of therapeutic empathy to ensure that the teaching, practice, and research of the concept are grounded in the lived experience of key stakeholders. This is especially important, given the relational nature of the concept [11] and the growing interest in it in health care contexts [1].

Research Aim

This study aimed to explore the perspectives of patients and practitioners on the definition of therapeutic empathy and how it should therefore be measured.

Methods

Design

We conducted an exploratory qualitative study underpinned by a social constructivist philosophical stance. From this perspective, meaning is actively constructed, tested, and modified by individuals through social interaction [37]. This stance was selected, as therapeutic empathy is described as being interactive [11].

Ethical Considerations

Ethics approval for this study was received from the University of Leicester's Research Ethics Committee (reference: 0375) in May 2024. All participants provided informed consent to take part in the study. Patient participants were remunerated in line with the University of Leicester's Patient and Carer Group hourly pay rate.

Sampling and Recruitment

We recruited patients from a patient and carer group who are involved across a medical school and school of health care and practitioners from the same 2 schools. This provided us with access to patients who represent diverse lived experiences of health and care and practitioners from a variety of health care professions. This was important, given that previous research has been limited to specific patient or practitioner groups [13,15,16]. We purposively sampled participants for maximum variation [38], including patients of different sexes, ages, and ethnicities, with diverse lived experiences, and practitioners of different sexes, ages, and ethnicities, from different professions. Purposefully sampled participants were recruited via their university email following ethics approval and permission from the relevant gatekeeper: the head of each school or the patient and carer group chair.

Patient Involvement

A patient advisory board was involved in the study design and the analysis. One researcher (AB-W) met with the board, which was comprised of 3 patient representatives, at the inception of the study and during analysis. The board helped to shape the topic guides to ensure accessibility for patient participants and offered insights into the interpretation of the data. Specifically, they highlighted the behavioral nature of participants' definitions of therapeutic empathy.

Data Collection

As a social constructivist study, it was important that the data were constructed through social interaction [37]. Accordingly, we conducted semistructured interviews aided by topic guides (Multimedia Appendix 1). The interviews explored, in depth, participants' own meanings and experiences of therapeutic empathy, along with their views on how it should be measured. To accommodate participants' needs, we provided the option of conducting the interviews in person or digitally. Sampling,

data collection, and analysis were iterative and concurrent; we ceased data collection when we had reached meaning saturation [39]. This is the point at which we had developed an in-depth understanding of the complexities and nuances of the concepts generated through data collection [39].

Data Analysis

Interviews were audio recorded, transcribed verbatim, and analyzed in NVivo (Lumivero). We analyzed the data using reflexive thematic analysis, a 6-phase approach to identify patterns of meaning in qualitative data [40]. Our approach to analysis was predominantly inductive to remain grounded in participants' accounts [40]. In phase 1 (familiarization), 1 author (AB-W) read each transcript several times. In phase 2 (coding), the author systematically coded interesting features of the data, before collating all codes into initial themes in phase 3 (generating initial themes). Phase 4 (developing and reviewing themes) involved writing short summaries of each theme and discussing them with a second author (JH) and patient representatives. During phase 5 (refining, defining, and naming themes), 1 author (AB-W) checked the themes against the raw data. Finally, in phase 6 (writing up), both authors selected vivid data extracts to illustrate each theme. Data from each stakeholder group (patients and practitioners) were initially analyzed separately. As the analysis progressed, we synthesized the accounts of patients and practitioners to triangulate the data [41].

Reflexivity

Under a social constructivist approach, being reflexive is important, as the researchers are viewed as directly influencing the research process [37]. We engaged in reflexivity throughout this study, noting our reflections on the research process and critically questioning our own assumptions about therapeutic empathy [42]. In particular, we were mindful of beginning the research with our own definition of the concept, based on our previous research [11]. We were cautious of projecting the components identified through this earlier work onto participants' accounts and consulted the raw data several times, along with the patient advisory board, to ensure that our analysis reflected participants' views [42].

Results

Overview

In total, 16 participants (8 patients and 8 practitioners) took part in interviews lasting approximately 60 minutes each in June and July 2024. A total of 9 participants took part in interviews digitally, and 7 took part in person. Each participant was assigned a unique participant identification (ID) code; patients were assigned "PTCRX" to represent "patient or carer X," and practitioners were assigned "HCPX" to represent "health care practitioner X." Table 1 summarizes participants' characteristics. In the interest of anonymity, patients' specific experiences of health and care are not shared; collectively, they represent experiences of various cancers, disabilities, mental health conditions, and stroke.

Reflexive thematic analysis revealed considerable overlap between the views of patients and practitioners on what therapeutic empathy means and how it should be measured. Accordingly, the analysis generated three overarching themes that synthesize both groups' perspectives. The themes included: (1) therapeutic empathy involves the practitioner showing the patient (that they are interested in the patient as a person, that they are actively listening, that they understand, that they are emotionally engaged, and that they are responding to their needs), (2) context matters, and (3) short, simple scales are a pragmatic approach to measurement. Given that the measurement of a concept is contingent on its definition [32], our analytic narrative considers the definition and measurement of therapeutic empathy together.

Table . Participant characteristics.

Participant ID code	Patient or practitioner (profession)	Age (years)	Sex	Ethnicity
PTCR1[a]	Patient	70	Female	White
PTCR2[b]	Patient	26	Female	Asian or Asian British
PTCR3	Patient and carer	64	Female	White
PTCR4	Patient and carer	59	Male	Asian or Asian British
PTCR5	Patient	55	Male	White
PTCR6	Patient and carer	65	Female	White
PTCR7	Patient	78	Male	White
PTCR8	Patient	48	Male	Asian or Asian British
HCP1	Practitioner (general practitioner)	54	Male	White
HCP2	Practitioner (palliative care consultant)	59	Female	White
HCP3	Practitioner (operating department practitioner)	35	Male	White
HCP4	Practitioner (radiographer)	37	Female	White
HCP5	Practitioner (midwife)	40	Female	White
HCP6	Practitioner (general practitioner)	45	Female	Asian or Asian British
HCP7	Practitioner (mental health nurse)	29	Female	White
HCP8	Practitioner (pharmacist)	56	Male	White

[a]PTCR: patient or carer.

[b]HCP: health care practitioner.

Therapeutic Empathy Involves the Practitioner Showing the Patient

Overview

Participants defined therapeutic empathy as the empathy expressed by practitioners toward patients. They framed the concept as patient-centered, comprised of a number of interrelated attitudes and behaviors including showing an interest in the patient as a person, actively listening, demonstrating understanding, emotionally engaging, and responding to the patient's needs. Importantly, participants emphasized that therapeutic empathy was about the practitioner successfully showing the patient that they were engaging in these attitudes and behaviors. For example, it was not enough for the practitioner to be interested in the patient as a person or to feel emotionally engaged; the practitioner also had to demonstrate this to the patient.

> *I think practitioners need to bring a skill set, show that they understand us. It's about acting like they care.* [PTCR4]
>
> *So, you know, it's a clinician's job to try and actually demonstrate empathy and show the patient they've heard and they care ... it ... needs to be communicated and demonstrated.* [HCP1]

Accordingly, participants argued that any scale to measure therapeutic empathy should prioritize assessment of practitioner behavior. One practitioner stated "... what you really want to know is that the patient perceives those things that you're experiencing and trying to communicate ..." (HCP2).

That They Are Interested in the Patient as a Person

Showing an interest in the patient as a person was described as an important aspect of therapeutic empathy. Participants explained that this found expression in the practitioner asking open-ended questions about the patient's familial, social, and cultural background. Relatedly, practitioners emphasized that the information obtained through such questions often provided important insights that could inform a patient's care.

> *... if you spend time asking questions about their actual lives, you'll learn a lot ... you're on the same wavelength ...* [PTCR7]
>
> *... what external things are happening in their life that are going to impact how they react ... and what they want from services? Ask them open-ended questions ... what's their life like outside of hospital?* [HCP5]

That They Are Actively Listening

Patients and practitioners considered active listening to be a core component of therapeutic empathy. They described this as

the practitioner's nonverbal communication, including eye contact, nodding, facing the patient, and making encouraging utterances. Practitioners added that they demonstrated active listening by repeating the patient's words. Importantly, active listening was characterized as being nonjudgmental.

> *I think they [practitioners] have to show they're listening. And also, not jump to conclusions ...* [PTCR6]

> *... to show empathy, your body language should demonstrate active listening. That nodding ... showing that you are with them and listening to them ... it's ... important.* [HCP8]

That They Understand Their Perspective

Demonstrating an understanding of the patient's concerns, emotions, and needs was perceived to be an essential part of therapeutic empathy. However, participants emphasized that it was impossible to fully understand another person's thoughts and feelings. Instead, participants explained that practitioners could demonstrate understanding by sharing their own interpretation of the patient's perspective, allowing the patient to confirm or refute their accuracy.

> *I've noticed ... doctors ... when they are empathising, will say "it sounds like you feel anxious." Or, "I can imagine that's really hard for you." And you think, "yeah, you've understood me."* [PCTR4]

> *... demonstrating that you've got what they're saying is either sharing what you hear ... or saying what you see ... sometimes we don't get it right and it gives people a chance to correct us.* [HCP2]

That They Are Emotionally Engaged

Participants took therapeutic empathy to involve the practitioner's emotional engagement with the patient. They agreed that it was inevitable that the practitioner would feel something in response to their understanding of the patient's perspective but emphasized that this feeling would not be the same as the patient's. Participants struggled to precisely define the feelings they referred to, broadly describing practitioners as being "... moved emotionally ..." (HCP1). Verbally, practitioners might describe how they feel after hearing the patient's story, while nonverbally, practitioners might have physical reactions to what they hear or see, such as holding a patient's hand. However, participants emphasized that emotionally engaging, and demonstrating this, was a fine balance. Feeling and demonstrating too much emotion might risk the practitioner's well-being, burden the patient, and impede the provision of care. Too little, and the patient-practitioner interaction may be perceived to be devoid of empathy.

> *I think emotion, but to keep control of it, is important. I have been in situations when I've ended up therapeutically helping the person who's supposed to be helping me. Which is too far the other way.* [PTCR5]

> *... emotion is part and parcel of the job ... there has to be a cut-off point ... where you're not getting too invested into the patients' lives so much that it affects your life ... otherwise you'll be burnt out ...* [HCP3]

That They Are Responding to Their Needs

Responding to the patient's needs was described as an important part of therapeutic empathy. While both patients and practitioners acknowledged that responding to the patient's needs may involve prescribing a medical treatment, they emphasized that the most helpful responses were often categorically "non-medical" (PTCR6), such as listening to the patient, validating their emotions, or offering small gestures.

> *... one midwife ... gave me a massage because I was hurting ... we just talked ... she was showing that she cared, that she understood what I needed. It was the kind of thing a friend would do ...* [PTCR1]

> *... I suppose it's responding to the patient's individual needs ... sometimes you don't have to do anything medical. I think sometimes people just want to be heard ...* [HCP4]

Context Influences Expression of Empathy

Participants identified contextual factors that influenced the expression of therapeutic empathy and that should be accounted for in the measurement of the concept. They explained that while all of the behaviors described earlier were important, not all would be appropriate in every context. For example, during an emergency, understanding and responding to the patient's needs should take precedence over asking questions about their wider lives and emotionally engaging with them. In this context, instead of engaging in active questioning and listening, practitioners may prioritize obtaining a clinically informed understanding of the patient's condition and taking action to help them. Several practitioners added that the expression of therapeutic empathy was dependent on time, particularly with complex patients. For example, in time-constrained consultations, exploring the patient's wider familial, social, and cultural background may take up too much time. However, patients disagreed and argued that engaging in all of the behaviors associated with therapeutic empathy would likely save time long-term.

> *... asking the patient questions about themselves and their lives ... that would save time further down the line ... you could push somebody down one route, and if you'd only asked the question, you probably wouldn't pursue that course of action.* [PTCR7]

> *... you're so pressured, aren't you? And you have to be task focused and there are some questions that you have to ask ... as a clinician, you have to have an element of structure and move things on ...* [HCP7]

Adding a further layer of complexity, participants stated that the expression of therapeutic empathy was influenced by the people within the context. They suggested that practitioners of different sexes, cultures, and ages may express therapeutic empathy differently. Similarly, participants thought that the patient's characteristics would influence the expression of therapeutic empathy. For example, showing emotional engagement through physical touch might not always be appropriate.

> *I mean, you've got the healthcare professionals, who because they understand ethnic minorities ... will greet my mother with a Hindu religious hello.* [PTCR4]

> *I think sometimes empathy can involve physical touch, putting a hand on patient ... but that's straining to that area of what's appropriate, what's not appropriate ...* [HCP1]

Short, Simple Scales Are a Pragmatic Approach to Measurement

Participants identified scales as a pragmatic method of measuring therapeutic empathy because they could be distributed to a large number of people and offered flexibility around completion. Participants identified 4 possible versions of a therapeutic empathy scale: patient-reported, practitioner-reported, student-reported, and observer-reported. They argued that the patient-reported measure was most important because they perceived therapeutic empathy to be patient-centered. However, they acknowledged that there were limitations to all 4 proposed versions of a therapeutic empathy scale. Both practitioner-reported and student-reported scales were criticized for their subjectivity. A patient-reported measure was considered to be at risk of response bias because patients with negative experiences might be more motivated to complete it. An observer-reported measure was criticized for requiring trained raters to ensure its reliability. Acknowledging these limitations, participants proposed that measurement of therapeutic empathy should involve data from multiple sources and that all versions of a scale should correspond to allow comparison between groups.

> *"... it'd be interesting to see how the patient scores the practitioner and how they score themselves ... you'd need to be able to match up those scores for either result to be meaningful.* [PTCR3]

> *I guess in terms of how you measure it ... for me it's actually how it's perceived by the patient because, you could be like really moved and not show that at all, and is that therapeutic empathy?* [HCP1]

Although participants expressed a clear preference for using scales to measure therapeutic empathy, this was contingent on the scales being short and simple. Short scales were considered essential for time-poor practitioners and for patients who were unlikely to want to spend a long time assessing their practitioner's empathy. Several participants specifically suggested a maximum of 5 items. Simplicity was perceived as facilitating shortness of scale length and as being necessary for ensuring accessibility across different populations if all versions of the scale were to correspond. Participants proposed that simplicity could be achieved by using lay language that would minimize the possibility of misinterpretation and, in turn, inaccurate responses.

> *I think the more questions, the more they'll be like "oh God, another long questionnaire" and not finish it ... people tend to like shorter questionnaires.* [PTCR2]

> *I'd be prepared to spend a couple of minutes completing a scale ... you lose the essence of it if you break it down too much. And, for patients, lots of questions can be daunting ... they might not understand the difference between the questions ...* [HCP2]

Discussion

Summary of Findings

This study has, for the first time, synthesized the perspectives of patients (with diverse lived experiences of health and care) with practitioners (from different professions) on what therapeutic empathy means and how it should be measured. The findings show that patients and practitioners define therapeutic empathy similarly as involving practitioners demonstrating 5 attitudes and behaviors: an interest in the patient as a person, active listening, understanding, emotionally engaging, and responding to the patient's needs. Expression of these attitudes and behaviors may depend on contextual factors, including the clinical scenario, time, and the patient themselves. Both patients and practitioners favored short, simple scales assessing all 5 attitudes and behaviors as an approach to measuring therapeutic empathy.

Comparison With Other Evidence

A recent review and thematic analysis of existing therapeutic empathy definitions identified 6 components, including exploring, understanding, shared understanding, feeling, therapeutic action, and maintaining boundaries [11]. These components align well with the attitudes and behaviors identified by participants in this study. "Exploring" is similar to showing an interest in the patient as a person and actively listening. "Understanding" and "shared understanding" map on to participants' description of understanding. "Feeling" and "maintaining boundaries" share similarities with the subtheme emotional engagement, and "therapeutic action" corresponds with responding to the patient's needs.

Our findings also share similarities with previous studies [14-16] of patients' experiences of therapeutic empathy. These studies identified listening, understanding (the patient as a whole person, including their emotions), and taking action to help the patient as characteristics of therapeutic empathy [14-16]. While these findings align with ours, we also found that the practitioner's emotional engagement, including their own feelings in response to the patient's situation, was perceived to be an important part of therapeutic empathy to patients and practitioners. This finding sits partly at odds with previous research, which found that practitioners rate emotional involvement as more empathic than patients [17].

This study offers 2 important additions to the evidence base. First, the findings suggest that not all of the elements of therapeutic empathy might be appropriate in all contexts for all patients. Participants identified contextual factors that necessitated the foregrounding of particular empathic behaviors over others. Second, participants implied that therapeutic empathy must be successfully demonstrated to patients in order to be meaningful. Previous definitions of therapeutic empathy

have focused on the practitioner's experience of empathy (eg, how they understand or feel), with limited consideration given to how this is conveyed to the patient [11]. Our findings emphasize that the latter is what makes empathy therapeutic. However, further research is needed to determine how to best express therapeutic empathy to patients in practice, before concrete recommendations or strategies can be suggested regarding specific behaviors to teach or adopt.

That being said, there are evidence-based strategies to convey empathy that align with the themes generated in this study [43]. For example, looking at the patient when talking to them (instead of a screen or paper notes), avoiding interrupting the patient, and being genuinely curious about them [43] align strongly with our themes pertaining to showing genuine interest in the patient and actively listening to them. Similarly, using facial expressions and other nonverbal communication to show understanding largely reflects our theme about understanding the patient's perspective, while giving positive messages of hope shares similarities with the theme about responding to patients' needs [43].

Relatedly, our findings clearly emphasize practitioners demonstrating empathic behaviors toward patients. This contrasts with previous research that contests that empathy is an innate "trait," something a practitioner either has or does not have [44-46]. As such, our findings contribute to the "state or trait" debate surrounding therapeutic empathy, introducing the possibility that a practitioner with limited "trait" empathy could, in theory, be perceived as empathic by their patients through the successful enactment of empathic behaviors.

Our findings also add to the debate over whether therapeutic empathy is an affective or cognitive concept. Affective empathy has long been disregarded by the clinical community for fears that it would hamper objectivity and lead to burnout [9,47]. More recently, however, authors have begun to argue that therapeutic empathy includes cognitive and affective components [1,48]. The findings of our study align with the latter argument, showing that patients' and practitioners' conceptualizations of therapeutic empathy include both cognitive and affective aspects.

Many existing measures of therapeutic empathy are long [22-29,34] and include negatively worded items [24,26,28,29,31]. This leads to potential problems with the reliability and validity of the responses generated [33]. This may be, in part, due to the fact that the development of existing measures has seldom included the patient voice [15,32]. This study revealed that both patients and practitioners have a preference for short, simple scales to measure therapeutic empathy. Moreover, our findings additionally highlight the absence of and need for corresponding patient-, practitioner-, student-, and observer-reported measures to allow triangulation of scores. Development of such a scale should be a priority for further research, given that there are discrepancies between practitioner self-ratings of empathy and patient ratings of practitioner empathy [19-21] that may prevent patients and practitioners from benefiting from therapeutic empathy downstream [4-7].

Finally, our finding that what patients consider to be empathic care varies according to context dovetails with the literature showing that what patients take to be empathic care is relative to ethnicity and culture [49].

Strengths and Limitations

Unlike previous research [13-17], this study explores and synthesizes patients' (with diverse experiences of health and care) with practitioners' (from different professions and health care services) perspectives on the definition of therapeutic empathy. Moreover, this is the first study to explore how therapeutic empathy should be measured from the perspectives of the stakeholders who will complete such measures. However, despite being conducted rigorously, this study has potential limitations. First, the sample was comprised of patients and practitioners from a medical school and a school of health care from 1 institution. As such, participants may not be representative of all patients and practitioners, and their views may have been, at least in part, shaped by their experiences at that institution. This is mitigated somewhat by our purposeful sampling of patients with different experiences of health and care and different ages, sexes, and ethnicities, along with practitioners from different professions and health care services and different ages, sexes, and ethnicities. Moreover, the purpose of this study (and indeed the purpose of most qualitative research) [37] was not to recruit a sample representative of all patients and practitioners, but rather to explore, in depth, diverse patients' and practitioners' views on therapeutic empathy. Additionally, we have provided a rich description of the context in which this research took place, supporting reflection about the transferability of the findings to other contexts [37]. Another potential limitation is that, to accommodate participants' needs, we offered them the option of completing their interviews digitally, and 9 participants opted for this. In-person interviews are considered the gold standard in qualitative data collection [50]; however, research shows that the depth and length of the data generated from web-based interviews are similar [51,52].

Recommendations for Further Research

Further research is needed to explore the ways by which the attitudes and behaviors that comprise therapeutic empathy are enacted in clinical practice and how this varies across different contexts (including those influenced by ethnic, cultural, and systemic factors), clinical scenarios (particularly those that may be considered challenging, like breaking bad news), and patient and practitioner demographics. This might be achieved using conversation analysis of video-recorded consultations. Relatedly, exploring perspectives on empathic communication beyond patient-practitioner interactions—for example, intra- and interprofessional empathy—and how this shapes patients' perceptions of therapeutic empathy in practice would be a worthwhile avenue for further research. Moreover, research would benefit from replicating this study with a larger sample across multiple contexts to develop our findings further. Finally, research should be conducted to develop and psychometrically test a "universal" therapeutic empathy measure that can be completed by patients, practitioners, students, and observers and is sensitive to context and complexity.

Conclusions

Little previous research has explored the synergies between views of patients and practitioners on the definition and measurement of therapeutic empathy and those who do often emphasize the differences between their perspectives [13,17]. On the contrary, we found that patients and practitioners have similar views on what therapeutic empathy means and describe it as involving the practitioner demonstrating 5 attitudes and behaviors to patients. These include showing an interest in the patient as a person, actively listening, understanding, emotionally engaging, and responding to the patient's needs. This perspective innovatively positions therapeutic empathy as a professional behavior and skill that should be demonstrated irrespective of patient reciprocity. A novel finding is that contextual factors, including the clinical scenario, time, and the patient, may influence whether, and how, these empathic attitudes and behaviors are expressed in practice. Measures of the concept should be developed with consideration for the role of context in empathy expression but, importantly, should be short and simple, unlike many existing measures.

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Data Availability

Data are presented in the main manuscript.

Conflicts of Interest

None declared.

Multimedia Appendix 1
Semistructured interview topic guide.
[DOCX File, 116 KB - jopm_v17i1e71610_app1.docx]

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Abbreviations

HCP: health care practitioner
PTCR: patient or carer

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Impact of Platform Design and Usability on Adherence and Retention: Randomized Web- and Mobile-Based Longitudinal Study

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Abstract

Background: Low retention and adherence increase clinical trial costs and timelines. Burdens associated with participating in a clinical trial contribute to early study termination. Electronic patient-reported outcome (ePRO) tools reduce participant burden by allowing remote participation, and facilitate communication between researchers and participants. The Datacubed Health (DCH) mobile app is unique among ePRO platforms in its application of behavioral science principles (reward, motivation, identity, etc) in clinical trials to promote engagement, adherence, and retention.

Objective: We evaluated the impact of platform design and usability on adherence and retention with a longitudinal study involving repeated patient-facing study instruments. We expected participants assigned to complete instruments in the DCH mobile app to stay in this study longer (increased retention) and complete more surveys while in this study (increased adherence) due to the enhanced motivational elements unique to the participant experience in the DCH app group, and this group's overall lower burden of participation.

Methods: A total of 284 adult participants completed 24 weekly surveys via 1 of 4 modalities (DCH app vs DCH website vs third-party website vs paper) in a web-based and mobile longitudinal study. Participants were recruited from open access websites (eg, Craigslist or Facebook [Meta]), and a closed web-based user group. All participation occurred remotely. Study staff deliberately limited communications with participants to directly assess the main effects of survey administration modality; enrollment and study administration were largely automated. Participants assigned to the DCH app group experienced behavioral science–driven motivational elements related to reward and identity formation throughout their study journey. There was no homolog to this feature in any other tested platform. Participants assigned to the DCH app group accessed study measures using passcodes or smartphone biometrics (face or touch ID). Participants in the DCH website group logged into a website using a username and password. Participants in the third-party website group accessed web-based surveys via personalized emailed links with no need for password authentication. Paper arm participants received paper surveys in the mail.

Results: Mode of survey administration (DCH app vs DCH website vs third-party website vs paper) predicted study retention ($F_{9,255}$=4.22, P<.001) and adherence ($F_{9,162}$=5.5, P<.001). The DCH app group had greater retention than the paper arm (t=−3.80, P<.001), and comparable retention to the DCH website group. The DCH app group had greater adherence than all other arms (DCH web: t=−2.42, P=.02; third-party web: t=−3.56, P<.001; and paper arm: t=−4.53, P<.001).

Conclusions: Using an ePRO platform in a longitudinal study increased retention and adherence in comparison to paper instruments. Incorporating behavioral science design in an ePRO platform resulted in further increase in adherence in a longitudinal study.

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KEYWORDS

behavioral science; electronic patient-reported outcomes; ePROs; retention; adherence; patient engagement; clinical trials; mobile phone

Introduction

Clinical trial retention and adherence rates vary greatly across and within therapeutic areas [1-3]. Low adherence and retention increase costs and negatively impact data quality and the validity of research findings. Mitigating the various retention and adherence challenges in clinical trials is a major focus of clinical trial sponsors and researchers [4]. Studies can improve retention by strategically recruiting individuals or populations more likely to complete a trial [1]. However, this can increase the risk of bias and decrease the degree of representativeness in the study sample. Retention challenges can especially impact at-risk populations, an effect that increases with study duration [5]. Thus, preselecting participants based on their likelihood of completing a longitudinal clinical trial may not best represent the targeted indication itself. Further, patterns of risky behavior may predict dropout as seen in bipolar disorder and adolescent depression treatment studies [6,7].

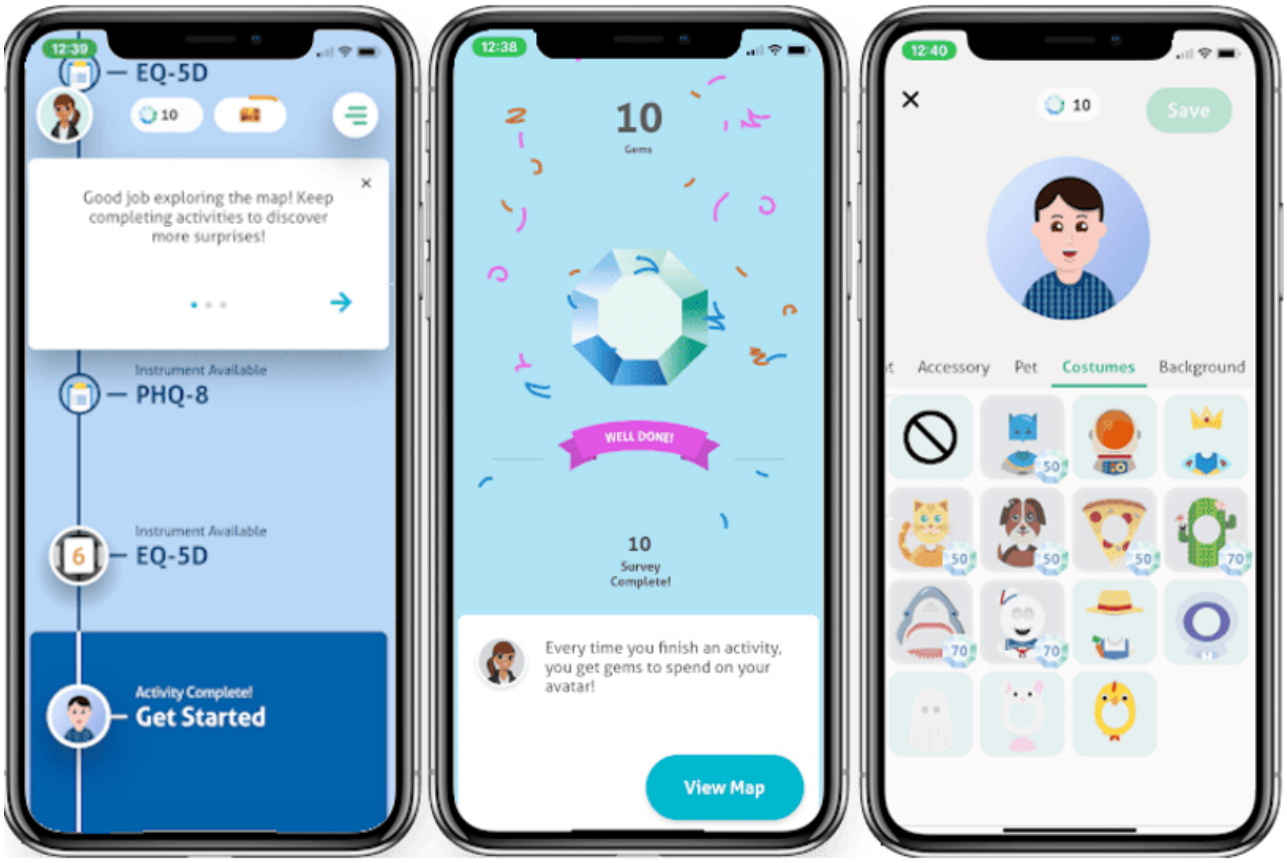
Researcher behavior and communication also impact participant retention. Retention increases with participants' positive attitudes toward study staff and the quality of their relationship with the study team [8,9]. Focusing on patient-centered communication and relationship building can therefore bolster retention in a clinical trial, but is not necessarily effective for all study designs and populations [4]. Participant burden further impairs study retention; the more difficult or inconvenient it is to participate in a study, the more likely participants are to stop participating [10]. The sources of participant burden vary with study design and indication. Common examples include longer trial duration, protocol complexity, financial difficulties, and travel-related burden [10-12].

eCOAs (electronic clinical outcome assessments) such as electronic patient reported outcomes (ePROs) and electronic diaries are popular ways to incorporate the patient perspective and reduce participant burden in clinical trials [13]. ePRO platforms vary in their design attributes and usability, and different study populations have different aesthetic and performance preferences [14,15]. Regardless, participants across diverse indications report high usability and tolerability of ePRO platforms [16-18]. In comparison to paper data collection, ePRO platforms improve timeliness of questionnaire delivery, minimize data entry errors, and reduce cognitive burden for study participation by automating reminders. Some ePRO platforms allow researchers to communicate with participants, fostering the development of a personal connection with the study team that has been associated with increased study retention [8,9]. Through creating an easier experience for participants, these features increase adherence and retention, a goal shared by all clinical research studies. Further, participants otherwise lost to follow up may continue providing data, if they have the option to do so remotely [18].

However, ePRO platforms have unique challenges that impact retention and adherence. Older adults are particularly concerned about security and data sharing with electronic platforms [19]. Regulatory guidelines often mandate that researchers prioritize data security when selecting an ePRO platform. Maximizing data security can increase participant burden by requiring complex passwords or additional security measures such as 2-factor authentication [20]. Researchers consequently have multifaceted challenges to contend with when designing a study that ensures ease of participation, while simultaneously complying with good clinical practice standards and maximizing data security.

Datacubed Health (DCH) offers one such ePRO platform. It is differentiated from other platforms by its behavioral science-focused user experience design and in-app motivational elements (Figure 1). In general, mobile app users report higher consumer loyalty and more positive attitudes toward core services when app usage involves reward, achievement, gaining knowledge, and identity formation [21]. ePRO platforms, which leverage these principles in their design, may especially maximize retention and adherence in clinical trials [22,23]. Participants using the DCH app achieve a sense of identity by creating an in-app avatar to represent them. As participants progress through the study, they are rewarded for completing study activities. Participants' progress is visualized dynamically, contributing to a sense of achievement. At the study level, researchers may choose to deploy educational materials about this study, treatment, or indication, allowing participants to gain knowledge. Together, these features encourage continued retention and adherence by fostering a positive attitude toward study participation. Previous studies using DCH's ePRO system have achieved high adherence (eg, 100% in [24]) and retention (eg, 93.5% in "virtual trials" [25]).

Figure 1. Behavioral science-based design of the DCH app. Participants assigned to complete surveys using the DCH app encountered in-app motivators and rewards throughout their study journey. DCH: Datacubed Health.



This study evaluated the impact of behavioral science–based ePRO platform features on adherence and retention in a longitudinal virtual study involving weekly completion of questionnaires for 6 months. Further, 3 ePRO platforms (DCH app, DCH website, and a third-party website) were compared to each other and to the traditional paper survey administration. We hypothesized that reducing friction and increasing motivation by administering ePROs using DCH's behavioral science-based mobile app would result in higher adherence and retention beyond the benefits of ePROs without these functions (ie, DCH website and third-party website).

Methods

Ethical Considerations

This study was conducted under institutional review board (IRB) approval from the BRANY (Biomedical Research Alliance of New York; #20-017-740) and the protocol is publicly available (DOI: 10.5281/zenodo.14807237) or available as Multimedia Appendix 1. All participants reviewed and completed informed consent in the DCH app using the Health Insurance Portability and Accountability Act and General Data Protection Regulation compliant eConsent feature of the app. Participants were required to answer challenge questions during the consent process to ensure they understood participation requirements. While participants provided their contact information to participate in this study, the dataset and all reported findings were deidentified before analysis. Participants were compensated US $5 for each survey they completed during this study. Payment schedule varied as an outcome measure as described further below.

Participant Recruitment

Participants were recruited from advertisements placed on open access websites including Craigslist, Facebook, and Snapchat. A subset of participants was recruited using the services of a closed user group, a participant recruiting platform for user experience research. Recruitment was fully automated; advertisements contained a link to the screening survey. Participants who met screening criteria received an automated email invitation to download the DCH app and a unique code to create an account within the app for informed consent. All participants reviewed the informed consent form remotely, via DCH's electronic consent module. Consent comprehension questions were required before electronic signature to ensure participants understood this study's requirements and duration. In order to complete eConsent procedures, participants were required to download the DCH app onto their personal smartphone device, and required to share a minimum of necessary data with the DCH app developers. There was not a possibility of individual data being bequeathed to or sold to third parties, with or without participant consent.

Eligibility Criteria

Participant demographics were unknown to researchers during recruitment in the interest of recruiting a diverse, heterogeneous set of participants. However, to facilitate study participation and comply with IRB requirements, we excluded participants who self-reported that they did not have access to a smartphone,

did not have a data plan, did not reside within the United States, were younger than 18 years, or did not speak English fluently. We further excluded participants whose IP address indicated they did not reside within the United States, or who were using IP spoofing software. We excluded participants who used the same IP address to complete the automated, web-based screening process multiple times; these participants were able to enroll in this study only once, provided they otherwise met eligibility criteria.

Participant Demographics

Participants completed a self-reported demographics questionnaire in their assigned administration modality during their first week of participation. Participants were on average aged 34.78 (SD 12.79) years and mostly identified as female (n=149, 54.18%) or male (n=116, 42.18%) from diverse racial or ethnic backgrounds (Table 1). A total of 180 participants were retained for the full 6-month study duration, meaning they completed the final or week 24 survey. Adherence was assessed based on data from these retained participants.

Table . Participant demographics. A total of 284 participants were randomly assigned to complete weekly surveys using 1 of 4 modalities (DCH[a] app vs DCH web vs third-party website vs paper). A total of 275 of these participants completed a survey providing their demographic data.

Demographics		Values
Age (year), mean (SD)		34.78 (12.79)
Gender identity, n (%)		
	Female	149 (54.18)
	Male	116 (42.18)
	Gender queer or gender nonconforming	8 (2.91)
	Prefer not to say	2 (0.73)
Race or ethnicity, n (%)		
	Asian	46 (16.73)
	Black or African American	37 (13.45)
	Hispanic or Latino	18 (6.55)
	White	149 (54.18)
	More than 1 race	20 (7.27)
	Other race	4 (1.45)
	Prefer not to say	1 (0.36)

[a]DCH: Datacubed Health.

Randomization

A total of 284 participants were randomly assigned to receive weekly surveys via 1 of 4 modes of administration (DCH app vs DCH website vs third-party website vs paper). Participants were assigned sequentially, based on the order in which they completed the automated screening and consent procedures. Due to the nature of this study, participants were not blinded and were aware of which mode of administration they were assigned to for the duration of this study. Similarly, study staff were not blinded. However, study staff interactions with participants were limited to IRB required communication, and mostly involved payment coordination via email.

Survey Administration

After randomization, participants received email instructions corresponding to their study arm assignment (Table 2). All surveys were completed remotely by participants without monitoring or intervention by study staff. Surveys were selected to be easy to complete with neutral subject matter, such as the Perceived Stress Scale [26] and Patient Health Questionnaire-8 [27]. While the majority of surveys used were standard, validated ePROs, we developed a novel survey ("Format Usability Survey") for this study to assess tolerability between different modes of administration, deployed at 3 time points throughout this study to all participants (weeks 4, 11, and 23). The Format Usability Survey included 30 items related to participants' assigned platform (eg, "The format is easy to use" or "The format is user friendly") rated on a 7-point Likert scale ranging from "strongly disagree" to "strongly agree," and 2 open-ended prompts in which participants listed the positive or negative aspects of their assigned platform.

Table . Modes of survey administration and authentication. A total of 284 participants were randomly assigned to complete weekly surveys via 1 of 4 modalities (DCH[a] app vs DCH website vs third-party website vs paper). These platforms differed in their modes of survey deployment and authentication.

Arm	Survey deployment	Authentication
DCH app	DCH app, with optional automated push notifications[b]	Username and password, smartphone biometrics, or passcode[c]
DCH website	Single email containing link to DCH website	Username and password
Third-party website	Single email containing link to third-party website	None
Paper	Mailed packets containing survey and stamped return envelope	None

[a]DCH: Datacubed Health.

[b]Participants were given the option to opt out of Datacubed Health app push notifications, if preferred.

[c]The Datacubed Health app can be configured to prompt participants to enable biometric authentication (eg, touch or face ID) after they first log-in with a username and password. Participants then create a numeric passcode. Participants may opt out of enabling biometric authentication and use only a passcode, if preferred.

Participant Communication

Survey Response Monitoring

Throughout the 6-month study duration, this study's team never proactively contacted study participants to remind them to complete surveys or encourage adherence. In general, communication with study participants across all arms was deliberately limited to assess the adherence capabilities of the 4 platforms without any confounds related to this study team's encouragement or involvement. Participants were provided with a study email address for any necessary communications (eg, questions about payment or requests for study withdrawal).

Survey response monitoring was not conducted in this study as the main goal was to evaluate the impact of survey administration format on retention, adherence, and engagement in a virtual community population. This was communicated with all participants in the informed consent form.

DCH App

Participants assigned to the DCH app arm received weekly surveys in the DCH app, which they had already downloaded to complete the consent process. Participants could log into the DCH app by using smartphone biometrics (face or touch ID) or a 4-digit passcode. Participants in the DCH app arm who enabled push notifications received automated push notifications reminding them to complete surveys on a weekly basis. Participants were given the option to opt out of push notifications at study start, or were free to turn them off in their smartphone settings at any point throughout this study. Additional motivational elements unique to the DCH app arm included various in-app rewards for completing surveys and making progress.

Participatory Involvement

The DCH app was developed using behavioral science research, focus groups, and surveys over several iterative rounds of user experience testing spanning several years [28]. At the time of study conduct the DCH app was in use commercially as a patient-facing ePRO platform for international clinical trials. Before deployment for an individual clinical trial or research study, the DCH app undergoes a study-level user acceptance testing (UAT) protocol in which sponsors evaluate both the patient and sponsor or site-level experiences within the DCH app. The UAT process can occasionally identify bugs in the patient-facing experience, which are then promptly fixed, sometimes involving the release of new versions in the Google Play or Apple App stores. Notably, backward compatibility is maintained such that older app versions remain functional. For this study, UAT was performed by study staff before enrolling the first study participant.

At study start, participants were able to download version 3.50.5 (Android; Google) or 3.50.4 (iOS; Apple) from the Google Play or Apple App store, respectively. Both Android and iOS versions of the DCH app were continuously updated throughout this study when absolutely necessary; for example, for major bug fixes needed to maintain functionality. However, the DCH app did not undergo major changes during study conduct and all relevant participant-facing motivational features (eg, avatars or rewards) remained constant for the duration of data collection. The DCH app is Health Insurance Portability and Accountability Act and General Data Protection Regulation compliant with appropriate security and privacy measures in place to encrypt and protect participant data during and after their participation.

Reporting Guidelines

This study was reported referencing the CHERRIES (Checklist for Reporting the Results of Internet E-Surveys) and CONSORT (Consolidated Reporting of Standardized Trials) guidelines [29,30].

DCH Website and Third-Party Website

Participants assigned to the DCH website or third-party website arm were instructed to delete the DCH app, and received weekly emails containing links to web-based surveys hosted on the DCH website or the third-party website, respectively. The third-party website arm clicked email links to complete questionnaires directly. The DCH website arm clicked email links, then entered a unique username and password to access the surveys each week.

Paper

Participants assigned to the paper arm were prompted to enter their mailing address in the DCH app they had used to give consent, and upon doing so were instructed to delete the app and informed they would receive mailed surveys going forward. There was no authentication associated with completing paper surveys. Participants in the paper arm received weekly paperboard mailers containing a stamped reply envelope with which to return their completed surveys.

Participant Compensation

All participants received US $5 via electronic transfer for each completed survey (Table 3). However, payment schedule varied to account for potential effects on adherence and retention for the paper arm participants whose mailed surveys needed to be returned and processed before compensation. This was of particular concern as data collection principally occurred during the height of the COVID-19 pandemic's impact on US Postal Service delays [31]. Therefore, approximately one half of participants (n=161, 56.7%) received biweekly payments of US $5 per survey completed within the previous 2 weeks (biweekly), and the other half (n=123, 43.3%) received 1 lump sum payment for all completed surveys at the end of their 6 months in this study or request to withdraw from this study early (bulk). All participants were eligible to receive a maximum of US $120 corresponding to 24 completed surveys, or 6 months of weekly surveys.

Table . Participant groups by study arm and payment group. A total of 284 participants were randomly assigned to complete weekly surveys via 1 of 4 modalities (DCH[a] app vs DCH website vs third-party website vs paper). Participants were further split into receiving ongoing payment for their study participation (biweekly) or 1 large payment upon their completion of this study (bulk).

Arm	Biweekly payment (biweekly)	One payment at study completion (bulk)
DCH app (n=95)	55	40
DCH website (n=45)	30	15
Third party website (n=88)	49	39
Paper (n=56)	27	29

[a]DCH: Datacubed Health.

Statistical Analysis

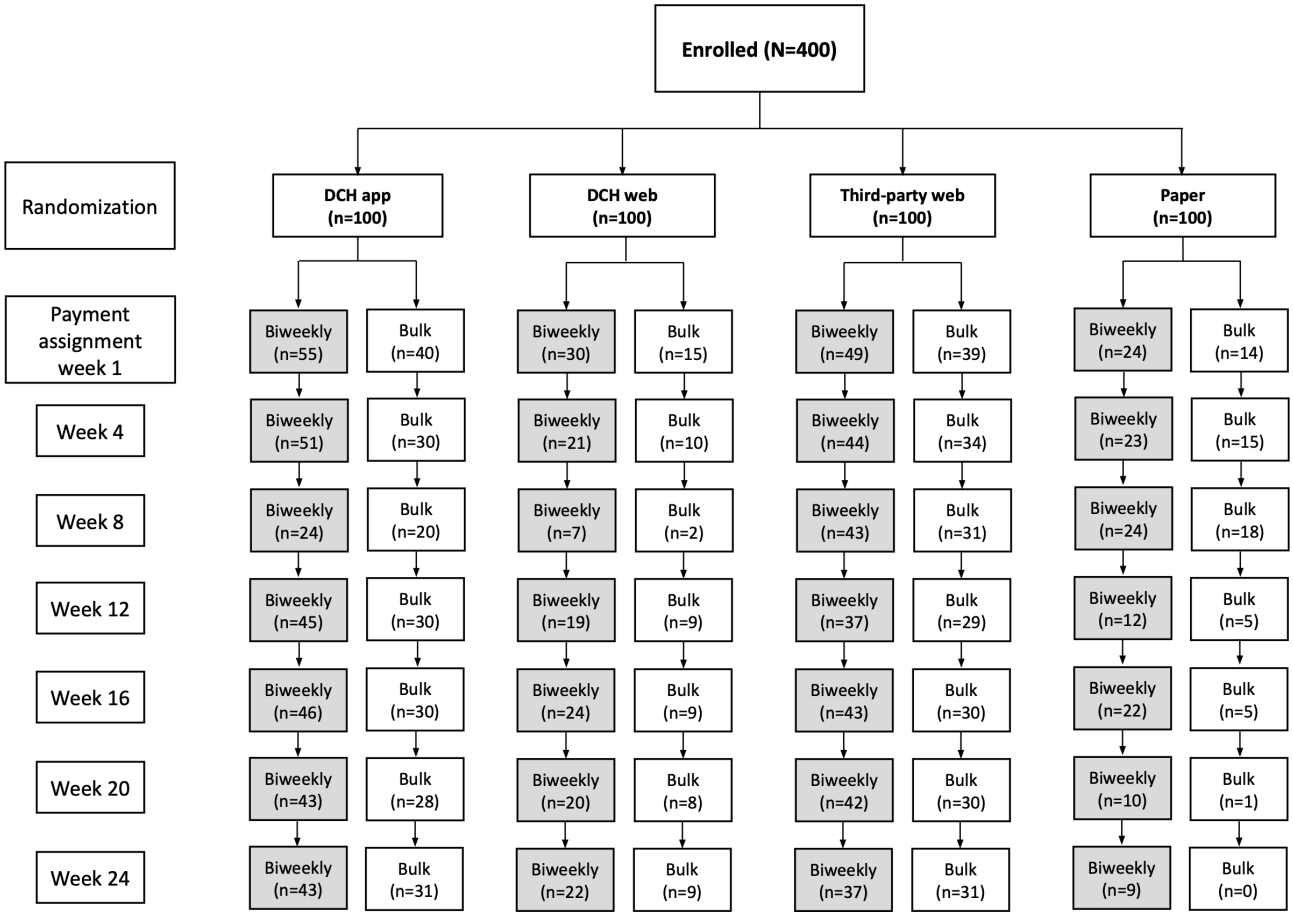
Descriptive statistics were evaluated for each of the 4 study arms. Multiple linear regressions with dummy coded categorical independent variables were performed to examine the effect of survey modality (DCH app vs DCH website vs third-party website vs paper), payment schedule (bulk vs biweekly), and demographic variables (ie, age, gender, and ethnicity), on the primary outcome measures of retention (number of days between the first and last completed surveys) and adherence (percentage of surveys completed). Retention was defined as remaining in this study for the entire, 6-month duration, regardless of the number of surveys completed in that time period. Adherence was defined as the proportion of surveys completed while enrolled in this study. The adherence analysis set was restricted to participants who were retained till the study end, that is, completed the last survey (n=172). All statistical analyses were conducted using RStudio (Posit PBC) [32].

Results

Recruitment

The analytic dataset included 265 participants, with 91 in the DCH app group, 45 in the DCH web group, 81 in the third-party web group, and 48 in the paper arm (Figure 2). For each group, 100 participants were recruited at baseline. Discrepancies in the number of participants in each group are attributable to differences between each study modalities' tolerability to participants and subsequent attrition (eg, high attrition in the paper arm). This was expected and is directly relevant to this study's primary outcomes of the impact of differences in retention and adherence based on the mode of survey administration. Participants were recruited between August 2020 through July 2021, and all individuals participated for a maximum of 6 months of follow-up.

Figure 2. Enrollment and group assignment. A total of 116 participants left this study before completing a single survey. Further, 284 participants were included in the analysis dataset. DCH: Datacubed Health.



Baseline Data

Descriptive statistics for demographic variables across each study arm are reported in Table 4.

Table . Participant demographics by study arm. A total of 10 (3.64%) participants who reported their gender as “other” or “prefer not to say” were excluded for the purposes of analyses. Ethnicity groups of “more than 1 race,” “hispanic or latino,” “other race,” and “prefer not to say” were merged as 1 “other” group due to small sample sizes for the purposes of analyses.

		Study arm			
		DCH[a] app	DCH web	Third-party web	Paper
Age (year), mean (SD)		34.99 (12.34)	35.38 (15.06)	34.59 (13.16)	35.73 (11.27)
Gender, n (%)					
	Female	50 (54.95)	26 (57.78)	46 (56.79)	27 (56.25)
	Male	41 (45.05)	19 (42.22)	35 (43.21)	21 (43.75)
Race or ethnicity, n (%)					
	Asian	13 (14.29)	10 (22.22)	14 (17.28)	8 (16.67)
	Black or African American	16 (17.58)	4 (8.89)	11 (13.58)	5 (10.42)
	Hispanic or Latino	8 (8.79)	6 (13.33)	3 (3.7)	—[b]
	White	48 (52.75)	22 (48.89)	47 (58.02)	29 (60.42)
	More than 1 race, prefer not to say, or other	6 (6.59)	3 (6.67)	6 (7.41)	6 (12.5)

[a]DCH: Datacubed Health.

[b]Not available.

Multiple Regression Results

Overview

Predictors of retention (Table 5) and adherence (Table 6) were examined using multiple regression. Before analysis, assumptions were evaluated including linearity (residuals vs fitted), normality (Q-Q residuals), homoscedasticity (scale-location), and influential outliers (residuals vs leverage). All assumptions were met except normality. While violations of normality were identified in both cases, considering the large enough sample size we proceeded with analyses without modifying the dataset.

Table . Predictors of retention.[a]

Independent variable	β value	Standard error	*t* test[b]	*P* value
Study arm [c]				
DCH[d] web (vs DCH app–)	−18.34	10.5	–1.75	.08
Third-party web (vs DCH app)	4.26	8.75	0.49	.63
Paper (vs DCH app)	–38.99	10.27	–3.8	<.001
Payment schedule				
Biweekly (vs bulk)	25.05	7.26	3.45	.001
Age (years)	0.14	0.29	0.49	.625
Gender				
Male (vs female)	1.24	7.16	0.17	.86
Ethnicity				
Asian (vs White)	10.24	10.16	1.01	.31
Black or African American (vs White)	–10.8	10.69	–1.01	.31
Other (vs White)	4.11	10.53	0.39	.70

[a]R^2=0.13, adjusted R^2=0.10. $F_{9.255}$=4.22, P<.001.

[b]2-tailed.

[c]Reference groups are included in parentheses where applicable.

[d]DCH: Datacubed Health.

Table . Predictors of adherence.[a]

Independent variable		β value	Standard error	*t* test[b]	*P* value
Study arm					
	DCH web (vs DCH app)	–3.72	1.54	–2.42	.02
	Third-party web (vs DCH app)	–4.38	1.23	–3.56	<.001
	Paper (vs DCH app)	–12.4	2.74	–4.53	<.001
Payment schedule					
	Biweekly (vs bulk)	–1.38	1.14	–1.21	.23
Age (years)		–0.05	0.04	–1.2	.23
Gender					
	Male (vs female)	2.69	1.11	2.43	.02
Ethnicity					
	Asian (vs White)	–3.51	1.57	–2.24	.03
	Black or African American (vs White)	–0.09	1.66	–0.06	.955
	Other (vs White)	–1.2	1.6	–0.75	.453

[a]R^2=0.23, adjusted R^2=0.19; $F_{9,162}$=5.5, P<.001.

[b]2-tailed.

Retention

The overall retention model was statistically significant ($F_{9,255}$=4.22, P<.001, R^2=0.13, adjusted R^2=0.10). The DCH app had greater retention than the paper arm (t=–3.80, P<.001). Biweekly payment schedule predicted greater retention than bulk payment (t=3.45, P=.001).

Adherence

The overall adherence model was statistically significant ($F_{9,162}$=5.5, P<.001, R^2=0.23, adjusted R^2=0.19). The DCH app arm had superior adherence to the other 3 study arms (ie, DCH web, t=−2.42, P=.017; third-party web t=−3.56, P<.001; and paper arms, t=−4.53, P<.001). Male participants had significantly greater adherence than female participants (t=2.43, P=.02). Participants who identified as Asian had significantly lower adherence compared to participants who identified as White (t=−2.24, P=.03).

Discussion

Principal Findings

We examined the effect of ePRO platform design on longitudinal retention and adherence in a siteless, virtual study involving weekly questionnaires in a sample of 284 US-based adults. Compared to paper administration, ePROs, when paired with rewards, have been shown to improve retention and adherence in clinical settings [18,22,23]. This study specifically examined the impact of behavioral science elements in the DCH ePRO platform (eg, rewards for completing instruments, gamification, or automated reminders) on retention and adherence, compared to web-based ePRO platforms without motivators, and paper. We expected participants assigned to complete weekly instruments in the DCH app to show higher adherence and retention, due to the added motivational elements and lower friction intrinsic to the DCH app.

As expected, mode of administration significantly impacted both adherence and retention (P<.001). The DCH app had significantly higher retention than the paper format (P<.001) and significantly greater adherence than the other 3 study arms (ie, DCH web, P=.03; third-party web and paper arms, P<.001). While the retention rate for the third-party website was similar to that of the DCH app, participant-level authentication is a general standard for ePRO completion in clinical research, limiting this tools' in vivo relevance for clinical trial use. Importantly, the DCH app arm, with secure authentication measures, had comparable retention to the third-party website, which had no authentication measures. These results suggest that unlike requiring a username and password, passcodes and biometric authentication are well tolerated security mechanisms that do not increase attrition in longitudinal studies.

The significant difference in adherence, but comparable retention, between the DCH app and third-party website arms suggests that differences between the 2 platforms contributed to higher overall adherence in the DCH app arm. The standard DCH app participant experience involves creating a representative avatar to build identity. As participants complete sequential surveys, they accumulate rewards and encounter various in-app motivators throughout this study's journey. In addition, the user interface uses dynamic, colorful changes and progress markers. In comparison, the third-party website has no indicators of overall study progress or explicit motivators; participants simply click an email link to directly complete a survey. When used in clinical trials, apps like the DCH app

allow study staff to enact more focused and immediate intervention in situations jeopardizing data completeness, for example, missing data, attrition, or app crashes in comparison to external website or survey platforms.

Among the examined demographic variables (ie, gender, ethnicity, or age), gender and ethnicity were significantly associated with adherence. Male participants showed significantly greater adherence (P=.02). However, the significance of this finding requires further exploration, ideally with a sample inclusive of nonbinary gender identities which were underrepresented in this study, and not reflected in the regression analysis. Participants who identified as Asian had lower adherence than participants who identified as White (P=.03). Future research can evaluate the meaning of these differences by recruiting a sample with expanded variability across gender and ethnicity groups.

To determine the impact of financial compensation on retention and adherence, participants were divided into 2 groups with different payment schedules. The results revealed that while the biweekly schedule was associated with greater overall retention than the bulk method (P=.001), payment schedule was not associated with adherence (P=.23) among those retained by study end. It is possible that restricting analyses to participants retained by study end represents a unique subgroup of individuals from the complete study sample.

Indeed, participants assigned to the paper arm were more likely to drop out if they also needed to wait 6 months to receive any compensation, such that 0 participants assigned to the paper arm with bulk payment schedule were retained to this study's end. Delays and friction intrinsic to paper survey completion account for the low retention in the paper arm overall. In the absence of regular financial compensation, the burdens appeared to outweigh the delayed benefit for those in the paper arm. Qualitative data from paper arm participants in the Format Usability Survey support this assertion (eg, "May require trip to the post office to send out …… If using pen and a correction needs to be made. White-out may need to be used, which is kind of a hassle." Additionally "Cumbersome especially if several pages, requires extra steps of sealing in envelope and dropping off in mailbox, writing is slower than typing."). Future research evaluating the interaction between study participation burden and payment schedule is needed to confirm this hypothesis. While this study found no significant impact of regular versus bulk study payments for the electronic arms, this could change with increased participation burden. This is important when weighing the choice of administrative burden (eg, weekly payments) and participant retention.

While not assessed in this study, using paper to collect patient reported outcome measures adds significant additional site and sponsor-facing burden. Paper responses must be entered into an electronic record, a complex process which not only adds administrative burden and prolongs timelines but importantly introduces the opportunity for human error to alter study results (eg, data entry errors). In turn, the process of correcting data entry errors creates further administrative burden. Using electronic methods of data collection mitigates much of the delay and opportunity for data errors associated with paper data collection.

Limitations

Participant notification within the DCH app arm varied based on individual preferences, because participants could opt out of push notifications alerting them to new or incomplete surveys. The DCH app arm was the only condition with the possibility for variability in notifications, but was also the only arm with any automated reminders. Other in-app motivators (eg, rewards or participant avatar) were equally available to all participants in the DCH app arm. Participants could not be blinded to their own arm assignment because survey administration platforms were this study's arms.

Differences between the DCH app and third-party website were not strictly limited to additional behavioral science elements within the DCH app since 1 was a mobile app and the other a website. Ideally, 2 identical app-based platforms that differ only in their use of behavioral science elements (eg, rewards, avatars, etc) would be compared to confirm with greater confidence the incremental impact of behavioral science elements on study retention and adherence. In this case, other ways (eg, being a mobile app instead of a website or the intuitive design of the app interface) in which the DCH app improved upon the overall user experience of the third-party website may have contributed, at least in part, to the increased adherence seen in the DCH app arm. We were unable to comprehensively address several essential aspects of electronic health studies such as average session length due to this study's design and lack of availability of an equivalent, comparable metric across the 4 platforms. Follow-up studies could incorporate these variables in their design.

Overall retention rates were somewhat low in this study, likely a consequence of this study's design. Researcher communication impacts retention [4,9,10], so we deliberately limited communication with participants to isolate the main effect of survey platform on retention and adherence. In clinical trial settings, researchers commonly contact participants at risk of dropout proactively, which is an important complement to the use of technology. Regardless, the retention differences between study arms enforce the benefits of low-friction platforms.

Conclusion

These results support the superiority of electronic administration over paper when conducting longitudinal data collection. However, not all ePRO platforms are equal; platform-level differences in participant-facing friction and motivators are associated with differences in retention and adherence, respectively. Specifically, reducing participant friction when logging in to an ePRO platform can promote retention. Longitudinally, participants were most willing to continue using platforms with lower-friction authentication methods, such as face or touch ID, in comparison to needing to remember and repeatedly enter a username and password. Additionally, the platform with behavioral science-based motivational features had significantly higher adherence than any other modality in this study, suggesting efficacy for long-term studies. Low retention and adherence pose a significant challenge to clinical

research conduct, increasing the time and costs required to bring novel interventions to patients who need them. By choosing ePRO platforms that make participation in clinical trials easier and more enjoyable for participants, researchers can reduce costs, minimize site burden, and maximize participant benefit by accelerating clinical trials. Clinical trial sponsors and study teams should consider the patient experience when selecting an ePRO platform.

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Data Availability

The datasets generated or analyzed during this study are available from the corresponding author on reasonable request.

Conflicts of Interest

Authors XJ, MT, and MO are former employees of Datacubed Health. Author EB is a current employee of Datacubed Health. Author MO owns stock options of Datacubed Health. All authors were involved in development of the DCH app and website. No author has served or currently serves on the editorial board of the *Journal of Medical Internet Research*. No author has acted as an expert witness in legal proceedings. No author has sat or sits on a committee for an organization that may benefit from publication of this work.

Multimedia Appendix 1
Study protocol.
[PDF File, 315 KB - jopm_v17i1e50225_app1.pdf]

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Abbreviations

BRANY: Biomedical Research Alliance of New York
CHERRIES: Checklist for Reporting the Results of Internet E-Surveys
CONSORT: Consolidated Reporting of Standardized Trials
DCH: Datacubed Health
eCOA: electronic clinical outcome assessment
ePRO: electronic patient reported outcome
IRB: Institutional Review Board
UAT: user acceptance testing

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Original Paper

Assessing Physician and Patient Agreement on Whether Patient Outcomes Captured in Clinical Progress Notes Reflect Treatment Success: Cross-Sectional Study

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Abstract

Background: It remains unclear if there is agreement between physicians and patients on the definition of treatment success following orthopedic treatment. Clinical progress notes are generated during each health care encounter and include information on current disease symptoms, rehabilitation progress, and treatment outcomes.

Objective: This study aims to assess if physicians and patients agree on whether patient outcomes captured in clinical progress notes reflect a successful treatment outcome following orthopedic care.

Methods: We performed a cross-sectional analysis of a subset of clinical notes for patients presenting to a Level-1 Trauma Center and Regional Health System for follow-up for an acute proximal humerus fracture (PHF). This study was part of a larger study of 1000 patients with PHF receiving initial treatment between 2019 and 2021. From the full dataset of 1000 physician-labeled notes, a stratified random sample of 25 notes from each outcome label group was identified for this study. A group of 2 patients then reviewed the sample of 100 clinical notes and labeled each note as reflecting treatment success or failure. Cohen κ statistics were used to assess the degree of agreement between physicians and patients on clinical note content.

Results: The average age of the patients in the sample was 67 (SD 13) years and 82% of the notes came from female patients. Patients were primarily White (91%) and had Medicare insurance coverage (65%). The note sample came from fracture-related encounters ranging from the second to the tenth encounter after the index PHF visit. There were no significant differences in patient or visit characteristics across concordant and discordant notes labeled by physicians and patients. Among agreement levels ranging from poor to perfect agreement, physician and patient evaluators exhibited only a fair level of agreement in what they deemed as treatment success based on a Cohen κ of 0.32 (95% CI 0.10-0.55; *P*=.01). Furthermore, interpatient and interphysician agreement also demonstrated relatively low levels of agreement.

Conclusions: The findings suggest that physicians and patients demonstrated low levels of agreement when assessing whether a patient's clinical note reflected a successful outcome following treatment for a PHF. As low levels of agreement were also observed within physician and patient groups, it is clear the definition of success varied highly across both physicians and patients. Further research is needed to elucidate physician and patient perceptions of treatment success. As outcome measurement and demonstrating the value of orthopedic treatment remain important priorities, it is important to better define and reach a consensus on what treatment success means in orthopedic medicine.

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KEYWORDS

patient outcomes; proximal humerus fracture; patient involvement; orthopaedic medicine; clinical progress notes

Introduction

In 1910, Ernest Amory Codman, an orthopedic surgeon, advocated for the concept of studying the "end result," or the idea that every surgeon should follow patients long enough to evaluate whether the treatment they received was successful [1]. Early on, as surgeons began adopting Codman's end result approach, physician-reported measurement of individual patient outcomes (eg, mortality, surgical complications, and degrees of range of motion) became the standard method to evaluate the success of orthopedic treatment. However, since that time, health care has continued to increase its appreciation of the patient's perspective on outcome achievement, and patient preferences for outcomes following care [2-6]. As outcome measurement and demonstrating the value of orthopedic treatment are becoming an increasing priority [7,8], it is important to better elucidate what treatment success means in orthopedic medicine [9,10]. To date, it remains unclear if physicians and patients share the same definition of treatment success following orthopedic care.

The electronic health record (EHR) system is the primary tool to document and store records of patient encounters in hospitals and outpatient clinics in the United States [11-13]. Clinical progress notes are generated for each encounter that patients have with their physician or health care provider. These contain rich information on current disease symptoms, rehabilitation progress, and unexpected complications [14]. Unstructured progress notes produce a record of a patient's history, physical findings, medical reasoning, and patient care and reveal distinct trajectories of patient outcomes after treatment [13,15,16]. In successful cases, the progress note documents the degree of improvement or relief experienced and reported by patients [17]. Conversely, when symptoms have not been resolved, are lingering, or when subsequent complications have arisen, these ongoing patient complaints and persistent treatment use are documented in the notes [18]. Clinical progress notes offer an opportunity to assess a range of outcome states and evaluate if physicians and patients have similar definitions of success following medical treatment for an orthopedic condition. Furthermore, the secondary use of EHR data is rapidly expanding, including the use of natural language processing and large language models to analyze unstructured clinical text [19-25]. One potential application of these methods includes using clinical notes as a data source to evaluate the success of orthopedic treatment. However, to correctly apply this method, a gold-standard definition of treatment success must be identified.

The objective of this paper was to assess agreement between patients and physicians on whether patient outcomes documented in clinical progress notes reflected successful or nonsuccessful treatment outcomes for patients receiving follow-up care for a leading shoulder condition, an acute proximal humerus fracture (PHF).

Methods

Study Sample

This was a cross-sectional analysis of a subset of progress notes from a larger study. The study included adult patients presenting in person to a Level-1 Trauma Center and Regional Health System for an acute PHF between January 1, 2019, and December 31, 2021. The index visit was defined as the first diagnosis at any health system site for PHF during the study period, with no previous visits for PHF within a year of the index visit. We identified all health system encounters (hospital encounters, office visits, etc) with a diagnosis of PHF or shoulder pain from the index PHF visit to 365 days after the index PHF visit. Of those encounters, we took the progress note from the last in-person office visit for PHF-related care, defined as a visit with a diagnosis of PHF (International Statistical Classification of Diseases and Related Health Problems 10th Revision [ICD10]: S42.2XXX) or shoulder pain (ICD10: M45.2XXX) to occur before 365 days postindex. This resulted in 1 note per person.

Patients were excluded from the study if they were less than 18 years of age, did not have at least 1 office visit with a diagnosis of PHF or shoulder pain that occurred 45 days or more days after the index visit, or if their last office visit was less than 500 characters. A minimum of 45 days after the index was used as this is the minimal time needed for healing of a PHF, before which treatment success cannot be assessed. The larger study included a sample of 1000 patients meeting these inclusion criteria. For this study, a sample of 100 progress notes was used to assess agreement between physicians and patients on their perceptions of treatment outcomes captured in the clinical notes. This study was approved by the Prisma Health Institutional Review Board (1924627-1).

Outcome Label Development Process

The University of South Carolina Patient Engagement Studio (PES) brings together patients, caregivers, community groups, health system innovators, clinicians, and academic researchers to produce meaningful research that advances health outcomes. The PES membership includes over 100 patients with diverse backgrounds and clinical experiences from across the United States trained to provide feedback and collaborate with research teams [26-28]. PES staff members assembled a panel of 5 patients all of whom had a previous orthopedic experience including a joint injury of the shoulder, wrist, or ankle. These patients experienced a mix of surgical and nonsurgical management for their condition. Specific demographics of the panel are not shared per PES policy as these patients are consultants rather than study participants. PES staff members facilitated the senior author (SBF) to lead 3 sessions to codevelop a range of outcome states following orthopedic treatment. Together, the PES members and senior author defined 4 distinct outcome states that spanned the range of outcomes patients could experience following treatment for PHF.

Figure 1 contains the 4 distinct outcome states, associated definitions, and indicators. The 4 outcome states included "Treatment Success" which is defined as patients resuming desired activities, achieving a sufficient range of motion, and no more than minimal or mild pain; "Improvement of Condition" included cases where there was a record of some level of pain or functional problems, but improvement of the condition was occurring; "Deterioration of Condition" occurred when there was a record of some level of pain or functional problems that were becoming more prohibitive to the patient's desired activities and no improvement was occurring; and "Treatment Failure" occurred when the patient was experiencing significant pain or limitations and required subsequent fracture-related care for fracture sequelae, complications, or nonunion. These 4 outcome state labels were available to patients and physician evaluators when labeling each note.

Figure 1. Treatment Outcome States, Definitions and Indicators Developed by Patient Engagement Studio and Research Team Members.

Outcome state	*Definition*	*Example indicators of outcome state found in the clinical note*
Treatment success	Treatment success occurs when a patient can resume desired activities, has a sufficient range of motion, and is in minimal/mild or no pain. After PHF it is possible for there to be some lingering motion limitations (patient may never return to 100%) or minimal pain, but these issues should not require ongoing treatment or be prohibitive to their desired lifestyle or daily activities.	• Radiographic healing noted on x-ray • Making good progress/improvements with current treatment or stopping treatment • Patient has returned to work or play. • No major complaints documented. • Only follow-up as needed
Improvement of condition	Improvement occurs when there is a record of some levels of pain or functional problems that are somewhat prohibitive to the patient's desired activities, but improvement is occurring. In these situations, physicians may continue to monitor patients, but do not alter care or treatment courses.	• Radiographic healing or signs of healing occurring. • Moderate loss of function or pain that interferes with desired activities, but no change in treatment. • Ongoing treatment and monitoring progress • Return in 2-6 weeks for repeat x-rays and recheck
Deterioration of condition	Deterioration occurs when there is a record of some levels of pain or functional problems that are becoming more prohibitive to the patient's desired activities. No real improvements are occurring, and physicians may escalate or alter care or treatment courses.	• Negative radiographic changes observed. • Moderate loss of function or pain that interferes with desired activities requiring a change in treatment. • Initiating or continuing treatment and monitoring progress. • Return in 2-6 weeks for repeat x-rays and recheck.
Treatment failure	Treatment failure occurs when the patient is experiencing significant pain or limitations and requires subsequent fracture-related care. Failing occurs when patients are unable to resume desired activities and may include fracture sequelae, complications, or nonunion.	• Ongoing, persistent treatment (injections, surgeries) for symptoms related to PHF. • Unrelenting pain • Surgical complications • Loss of significant motion • Extreme pain • Fracture-related sequelae (eg, avascular necrosis)

Note Labeling Process

Physician Evaluators

A total of 4 orthopedic residents were recruited to participate in the note-labeling process as part of the larger study. Each orthopedic resident received a 1-hour training on the study objective and outcome state labels. Residents were instructed to assess the current outcome state reflected in the note. The physician evaluators included 3 male and 1 female orthopedic residents, each of which had a minimum of 2 years of residency experience. When discordance occurred between residents' labels, an attending orthopedic surgeon and the Chair of the Department of Orthopaedic Surgery served as the final note evaluator. REDCap (Research Electronic Data Capture; Vanderbilt University) [29,30] was used to organize and store physician labels for each note. From the full dataset of 1000 labeled notes, a stratified random sample of 25 notes from each

outcome label group was identified, and the note sample (N=100) for patient labeling was created.

Patient Evaluators

We recruited 2 patients from the PES to participate in this study. Both patients were female and had personal orthopedic experience including upper and lower extremity conditions, but their personal clinical data were not included in our study sample. The patient evaluators brought both experiential expertise from their personal musculoskeletal conditions and specialized research training, enabling them to contribute effectively to this study. This aligns with current best practices in patient engagement, which emphasize the value of relevant patient perspectives and training over the necessity for identical clinical conditions [31-34]. Similar to the physician evaluators, patient evaluators also received a 1-hour training on the study objective and outcome state labels. The training included a group review of example charts and common language used in medical charts. In addition, we trained patients in the subjective, objective, assessment, and plan sections [14] format typically used in medical documentation to increase their familiarity with navigating a medical chart. All clinical progress notes were redacted to conceal patient identifiers before patient review.

Both patient evaluators reviewed all 100 notes and provided labels. In addition to the 4 outcome state labels, a label of "Insufficient" was available for patient evaluators for notes deemed to have insufficient information to assign an outcome label. When discordance occurred between patient evaluators, the Program Manager of the PES (KP) served as the final note evaluator. After review by the Program Manager, all notes had a final label, and all labels of "insufficient" were resolved.

Patient and Visit Characteristics

Patient characteristics associated with the 100 clinical notes included in the analysis were extracted from the health system EHR, Epic, and included patient age, sex, race, and insurance provider. Patient characteristics were identified from the index PHF visit. In addition, visit characteristics, including days between the index visit and visit date for the clinical note, the number of PHF-related encounters, surgical treatment use, and note length, were also included in the analysis. Patients receiving surgery were defined as those patients undergoing reverse shoulder arthroplasty, hemiarthroplasty, or open reduction internal fixation between the index and 365 days.

Statistical Analysis

The 4 outcome labels were aggregated into a binary classifier representing treatment success or failure. Success was represented by notes labeled "Treatment Success." The 3 remaining labels, including "Improvement of condition," "Deterioration of condition," and "Treatment Failure" were grouped into the Treatment failure group. Treatment failure was comprised of all labels with documentation of lingering, symptomatic problems requiring ongoing care.

Agreement between physicians and patients was calculated across binary groups of treatment success or failure. Discordant labels were defined as notes with differing outcome states provided by the respective labelers. Cohen κ statistics were used to assess the degree of agreement between patient evaluators, as well as the degree of agreement between physician and patient labels. In addition, physician agreement was reported for the larger sample of 1000 notes and was assessed using Fleiss κ [35]. We used the benchmarks for agreement for categorical data as described by Landis and Koch [36], where 0.00-0.20, 0.21-0.40, 0.41-0.60, 0.61-0.80, and 0.81-1.00 indicate poor, fair, moderate, substantial, and almost perfect agreement, respectively. A Bangdiwala agreement chart is presented to display the agreement between physician and patient labels [37].

Descriptive analyses were used to assess the characteristics of the progress note sample. Mean and SD were reported for parametric variables. Median and IQR (25% and 75%) were reported for nonparametric variables. Two-sample *t* test, Wilcoxon-Mann-Whitney, and chi-square tests were used to assess differences in concordant and discordant notes. Analyses were performed with SAS (version 15.2; SAS Institute), R studio (R Core Team), and Microsoft Excel.

Results

Progress Note Characteristics

The sample of 100 progress notes for this study came from patients treated across 24 departments and 54 distinct physicians within one regional health system. The 24 departments from which the notes were identified included 21 orthopedic practices or departments, 2 family medicine, and 1 pain management clinic. Notes were authored by both physicians and advanced practice providers. Of the 41 physicians, 35 (85%) specialized in orthopedics, whereas the remaining 6 (15%) were specialists in family medicine. In addition to the 41 physicians, 13 advanced practice providers completed notes and 10 (77%) of these providers specialized in orthopedics, while the remainder had other specialty training including general surgery and pain medicine.

The average age of the patient was 67 (SD 13) years and 82% of the notes came from female patients. Patients were primarily White (91%) and had Medicare insurance coverage (65%). The note sample came from fracture-related encounters ranging from the second to the 10th encounter after the index PHF visit, with a median time of 115 (IQR 73-215) days after the index. The progress notes text lengths ranged from 981 to 15,297 characters with a median length of 5098 (IQR 2846-7810) characters. There was no significant difference in progress note characteristics across concordant and discordant notes (Table 1).

Table 1. Patient and visit characteristics of the clinical progress note sample presented by patient and physician agreement (N=100). Mean and SD were reported for parametric variables. Median and IQR (25% and 75%) are reported for nonparametric variables. A 2-sample *t* test was used for parametric variables and the Wilcoxon-Mann-Whitney test was used for nonparametric comparisons.

Patient characteristics	Total sample (N=100)	Concordant notes (n=78)	Discordant notes (n=22)	*P* value
Patient age (years), mean (SD)	67 (13)	67 (13)	68 (13)	.73
Patient sex, n (%)				.22
Male	18 (18)	16 (20)	2 (9)	—[a]
Female	82 (82)	62 (79)	20 (90)	—
Patient race, n (%)				.72
White	91 (91)	71 (91)	20 (91)	—
Black	5 (5)	3 (4)	2 (9)	—
American Indian or Alaskan	1 (1)	1 (1)	0 (0)	—
Hispanic	1 (1)	1 (1)	0 (0)	—
Unknown	2 (2)	2 (3)	0 (0)	—
Insurance provider, n (%)				
Medicare	65 (65)	51 (65)	14 (64)	.44
Medicaid	7 (75)	7 (9)	0 (0)	—
Private	21 (21)	15 (19)	6 (27)	—
Other	7 (7)	5 (6)	2 (9)	—
Visit characteristics				
Days from index, median (IQR)	115 (73-215)	113 (74-219)	115 (65-170)	.65
PHF[b]-related encounter, median (IQR)	4 (3-6)	4 (3-6)	4 (3-6)	.44
Patient treated surgically, n (%)	25 (25)	21 (27)	4 (18)	.40
Note character length, median (IQR)	5098 (2846-7810)	5202 (2901-8155)	4320 (2672-6428)	.19

[a]Not applicable.

[b]PHF: proximal humerus fracture.

Agreement Between Patients

Both patient evaluators were assigned the full sample of 100 notes to review and label. Of the 100 notes, 34 notes were discordant between patient evaluators. A total of 23 of the discordant labels were between success and failure labels between patient evaluators. In addition, there were a total of 11 cases (across patient evaluators 1 and 2) that received a label of "insufficient." There was a statistically significant level of agreement between the 2 patient evaluators (Cohen κ=0.41, 95% CI 0.23-0.59; *P*<.001), and the strength of agreement was classified as moderate, according to Landis and Koch. Tables 2 and 3 show the agreement in note labels between patient evaluators and physicians and patient evaluators.

Table 2. Agreement in note labels between patients (N=100).

Patient rater 1	Patient rater 2				Agreement
	Success	Failure	Indeterminate[a]	Total	
Success	15	3	1	19	Moderate (κ=0.41)[b]
Failure	20	51	8	79	
Indeterminate[a]	0	2	0	2	
Total	35	56	9	100	

[a]A label of indeterminant was available for use by patient evaluators for notes deemed to have insufficient information for a label. Notes labeled as insufficient were reviewed by the PES Manager for final label assignment. After final review, all notes had a final label, and all labels of insufficient were resolved before future analysis.

[b]Cohen κ used to assess agreement. 0.00-0.20, 0.21-0.40, 0.41-0.60, 0.61-0.80, and 0.81-1.00 indicate poor, fair, moderate, substantial, and almost perfect agreement.

Table 3. Agreement in note labels between physicians and patients (N=100).

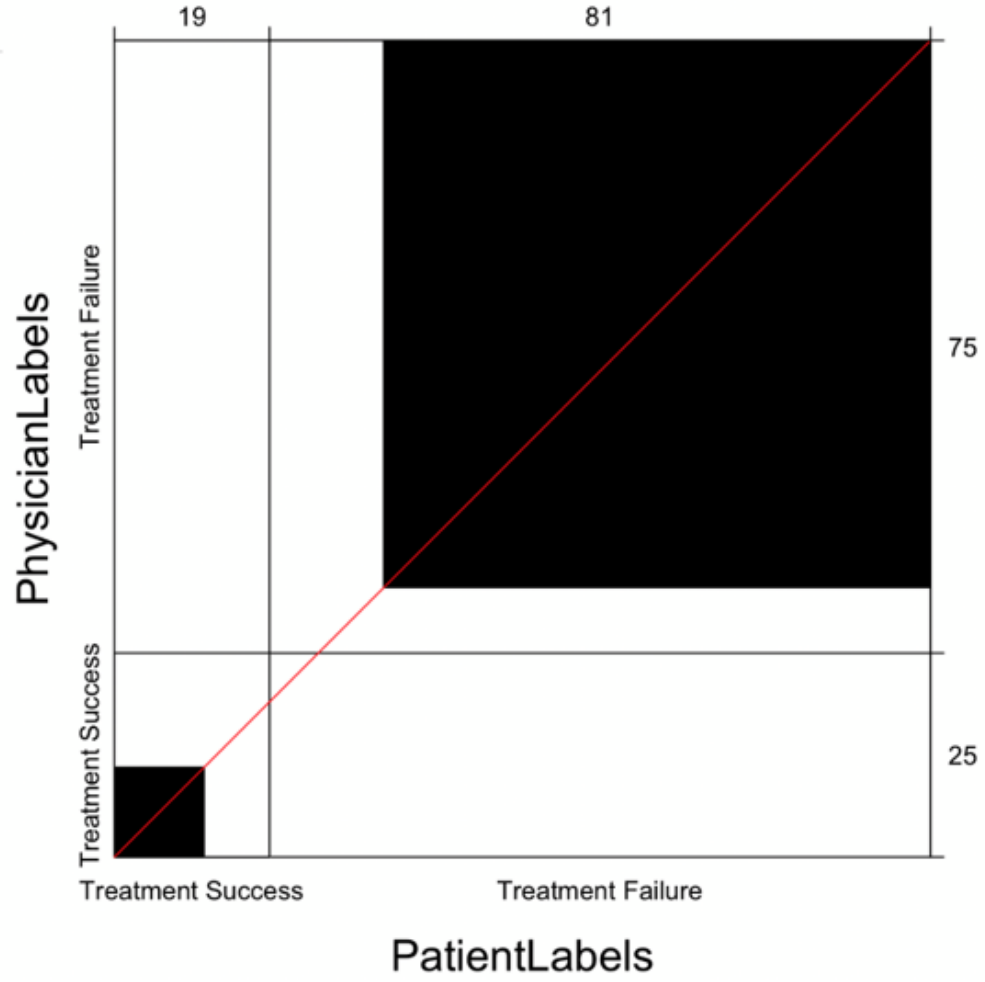
Physician labels	Patient labels			Agreement
	Success	Failure	Total	
Success	11	14	25	Fair (κ=0.32)[a]
Failure	8	67	75	
Total	19	81	100	

[a]Cohen κ used to assess agreement. 0.00-0.20, 0.21-0.40, 0.41-0.60, 0.61-0.80, and 0.81-1.00 indicate poor, fair, moderate, substantial, and almost perfect agreement.

Agreement Between Physicians and Patients

A total of 22 notes were discordant between physicians and patient evaluators. Of the 25 notes labeled as treatment success by orthopedic surgeons, 11 notes were also labeled as treatment success by patients. The remaining 14 treatment success notes were labeled as treatment failure by patient evaluators. Of the 75 notes deemed as treatment failure, 67 were also labeled as treatment failure by patient evaluators. There was a statistically significant level of agreement between orthopedic physicians and patient evaluators (Cohen κ=0.32, 95% CI 0.10-0.55; *P*=.01). The strength of agreement between patients and physicians was classified as fair, according to Landis and Koch. Figure 2 includes a Bangdiwala chart used to display agreement between patients' and physicians' assessment of treatment success or treatment failure from analyzed clinical notes.

Figure 2. Bangdiwala agreement chart for physician and patient note labels (N=100). Bangdiwala chart used to assess agreement between patients and physician's indications of treatment success or treatment failure from analyzed clinical notes. Black boxes indicate overlap of agreement.



Although not the focus of this paper, physician agreement was assessed using the larger sample of 1000 notes. Agreement between physicians was assessed using Fleiss κ and agreement between orthopedic physicians was moderate (Fleiss =0.49, 95% CI 0.30-0.68; *P*=.04).

Discussion

Principal Findings

The objective of this paper was to assess if physicians and patients agree in their assessment of whether patient outcomes

in clinical progress notes reflected a successful treatment outcome following orthopedic care. This is an important question to answer for the field of orthopedic medicine which has experienced a paradigm shift in the way in which outcomes are assessed [3,38,39]. Outcome assessment in orthopedics dates back over 100 years. Early on, physician-reported measurement of individual patient outcomes was the standard method by which to evaluate the outcomes of orthopedic care. However, today outcome measurement directly from a patient's perspective is viewed as the gold standard in orthopedic medicine [39,40]. We were interested in exploring if patients and physicians have similar definitions of what successful outcomes mean following orthopedic treatment.

In our analysis, we had patients and physicians review a subset of 100 clinical progress notes and label the note as a successful or unsuccessful outcome. We found that physicians and patients only exhibited a fair level of agreement in what they deemed as treatment success documented in progress notes. In addition, we found that physicians and patients had higher levels of agreement in what represented treatment failure compared with treatment success. Furthermore, interpatient and interphysician agreements also demonstrated relatively low levels of agreement, signaling that even within patients and physician groups, the definition of success is not clearly defined or agreed upon.

Comparison to Previous Work

A potential explanation for the low level of agreement between patients and physicians may simply be that patients and physicians have different expectations following care. Our findings might signal that physicians have different expectations of patient's capabilities following a serious upper extremity injury, such as PHF [41,42]. For other orthopedic treatments, it has been reported that patient expectations may be greater than a physician's expectations [43]. For example, in total hip and knee arthroplasty, most patients had higher expectations for recovery than their surgeon [43]. This might explain why over half of the notes labeled as treatment success by orthopedic surgeons were labeled as treatment failure by patients. Patients appeared to have a more stringent definition of success compared with physicians. Although not the goal of our study, this finding does emphasize the importance of shared decision-making within orthopedic encounters, to ensure patients have realistic expectations of outcomes following care [44].

An alternative explanation for our finding could be that physicians and patients define success differently. In a study assessing patient-physician agreement on the management of musculoskeletal injuries and pain associated with those injuries, authors found that patients and physicians prioritize different goals when assessing a patient's treatment outcome [4,45]. For example, physicians may have a more clinically based definition of treatment success driven by objective measures such as radiographic measures of healing and degrees of range of motion, whereas patients may be more focused on the ways in which outcomes like pain and joint function relate to daily capabilities and quality of life [5].

We found that physicians and patients had higher levels of agreement in what represented treatment failure compared with treatment success. Other studies measuring patient and physician agreement following orthopedic surgery concluded that patients and physicians agreed more when the patient had good health outcomes [4,46,47]. These conclusions are not consistent with our study findings. We found that physicians and patients were in agreement for a larger share of the treatment failure notes, compared with the treatment success notes. It is our belief that treatment failure is more clear-cut (eg, surgical complications, persistent pain, and fracture nonunion), whereas treatment success is more variable and patient-specific. Consequently, it may be easier to recognize when outcomes are unfavorable, but pinpointing a positive outcome proves challenging due to the variability and outcome preferences across individual patients [48,49]. Furthermore, we believe the concept of a patient-specific definition of success is supported by the moderate level of agreement we observed between patients. This signals that even among patients, there is a differential evaluation of an acceptable outcome. There is not 1 singular definition of treatment success, instead, treatment success depends on an individual patient's lifestyle and desired goals. Finally, even among physicians, we still observed relatively low levels of agreement, signaling that the definition of success remains unclear across physicians.

Limitations

Our work has several limitations that should be acknowledged. First, we used a relatively small sample of progress notes from 1 clinical condition that lacks patient diversity. Furthermore, our results are highly reflective of the small sample of physicians and patient evaluators who completed the labeling. Next, we were unable to assess the characteristics of treating physicians who authored the progress notes. It is possible physician characteristics like subspecialty training, years of experience, and so on. may explain some of the discordance in note labels. In addition, we worked with resident physicians who may be less experienced in assessing patient outcomes following care. This could affect physician agreement, as well as physician-patient agreement results. Also, the way in which we aggregated patient labels may influence the level of agreement we observed. For example, more categories could potentially lead to lower concordance among evaluators. Finally, it is possible that as nonmedically trained individuals patient evaluators' labeling may have been influenced by their lack of medical training.

Future Directions

Although outside the scope of this work, there remain questions surrounding the accuracy of clinical notes. There are mixed reports of the accuracy, completeness, and quality of progress note content [50-53]. Multiple studies have found that health care professionals produce accurate documentation for concrete and overt symptoms, such as range of motion and impaired physical functioning [54]. However, it must be acknowledged that we did not directly assess the accuracy of physician reporting of patient outcomes captured in the clinical notes. Secondary use of EHR data is rapidly expanding, including the use of natural language processing and large language models to analyze unstructured clinical text [19-25]. One potential use could be to use clinical notes to evaluate the success of

orthopedic treatment. However, to appropriately assess and classify outcomes as either successful or unsuccessful, the accuracy of clinical notes must be assessed.

In addition, as we work to continue to understand the concept of treatment success in orthopedic medicine, it may be helpful to conduct follow-up interviews with physicians and patients as they conclude the labeling process. This could reveal a deeper understanding of each perspective on what treatment success means. Furthermore, we anticipate that future work will incorporate multiple clinical notes across the episode of care to capture a more complete outcome assessment, as interim visits may reveal incremental improvements before the final visit.

Conclusion

The objective of this study was to assess if physicians and patients agree on whether patient experiences captured in clinical progress notes reflect a successful patient outcome following orthopedic treatment. In performing a cross-sectional analysis of clinical progress notes from an acute follow-up of patients treated for a PHF, we found fair agreement between patients' and physicians' assessments of patient outcomes reflecting treatment success. These results indicate that patients and physicians do not fully agree on what constitutes treatment success. Our findings emphasize the need to analyze both patient and physician perspectives when determining treatment success. Further research is needed to examine how different perceptions of treatment success may influence outcome development and use in orthopedic medicine.

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Data Availability

The datasets generated during and/or analyzed during this study are available from the corresponding author on reasonable request.

Authors' Contributions

SF and ABK contributed to study conceptualization, data analysis, result interpretation, and manuscript drafting and editing. JS, MO, MM, LF, BJ, and ZR handled data analysis, result interpretation, and manuscript drafting and editing.

Conflicts of Interest

None declared.

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Abbreviations

EHR: electronic health record
ICD10: International Classification of Diseases, 10th Revision
PES: Patient Engagement Studio
PHF: proximal humerus fracture
REDCap: Research Electronic Data Capture

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Principles and Practices of Community Engagement in AI for Population Health: Formative Qualitative Study of the AI for Diabetes Prediction and Prevention Project

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Abstract

Background: Preventing diabetes is a priority for governments and health systems worldwide. Artificial intelligence (AI) has the potential to inform prevention and planning. However, there is little guidance on how patients, caregivers, and communities are engaged in AI life cycle stages.

Objective: This formative qualitative study aimed to identify principles for meaningful community engagement. The goal was to support the responsible use of machine learning models in diabetes prevention and management.

Methods: We conducted a literature scan on how AI or digital health initiatives have engaged patients and communities. A participatory workshop was then organized with patients, caregivers, community organizations, clinicians, and policymakers. In the workshop, we identified and ranked guiding principles for community engagement in AI for population health. We also outlined key considerations for implementing these principles.

Results: We identified 10 principles for patient and community engagement in AI for health care from 6 papers and developed a conceptual framework for community engagement on AI. A total of 30 workshop participants discussed and ranked the top 6 principles: trust, equity, accountability, transparency, codesign, and value alignment. Participants noted that embedding community engagement in the AI life cycle requires inclusivity and diversity. Additionally, implementers should leverage existing resources and adopt a centralized approach to AI decision-making.

Conclusions: Our study offers useful insights for community-focused AI deployment that centers the values of patients and communities. The identified principles can guide meaningful engagement on the use of AI in health systems, while future research can operationalize the conceptual framework.

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KEYWORDS

artificial intelligence; Canada; community engagement; diabetes; patient engagement

Introduction

Artificial intelligence (AI) has significant potential to improve health outcomes and health care effectiveness [1,2]. In particular, machine learning, a subset of AI, has demonstrated strong predictive capabilities in disease risk assessments for cardiovascular diseases, cancers, Alzheimer disease, and diabetes [3,4]. Despite such potential, the translation of AI to solve population health concerns remains slow due to multiple barriers, including implementation challenges, limited validation, data uncertainties, and social acceptability concerns

[5,6]. Current research on the use of AI in health care primarily emphasizes macro-level governance and technical optimization, with less attention given to patient and community perspectives [7]. Although patients and communities are directly impacted by AI-informed health care decisions, their engagement in its design and deployment is limited [8,9]. Enhanced social acceptability, achieved through meaningful community engagement, can improve AI uptake, yet guidance on systematically engaging communities in AI deployment remains scarce [9].

With an estimated prevalence of 783 million cases by 2045, type 2 diabetes (T2D) is a public health issue globally [10]. In Canada, diabetes affects approximately 11.9 million people and significantly impacts health care expenditure [11]. Structural barriers, such as socioeconomic disparities, limited access to health care and healthy foods, and restrictions posed by built environments, continue to impede population-wide diabetes prevention efforts [12,13]. Addressing these barriers requires scalable, inclusive strategies, potentially supported by AI-driven solutions that are collaboratively designed and well-implemented [14]. Members of our research team previously used routine health administrative data of patients accessing the publicly funded health system in 1 Canadian province to develop and validate 2 machine learning models. These models predict the risk of T2D onset and diabetes-related complications and have demonstrated robust predictive accuracy across diverse populations. The details of the model development and validation are reported elsewhere, and they show consistent calibration across sociodemographic subgroups by sex, ethnicity, immigration status, and material deprivation [15,16]. In 2023, we received funding from the Canadian Institute for Advanced Research to establish the AI for Diabetes Prediction and Prevention (AI4DPP) Solution Network. The goal of the network is to deploy both machine learning models by (1) identifying implementation barriers, (2) developing a visual analytics dashboard of population-level diabetes risk, (3) creating a governance framework for responsible AI deployment, and (4) evaluating the use of the model and dashboard at a population level.

Several studies highlight the role of patient and public engagement in shaping more equitable and context-specific interventions [17-19]. The value of multi-stakeholder engagement in enhancing accountability and trustworthiness of AI systems has also been established [20]. However, there is comparatively limited guidance on how patient and public engagement occurs across the AI life cycle. Some initiatives have begun to address this gap. A recent scoping review on AI and machine learning applications in health care identified 21 papers (of 10,880 searched) that mentioned community involvement at any stage of the AI life cycle [9]. Another example is the Artificial Intelligence/Machine Learning Consortium to Advance Health Equity and Researcher Diversity in the United States to understand community perspectives on AI and its impact on health equity [21]. Participants from that study emphasized the need for context-sensitive, hyperlocal approaches to AI design and deployment.

This study contributes to the limited body of research on how to meaningfully engage communities in the deployment of AI tools for public health. We applied insights from a literature scan to inform a participatory workshop involving professionals and people with lived and living experience of T2D.

Methods

We used a formative qualitative study design to explore the principles and associated practices of community engagement in the implementation of population-level AI tools for T2D prevention and management.

Study Setting

The AI4DPP project is being implemented in Peel region, Ontario [22], which has a high prevalence of T2D, particularly among South Asian, Asian, Arab, African, and Hispanic populations [23]. In 2015, the incidence of diabetes in Peel was 1192/100,000, reflecting an increase of 182% within 2 decades [24].

Our team works with health system practitioners, decision-makers, community organizations, and people with lived and living experience of T2D in Peel region. This partnered approach aims to ensure that the 2 machine learning models can be implemented in a way that is responsive to local needs [25] when applied at a population level. The AI4DPP Solution Network hosts a biannual full-day meeting for patient and public stakeholders in Peel region to share project updates. The May 2024 in-person edition of the network meeting served as the setting for the participatory workshop we conducted for this study.

Ethical Considerations

This study was reviewed by Trillium Health Partners Research Ethics Board and was determined to not qualify as human participant research (reference #247). The AI4DPP study also underwent ethics review and approval by the Health Sciences Research Ethics Board at the University of Toronto, Dalla Lana School of Public Health (protocol number: 46174). When invitations to the network meeting were sent out, we notified participants that anonymized handwritten notes for research purposes would be taken during the workshop and that no participant would be identified or quoted by name in the analyses or outputs. Invitees were requested to contact the research team if they had questions or would like to opt out ahead of the meeting. Verbal group consent and confidentiality of discussions were established at the beginning of the meeting. Community representatives and people with lived and living experience were each given a CAD $150 (US $107.60) gift card as honorarium after the meeting. We also reimbursed their parking and transportation costs, where applicable.

Data Collection and Analysis

We conducted a literature scan [26] to identify strategies for engaging community organizations and people with lived and living experience on AI for health care. This was followed by a 90-minute participatory workshop at the AI4DPP Solution Network meeting.

Literature Scan

We conducted a literature scan to identify and build upon existing knowledge on patient and public engagement in AI for population health. The goal was not to conduct a comprehensive review but to inform the design of the workshop. At least 2 members of the research team reviewed recent literature in the PubMed database using random iterative combinations of the following search terms with Boolean operators (AND, OR): "community engagement," "patient engagement," "artificial intelligence," "machine learning," "digital technology," and "health." No date limits or restrictions on the number of results were applied, but priority was given to papers published within the last 5 years that described frameworks or strategies for patient and public engagement on AI in health.

From an initial batch of 27 identified papers, we screened papers by title, abstract, and full-text review. This yielded 6 relevant papers that captured guidance on processes and strategies that support patient and community engagement. We synthesized review findings using a narrative approach informed by qualitative content analysis [27]. To do this, we reviewed full texts, identifying key themes related to community and patient engagement and grouped findings into principles. Where papers reported specific frameworks or approaches used to inform their work, we took note of these. We ultimately used the AI life cycle as a framework for conceptualizing where (ie, stage of life cycle) and how (ie, principles) patient and public engagement was occurring. The AI life cycle has been described by different authors with varying degrees of detail and language, but with several points of overlap in the core ideas they capture [21,28,29]. In summary, the AI life cycle can be described to include 5 broad stages: (1) *define* (ie, definition of the health problem for which an AI tool will be developed), (2) *design and test* (ie, development, validation, and testing of the AI model including assessing the model for bias and fairness), (3) *deploy* (ie, implement the AI model for use in the real world), (4) *evaluate* (ie, assess the performance of the AI model in the real world, and identify areas for improvement), and (5) *improve* (ie, update the AI model using real-world data and evaluation findings). This analysis resulted in the development of a conceptual framework on the interplay between the AI life cycle and levels of public participation (see the Results section).

Participatory Workshop

Overview

A participatory multistakeholder workshop was conducted during the May 2024 AI4DPP network meeting. Other activities conducted during the full-day meeting that are not reported in this paper included a presentation on AI adoption in health care and a session to elicit feedback on the analytics dashboard we were designing as part of the overall project. The decision to use a participatory approach was informed by its effectiveness in eliciting diverse stakeholder perspectives, fostering equity in participant contributions, and promoting collective decision-making through structured activities [30].

Recruitment

Identification of participants used both convenient and purposive recruitment methods. Due to the capacity limits of the venue, we planned for approximately 40 attendees. First, we extended invitations to individuals who had attended the inaugural AI4DPP Solution Network meeting in November 2023. Because people with lived and living experience of T2D and community representation had been limited at that event, we purposefully reached out to community organizations in Peel who provide T2D prevention and management services, leveraged our existing relationships with Peel Public Health and connections from prior community-based research projects.

To recruit people with lived and living experience, we used a previously successful approach wherein we collaborated with the Patient and Family Partners (PFP) unit of a large hospital system in Peel. Through the PFP coordinator, the project overview and meeting details were shared with PFP members with an invitation to the workshop. We conducted 3 virtual briefing sessions to accommodate varying schedules for 6 individuals who expressed interest. Briefing sessions covered meeting agenda, logistics (eg, accessibility, dietary needs, parking), honoraria, and transportation reimbursement. Informed consent was obtained during these sessions, and participants were encouraged to ask questions.

Workshop Facilitation

IOOA and IUI, who have expertise in qualitative research and community engagement methods, jointly facilitated the workshop. Facilitation employed a modified format of the nominal group technique (NGT)—an effective method for enabling active discussions within group settings [31,32] and managing equitable participation [33]. This was an important consideration in our study where the different professional roles of participants introduced power differentials. The workshop included the following:

1. A presentation on participatory approaches to community engagement, findings from the literature scan, and the framework for community engagement on AI which was developed by the research team based on the literature scan.
2. In line with nominal group technique, perspectives on meaningful community engagement were elicited through silent idea generation by way of individual reflections and note-taking following question prompts such as "*Who is the community?*" and "*How should meaningful community engagement in the AI4DPP project be realized?*".
3. Ranking exercises on individuals' mobile phones or laptops using an online poll created in Mentimeter (2024). Mentimeter is a web-based tool that enables real-time audience participation and generates ranked output based on weighted responses. Each participant was asked to rank their top 6 principles from the 10 identified in the literature scan. The decision to select 6 principles was because we deemed this number feasible to manage—providing a breadth of options but easy to recall and keep discussions focused. Before ranking, participants were asked to suggest principles they felt were relevant but not captured in the literature findings. We facilitated a round-robin discussion after the results of the ranking exercise were revealed.
4. A walk-around exercise wherein participants offered suggestions on how the prioritized principles can be put into action (ie, operationalized). Insights on best practices

for each of the 6 engagement principles were captured on sticky notes. Participants also noted additional considerations and potential challenges to realizing each principle.

We invited participants to consider their responses to the discussion prompts not only within the AI4DPP project, but for other conceivable population-level AI health applications. The meeting was not audio-recorded, but 2 trained note-takers documented discussions throughout the day. At the start of the meeting, attendees were reminded that the activities and outputs of the meeting would be used for research purposes. Sociodemographic data were not collected, as it was not essential to workshop objectives and might have discouraged participation. However, we recognize that participants brought additional forms of diversity including racial, cultural, and socioeconomic experiences, which may have shaped their perspectives.

Workshop Data Analysis

After the workshop, 2 members of the research team with experience in qualitative methodology collated data from sticky notes, flipcharts, and meeting notes. Analysis was guided by a thematic approach where we integrated both deductive and inductive strategies. Deductive coding was guided by the principles identified from the literature scan, which served as a reference framework. The data were manually organized, clustering similar contributions and developing summary memos to refine the framing of each principle and associated practices for operationalizing them. In parallel, we conducted inductive coding to allow new themes and insights to emerge directly from the workshop data. This iterative process supported convergence across participant perspectives, leading to the final set of principles and practices reported in the Results section. Our analysis was not geared to inform theoretical knowledge but to highlight practical insights related to meaningful community engagement in AI for population health.

Results

Overview

First, we present findings from the preworkshop activities—literature scan and the conceptual framework for community engagement on AI developed by the research team. Next, workshop findings are presented under 3 subheadings: participants' perspectives on community engagement on AI, key principles for community engagement on AI, and practical considerations for operationalizing the key principles. A total of 30 people attended the workshop: 6 people with lived and living experience (patients and caregivers), 2 community organization representatives, 3 senior leaders from Peel Public Health, 4 health care providers, 12 AI4DPP team members (including 4 trainees), and 3 representatives from the project funder, the Canadian Institute for Advanced Research.

Literature Findings: AI and Community Engagement

Synthesis across the 6 papers resulted in a compilation of 10 community engagement principles for AI: (1) trust, (2) power-sharing, (3) empowerment, (4) value alignment, (5) equity, (6) codesign, (7) transparency, (8) education, (9) early engagement, and (10) accountability. Practices identified in the literature for engaging patients and communities in AI and technology interventions included a need for early and meaningful engagement of patients and communities, ensuring diversity of participants [34-36] and adopting transparent and bidirectional communication where the community feels empowered and able to participate in decision-making [36]. Patient education was emphasized as being crucial to meaningful engagement to inform patient-centered design and build trust [34,36]. The papers drew from diverse approaches, particularly community-based participatory research and citizen science.

The International Association for Public Participation spectrum of engagement—a framework that defines levels of public engagement starting from being informed to being consulted, being involved, collaborating, and finally, empowering—the highest level of engagement [36,37], was explicitly adopted or referenced in most of the 6 papers. At the first level of the International Association for Public Participation spectrum—*inform*—patients and community organizations are informed about an AI-related health project including the benefits, risks, and potential impact. At the second level, *consult*, patients' and community organizations' perspectives on the feasibility and utility of the project are solicited. At *involve*, the third stage, project teams should be working with patients and community organizations to consider and address any concerns related to the AI intervention, and at the *collaborate* stage, patients and community organizations should be active decision-makers regarding the project. When at the *empower* level, patients and community organizations should ideally take the lead in setting priorities and making decisions on the project. Collectively, these insights from the literature captured in Table 1 informed the discussion prompts for the workshop.

Table . Overview of selected literature on community engagement for artificial intelligence (AI) and digital health.

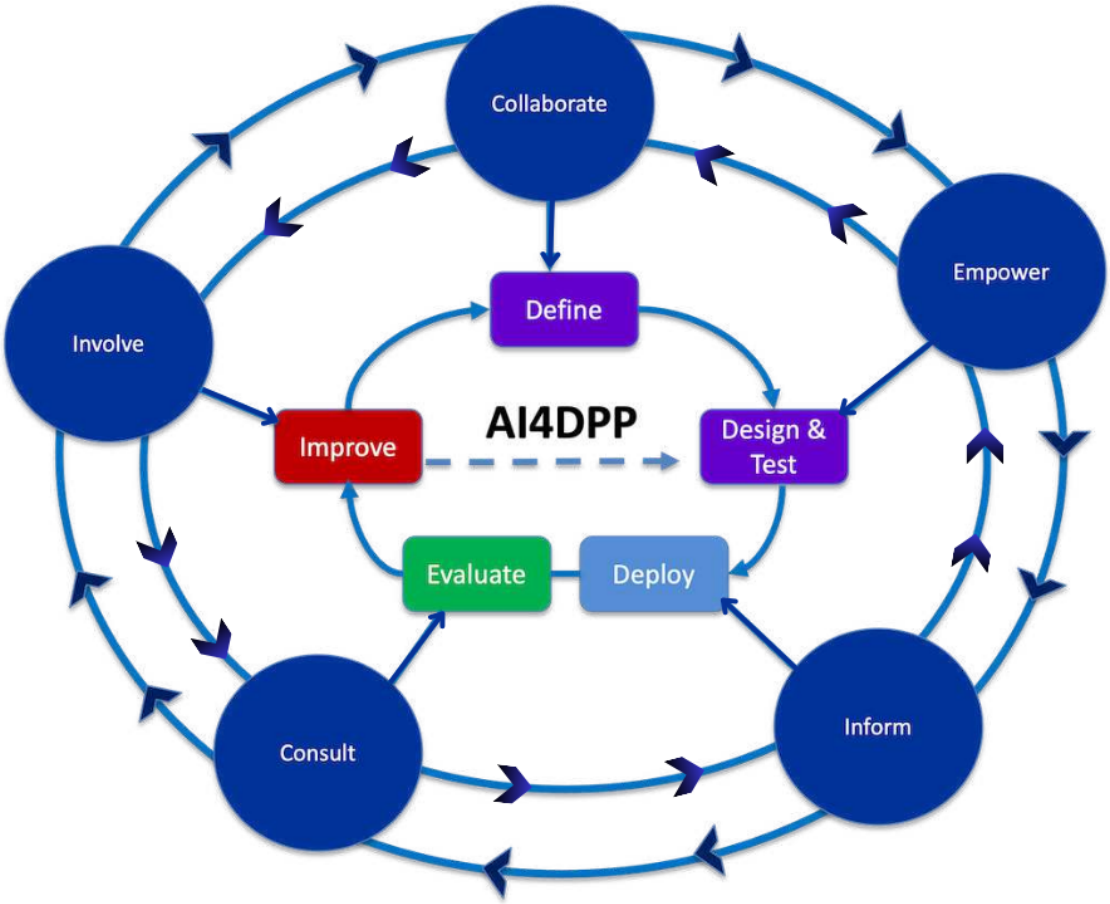
Reference	Summary
Adus et al [34]	Qualitative study to understand patient perspectives on being engaged in the development of AI. Findings emphasized early patient involvement in problem identification, diverse recruitment strategies, and multi-modal engagement methods. A framework for effective patient engagement in AI development is proposed, emphasizing the importance of addressing health inequities and ensuring patient-centered design [34].
Pillai et al [36]	The authors advocate for a paradigm shift in health care natural language processing to address how the perspectives of patients and community members are frequently overlooked. They propose a community-based natural language processing (CBNLP) framework, inspired by the principles of community-based participatory research. The framework outlines 5 levels of community engagement that align with the International Association for Public Participation (IAP2) levels of public engagement [36].
Moodley and Beyer [38]	This study makes a call for an Afro-centric community engagement model for genomic banking based on Ubuntu, an African philosophy. By emphasizing interconnectedness and communal well-being, Ubuntu can significantly enhance community engagement practices. Authors propose an 8-step framework called the TRUCE model to guide effective and ethically sound community engagement in genomic biobanking. Community consultation and co-ownership of knowledge production throughout the research process are recommended, similar to the CBNLP framework [38].
Richardson et al [39]	This paper emphasizes the ethical imperative of understanding and incorporating patient views to ensure AI technologies align with patient needs and values. A conceptual implementation-evaluation framework for AI that highlights the interplay of patient experiences, health systems, and technology is proposed [39].
O'Connor et al [40]	The paper presents synthesis from 19 qualitative studies on the barriers and facilitators impacting patient and public engagement with digital health interventions. Findings are presented in the Digital Health Engagement Model, which focuses on 4 main factors that influence individuals' willingness to engage with and enroll in digital health interventions—perceived value, assessed quality, engagement approach, and ability to actively use the intervention. Digital health developers and implementers are encouraged to prioritize and invest in patient-centered approaches to foster trust and ensure equitable access to emerging health care technologies [40].
Barony Sanchez et al [35]	Using the Virtual Community of Patients and Citizens Partners (COMVIP) project as an example, this study calls for patient and citizen engagement as an essential component of digital health technologies. Beyond tokenism, implementers are encouraged to actively involve patients and citizens as partners in the technology co-creation process using iterative and inclusive approaches. Authors argue that a multistage cocreation process involving patients and communities will ensure that technologies are tailored to the needs and preferences of diverse patient populations, leading to a more inclusive and equitable digital health ecosystem [35].

Conceptual Framework for Community Engagement on AI

Overview

Since the IAP2 spectrum of public participation emerged as the most frequently referenced framework for community engagement, the research team conceived that for community engagement to be integrated into the use of AI tools for public health, the 5 cyclical stages of the AI life cycle should be integrated with the 5 levels of public participation. AI projects that seek to meaningfully engage patients or community organizations at any stage of the AI life cycle can do so at any of the IAP2 levels. This was captured in a conceptual framework developed by the research team (Figure 1) that shows the superimposed and interconnected relationship between the AI life cycle (define, design and test, deploy, evaluate, and improve) and IAP2 levels of public participation (involve, collaborate, empower, consult, and inform). The AI4DPP project served as the first case study through which this conceptual framework was explored (Figure 1).

Figure 1. Conceptual framework of interplay between community engagement and artificial intelligence (AI) life cycle. All levels of public participation may be employed at each stage of the AI life cycle in a cyclical and iterative fashion. Learnings from the "improve" stage of the life cycle feedback into a continuous process of redesign and testing. AI4DPP: AI for Diabetes Prediction and Prevention.



Participants' Perspectives on Meaningful Community Engagement on AI

Workshop participants expressed that meaningful community engagement should be inclusive and representative of the target end beneficiary and should adopt diverse accessible formats of communication (eg, newsletters, arts-based methods, reports, infographics). Participants suggested that culturally appropriate strategies for engagement should be tailored to the different population groups, especially in a setting as diverse as Peel. Emphasis was placed on leveraging existing resources and strengths in the community such as faith-based organizations or community peer workers to facilitate building trust, community participation, and ownership of AI-driven innovations. A notable community asset, which was highlighted during the group discussion, was the community health ambassadors' (known in other contexts as community health workers or cultural brokers) model. Community ambassadors play critical health promotion roles and are best suited to reach structurally marginalized groups and facilitate community engagement [41].

Additionally, participants spoke to the sustainability of engagement activities, recommending a departure from project-specific initiatives to a centralized regional model in Peel involving other sectors such as pharmaceutical companies and municipal leaders. There was encouragement to consider using the AI4DPP project as an exemplar to demonstrate the feasibility of community engagement in deploying AI models, which can be adapted for other health-related AI applications and geographic locations. Patient and community organization representatives emphasized that engagement must occur consistently and on the terms of the community, not of the AI intervention.

Key Principles of Community Engagement on AI for Population Health

When meeting attendees provided feedback on the conceptual framework (Figure 1) and the 10 engagement principles identified in the literature scan, there was agreement that community engagement can be initiated at any stage of the AI life cycle, starting from any level of the engagement spectrum. The starting point for engagement was said to depend on the extent to which previous projects and relationships had set the stage for a collaborative model of engagement.

No new principles were suggested to be added to the 10 identified ones. Rather, it was decided that 2 of the principles—education and early engagement—were already captured by other principles. Thus, workshop participants collectively decided to focus the discussion on the other 8 principles. Participants emphasized the importance of involving community organization representatives, but also directly involving people with lived and living experience—ensuring diverse representation of age, sex, gender, ethnicity, and immigration status. Discussions surfaced the need to consider and accommodate availability and accessibility needs of individuals, which may vary throughout the AI development and deployment cycle. For example, engagement may manifest at the level of *collaboration* in the IAP2 spectrum during the *define and design* stages of the AI life cycle, but for different reasons, people with lived and living experience and community may only be *involved* (IAP2 level) during the *evaluation* stage of the AI life cycle. However, it was noted that a shared bidirectional governance model between the community and the project team was central to a collaborative approach to engagement, irrespective of the AI life cycle stage.

A total of 23 workshop attendees participated in the ranking exercise with the top 6 principles (starting with the highest ranked) being: trust, equity, accountability, transparency, codesign, and value alignment.

Practical Considerations for Operationalizing the Key Community Engagement Principles

Participants provided insights into the practical considerations for realizing the 6 top-ranked principles to guide community engagement regarding AI deployment for addressing the burden of diabetes and other population health issues. These are in the order of ranked priority and summarized in Textbox 1.

Textbox 1. Finalized principles of community engagement and associated practices for operationalizing each.

Practices

Trust:

- Engage credible and trusted members of the community such as community leaders
- Repeated engagement with clear, honest, and consistent 2-way communication
- Demonstrated commitment to collaboration by the community and health system actors

Equity:

- Inclusiveness, diversity of community participants, and cultural responsiveness in engagement approaches
- Engagement should be responsive to the cultural and structural factors that could prevent community members from engaging in prevention practices
- Using multiple ways to engage community members in the co-design process and in the project's governance

Accountability:

- Regular communication and feedback through community tables, gatherings, and reports
- Community coleadership in decision-making, with clear roles and responsibilities outlined
- Ability to course-correct informed by regular monitoring of the artificial intelligence (AI) tools

Transparency:

- Honest communication, declaring relevant conflicts of interest of different stakeholders, and clarity on the limitations of the AI tools
- Democratized and openly accessible platforms (eg, websites) for knowledge sharing and project updates

Codesign:

- Codesign should include diverse participants and be accessible for participation
- Continuous and iterative feedback on designing and deploying the AI tool

Value alignment:

- AI developers and implementers should understand the community's values and priorities through meaningful dialog
- Cultural and diverse perspectives should be respected while aligning the goals of the AI tool to the community's values

1. Trust: At least 3 concepts were described in relation to trust: building on existing relationships, giving it time, and understanding that it requires a collaborative mindset shift (in perceptions and behaviors toward each other) between the community and the health system. Participants emphasized the need for community engagement to be anchored on any existing relationships with community members and organizations who are credible, trusted by members of the community, and recognized as community leaders. Suggestions were offered on informal ways of building relationships such as spending social time together in community (eg, through community events) and fostering

relationships outside specific projects or health care interactions. Discussions acknowledged that building trust on a topic as sensitive and obscure as AI would require repeated engagement with clear, honest, and consistent 2-way communication between the project team and community members. Participants expressed that if project teams failed to follow through with their commitments and responsibilities, there was a risk that whatever ground had been gained would be lost. Some additional concepts that emerged in relation to trust building were inextricably linked to the concept for accountability (ranked as the third top principle), including open and accessible communication modalities.

2. Equity: Equity was discussed from multiple perspectives, recognizing that it is not only a principle of engagement that is central to how community engagement is achieved (ie, a process measure), but is furthermore an outcome of meaningful engagement. Inclusive practices that ensure a diversity of knowledge users and representatives of people with lived and living experience, particularly in the project's governance, were cited as an enabler for ensuring that every voice is heard. Cultural responsiveness was mentioned as a subconcept under inclusiveness and diversity. It was recommended that engagement should consider and be responsive to cultural and structural factors that make it difficult for patients to engage in preventive and promotive health behaviors. The social determinants of health were cited as shaping how community engagement on AI may address or reinforce historical and structural harm. The discussions suggested using multiple ways to engage community members in the codesign process and in the project's governance.
3. Accountability: Accountability was linked to regular communication and feedback, project governance, and mechanisms for responsive monitoring. Some examples of avenues for regular communication and feedback at a community level included community tables, community gatherings, and through annual or biannual reports, as well as the biannual AI4DPP Solution Network meetings to share and discuss results. The ideal state was for community coleadership throughout the AI life cycle with clear roles and responsibilities by both the project team and community members, outlined in a formalized document such as a term of reference. Regular monitoring of the use of the AI tools, especially of unintended consequences, was stressed as being crucial to accountability. Feedback from workshop participants underscored the importance of a firm commitment from the project team to act on any concerns or unintended consequences that arose during AI implementation.
4. Transparency: Linked to accountability and trust, workshop participants voiced expectations of honest communication between project teams and community members with respect to knowledge sharing, and acknowledgment of the limitations of AI. For example, they suggested that users of AI need to understand the model's limitations such as data biases. Similarly, participants noted that regular, open, and accessible communication would not only capture what works, but what is not working throughout the deployment, implementation, and evaluation phases. There were suggestions to have a project website for open dialog, feedback, and other forms of information dissemination. A participant acknowledged that the fear of failure was a disservice to the much-needed mindset of continuous improvement and learning. Establishing a community-involved governance structure was noted as an enabler for transparency and accountability.
5. Codesign: Participants proposed that codesign should include diverse participants and should consider the impact of AI on minority populations such as new immigrants and Indigenous communities. They also recommended creating a welcoming environment that promotes participation in co-designing the AI tool and its uses. To quote one of the participants, "*There aren't any 'points of no return,' meaning that decisions can be reflected on and changed.*" Codesign was not perceived to be a single occurrence event, but rather, characterized by continuous and iterative feedback in AI design and deployment and throughout the life cycle.
6. Value alignment: Participants suggested that the alignment of the goals of the AI solution with community values through dialog and respect for cultural diversity was a way by which this principle could be put in action. Some participants proposed that AI developers should understand the community's values and priorities through meaningful dialog and should use "values language." They elaborated that any AI solution should clearly demonstrate utility in delivering benefits to the community, which could be challenging when there are diverse perspectives and cultural values within a community.

Suggestions were provided on concrete actions to guide community engagement, including the need to consider the community context, to incorporate storytelling and lived experiences from patients, and a sensitivity to knowing the right time to engage (ie, tactical engagement). Patients and people who are champions or early adopters of AI in managing their health conditions or for health promotion could strengthen community involvement by sharing compelling stories from their experiences, backed with data (eg, number of diabetes cases prevented). For project teams to demonstrate these principles, participants noted that the foundation of meaningful community engagement is building a digitally informed and literate citizenry that is empowered to contribute meaningfully to AI solutions and decisions.

Discussion

Principal Findings

In this study, we engaged community members, people with lived and living experience, and other health sector stakeholders to identify 6 priority principles and accompanying practices for engaging communities in population-wide deployment of AI tools, using the AI4DPP project as an example. The approach of workshop activities aligned primarily with the Involve and Collaborate levels of the IAP2 framework. Participants' insights were reflected directly in the prioritization and operationalization of principles (Involve), and they actively influenced

decision-making on which principles would be prioritized and how they would be operationalized (Collaborate). Since population level use of AI/machine learning models in health systems is geared primarily toward health care decision-makers and health care providers, our study's findings are relevant for incorporating the missing perspective in the AI development cycle. That is, the perspectives of patients, caregivers, and other end beneficiaries. Our findings align with and extend prior research on community engagement in AI and digital health, particularly around themes of trust, diversity, transparency, and codesign. In this section, we compare our results with existing literature and reflect on their implications for health care AI implementation.

Only recently has the AI community started shifting from model-centric AI (where the accuracy of the models is the most important parameter) to data-centric AI (where the understanding of how data are collected, collated, questioned, analyzed, and interpreted is paramount) [42]. The social power that patients and their caregivers indirectly exert in shaping the sociotechnical milieu of AI adoption in health care has not been sufficiently prioritized in addressing population-level adoption of AI tools [43]. Yet, evidence shows that social acceptability of AI in health care can improve patient engagement in decision-making and enhance patients' compliance with AI-informed care plans [44,45]. Trust was identified as the most important principle of community engagement. This is perhaps not surprising since AI has often been referred to as a "Blackbox," increasing skepticism about its negative and unintended impact. In turn, lack of patient and public trust hinders AI implementation in health [46]. Trust is also central to how societies perceive health research and interventions, and trustworthiness is a key tenet in the ethical and responsible use of AI. There is a role, therefore, for AI researchers to open this "Blackbox" by using methods that enhance the explainability of machine learning models [47]. However, explainability from the perspective of patients and communities may differ significantly from those of technical audiences. While a full discussion of community-centered explainability is beyond the scope of this paper, we raise this point to emphasize the need for ongoing dialog on how transparency and trust in AI can be codeveloped with affected communities.

Open dialog has been reported as critical to meaningful community engagement in AI [48], and regular communication and feedback throughout a project can facilitate understanding. Patients and community partners expect honest communication about the limitations and results—positive and negative—of AI in accessible ways. They want AI researchers to commit to regularly monitor and share the results of AI implementation in health care, and to act on feedback received from community members [8]. Transparent governance structures, for example, through community advisory boards, have also been recommended to ensure accountability and build trust when involving communities on AI for health [8,49]. Because building trust takes time, necessitating ongoing engagement [48,50], it is recommended that patients and community members are engaged early, ideally at the problem identification stage and throughout the AI life cycle [51,52]. Furthermore, early engagement ensures that implementers are asking the right questions and that critical contextual factors are considered sooner than later [53]. Other researchers have also demonstrated that early and continuous involvement of community members helps to avoid tokenism [38]. Ultimately, proper alignment of researcher and community values is necessary for successful collaboration between AI researchers, developers, and communities [54].

Addressing diversity has been reported as a neglected area in patient and public involvement in health care [55,56]. Therefore, it is not surprising that inclusivity and diversity of participants in community engagement was a recurrent point raised in our study, similar to the work of others [49,51]. This is strongly related to equity, the second-ranked principle. Workshop participants stressed the need to include diverse participants across demographics, especially minorities, not only for community engagement activities but also in governance. Similarly, participants in our sessions noted that inclusivity will require culturally responsive approaches to engagement and an understanding of diverse backgrounds which may be rooted in historical and structural harm. Bringing all voices to the table can help ensure fairness and could potentially limit the perpetuation of systemic biases inherent in data and AI algorithms [47,57]. Although education was not prioritized as a standalone principle, workshop participants noted that meaningful community engagement would require a digitally informed and literate citizenry, making it nonetheless foundational for community-engaged AI interventions. The importance of AI patient education has been highlighted as crucial to meaningful community engagement and codesign [36,50].

Strengths and Limitations

Although the starting point of our study was a rapid literature scan, which could have resulted in missing some relevant papers, the use of a participatory approach involving diverse actors including people with lived and living experience helped strengthen our findings. An additional strength of our approach is that stakeholders have now been involved early—during the pre-implementation phase of the project, which sets the stage for their contributions in other phases. Third, using a modified NGT encouraged participation and openness, elevating the perspectives of community members. Additionally, although power dynamics are often a concern in mixed-stakeholder engagement, we did not observe this. This may be due to the experience of participants with lived and living experience in patient engagement and our teams' efforts to foster an inclusive setting before and during the workshop.

Our process has some limitations worth mentioning. While previous studies have established the significant burden of T2D in Canada [11] and Peel [24], patients and community partners were not involved in problem identification (ie, define the stage of the AI life cycle) and machine learning model development (ie, design and test stage of the AI life cycle) of the AI4DPP project. As such, community engagement was not fully embedded as conceptualized in Figure 1. Also, workshop participants represent only a small subset of the broader community—only 6 of the 30 workshop attendees were people with lived and living experience. While this limits the

representativeness of perspectives reflected in this formative study, the workshop was intended as an initial step in a continual process of community engagement. Finally, using a predefined conceptual framework (Figure 1) to guide workshop discussions may have constrained the emergence of fresh ideas. Despite these limitations, our community engagement approach is a valuable contribution to the field since most existing community engagement frameworks in AI for health focus solely on the design phase of the AI life cycle [9].

Future Directions

Building on this work, our next step is to establish a community advisory group composed of people with lived and living experience and community organization representatives. This group will support the implementation and evaluation phases of the AI4DPP project, providing feedback on how well the principles and practices identified in this study are being enacted. This will inform the development of community-informed guidelines to support AI deployment in public health. The identified principles and practices are early inputs for a community engagement framework to deploy AI prediction tools for population health, which will be refined and tested in subsequent phases of the AI4DPP project. Future research could further refine participatory strategies and embed longitudinal engagement mechanisms throughout the AI life cycle.

Conclusions

This study described a formative qualitative process used to identify principles and practices for meaningful community engagement in the deployment of AI tools for diabetes prevention and management. Using the context of Peel region, these insights reflect the priorities and expectations of community members, patients, and public health stakeholders. While the outputs are specific to our study context, they may be useful to others designing or adapting engagement strategies for AI implementation in public health settings. Our findings offer practical considerations for researchers, AI developers, clinicians, and community partners seeking to embed equity-oriented engagement practices into the design and deployment of AI-driven interventions.

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Authors' Contributions

IOOA conceptualized the manuscript and the design of the workshop. IOOA and IUI facilitated the participatory workshop with contributions from all other authors and co-led the analysis and interpretation of workshop outputs. IUI drafted the manuscript with support from IOOA, JS, RZ, KK, and LCR. All authors contributed to revising the manuscript and agree to be accountable for the final submitted version.

Conflicts of Interest

None declared.

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Abbreviations

AI: artificial intelligence
AI4DPP: Artificial Intelligence for Diabetes Prediction and Prevention
PFP: Patient and Family Partners
T2D: type 2 diabetes

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Patient Perspectives on Artificial Intelligence in Medical Imaging

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Abstract

Artificial intelligence (AI) is reshaping medical imaging with the promise of improved diagnostic accuracy and efficiency. Yet, its ethical and effective adoption depends not only on technical excellence but also on aligning implementation with patient perspectives. This commentary synthesizes emerging research on how patients perceive AI in radiology, expressing cautious optimism, a desire for transparency, and a strong preference for human oversight. Patients consistently view AI as a supportive tool rather than a replacement for clinicians. We argue that centering patient voices is essential to sustaining trust, preserving the human connection in care, and ensuring that AI serves as a truly patient-centered innovation. The path forward requires participatory approaches, ethical safeguards, and transparent communication to ensure that AI enhances, rather than diminishes, the values patients hold most dear.

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KEYWORDS

artificial intelligence; medical imaging; patient-centered care; patient participation; health equity; medical ethics; digital health; participatory medicine

Introduction

The integration of artificial intelligence (AI) into medical imaging is widely regarded as a groundbreaking advancement, with the potential to enhance the speed, accuracy, and efficiency of radiological diagnoses [1]. For patients, this can lead to faster results, earlier disease detection, and more personalized treatment plans. In the realm of medical imaging, AI systems represent the next frontier of innovation—building on trends such as outsourcing—by transforming clinical workflows with rapid and highly precise diagnostic capabilities.

However, as AI transitions from experimental stages to clinical implementation, its success depends not only on technical performance but also on patient perception and acceptance. Understanding patient perceptions is critical to adoption, regardless of AI's technical promise. Medical imaging, such as other areas of health care, depends on both technical expertise and the trust inherent in patient-provider relationships. While AI has demonstrated remarkable accuracy in medical diagnostics, its presence can alter the dynamics of these relationships.

The purpose of this commentary is to synthesize current evidence on patient perspectives regarding AI in medical imaging and to argue that proactively understanding and integrating these views through participatory approaches is indispensable for the successful and ethical adoption of AI in radiology. Here, "successful adoption" is defined not merely by technical performance, but by AI's ability to enhance diagnostic capabilities while simultaneously building patient trust, ensuring equitable access, and preserving the human-centered nature of care. Without centering patient perspectives, AI risks becoming a technology that, despite its potential, fails to achieve widespread acceptance or deliver its benefits equitably.

AI in Medical Imaging and Participatory Medicine

AI in medical imaging is rapidly advancing, creating a dual challenge: enhancing diagnostic capabilities while integrating these advancements into patient-centered care. AI systems can process vast amounts of data at unprecedented speeds, offering significant support to radiologists in quickly detecting complex diseases and identifying patterns that may be difficult for even highly trained human eyes to detect [2]. This technological efficiency, however, may not be enough on its own. AI use should be considered within the broader framework of participatory medicine.

Participatory medicine emphasizes patients as active partners in their care. This approach challenges traditional models of health care, where decisions are made for patients rather than with them. In the context of AI, participatory medicine emphasizes the importance of ensuring that patients' concerns and priorities are integral to the design and deployment of these technologies. Research has revealed that many patients are not fully aware of how AI is integrated into medical imaging, which may hinder its acceptance [3,4]. Without a basic understanding of how AI is used, patients cannot meaningfully participate in

decisions about its implementation or provide informed consent for its use. For AI to be successful from the perspectives of all stakeholders, it should strive to be transparent, accessible, and, most importantly, aligned with the values of the patients it serves. A participatory approach could build on successes in other medical domains by establishing patient advisory boards to provide input on AI implementation, collaborating with patients to develop educational materials that explain AI's role in their care, and offering patients choices regarding the level of AI involvement in their diagnostic process.

Understanding Patient Perspectives on AI in Medical Imaging

While technical performance is significant, the integration of AI into medical imaging may also be shaped by how patients perceive and accept these technologies [3,5]. A growing body of literature reveals a complex tapestry of patient attitudes, characterized by cautious optimism, specific concerns, and a strong desire for human oversight. Understanding these perspectives is critical for developing and deploying AI in a manner that is not only technologically advanced but also genuinely patient-centered.

Broad Patient Attitudes Toward AI in Health Care

Establishing patient trust is foundational for the successful integration of AI into medical imaging. This trust is often linked to patients' understanding of AI's general role in their care, its potential benefits, and its inherent limitations. While many patients recognize the broad potential of AI to enhance diagnostic accuracy and efficiency across health care, general concerns persist regarding where to appropriately place their trust, alongside fears of diminishing the essential human connection in medical interactions [5]. Patients often approach AI with a blend of hope for improved outcomes and apprehension about the technology's autonomy and the security of their data [4,5]. This initial disposition underscores the need for clear communication and transparency from the outset.

Key Themes in Patient Perspectives on AI in Medical Imaging

When focusing specifically on AI in medical imaging, several key themes emerge consistently from patient perspectives.

Conditional Trust and Human Oversight

A predominant theme is that of conditional trust. While patients are often open to AI, it is typically viewed as a complement to, not a replacement for, human clinical expertise. For example, a study on AI in mammography found that the majority of women surveyed (77.8%) were uncomfortable with the idea of AI functioning independently without radiologist oversight [6]. This sentiment is echoed in other research, with one study finding that 76% of patients would not be comfortable receiving a diagnosis generated solely by AI [7]. The prevailing view is that AI should augment the clinician's role, supporting human decision-making rather than supplanting it. Central to this is the interaction between clinician and patient—a relationship ideally built on empathy, communication, and trust, qualities AI cannot yet replicate. Patients value the communication they receive from radiologists, reporting that personal interaction enables them to ask questions comfortably and develop a shared understanding of findings [8]. Concerns about a potential lack of human connection are common, with patients emphasizing the importance of human empathy and the "ability to understand with flexibility" [5]. Research consistently indicates a strong patient preference for human involvement in interpreting diagnostic findings, reinforcing the idea that AI is a tool to support, not replace, the human touch that defines patient-centered care [9]. The radiologist's expertise remains critical in ensuring that AI's outputs are interpreted and communicated with empathy and clarity.

Hopes for Enhanced Diagnostic Capabilities and Efficiency

From patients' perspectives, a significant promise of AI in medical imaging lies in its potential to improve diagnostic accuracy and reduce waiting times [5]. This is not seen as a theoretical gain but as an immediate practical advantage. AI's ability to rapidly analyze large volumes of data without experiencing human constraints such as fatigue offers advantages in environments where errors can have critical consequences. Research suggests that patients generally have an optimistic outlook regarding AI's potential to streamline diagnostic workflows [4,7,10]. Many patients hope AI can reduce the anxiety associated with waiting for test outcomes [5]. By expediting image analysis, AI may enable radiologists to communicate results more promptly, thereby reducing psychological distress. In addition, AI systems are sometimes viewed as valuable for providing personalized health information in a timely manner, potentially empowering patients in their health care decisions [4].

Apprehensions and Ethical Concerns

Despite optimism, patients remain cautious about potential trade-offs. While expecting faster analysis, they also worry about AI's limitations, fearing it might lead to narrow interpretations or incorrect diagnoses [8]. The quality, trustworthiness, and accuracy of medical information provided by AI systems are major patient concerns [4]. The perception that AI could overlook critical information or misinterpret complex data highlights the need for rigorous validation before clinical integration. A primary apprehension is the potential depersonalization of care, with patients concerned about becoming "numbers" in a technology-driven system [8,10]. This stems from the perception that AI, despite technical proficiency, may lack the emotional intelligence integral to effective care [8]. Furthermore, some patients worry about over-reliance on AI at the expense of human judgment [7,10]. Although generally viewing AI-based systems positively, they often express that such technologies should serve as a supportive tool, reflecting an understanding of AI's limitations in intuitive and compassionate decision-making [4,5,7,8].

Demographic Nuances in AI Perception

Overview

Some studies suggest trends related to age, education, or gender in how patients perceive AI in medical imaging, but these should be interpreted with caution to avoid overgeneralization and amplifying small differences found in small studies. Individual views are paramount, and people are not defined by their demographics. These observations primarily highlight the need for adaptable, person-centered communication rather than rigidly tailored approaches based on demographic profiles.

Age-Related Differences

Age has been observed to influence patient perceptions. Some studies suggest older adults may exhibit more skepticism toward standalone AI systems, often emphasizing the need for radiologist oversight [3,7-9,11]. Research indicates that older participants (≥65 y) have reported higher concerns regarding AI's trustworthiness and accountability compared to younger groups [7,10], with notable discomfort regarding personal data security [10]. Furthermore, they have, in some studies, tended to rate AI lower in terms of efficiency, perceiving limited potential for improving health care processes [9,10]. Younger patients, in contrast, have sometimes expressed greater openness to AI integration, highlighting AI's potential role in enhancing efficiency [7-10], reducing wait times [7,8], and improving access [8]. In some instances, they have displayed confidence in AI-assisted interpretations, demonstrating a readiness to trust AI when validated as accurate and reliable [6-8,11].

Education and AI Trust

Educational attainment has also been identified as a factor. Some studies indicate that university-educated patients may exhibit higher confidence in AI's capabilities and express more willingness to accept its use, especially if AI demonstrates superior diagnostic performance [7,9-13]. They may also be more likely to trust hybrid AI-radiologist models and prioritize AI's ability to enhance precision [3,9]. Conversely, individuals with lower formal educational levels have, in some research, exhibited greater skepticism [7,9,12,13], sometimes viewing AI as a "black box" lacking transparency [8]. They may place greater emphasis on human oversight and radiologist accountability [8].

Gender-Based Variations

Some studies have reported gender-based differences in AI perceptions. Women have, at times, been found to be more skeptical, voicing concerns about AI's ability to replace human empathy and judgment [7,10]. They may place greater emphasis on personal interactions with radiologists and express a stronger preference for clinician-led care [8]. Conversely, men have, in some contexts, exhibited greater confidence in AI as a diagnostic tool, particularly when emphasizing efficiency and cost-effectiveness [7,8], and expressed fewer concerns about depersonalization, while still emphasizing the need for clear accountability [8].

Implications of Observed Variations

While observed trends in some studies suggest that factors such as age, education, or gender may sometimes correlate with varying nuances in AI perception [3,6-13], it is crucial to avoid generalizations and stereotyping. People are individuals, not merely representatives of demographic groups. These observations should sensitize providers to the potential diversity of patient concerns and starting points. The most effective approach is always person-centered: actively listening to each patient, eliciting their specific questions and anxieties, and providing clear, empathetic explanations. For example, focusing on procedural transparency and human oversight may be helpful for any patient expressing skepticism, regardless of age. Similarly, simplifying complex AI concepts can benefit any patient, irrespective of educational background. The goal is to foster trust through responsive, individualized dialog that acknowledges potential differences in starting points or concerns without prejudging individuals based on demographic characteristics.

The Enduring Imperative of Human Oversight in an AI-Assisted Future

The existing landscape of radiologist-patient interaction is diverse. In certain radiological subspecialties, such as mammography or interventional procedures, direct consultation and the development of ongoing patient-radiologist relationships are relatively common. However, in many other areas of diagnostic radiology, communication is frequently mediated through referring clinicians, meaning patients may have limited or no direct contact with the radiologist responsible for interpreting their medical images. This variability in direct human connection forms a critical backdrop to the introduction and perception of AI in the field.

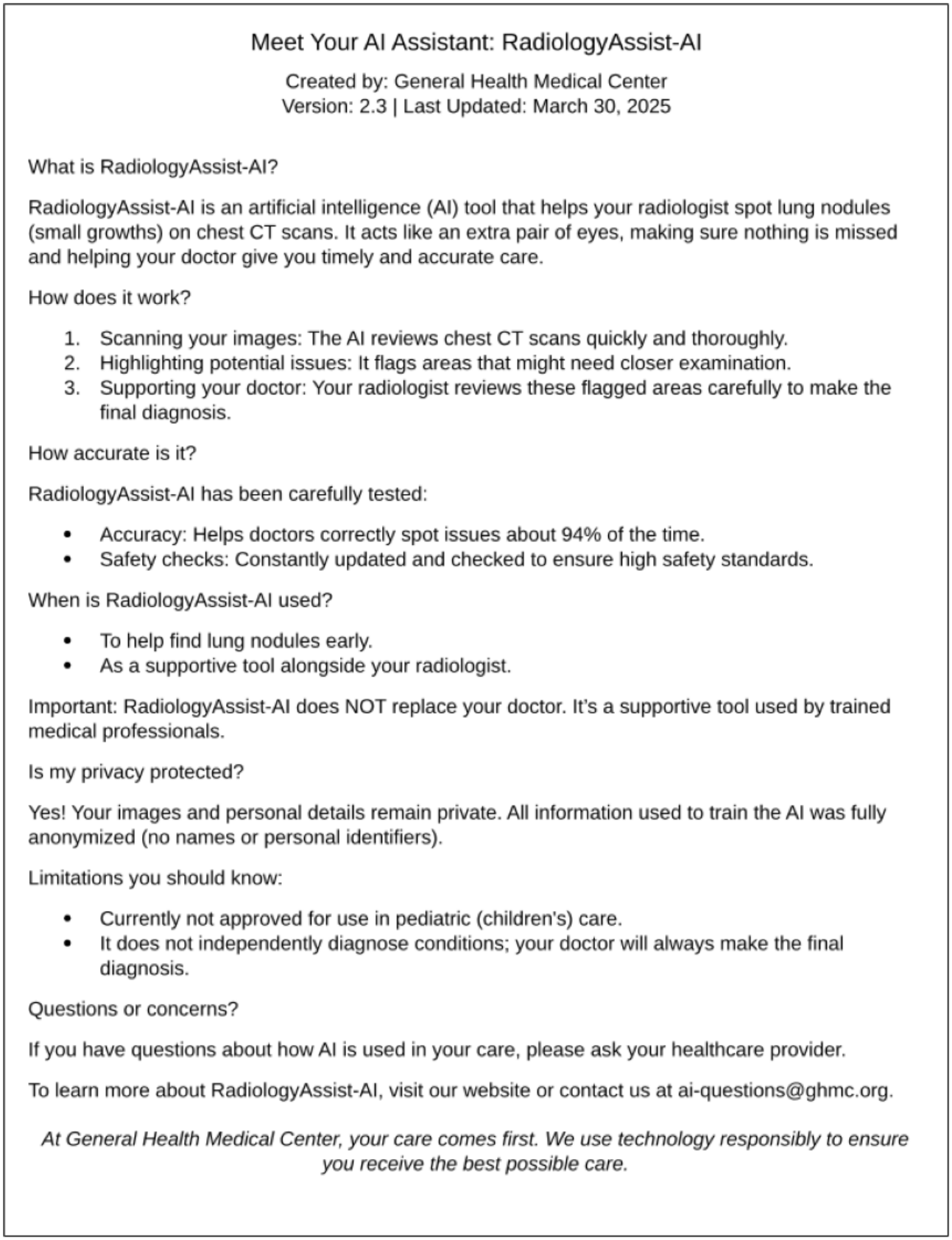
Perhaps ironically, the integration of AI into medical imaging, a technology often perceived as potentially distancing, appears to intensify, rather than diminish, the patient need for assurance that human experts remain firmly in control and centrally involved in their care [5,8,9]. Even in scenarios where direct patient-radiologist interaction is traditionally low, the knowledge that a skilled human clinician is ultimately responsible for overseeing AI-generated findings, critically evaluating its outputs, and making the final diagnostic decision is paramount for patient trust [5,9]. The perceived "distance" in mediated communication pathways could, in fact, heighten anxieties about AI if this human element—the radiologist's expertise, ethical responsibility, and ultimate accountability—is not proactively and clearly affirmed. Therefore, as AI tools become more prevalent, the focus should extend beyond simply maintaining existing levels of human interaction; it should actively reinforce and communicate the indispensable role of human clinical judgment in the diagnostic loop. This ensures that patients trust the process and the outcomes, confident that technology serves as an aid to, not a replacement for, human expertise.

Accountability and Ethical Concerns

As AI takes on a more significant role in medical imaging, questions of accountability become inevitable. Who is responsible if AI contributes to diagnostic errors or adverse outcomes? Studies suggest that patients generally support shared accountability among hospitals, radiologists, and AI developers, reflecting a desire for clarity in how such errors are addressed [13]. Ethical guidelines, including the multisociety statement on AI in radiology endorsed by organizations such as the American College of Radiology and European Society of Radiology, emphasize that ultimate accountability should rest with human clinicians and developers [14,15]. These principles align with patients' preference for human oversight, which reinforces trust in the health care system.

While questions of accountability are central to ethical concerns, transparency in how AI functions is equally critical in building patient trust. Many patients express interest in understanding the role of AI in their care, including its limitations, accuracy, and potential risks [4,8]. Tools such as "model cards" (Figure 1) have been proposed to outline an AI system's design, intended use, performance characteristics, and known limitations [16]. Some researchers also advocate for more comprehensive "System Cards" to provide in-depth analyses of AI performance and biases, which could enable clinicians to better explain the technology to patients [15]. However, despite these proposals to enhance transparency by detailing AI design, performance, and biases, the routine integration of such tools into clinical systems for direct patient access or automated sharing is not yet widespread. Consequently, transparency often relies heavily on clinicians to convey this information, underscoring the need for more systemic and readily accessible solutions. Frameworks such as the FDA's Software as a Medical Device classification may also help clinicians clarify AI's intended functions—whether assisting with measurements, highlighting abnormalities, or offering diagnostic suggestions—ensuring that patients have a clearer understanding of the technology's role in their care [16].

Figure 1. Sample patient-facing model card for AI-supported lung cancer screening.



Meet Your AI Assistant: RadiologyAssist-AI

Created by: General Health Medical Center
Version: 2.3 | Last Updated: March 30, 2025

What is RadiologyAssist-AI?

RadiologyAssist-AI is an artificial intelligence (AI) tool that helps your radiologist spot lung nodules (small growths) on chest CT scans. It acts like an extra pair of eyes, making sure nothing is missed and helping your doctor give you timely and accurate care.

How does it work?

1. Scanning your images: The AI reviews chest CT scans quickly and thoroughly.
2. Highlighting potential issues: It flags areas that might need closer examination.
3. Supporting your doctor: Your radiologist reviews these flagged areas carefully to make the final diagnosis.

How accurate is it?

RadiologyAssist-AI has been carefully tested:

- Accuracy: Helps doctors correctly spot issues about 94% of the time.
- Safety checks: Constantly updated and checked to ensure high safety standards.

When is RadiologyAssist-AI used?

- To help find lung nodules early.
- As a supportive tool alongside your radiologist.

Important: RadiologyAssist-AI does NOT replace your doctor. It's a supportive tool used by trained medical professionals.

Is my privacy protected?

Yes! Your images and personal details remain private. All information used to train the AI was fully anonymized (no names or personal identifiers).

Limitations you should know:

- Currently not approved for use in pediatric (children's) care.
- It does not independently diagnose conditions; your doctor will always make the final diagnosis.

Questions or concerns?

If you have questions about how AI is used in your care, please ask your healthcare provider.

To learn more about RadiologyAssist-AI, visit our website or contact us at ai-questions@ghmc.org.

At General Health Medical Center, your care comes first. We use technology responsibly to ensure you receive the best possible care.

Transparency in AI Deployment

Achieving transparency in the deployment of AI, which is crucial for fostering patient confidence and engagement, is a shared responsibility. While individual clinicians are at the frontline of patient communication, health care organizations hold a fundamental responsibility for establishing policies, ethical frameworks, and technological infrastructures that mandate and support transparency regarding AI use. This includes providing clinicians with the necessary training and

tools [15]. With this foundational support, transparency becomes particularly important in clinical decision-making, where AI's role should be clearly communicated to support trust and engagement. When AI plays a significant role in shaping diagnostic or treatment recommendations, clinicians could consider including information in imaging reports or after-visit summaries about:

1. The specific role AI played in the diagnostic process (eg, prioritizing findings, generating a differential diagnosis, or suggesting treatment pathways).
2. How the clinician evaluated and incorporated AI recommendations into their final decision.
3. Whether the AI's recommendation differed from the clinician's judgment and, if so, the reasoning behind the chosen course of action.

In instances where AI and clinician recommendations diverge, it is crucial to clarify the context of such divergence. This pertains to scenarios within the clinical diagnostic process where an AI tool used by the health care team generates a finding or recommendation that differs from the supervising clinician's independent assessment. It does not primarily refer to patients independently consulting consumer-facing AI tools, an emerging area with its own distinct considerations. The focus here is on how clinicians navigate these situations and transparently communicate decisions when their expert judgment and an AI's output are not fully aligned. Shared decision-making discussions with patients are then vital to ensure transparency and respect for patient autonomy. These discussions should include explaining the differences between the AI's recommendation and the clinician's judgment, the rationale for the clinician's chosen course of action, and an affirmation that the clinician's expertise ultimately guides the final decision-making process.

Patients may also benefit from understanding the validation status and certification of the AI systems involved in their care. This could include sharing whether the AI system has been approved by regulatory bodies, such as the FDA or equivalent agencies [16], and any information on its intended use and known limitations. Including these details in patient education materials or as part of prediagnostic consent processes might help demystify the technology and enhance patient confidence in its use.

Data Privacy and Security

Data privacy and security concerns remain a central issue for patients, many of whom are willing to share their health data for AI development only if robust protections are in place [4,5]. Legal frameworks such as General Data Protection Regulation (GDPR) in Europe and Health Insurance Portability and Accountability Act (HIPAA) in the United States establish foundational safeguards, while advanced methods such as differential privacy and federated learning are being explored to address privacy concerns specific to AI systems [17]. Offering patients clear information about their rights regarding data inclusion, such as the ability to opt out even for anonymized datasets, may further demonstrate respect for their autonomy and foster trust [15]. Ensuring that patients feel informed and protected is likely to play a critical role in their acceptance of AI.

Ensuring that patients feel informed and protected regarding their data is likely to play a critical role in their acceptance of AI. Recognizing the multifaceted ethical challenges, including those related to data governance and transparency, prominent national and international radiology societies such as the American College of Radiology, Canadian Association of Radiologists, European Society of Radiology, Royal Australian and New Zealand College of Radiologists, and Radiological Society of North America (are actively developing guidelines and practical recommendations for the ethical development, deployment, and monitoring of AI tools [15]. These comprehensive efforts include emphasizing the need for robust data privacy measures, clear data handling protocols, and continuous education for radiologists on AI's capabilities and limitations to help manage biases and challenges related to AI systems [15]. Open communication about AI's limitations, alongside reassurance of ongoing clinician involvement, can further address patient concerns and foster trust in AI-supported care.

By addressing these ethical considerations with a patient-centered approach, health care providers can better align AI implementation with patient expectations. Transparency, accountability, and proactive engagement with patient concerns are essential for fostering trust and ensuring that AI in medical imaging ultimately enhances the quality of care and patient outcomes.

Algorithmic Bias, Health Disparities, and the Erosion of Patient Trust

The efficacy and fairness of AI systems in medical imaging are fundamentally dependent on the data they are trained on. The use of unrepresentative datasets in AI training not only risks developing algorithms that perform inequitably across diverse patient populations [18], thereby potentially leading to misdiagnosis and exacerbating existing health disparities, but it can also severely undermine patient trust. If patients, particularly from underrepresented or historically marginalized groups, perceive or learn that AI systems may not be accurate or fair for them, their confidence in AI-assisted diagnostics—and potentially the health care system using them—will inevitably be eroded.

Demographic imbalances in training datasets—whether related to race, ethnicity, gender, age, or socioeconomic status—can introduce insidious biases into AI models. An AI system predominantly trained on images from one demographic group may exhibit reduced accuracy or reliability when applied to others, leading to diagnostic errors or missed conditions for those in underrepresented groups [18]. This not only perpetuates but can amplify existing health inequities. From a patient perspective, the realization that an AI tool might be less effective or even harmful due to their demographic background strikes at the core of equitable care and can foster deep-seated mistrust.

Therefore, ensuring that AI models are developed and validated using diverse, representative datasets is not merely a technical

imperative but a crucial ethical obligation directly linked to patient well-being and trust. Proactive strategies to detect, assess, and mitigate bias throughout the AI lifecycle are essential [18]. This commitment to fairness and equity is fundamental to building AI systems that are genuinely transparent, trustworthy, and capable of enhancing health care for all patients, thereby upholding the principles of participatory and patient-centered medicine.

Balancing Systemic Benefits and Risks of AI in Medical Imaging

The integration of AI into medical imaging offers a complex interplay of substantial potential benefits and notable risks that extend beyond immediate patient perceptions, impacting clinical workflows, health care systems, and the practice of radiology itself.

Systemic and Operational Benefits

Beyond the enhancements to diagnostic accuracy and efficiency that are often highlighted, AI presents several broader advantages:

1. Standardization and quality improvement: AI tools can contribute to greater consistency in image interpretation and reporting, potentially reducing inter-reader variability and supporting adherence to best-practice guidelines [1,15].
2. Workflow optimization and radiologist support: AI can automate repetitive or time-consuming tasks (eg, image segmentation and preliminary flagging of normal studies), prioritize urgent cases for review, and serve as a "second reader," potentially alleviating radiologist workload, reducing burnout, and allowing more focused attention on complex cases or direct patient communication where appropriate [1,15].
3. Advancement of medical knowledge: the application of AI to large-scale imaging datasets can accelerate research, facilitating the discovery of novel imaging biomarkers, improving understanding of disease pathophysiology, and aiding in the development of personalized medicine approaches [2,15].
4. Potential for enhanced accessibility: in resource-constrained environments, AI could theoretically augment diagnostic capabilities where specialist radiologists are scarce, although equitable access and implementation remain significant global challenges [15,16].

Systemic Risks and Implementation Challenges

Alongside these benefits, a range of risks and challenges should be proactively addressed for responsible AI adoption:

1. Technical limitations and generalizability: AI models can exhibit "brittleness," performing well on data similar to their training sets but potentially failing or underperforming when encountering out-of-distribution data, novel disease presentations, or images from different scanners or protocols. Ensuring robustness and reliable generalization across diverse clinical scenarios is a critical ongoing challenge [15,18].
2. Automation bias and clinician over-reliance: a significant concern is the potential for 'automation bias,' where clinicians may develop an undue reliance on AI-generated outputs, potentially accepting incorrect AI suggestions without sufficient critical scrutiny, or experiencing a gradual deskilling in certain interpretive tasks. This can diminish the vital role of human judgment and oversight, potentially leading to diagnostic errors if AI outputs are not rigorously evaluated as part of a comprehensive clinical assessment [7,13].
3. Integration and workflow disruption: successfully embedding AI tools into established clinical workflows is a complex undertaking, often requiring substantial investment in IT infrastructure, interoperability solutions, staff training, and careful redesign of existing processes to avoid unintended negative consequences. This challenge of workflow disruption with new technology is not unique to AI, as similar significant issues have been well documented with the integration of electronic health records [19].
4. Data governance, privacy, and algorithmic bias: ensuring robust data governance, protecting patient privacy, and actively mitigating algorithmic biases that could exacerbate health disparities are fundamental prerequisites for ethical AI deployment [17,18].
5. Interpretability and the "black box" issue: the lack of transparency in the decision-making processes of some complex AI models (the 'black box' phenomenon) can pose challenges for clinical validation, error analysis, establishing clinician trust, and explaining AI-influenced decisions to patients.
6. Regulatory, legal, and ethical frameworks: the evolving regulatory landscape for AI as a medical device, along with establishing clear lines of accountability for AI-related errors and navigating other ethical complexities, requires ongoing attention and development of robust governance structures [14-16].

Effectively harnessing AI's transformative potential in medical imaging necessitates a comprehensive strategy that actively seeks to maximize these benefits while diligently mitigating the associated risks through rigorous validation, continuous performance monitoring, comprehensive clinician training, and transparent, adaptive governance frameworks.

Recommendations for Patient-Centered AI Integration

The successful and ethical integration of AI into medical imaging is contingent upon addressing core patient expectations, primarily the need for transparency regarding AI's role and the paramount importance of preserving human interaction and oversight. These foundational patient priorities necessitate proactive, concrete strategies to ensure AI adoption is patient-centered and builds trust; the following recommendations aim to guide this process.

Enhance Transparency and Build Trust

Patients consistently express a desire to know whether AI contributed to their diagnosis and the specific role it played [4,5,8].

- Clear communication: provide clear and accessible information about AI's involvement, such as labeling AI-assisted results in medical records or patient portals. This demystifies the technology and empowers patients for informed discussions.
- Implement transparency tools: the "Model Cards" (Figure 1) [16] and "System Cards" [15] previously discussed offer structured ways to detail AI design, performance, and limitations. These tools should be actively pursued and integrated into clinical practice. Doing so can empower clinicians in their discussions with patients and significantly support informed consent processes.
- Shared decision-making: incorporate AI into shared decision-making processes, allowing radiologists to explain how AI contributed to a diagnosis and discuss how its outputs align with clinical observations. This fosters transparency, trust, and patient empowerment.

Uphold the Primacy of Human Interaction and Empathy

While patients appreciate AI's ability to enhance diagnostic accuracy and efficiency, they emphasize the irreplaceable value of human empathy and clinical judgment [5,8,9].

- Reinforce clinician role: radiologists play a critical role in interpreting AI-generated results and ensuring that these insights are communicated with clarity and compassion. AI should be consistently framed as a tool to support, not replace, the human connection that underpins trust and comfort in healthcare settings.

Champion Participatory Approaches

Achieving meaningful patient engagement requires actively involving patients in the development, deployment, and evaluation of AI technologies.

- Patient advisory boards: establish advisory boards composed of diverse patient representatives to ensure patient concerns and priorities are integrated into decisions about AI development and implementation, including input on algorithm design, ethical guidelines, and clinical workflows.
- Cocreation of educational materials: collaborate with patients to create accessible materials (eg, visual guides, videos, and interactive platforms) that explain AI's capabilities, limitations, and role in imaging, tailored to different patient populations.
- Feedback mechanisms: develop channels for patients to provide feedback on their experiences with AI-driven diagnostics to help refine these systems and ensure they meet patient needs and expectations.

Ensure Ethical Governance and Accountability

Ethical considerations are crucial for patient acceptance and trust.

- Clear accountability: establish and communicate clear lines of responsibility among radiologists, AI developers, and health care institutions in the event of diagnostic errors involving AI.
- Data privacy and security: maintain robust safeguards for sensitive patient information. Transparent communication about data use and compliance with privacy regulations (eg, HIPAA and GDPR) is essential to reinforce patient trust.
- Mitigate bias: proactively address and mitigate potential biases in AI algorithms (as discussed in "Algorithmic Bias, Health Disparities, and the Erosion of Patient Trust") to ensure equitable outcomes.

Foster Patient Agency and Continuous Improvement

Looking ahead, empower patients and ensure AI systems evolve responsibly.

- Promote patient choice: as AI technologies become more transparent and validated, explore offering patients understandable options regarding AI tools or diagnostic pathways, where clinically appropriate and feasible, to enhance autonomy.
- Incorporate patient feedback for iteration: use patient feedback to continuously improve AI systems, ensuring they remain responsive, ethical, and centered on patient needs.

Meeting patient expectations for AI in medical imaging requires more than technological advancement. It demands a thoughtful, inclusive approach that prioritizes transparency, human connection, participatory engagement, and ethical integrity. By addressing these priorities, AI can enhance clinical workflows, support equity, and improve the patient experience, ensuring its transformative potential benefits all.

Future Directions

Overview

The integration of AI into medical imaging is a dynamic and evolving field. Continued vigilance and proactive adaptation focused on patient-centered principles will be essential for its responsible advancement and to realize its full transformative potential, moving beyond mere enhancement of current practices. To guide this evolution and address remaining knowledge gaps, several key research and development priorities emerge.

Enhancing Patient Education and Meaningful Understanding

Future efforts should go beyond basic information provision. Research should focus on developing and rigorously evaluating innovative educational strategies that effectively clarify AI's role, capabilities, and inherent limitations in medical imaging. The goal is to foster genuine, informed trust and empower patients to engage meaningfully in discussions about AI-assisted care, moving past potential skepticism or uncritical acceptance [9].

Longitudinal and Cross-Cultural Assessment of Patient Attitudes

As AI becomes more deeply embedded in clinical practice, it is crucial to conduct longitudinal studies. These studies should track the evolution of patient attitudes, concerns, and expectations over time. Furthermore, comparative research across diverse health care systems and cultural contexts is needed to understand how varying societal values and health care structures influence patient perspectives on AI.

Optimizing Clinician-Patient Dynamics in AI-Mediated Care

The impact of AI integration on radiologist-patient relationships and communication warrants deeper investigation. Research should explore how AI-enabled tools—such as interactive reports or AI-augmented consultation platforms—can be designed to enhance, rather than hinder, patient trust, comprehension, and engagement, particularly in varied communication models (direct vs mediated).

Strengthening Ethical Frameworks and Championing Patient Co-Design

The ethical governance of AI requires continuous refinement, with an unwavering focus on accountability, data security, privacy, and the mitigation of bias. Critically, future research and development should prioritize the direct and active involvement of patients as collaborators and co-designers throughout the AI lifecycle—from conceptualization and algorithm development to deployment and evaluation—to ensure AI solutions truly align with the “nothing about me without me” principle.

Conclusions

AI holds transformative potential for medical imaging, promising enhancements in diagnostic accuracy, efficiency, and patient outcomes. However, this commentary has argued that the successful and ethical realization of this potential is inextricably linked to a patient-centered approach. Such an approach should prioritize transparency, uphold the critical role of human connection and oversight, and actively integrate patient perspectives through participatory methods.

While patients express conditional optimism toward AI, their trust is contingent upon addressing concerns regarding depersonalization, accountability, fairness, and data privacy. As demonstrated, fostering this trust requires more than technological sophistication; it demands a commitment to clear communication, shared decision-making, and the cocreation of AI solutions with patients, not just for them.

Ultimately, the integration of AI into medical imaging will be most beneficial if it reinforces, rather than erodes, the humanistic core of health care. By embracing the principles of participatory medicine, stakeholders—radiologists, developers, institutions, and policymakers—can collaboratively guide AI’s evolution. This ensures that AI serves as a tool to empower individuals, reduce health disparities, and elevate the standard of care, truly aligning technological advancement with the enduring values of patient-centeredness and ethical integrity.

Conflicts of Interest

None declared.

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Abbreviations

AI: artificial intelligence
GDPR: General Data Protection Regulation
HIPAA: Health Insurance Portability and Accountability Act
RANZCR: Royal Australian and New Zealand College of Radiologists
RSNA: Radiological Society of North America

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Patient Perspectives on Artificial Intelligence in Health Care: Focus Group Study for Diagnostic Communication and Tool Implementation

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Abstract

Background: Artificial intelligence (AI) is rapidly transforming health care, offering potential benefits in diagnosis, treatment, and workflow efficiency. However, limited research explores patient perspectives on AI, especially in its role in diagnosis and communication. This study examines patient perceptions of various AI applications, focusing on the diagnostic process and communication.

Objective: This study aimed to examine patient perspectives on AI use in health care, particularly in diagnostic processes and communication, identifying key concerns, expectations, and opportunities to guide the development and implementation of AI tools.

Methods: This study used a qualitative focus group methodology with co-design principles to explore patient and family member perspectives on AI in clinical practice. A single 2-hour session was conducted with 17 adult participants. The session included interactive activities and breakout sessions focused on five specific AI scenarios relevant to diagnosis and communication: (1) portal messaging, (2) radiology review, (3) digital scribe, (4) virtual human, and (5) decision support. The session was audio-recorded and transcribed, with facilitator notes and demographic questionnaires collected. Data were analyzed using inductive thematic analysis by 2 independent researchers (GF and JB), with discrepancies resolved via consensus.

Results: Participants reported varying comfort levels with AI applications contingent on the level of patient interaction, with digital scribe (average 4.24, range 2-5) and radiology review (average 4.00, range 2-5) being the highest, and virtual human (average 1.68, range 1-4) being the lowest. In total, five cross-cutting themes emerged: (1) validation (concerns about model reliability), (2) usability (impact on diagnostic processes), (3) transparency (expectations for disclosing AI usage), (4) opportunities (potential for AI to improve care), and (5) privacy (concerns about data security). Participants valued the co-design session and felt they had a significant say in the discussions.

Conclusions: This study highlights the importance of incorporating patient perspectives in the design and implementation of AI tools in health care. Transparency, human oversight, clear communication, and data privacy are crucial for patient trust and acceptance of AI in diagnostic processes. These findings inform strategies for individual clinicians, health care organizations, and policy makers to ensure responsible and patient-centered AI deployment in health care.

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KEYWORDS

co-design; diagnostic safety; artificial intelligence; patient engagement; communication

Introduction

Artificial intelligence (AI) has been widely adopted in numerous social and scientific areas, including integration into various health care applications [1,2]. AI offers great potential for improving patient care, especially in enhancing the early detection of diseases, automating routine works and tasks to manage patients and resources, and improving and streamlining workflow processes [3]. Through its ability to accommodate complex data, AI has shown great promise in enhancing diagnostic opportunities in a variety of clinical processes of the electronic health record, including diagnostic imaging, clinical decision support systems, and patient monitoring tools [4-8]. As AI continues to be rapidly deployed in various aspects of clinical practice, there are diagnostic safety implications given that diagnostic errors remain the leading cause of adverse outcomes in health care [9].

Existing research highlights the potential of AI to enhance diagnostic safety by identifying patterns in clinical data, improving early detection of diseases, and supporting decision-making [10-12]. For example, AI-based radiology tools have demonstrated the ability to detect pathologies like fractures or cancers with accuracy comparable to human radiologists [13,14]. Similarly, decision support tools use patient data to recommend diagnoses or tests, potentially mitigating diagnostic errors [15]. These AI tools, designed to support the diagnostic process, have the potential to reduce diagnostic errors by providing additional diagnostic information but can only do so through effective communication to ensure that patients are informed, engaged, and empowered in their care. As the adoption of these novel AI technologies will directly impact diagnosis and subsequently patient health outcomes, incorporating patient viewpoints into the design and implementation processes is critical to their widespread acceptance [16].

Few studies explore patient perspectives on AI's role, particularly in diagnosis and diagnostic communication [17]. Including these perspectives is critical, as patient and family input can shape the development and use of AI in health care in ways that align with their needs, priorities, and values. Despite the rapid expansion of AI technologies, most studies to date focus on consumer attitudes toward AI broadly, emphasizing trust, acceptance, or perceived accuracy, rather than investigating how patients and families believe AI should be integrated into the diagnostic process and its communication [18-21]. These studies provide limited insights into the potential for AI to enhance shared decision-making, improve transparency in diagnostic reasoning, or address systemic inequities in health care delivery. Some research has examined patient attitudes toward AI in specific contexts, such as radiology. For instance, 2 recent studies explored patient perceptions of AI-based diagnostics in radiology image interpretation and the communication of results [22,23]. These studies highlight important themes, such as patients' reliance on clinician expertise to contextualize AI findings and their concerns about how AI might influence trust in the diagnostic process. However, these findings remain confined to radiology and do not address broader questions about how AI can enhance diagnostic communication across diverse health care settings.

Furthermore, the role of families in understanding and interpreting AI-driven diagnostic information has been largely overlooked, despite evidence suggesting that family engagement can significantly impact health care outcomes [24,25]. This gap underscores the need for a more comprehensive exploration of how AI can support patient and family-centered care, particularly in fostering understanding, trust, and collaborative decision-making.

Our study aims to address this gap by investigating patient and family perspectives on AI's role in diagnosis and diagnostic communication across various theoretical and practical applications through a co-design approach. By engaging patients and families as partners in this research, we seek to uncover their expectations, concerns, and preferences for how AI should be used to enhance diagnostic safety, support clinician-patient communication, and promote equitable health care delivery. This inquiry not only expands the existing body of literature but also provides actionable insights to inform the design and implementation of patient-centered AI technologies in health care.

Methods

Study Design and Setting

This study employed a focus group methodology informed by co-design principles to explore patient and family member perspectives on the use of AI in clinical practice. Focus groups were selected to facilitate rich, interactive discussions, enabling participants to build on each other's insights while generating diverse perspectives. While the primary aim was to gather feedback on specific case scenarios illustrating AI use in health care, the session was structured to go beyond simple elicitation of opinions. Co-design principles were incorporated to actively engage participants in collaboratively identifying key concerns, priorities, and desired safeguards for AI integration. Rather than developing a tangible product, the co-design focus centered on shaping participant-driven guidelines and recommendations for how AI should be implemented in ways that support patient-centered care.

A single 2-hour session was conducted in a centrally located research office with a large conference room and breakout rooms. The session combined full-group discussions with smaller, scenario-specific activities designed to promote collaboration and iterative refinement of ideas. This approach allowed participants to reflect on real-world examples while contributing to the development of contextually relevant strategies for responsible AI use in clinical settings.

Participants

Adult patients and family members aged 18 - 80 years were recruited through email outreach, word of mouth, and networks such as our Patient and Family Advisory Council for Quality and Safety and the Georgetown University network. Recruitment focused on ensuring diversity in participant demographics, backgrounds, and health care experiences to capture a wide

range of perspectives. Eligibility criteria included being English-speaking and willing to engage actively in the session.

Procedures

The session was facilitated by a multidisciplinary team with expertise in human factors engineering, diagnostic safety, and patient engagement. Lead facilitators, trained in qualitative research methods, guided the session using a structured agenda designed to balance education, discussion, and cocreation. Recognizing the varying levels of participant familiarity with AI, the session began with an activity explicitly designed to surface and build a foundational understanding. This included group discussion of everyday AI examples (eg, navigation apps and virtual assistants) to ensure shared baseline knowledge before exploring health care–specific applications. We did not formally assess or quantify participants' previous knowledge of AI or their digital literacy.

The session consisted of the following five key activities: (1) introduction and icebreaker (a brief overview of the session's objectives, followed by an icebreaker to create a comfortable and engaging atmosphere), (2) "What is AI?" activity (participants discussed examples of AI in everyday life to build foundational understanding), (3) breakout sessions (participants were divided into smaller groups for 5 specific AI scenarios), (4) guideline or recommendation development, and (5) reflection and feedback (the session concluded with a debrief where participants shared insights and reflections). Materials provided to participants included an agenda, activity materials, and data collection for demographics and session evaluation.

In total, 5 scenarios were selected and developed to represent a diverse range of AI applications relevant to the diagnostic process and communication. These scenarios were designed to align with the study's goal of examining patient perceptions of AI in diagnostic care by highlighting applications that varied in complexity, patient interaction, and clinical context. Each scenario was informed by a review of current AI use cases in health care and refined with input from our research team, including experts in diagnostic safety, human factors, and patient engagement. The five scenarios presented included: (1) portal messages (use of AI for patient portal messaging), (2) radiology review (use of AI in radiological imaging review), (3) digital scribe (ambient digital scribe for documentation in primary care), (4) virtual human (a virtual human presents a new diagnosis during a telehealth encounter), and (5) decision support (use of AI for clinical decision support to identify patients that would benefit from HIV testing) (Table 1). The scenarios were designed to elicit feedback based on different levels of patient interaction ranging from high interaction (virtual human and portal messages) where patients directly communicate with AI to indirect interaction (digital scribe) where AI is present during interaction with a human physician to minimal interaction (decision support and radiology review) where there is no direct communication between the AI and the patient. The specific scenarios can be found in Multimedia Appendix 1.

Table . Brief description of each scenario used for the co-design session.

Scenario	Description
Digital scribe	Before a routine checkup, the doctor asks permission to use an AI[a]-based app on their phone as a digital scribe to listen and document notes based on the visit.
Radiology review	A radiologist initially sees nothing on a CT[b] scan for severe back pain, but AI software identifies a herniated disc, which the radiologist then confirms.
Decision support	During a routine wellness visit, an AI system recommends HIV screening based on interpreted medical and social history, prompting the clinician to offer the test.
Portal messages	After a routine visit with recommended laboratory work, a patient accesses the portal and finds a chatbot that uses AI to review all records and offer opinions and perspectives.
Virtual human	A physician diagnoses diabetes after a routine blood count and uses an AI-generated virtual assistant with a human appearance to communicate the diagnosis to the patient via telehealth (without the physician also being present).

[a]AI: artificial intelligence.

[b]CT: computed tomography.

Data Collection

Breakout sessions included small group discussions (2 - 4 participants) focused on the specific AI health care scenarios. Each scenario was presented by a dedicated facilitator who rotated between groups, ensuring that all participants discussed all 5 scenarios. Facilitators used standardized, prewritten scripts to introduce each scenario with a concise (approximately 1 minute) verbal description. To ensure consistent understanding, facilitators were prepared to clarify scenario details and answer participant questions as needed, using uniform prompts and clarifications.

For each scenario, facilitators guided the discussion using a structured set of questions designed to explore participants' perspectives on that specific AI application in a clinical context.

The first question asked participants to rate their comfort with the use of AI in the given scenario on a 1 - 5 scale (1 being least comfortable and 5 being most comfortable). This question was explicitly framed to focus on the comfort level with the AI application as described in the scenario, not general attitudes toward AI. Additional questions probed what information participants would need to feel confident in the AI's use, perceived benefits, potential concerns, and preferences for communication of AI-generated results. To promote consistency across discussions, facilitators received training on using the scripts, maintaining neutrality, and applying the structured question guide uniformly. Regular check-ins among facilitators during the session helped ensure alignment in approach and responses to participant questions. Facilitators also encouraged participants to share specific examples and personal experiences to enrich the discussion.

The session was recorded and transcribed verbatim, with facilitator notes collected to supplement the transcripts. A demographic questionnaire captured participant characteristics, including age, gender, health care experience, and self-reported medical conditions. Participants were asked to indicate any chronic illnesses or health conditions as part of a presession survey to better understand how their clinical experiences might inform their perspectives. In addition, participants were asked about their familiarity with AI and the frequency of AI use in their daily lives through structured survey questions, such as "Have you used AI applications like virtual assistants or automated systems? If so, how often?" These responses provided context for interpreting participant perspectives during the session. A postsession evaluation form gathered feedback on the session's content, structure, and overall experience.

Data Analysis

Thematic analysis was conducted using an inductive approach to identify patterns and themes within the focus group discussions. Furthermore, 2 researchers (GF and JB) independently coded the transcripts and resolved discrepancies through consensus. The initial coding process involved independently reviewing transcripts and assigning codes that captured key ideas and recurring sentiments. The coding team then iteratively refined and organized these codes into broader themes as a group. The process was informed by the discussion prompts, with themes often reflecting areas of interest, such as trust, communication, and perceived benefits or concerns. However, the themes were not strictly limited to the prompts, as additional insights emerged organically from participant discussions. To ensure the validity and relevance of the findings, the initial themes were presented to a patient-led steering committee as part of our AHRQ-funded Patient-Partnered Diagnostic Center of Excellence. This committee, comprising patient advocates and representatives, reviewed the themes, validated the findings, and provided additional feedback and considerations that were incorporated into the final analysis. Analytical memos documented the rationale for decisions and theme development throughout this iterative process. The final themes were organized to highlight both scenario-specific findings and cross-cutting issues, ensuring a comprehensive understanding of patient perspectives on AI applications in diagnostic communication.

Ethical Considerations

This study received institutional review board approval by the MedStar Health Research Institute (STUDY00005888), and participation was voluntary. Informed consent was waived under the approved protocol. Participants were provided a US $100 gift card as compensation for their time and contributions during the 2-hour session. All data collected were deidentified prior to analysis to protect participant privacy and confidentiality. No personally identifiable information (PII) was retained or linked to study records. Data were securely stored on password-protected servers accessible only to the research team. These procedures were implemented to ensure compliance with ethical standards for human subjects research, including safeguards for confidentiality and privacy.

Results

Participant Demographics

A total of 17 participants attended the AI focus group session, representing a diverse range of perspectives and varied experiences with health care (Table 2).

Table . Artificial intelligence co-design workshop participant demographics (n=17).

Characteristics	Patients (N=17), n
Age (y)	
18 - 24	4
25 - 34	4
35 - 44	2
45 - 54	2
55 - 64	2
65 - 74	3
75 and older	0
Prefer not to answer	0
Gender	
Men	4
Women	13
Nonbinary	0
Prefer not to say	0
Race	
White (non-Hispanic)	5
White (Hispanic)	0
African American or Black	4
Asian	6
American Indian or Alaska Native	0
Native Hawaiian or Other Pacific Islander	0
More than one race	1
Prefer not to answer	1
Highest level of education	
Some high school	0
High school graduate	0
Some college or associate's degree	2
Bachelor’s degree	3
Master’s degree	10
Doctoral or professional degree	1

Participants reported a variety of medical conditions, reflecting a diverse range of health experiences. These included chronic conditions such as polycystic ovary syndrome, generalized anxiety and depression, hypertension, ulcerative colitis, arthritis, and diabetes. More complex conditions were also represented, such as avascular necrosis, stroke, kidney transplant, heart transplant, cancer, and post-traumatic stress disorder. This range of conditions provided valuable perspectives on the integration of AI in addressing diverse health care needs.

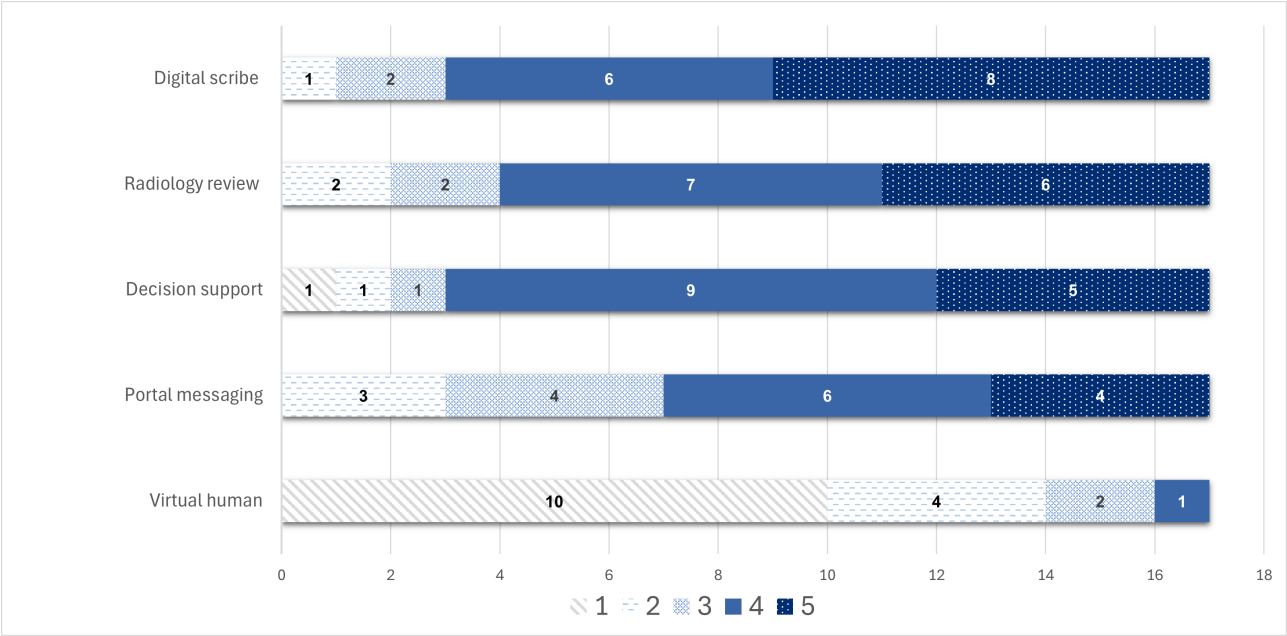
Patient Comfort Across Scenarios

Participants expressed overall comfort with AI being integrated into the diagnostic process, as long as implementation involved key themes that addressed their concerns and expectations (Table 3, Figure 1). However, participants’ comfort levels varied significantly depending on the level of human interaction involved in the AI scenario. The results showed that comfort level drastically decreased as the amount of human interaction decreased in the AI process. For example, the scenario with which participants were least comfortable was the virtual human telehealth visit in which an AI-generated human would replace the physician when communicating a new diagnosis. Similarly, participants also appeared less comfortable with an AI chatbot sharing details about laboratory results. In contrast, participants were most comfortable with the ambient digital scribe scenario, in which an AI scribe documents clinical notes during a patient visit.

Table . Participants' comfort levels (average and range) with each artificial intelligence scenario on a scale of 1 to 5 (1 being the least comfortable and 5 being the most comfortable).

Scenario	Average comfort level, mean (range)
Digital scribe	4.24 (2 - 5)
Radiology review	4.00 (2 - 5)
Decision support	3.94 (1 - 5)
Portal messages	3.68 (2 - 5)
Virtual human	1.68 (1 - 4)

Figure 1. Frequency of participants' comfort levels with each artificial intelligence scenario on a scale of 1 to 5 (1 being the least comfortable and 5 being the most comfortable).



Scenario-Specific Findings

Across scenarios, participants expressed a mix of enthusiasm and caution, highlighting specific concerns around AI's accuracy, transparency, and ability to meet individual patient needs.

Digital Scribe

Participants viewed the digital scribe scenario as a promising tool to improve documentation efficiency and reduce administrative burdens on clinicians. However, concerns centered on informed consent and the security, storage, and transfer of data generated by the scribe. Participants indicated a strong preference for receiving notification about the use of an AI scribe before the encounter, with 1 participant expressing:

> *I would rather have the opportunity to know about it, think about it, review it, know what the process is, then decide.*

Many participants also questioned how their sensitive health information would be handled, with 1 asking:

> *How is the database encrypted? Are you using software that other people won't have access to? How are we protecting that personal health information?*

Similarly, others sought clarity on how notes were processed and uploaded into their electronic health records, with 1 participant requesting:

> *I would like to review it before it gets uploaded...at what point does it get into my chart?*

These concerns reflect a broader apprehension about losing control over personal data in health care settings. Participants were also wary of the scribe's potential to misinterpret or omit critical details during documentation. They expressed a preference for providers to review and validate the scribe's work to ensure accuracy and context. For example, 1 participant remarked:

> *I think it's important for my doctor to verify what's documented—AI might miss something I said.*

Despite these concerns, some participants noted that AI might handle routine documentation tasks more effectively than humans, particularly in scenarios with a high cognitive load for clinicians.

Radiology Review

Participants expressed mixed reactions to the use of AI in interpreting radiological images. While many appreciated the potential for AI to identify abnormalities more efficiently and with fewer errors, they also stressed the importance of

transparency about the tool's error rates and limitations. One participant stated:

> *For me, I want to know some stats. I want numbers. So percentages in terms of its accuracy, and frequency use…*

Concerns about bias in AI training datasets were also prevalent, with participants questioning whether the tool was designed to account for variations in patient demographics. One participant remarked:

> *I would worry about the biases in selecting the populations for these diagnoses. What may look normal for some people could be different for others.*

Many participants agreed that AI could be a valuable supplementary tool for radiologists, but not a replacement. One participant summarized this sentiment, saying:

> *If it's used as a tool by a physician, and the physician is still very much involved, I'm okay with it.*

Decision Support

The decision support scenario elicited significant discussion about trust in AI-generated recommendations. Participants were particularly concerned about whether the tool's algorithms adhered to current clinical guidelines and standards of care. One participant stated, "I'd want to know if it's based on current standards of care," emphasizing the need for evidence-based systems. Transparency about how the tool generated its recommendations was also a priority, with one participant asking:

> *How did it make that decision? What [the AI] is drawing its information from truly makes a difference.*

Participants highlighted the importance of maintaining provider oversight in decision-making, expressing discomfort with the idea of AI functioning autonomously. One participant remarked:

> *I don't want the AI to be the final say for my diagnosis. I think the doctor should have that final say.*

However, some saw value in AI serving as a secondary layer of support, particularly for routine or low-stakes tasks, such as flagging potential issues in laboratory results or medical records.

Portal Messages

The portal messaging scenario was met with cautious optimism. Participants valued AI's ability to summarize test results and provide routine reminders but raised concerns about its ability to personalize messages. One participant questioned:

> *If we all use the same algorithm, but we have different diet habits or lifestyles, how does it account for those differences?*

Transparency and communication were critical to participants' comfort with this scenario. They emphasized the need to clearly distinguish between AI-generated messages and clinician-written notes. One participant stated:

> *I want to know upfront if this is summarizing or interpreting my results.*

While participants generally supported the use of AI for straightforward tasks, they were less comfortable with it providing interpretations or clinical recommendations without a provider's input.

Virtual Human

The virtual human scenario sparked significant debate about the appropriateness of AI for certain types of interactions. Participants expressed openness to using AI for follow-up care or routine questions, such as those related to medication instructions or dietary advice. One participant noted:

> *I think it would be a good use as a supplement...If you forget something from the doctor's visit, you could go back and use the AI for that purpose.*

However, participants were clear that AI should not replace human clinicians in delivering sensitive or high-stakes information, such as a serious diagnosis. One participant stated:

> *If you're telling me I have a brain tumor, I don't want AI telling me that.*

Others emphasized the importance of empathy and understanding, which they felt AI systems could not replicate. For example, one participant shared:

> *When it comes to major lifestyle issues, I'd rather hear personally from my doctor to get some empathy and understanding.*

Cross-Cutting Themes

Analysis of the co-design session discussions revealed 5 key themes that highlighted participants' concerns, expectations, and opportunities for AI integration into clinical workflows: validation, usability, opportunities, transparency, and privacy (Figure 2). These themes provide critical insights into how patients perceive and evaluate AI technologies, which were further reflected in their comfort levels across different AI implementation scenarios.

Figure 2. Key themes identified from participant discussions, highlighting concerns, expectations, and opportunities related to the integration of AI into health care. AI: artificial intelligence.

Theme 1: Validation—Concerns Around Model Development and Accuracy

Participants emphasized that trust in AI tools hinges on their validation through rigorous processes to ensure safety, accuracy, and reliability. Across scenarios, they raised questions about how AI systems are developed, trained, and evaluated to meet clinical standards. Many participants expressed a desire for transparency about the data sources used to train AI models and whether these systems could handle the complexities of health care. One participant in the decision support scenario asked:

> *Where does this data come from that it's following algorithms? What features is it using?*

Similarly, in the digital scribe scenario, another participant queried:

> *What's its database? And where's it pulling its information from to make translations as a scribe?*

Concerns about accuracy and reliability were prevalent, with participants wanting clarity on error rates and diagnostic limitations. These comments highlight a strong preference for metrics and transparency regarding AI performance. Participants also emphasized that AI tools should be aligned with clinical guidelines and standards of care to ensure they provide evidence-based recommendations. Without robust validation processes and clear communication regarding reliability, participants expressed skepticism about trusting AI systems.

Theme 2: Usability in Supporting Diagnostic Processes and Communication

Participants discussed AI's role in achieving effectiveness, efficiency, and satisfaction in diagnostic processes and communication. They consistently emphasized that AI tools should act as supportive, assistive technologies that enhance provider workflows and patient experiences, rather than replacing human decision-making or interactions. Across

scenarios, participants expressed a strong preference for AI to serve as a secondary tool that complements clinician expertise, ensuring accuracy and maintaining trust. For example, 1 participant in the virtual human scenario stated:

> *I think it would be good to use as a supplement or a good reference point...but I don't think it should be used as the primary source of education for any diagnosis.*

This reflects a concern for maintaining human oversight and judgment in critical health care decisions. Participants also highlighted the importance of tailoring AI's involvement to the complexity and context of the task. Many were more comfortable with AI handling routine or low-stakes tasks, such as summarizing medical records or flagging potential issues, as these functions contribute to efficiency without undermining patient-clinician communication. In the decision support scenario, 1 participant noted:

> *Routine testing I would feel comfortable for, like diabetes or things like blood pressure.*

However, they expressed hesitancy about AI's ability to independently manage complex or high-stakes decisions, where human expertise is essential. While participants appreciated AI's potential to improve efficiency, they consistently emphasized that these gains should not come at the cost of quality, personalization, or the human connection in care. Balancing these considerations is essential to ensure that AI tools achieve their intended usability in the diagnostic process and communication.

Theme 3: Transparency—Expectations Around Disclosure of AI Usage

Transparency emerged as a critical factor for fostering trust in AI tools. Participants consistently emphasized the need to understand AI's role in their care, its capabilities, and its limitations. Across scenarios, participants requested clear explanations of what contributions AI made to clinical decisions or communication. In the radiology review scenario, 1 participant stated:

> *If the AI found something, I would want to know if it was found by the AI.*

Another participant in the digital scribe scenario expressed a similar sentiment, asking:

> *How is this being processed and what is the accuracy?*

Timing of communication also mattered to participants, with many stressing that AI usage should be disclosed before it is implemented in their care. In the portal messaging scenario, 1 participant said:

> *I want to know about it [AI involvement] before I get to the doctor...I'd rather have the opportunity to think about it and review it beforehand.*

Informed consent for AI usage was particularly important in high-stakes situations, with participants calling for providers to explain AI's role and limitations clearly. Transparency, participants felt, was not just about disclosure but also about respecting patient autonomy and ensuring they have the necessary information to make informed decisions.

Discussions in the radiology review scenario also reflected concerns about how AI tools integrate into clinical workflows. Participants wanted assurances that these tools enhance rather than disrupt existing systems, emphasizing the importance of effective implementation strategies that support both patients and providers. One participant queried:

> *Are they going to connect it to the machine that's doing the scans or the MRIs?*

Such concerns highlight the need for clear communication about how AI integrates into care processes to maximize effectiveness and satisfaction for users.

Theme 4: Opportunities—Excitement and Opportunities for AI to Better Address Patient Needs

Despite their concerns, participants expressed optimism about AI's potential to improve patient engagement, understanding, and comfort. Many viewed AI as a valuable tool for providing supplemental information, clarifying complex medical concepts, and answering follow-up questions. In the virtual human scenario, one participant remarked:

> *I like the idea of having supplemental information I can access outside of appointments.*

In the portal messaging scenario, another participant noted:

> *I would say I like the idea of having the supplemental information and being able to access that.*

Participants also highlighted AI's potential to enhance comprehension for patients with limited health literacy or digital skills. One participant shared:

> *My parents, when they read their medical history and the doctor's notes, have no clue what any of it means. They have to put it in ChatGPT so it could be easier to understand.*

However, participants emphasized that the effectiveness of AI in these roles depends on its accessibility, adaptability to diverse patient populations, and ability to integrate seamlessly into existing systems. Barriers, such as digital literacy gaps and language differences, were flagged as critical considerations for designing inclusive AI tools.

Theme 5: Privacy—Patient Concerns Around Data Protection, Privacy, and Security

Concerns about data privacy and security were prominent across all scenarios, with participants expressing apprehension about how their sensitive health information would be stored, accessed, and used. Participants in the digital scribe scenario were particularly concerned about data transfer and storage, with one asking:

> *Is it transferable? Is it something that would stay within my healthcare unit, or could others access it?*

Another participant queried:

> *How is it stored? Is it going to be posted on the patient portal? Are we able to access it?*

Participants also raised concerns about potential misuse of data, particularly for non–care-related purposes. In the virtual human scenario, 1 participant worried about the possibility of data mining, asking:

> *Would it be a gain for me, like if it was mining my data?*

Similarly, in the portal messaging scenario, a participant asked:

> *How much does the chatbot know?*

These concerns underscore a broader mistrust of data handling practices and the need for robust privacy protocols to safeguard patient information. Participants consistently called for systems to prioritize transparency and informed consent regarding data collection and usage, ensuring that personal information is used solely for its intended purposes.

Participant Evaluation of the Co-Design Sessions

Participants provided largely positive evaluations of the co-design session (Table 4).

Table . Participant evaluation of the artificial intelligence (AI) co-design workshop (N=17).

Overall experience	Response, n (%)				
	1	2	3	4	5
How would you rate the meeting overall?[a]	0 (0)	0 (0)	0 (0)	2 (12)	15 (88)
In general, how useful was the meeting?[b]	0 (0)	0 (0)	0 (0)	4 (24)	13 (77)
What did you think about the materials presented and discussed during the meeting?[b]	0 (0)	0 (0)	0 (0)	5 (29)	12 (71)
What did you think about the guideline/recommendation discussion?[b]	0 (0)	0 (0)	1 (7)	5 (33)	9 (60)
How much did the meeting contribute to a shared awareness of AI and diagnostic safety?[c]	0 (0)	0 (0)	3 (6)	8 (47)	8 (47)
How much say did you feel you had in the discussion?[d]	0 (0)	0 (0)	2 (12)	0 (0)	15 (88)
Do you think that the opinions of the different stakeholders that were present at the meeting were all taken into consideration?[d]	0 (0)	1 (6)	3 (18)	6 (35)	7 (41)

[a]1=Poor, 5=Excellent.

[b]1=Not useful, 5=Very useful.

[c]1=Almost nothing, 5=A lot.

[d]1=Not at all, 5=Very much.

Participants highlighted several aspects of the workshop that they liked best. They appreciated the open and nonjudgmental environment, which allowed for free sharing of opinions and thoughts without bias or pressure. Many valued the interactive nature of the session, particularly the small group discussions, which facilitated deeper engagement, diverse perspectives, and meaningful participation. The diverse backgrounds of participants, including patients from different races and professions, enriched the discussions and provided new insights. Participants also found the materials well-prepared, appreciated the brief AI introduction, and enjoyed the opportunity to learn more about AI in relation to their health care. Overall, the combination of open dialogue, group interaction, and thoughtful organization was highly praised.

Participants shared a few areas for improvement in the workshop. The most common concern was the limited time available, with several noting the need for more time to discuss topics in greater depth and brainstorm ideas. Some also suggested dedicating additional time for group discussions and addressing specific examples of AI currently in use or relevant case studies. Suggestions included incorporating more complex cases or scenarios, discussing AI bias in greater detail, and diversifying both the researcher backgrounds and participant groups to include more primary care providers, individuals from

different socioeconomic groups, and a broader generational representation. While some recommended separating patients based on their AI knowledge for tailored discussions, others emphasized maintaining a mix of diverse perspectives within groups. Overall, participants highlighted opportunities to enhance inclusivity, depth of discussion, and time for meaningful engagement.

Discussion

Principal Results

AI, while previously a technology of the future, has become a technology of the present. AI-driven technologies, including machine learning-driven decision support algorithms, deep-learning radiology scan classifiers, and large language model–driven digital scribes, have already been implemented in hundreds of hospitals nationwide. This study, in examining patient perceptions of 5 different scenarios describing current and future AI technologies in health care, provides a contemporary view of the multifaceted patient perspectives on AI's role in providing diagnostic information, facilitating communication, and supporting decision-making. Many patient perceptions held true across all scenarios. First, a need for transparency in the development and validation of AI models, including their ability to reliably address the diverse needs of patients. Second, a preference for AI to complement rather than replace human providers, with an emphasis on maintaining human oversight in clinical decision-making. Third, the importance of clear and respectful communication about AI's role in care, including obtaining patient consent, was seen as essential for building trust. Fourth, the potential for AI to enhance patient engagement, understanding, and access to information, provided it is implemented as a supportive tool that respects patient autonomy. Finally, concerns regarding the security and privacy of patient data highlight the need for transparency and robust safeguards to prevent misuse or unauthorized access.

The outlook on AI implementation into the diagnostic process was generally positive, with participants consistently highlighting AI's ability to identify patterns and provide supplemental diagnostic information that might otherwise be overlooked by human providers. However, they emphasized that AI tools must integrate seamlessly into clinical workflows and preserve the essential human connection in patient-provider communication, as seen in the results regarding patient comfort levels across scenarios. Participants reported lower average comfort levels with high AI-patient interaction scenarios. For example, the scenario participants were least comfortable with was the virtual human scenario in which an AI-generated human would replace the physician when communicating a new diagnosis. Similarly, participants also appeared less comfortable with an AI chatbot sharing details about laboratory results. In contrast, participants were most comfortable with the digital scribe scenario, in which the application of AI was intended to enhance patient-provider communication by removing the need for providers to focus on documentation during clinic visits.

These findings highlight the importance of understanding patient perspectives within their specific health care contexts, offering insights into how AI can be integrated to enhance diagnostic processes and communication. For example, rural communities, where health care access and infrastructure often differ from urban settings, may present unique opportunities for AI to address gaps in care. Designing AI systems that are adaptable to varying levels of digital literacy, resource availability, and cultural expectations can help ensure these tools are both effective and equitable across diverse populations. Similarly, the interactive focus group discussions demonstrated the value of engaging patients with varying experiences and levels of familiarity with health care technologies. This diversity of input underscores the potential for AI to be developed in ways that resonate with patients from different backgrounds, fostering trust and satisfaction. By actively seeking and incorporating a wide range of perspectives, AI tools can be tailored to address the specific needs of different communities, ultimately supporting a more inclusive and patient-centered approach to care.

Comparison With Previous Work

The findings of our work that held true across all scenarios are expectedly consistent with previous work – patients' concerns with privacy, data security, and bias have been well-documented [26,27]. Specifically, our findings align well with the findings that patients have a generally positive outlook on AI's implementation into their care as long as there are adequate guardrails to protect against a variety of potential harms [28]. Our work was unique in its focus on how such concerns are explicitly perceived in the context of AI applied to diagnosis and its communication in a variety of clinical contexts. Few qualitative studies have explored patient perceptions of AI in the context of diagnosis and communication, but our results appear to be in alignment with previous findings. Patients considered AI to be a helpful supplementary tool that should not serve as a replacement to human clinicians, a sentiment already documented for applications of AI in radiology [23].

While there is previous work identifying patient perceptions on the implementation of AI in health care broadly, there has been limited work identifying patient perceptions of AI's role in reducing diagnostic errors through the enhancement of patient-provider communication. A recent scoping review identified that patients' attitudes toward AI (which may impact their experiences when they interact with these tools in practice) are influenced by various factors, including familiarity with function, previous exposure to similar tools, supervision during use, and tool simplicity, validity, and cost. In light of this, it is imperative to consider patient perceptions of AI applications in a variety of clinical workflows in the context of diagnostic communication [17]. As AI becomes ubiquitous both inside and outside of health care, patients' familiarity (and thus their attitudes toward AI) will continue to evolve. It is critical that patient perceptions of AI tools are continually assessed and used to enhance the diagnostic process and communication so that AI can be designed and integrated into the health care system in such a way that maximizes patient care and satisfaction.

Implications at the Individual Clinician, Organizational, and Policy or Regulatory Levels

Our findings have clear implications for clinical practice, finding that patients consistently stressed the importance of clinicians playing a central role in facilitating their experience with AI tools. Patients emphasized that their trust in AI would be built through transparent communication and clinician endorsement. Patients valued clinician involvement in contextualizing AI's outputs, interpreting its recommendations, and providing assurances about its accuracy and reliability. Patients additionally expressed concerns that AI could disrupt workflows or reduce human interaction, particularly in scenarios where key diagnostic information was to be communicated. To address this, organizations should prioritize the implementation of AI tools that enhance human connection in care, such as those that reduce administrative burdens. These tools should be designed in ways that enhance, rather than overshadow, the clinician's role in communicating diagnoses.

From a policy perspective, our findings reinforce the urgency of addressing gaps in regulations governing AI in health care, particularly concerning equity [29]. Patients expressed concern that biased data inputs could undermine the diagnostic accuracy of AI tools and have harmful effects on historically underserved populations. Policies should ensure that tools are trained on diverse datasets and are validated across representative populations in order to build patient trust and acceptance. Patients also expressed calls for transparency and informed consent regarding how health data is collected and used by AI systems in health care, aligning well with findings from a study [30]. These concerns should be addressed by policies that establish clear standards for disclosing when AI is used in care, and for ensuring that patients understand what personal information is being used, how it contributes to the diagnostic process, and how it influences the outputs from AI systems. Strengthening privacy and communication protocols will not only help address these concerns but also reinforce patient autonomy and trust in AI by supporting its ethical implementation in clinical settings.

Importance of Involving Patients in AI Deployment

Our findings underscore the critical role patients play in the acceptance and success of AI tools designed to enhance the diagnostic process, emphasizing the need to involve them in the development and implementation of these technologies. As primary stakeholders most directly impacted by changes to diagnostic workflows, patients have invaluable insights that can guide the design of tools to align with their expectations and foster trust [31]. Participants in this study expressed a dynamic view of AI tool implementation, with key insights into concerns that should be addressed during design and implementation, such as the importance of human connection and interaction, concerns regarding equity, personalization, and data security, and the pivotal role clinicians have in their understanding and comfort with new technology. By involving patients in the development of these tools, the health care system can better anticipate risks, communicate with patients more effectively, and deploy tools that not only improve the diagnostic process but also enhance trust and adoption, ensuring alignment with patient values and priorities.

Limitations

This study has several limitations. First, focus groups were guided by different facilitators, which may have introduced variability in discussions due to differences in facilitation styles. The breakout sessions included only 2-4 participants per group, which allowed for in-depth discussions but may have limited the diversity of viewpoints within each session. This could affect the robustness of the findings; however, insights were aggregated across groups to capture broader themes. Future studies could address this by increasing group sizes or incorporating complementary methods such as individual interviews. Time constraints limited the discussion duration for each scenario, potentially restricting exploration of nuanced perspectives and the ability to achieve thematic saturation. In addition, the use of specific diagnostic-related AI scenarios provides structure but limits the generalizability of findings to other clinical contexts.

Participants were recruited through advisory networks, which may have introduced selection bias favoring individuals with an interest or familiarity in health care technologies. The participant demographics also reflect limitations in diversity, as more than 70% (n=13) were women, almost 65% (n=11) held graduate degrees, and none identified as having a Hispanic background. In addition, no participants reported high school or lower as their highest education level. According to national data, approximately 62% (n=115,011) of individuals aged 25 years and older in the United States have not attained a bachelor's degree, suggesting that our sample overrepresented highly educated individuals [32]. Perspectives from participants with less formal education or from underrepresented backgrounds may have differed significantly, potentially revealing lower trust in AI, different concerns about its use, or alternate expectations for its role in health care. This lack of demographic diversity may limit the generalizability of the findings, as perspectives from individuals with different educational or cultural backgrounds could provide unique insights into AI applications in health care. We also did not assess baseline AI familiarity or digital literacy, which may have influenced participant engagement. Finally, this study is not comprehensive of all patient concerns about AI, with a focus on diagnostic applications shaping the discussions. Future research should aim to include a more demographically representative sample, explicitly assess AI literacy, and explore a wider range of clinical and nonclinical AI use cases to better understand how diverse patient populations perceive and respond to its implementation in the health care setting.

Conclusions

This study highlights the nuanced perspectives of patients on the use of AI in health care, with a particular focus on diagnostic communication. While participants recognized the potential of AI to improve diagnostic accuracy, efficiency, and equity, they also voiced significant concerns about transparency, trust, and the preservation of human connection. These findings underscore the importance of ensuring that AI tools are developed and integrated in ways that align with patient values

and priorities. Key patient-oriented considerations include the need for clear communication about AI's role in care, consent processes for its use, and opportunities for patients to actively participate in its development and implementation. Participants emphasized the importance of maintaining provider oversight, fostering understanding through accessible explanations, and designing systems that prioritize inclusivity and respect for patient autonomy.

As AI technologies continue to evolve and permeate health care, it is essential to iteratively assess and incorporate patient feedback to ensure these tools not only meet technical and clinical standards but also uphold the values of equity, transparency, and shared decision-making. By centering patients in the design and deployment of AI, we can create systems that not only enhance health care delivery but also foster trust and meaningful engagement between patients and providers.

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Conflicts of Interest

None declared.

Multimedia Appendix 1
Artificial intelligence (AI) scenarios for breakout discussion.
[DOCX File, 15 KB - jopm_v17i1e69564_app1.docx]

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Abbreviations

AI: artificial intelligence

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Consumer Data is Key to Artificial Intelligence Value: Welcome to the Health Care Future

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Abstract

Humanity stands at the threshold of a new era in biological understanding, disease treatment, and overall wellness. The convergence of evolving patient and caregiver (consumer) behaviors, increased data collection, advancements in health technology and standards, federal policies, and the rise of artificial intelligence (AI) is driving one of the most significant transformations in human history. To achieve transformative health care insights, AI must have access to comprehensive longitudinal health records (LHRs) that span clinical, genomic, nonclinical, wearable, and patient-generated data. Despite the extensive use of electronic medical records and widespread interoperability efforts, current health care organizations, electronic medical record vendors, and public agencies are not incentivized to develop and maintain complete LHRs. This paper explores the new paradigm of consumers as the common provenance and singular custodian of LHRs. With fully aligned intentions and ample time to dedicate to optimizing their health outcomes, patients and caregivers must assume the sole responsibility to manage or delegate aggregation of complete, accurate, and real-time LHRs. Significant gaps persist in empowering consumers to act as primary custodians of their health data and to aggregate their complete LHRs, a foundational requirement for the effective application of AI. Rare disease communities, leaders in participatory care, offer a compelling model for demonstrating how consumer-driven data aggregation can be achieved and underscore the need for improved policy frameworks and technological tools. The convergence of AI and LHRs promises to transform medicine by enhancing clinical decision-making, accelerating accurate diagnoses, and dramatically advancing our ability to understand and treat disease at an unprecedented pace.

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KEYWORDS

consumer data; artificial intelligence; longitudinal health records; data interoperability; large language models; health IT standards; policy regulation; rare disease registries; translational science; precision medicine; patient participation; genomic and wearable data; nodal graph architecture; FHIR; 21st Century Cures Act; resilient systems; Fast Healthcare Interoperability Resource

Introduction

Artificial intelligence (AI), particularly large language models (LLMs), holds extraordinary promise in unlocking and interpreting vast volumes of data for public and professional use. Of the projected 180 Zettabytes [1] of global data to be collected by 2025, less than 1% is ever tagged or analyzed [2]. Without the aid of AI, the sheer volume of data exceeds human capacity to meaningfully use this valuable collection.

Health care represents one of the most data-intensive sectors, contributing one-third of the world's data through electronic medical records (EMRs), imaging technologies, genomics, and personal devices [3]. LLMs offer unprecedented capabilities to process this magnitude of data. Untiring and limitless, LLMs' computational power liberates the human burden of manual analysis to unlock intellectual and creative potential. The ability of AI to expedite biomedical discovery advancement is profound and exciting.

However, it is important to acknowledge AI will only ever access a small fraction of the global data landscape. Currently, less than 3% [2] of the world's data is openly accessible; the vast majority remains proprietary, restricted, or siloed within the organizations that generated it.

To realize the full potential of AI in health, models must be trained on rich, proprietary, real-time datasets. This paper outlines the pathway and necessary processes for LLMs to ingest and learn from comprehensive, longitudinal health data—empowering consumers, transforming personalized care, and increasing biological and disease understanding by a significant measure.

AI Appetite

Foundational LLMs, such as GPT-40 [4], Claude [5], or Llama [6] are trained on open data commons, including papers, articles, books, websites, and others from sources, such as Common Crawl [7], Wikipedia [8], PubMed [9], Data.gov [10], World Digital Library [11], GitHub [12], and so on. LLMs use these large data stores to explain, assist, and suggest solutions to user prompts. Open data repositories are continuing to grow and become more frequently used. However, privacy, security risks, and commercial interests remain significant factors in LLMs' accessibility to data. The value of LLMs for health is inextricably tied to the quantity and quality of the data on which it is trained and the proprietary data on which it is fed.

Data Gold

Organizations tag and analyze vast volumes of proprietary data to enhance efficiency, manage risk, improve customer experience, and maintain a competitive advantage. Manufacturing, finance, telecommunication, eCommerce, and health care are the most significant contributors to the world's data. AI models enable organizations to maximize the use of their raw data. By feeding LLMs comprehensive custom data, entities can harness their proprietary datasets to uncover novel insights to make optimal strategic decisions.

Health Data

Epic Systems [13] is the world's largest EMR vendor, followed by Oracle Health (formerly Cerner) [14], MEDITECH [15], and Veradigm (formerly Allscripts) [16]. EMRs encompass patient demographics, medical history, clinical notes, medications, lab results, radiology reports, procedures, and other therapeutic data.

Epic holds at least 1 record for nearly 94% [17] of Americans; over 325 million US citizens have a health record in Epic [18]. Their market share grew from 31% in 2021 [19] to 37.7% in 2024, adding 153 new hospitals and now covering over half of acute care multispecialty beds nationwide [20]. In addition to enterprise and billing capability, Epic's strengths include a comprehensive platform with a focus on interoperability, continuity of care, and ability to integrate with a variety of information technology systems. Epic's "Care Everywhere" platform enables patient health information exchange across multiple provider organizations and EMR systems. Providers can query other health systems connected through "Care Everywhere" and import patient data into their EMR with aims of enhancing care, reducing medical errors, and improving patient outcomes.

Epic's popularity is also due to their patient portal, MyChart, which addresses the growing patient demand of taking an active role to manage their health and meet the requirements of the 21st Century Cures Act [21]. MyChart provides patients access to their medical records, appointment scheduling, secure messaging, bill pay, prescription management, telehealth capability, and wellness tracking.

Pivotal Policy

As health data collection and consumer participatory behavior grows, so does the need for policies fostering greater data exchange and accessibility. The 21st Century Cures Act, signed into law by President Obama on December 13, 2016, promotes health interoperability and gives patients access and more control over health data.

Since the Cures Act signing, the Assistant Secretary for Technology Policy (ASTP)/Office of the National Coordinator for Health Information Technology (ONC) [22] introduced several provisions, which mandate for interoperability, patient access to health information, data privacy and security, information blocking prevention, and application programming interface requirements to access data.

The United States Core Data for Interoperability (USCDI) [23], first released by the ASTP in July 2020, are foundational standards that define minimum data elements for national data exchange across health systems. USCDI defines specific categories of health information (data classes) and essential data elements within those categories. These include patient demographics (name, date of birth, address, and contact information), clinical information (allergies, medications, immunizations, laboratory test results, and vital signs), and care coordination (clinical notes, goals, and health concerns).

Necessary Technology

A crucial component of contemporary health data policy is the adoption of Fast Healthcare Interoperability Resource (FHIR), one of the most significant advancements in EMR data exchange [24]. Developed and maintained by Health Level 7 International (HL7), FHIR is an open, license-free standard that is publicly available and designed to promote seamless interoperability. FHIR builds upon its predecessor, the HL7 Consolidated Clinical Document Architecture (C-CDA) [25], a document-based standard used to capture a "point-in-time" snapshot of a consumer health record.

Unlike C-CDA, FHIR uses modern web technology, such as RESTful APIs, JSON, and XML to enable consistent data exchange. Importantly, FHIR APIs allow for "real-time" data exchange through their discrete resource design. Unlike other standards, FHIR modular structure enables users to query specific granular data elements, rather than entire documents, offering greater precision and instant access to patient records. On April 5, 2021, the ASTP enacted rules mandating FHIR-based APIs, requiring health IT developers, EMR vendors, and health care providers to adopt standard-based APIs using FHIR to access and share health data efficiently. FHIR adoption is rapidly expanding globally, with strong support from governments, international health organizations, and technology vendors. With FHIR, patients can finally retrieve their data on demand, giving them greater control over their medical information—realizing a key objective of the 21st Century Cures Act.

Lone Custodian

Health data has historically been managed by health care organizations through their Health Information Management (HIM) departments and controlled by the EMR vendors. The quality, accuracy, and completeness of a patient's record have largely depended upon the capabilities and priorities of these institutional custodians.

A 2010 study found that the average patient will see 28.4 different providers over their lifetime [26]. As consumer participation evolves with patients seeking alternative treatment pathways and second opinions, this number is likely to grow. As a result, patient data becomes more scattered across different health systems and EMR platforms.

Meanwhile, a vast amount of valuable nonclinical patient-contributed data (PCD), often not collected in clinical settings, remains outside EMR. This includes data from genomic sequencing, wearable trackers, social determinants of health, remote monitoring devices, patient-reported outcomes, lifestyle data, such as nutrition and fitness, behavioral health factors, family history, symptomatic, mobile app logs, and patient-generated data. Far more abundant than the clinical data captured in EMRs, PCD, much of which is in the possession of the consumer, is increasingly recognized as essential for personalized care, prevention, wellness, and chronic disease management. Studies continue to confirm the importance of health data not included in the EMR [27].

No single health care provider, health care system, or EMR vendor can maintain a complete longitudinal health record (LHR) for a consumer. With HIPAA (Health Insurance Portability and Accountability Act) privacy laws and institutional limitations (Figure 1), health care systems are neither motivated nor incentivized to aggregate, manage, and maintain a comprehensive LHR particularly if data includes genomic, nonclinical, PCD, and wearable data. Regardless of technical capability and well-equipped EMRs, health care organizations will never assume the role of custodian for complete LHRs.

Instead, the consumer is emerging as the only viable steward of their full longitudinal health data—uniquely positioned to manage, integrate, and share across clinical and nonclinical domains. LHRs, which include all USCDI-tagged medical data along with nonclinical and personal health information, will prove immensely valuable for managing and optimizing individual and population outcomes. The consumer is, and will always be, the only custodian of the complete and real-time personal LHR. As such, the aggregation or delegation of their LHR plays a crucial role in empowering providers to apply their expertise more effectively.

Figure 1. Health care system challenges to a longitudinal health record. EMR: electronic medical record; HIPAA: Health Insurance Portability and Accountability Act.

Time and Intent

Despite their education, deep experience, and oath to provide the best possible care, clinicians face constraints: limited time, health care organization incentives, and competing demands. Though no fault of their own, they are overworked and undersupported, juggling large patient loads, administrative duties, fiduciary responsibilities, malpractice concerns, and the pressures of their personal lives. Throughout history, medical professionals have increased the quality and longevity of humans' lifespan through advances in epidemiology, microbiology, vaccination, imaging, molecular biology, therapeutics, such as antibiotics, organ transplantation, and stem cell and gene-based treatments.

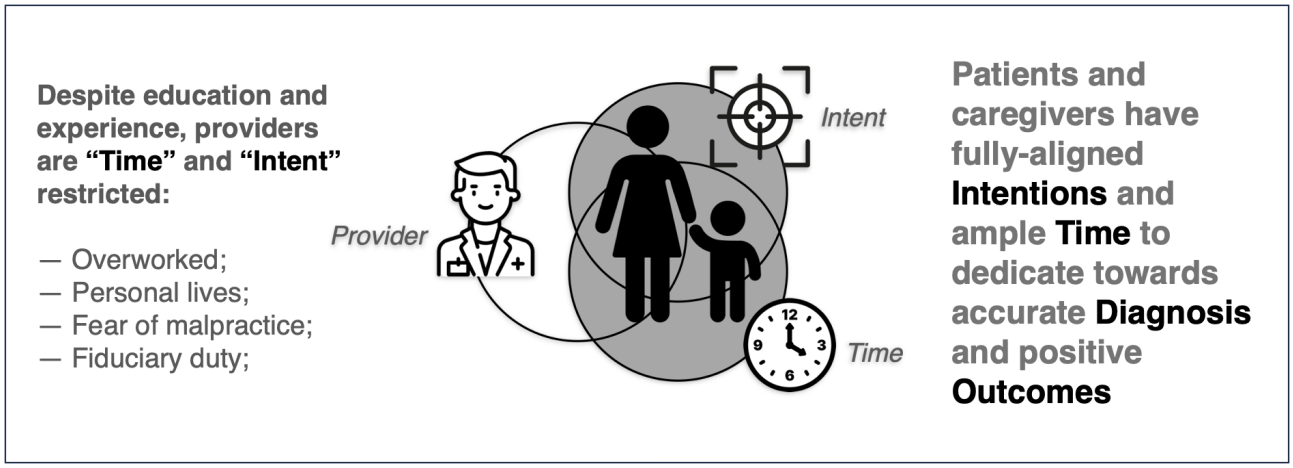
For centuries, patients have been entirely dependent on clinicians' knowledge and ability to diagnose and treat disease. The paternalistic relationship excluded consumers from any meaningful role in their health between encounters. Patient expectations were shaped solely on the last clinical encounter or lab test results and remained unchanged until the next visit.

New Paradigm

Patients and caregivers live with their disease and symptoms 24/7. They have ample time and fully aligned intentions to dedicate to achieving better outcomes. Though patients have no formal medical training or experience, their engagement is invaluable. With access to the same information as medical students and practitioners, consumers can use their time and intent to enhance their health literacy. Open forums, such as PubMed, Google, and Facebook (Meta) groups provide generous helpings of information for consumers to absorb. This knowledge positively impacts face-to-face encounters and demonstrates participatory care, helping achieve accurate diagnoses and optimal treatment outcomes. As consumers increasingly realize their value, active participatory patient

behavior will become more universal and forever change the practice of medicine (Figure 2).

Figure 2. Contextual factors contributing to participatory care.



Principal Responsibility

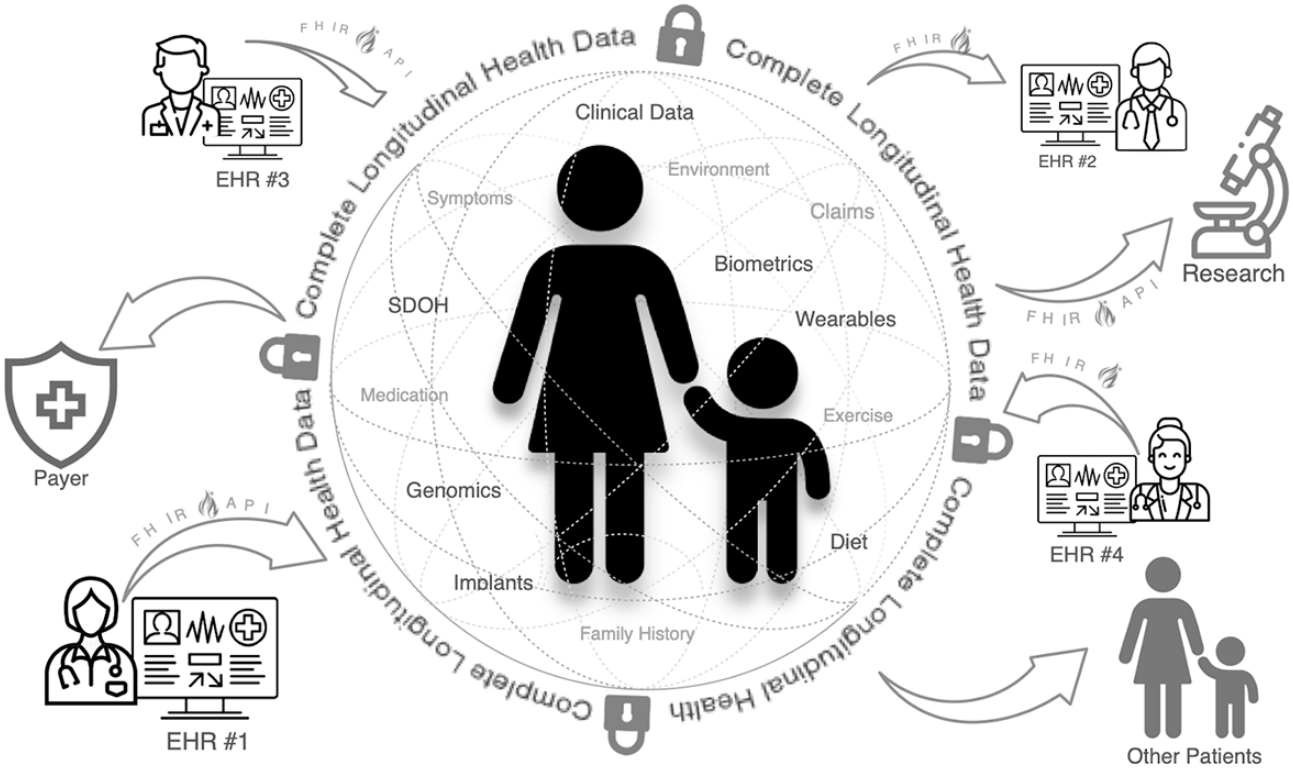
As health care evolves beyond paternalistic models, the intensity and frequency of consumer participation will naturally vary based on individual cognitive capacity, creativity, and motivation. However, regardless of the consumer's level of engagement, or lack thereof, they or their caregiver have the sole administrative responsibility to aggregate and manage their health data. At every state of health and disease, assembling a comprehensive and complete personal LHR will always be consumers' most basic role. While advances in technology, government policy, legacy health care systems, and 3rd party application developers improve data aggregation capabilities, the enduring burden to maintain a complete, accurate, and up-to-date LHR rests with the consumer.

Innovations in data exchange, driven by evolving consumer behavior, ASTP policy, and FHIR standards have introduced the new paradigm of a singular, unified LHR (Figure 3).

For the first time, it is technically possible for patients to consolidate all their EMR, genomic, nonclinical, and wearable data into a central repository for analysis or sharing. Access to complete LHRs allows providers to use their expertise to achieve more positive outcomes. This shift has profound implications. Most importantly, the integration of LHRs with LLMs unlocks the ability to synthesize and interpret exhaustive and up-to-date patient health histories. Given the time and cognitive limitations of humans (clinicians, patients, and caregivers), such analysis would not be feasible without LLMs—making LHRs plus AI essential partners for personalized precision care (Figure 4).

Figure 3. Patient and caregiver participation is crucial, along with government policy and technology standards, to assembling longitudinal health records. FHIR: Fast Healthcare Interoperability Resources; HL7: Health Level 7.

Figure 4. The consumer is the sole aggregating custodian of longitudinal health records consisting of multiple clinical providers and electronic medical records vendors and patient-contributed data, including genomic, mobile, symptom, behavior, and wearable data. API: application programming interfacing; EHR: electronic health record; FHIR: Fast Healthcare Interoperability Resource; SDOH: social determinants of health.



Forever On-Call

While GPT-4 may lack clinical intuition or the real-world experience physicians develop over time, its usefulness is undeniable. Open AI GPT-4 scored 90% [28] on the United States Medical Licensing Examination (USMLE), surpassing the minimum passing threshold for medical students and demonstrating strong medical knowledge application.

AI and LLMs augment clinicians' education and experience and have the potential to enhance clinical decision-making. LLMs facilitate knowledge extension, enabling general practitioners to deepen their understanding of specialty areas and encourage specialists to consider broader perspectives beyond their domain expertise. In doing so, LLMs promote more integrative care.

A growing number of use cases show LLMs' capability to support diagnostic accuracy and treatment recommendations, particularly when provided with LHR datasets. One compelling example involves Courtney Morales Hoffman, the mother of a child who remained undiagnosed after seeing 17 different providers. Her son lost mobility and was failing to thrive, so she turned to GPT-4 for answers [29]. After inputting his health data, she received a possible diagnosis: Tethered Spinal Cord Syndrome. Her son's physician confirmed the diagnosis, leading to corrective surgery. Today, her son is a healthy boy.

Human processing capacity is limited, but LLMs are always available, operating 24/7. They are tireless medical consultants for both clinicians and consumers seeking clarity, analysis, explanation, and insight. LLMs can offer diagnoses and recommend treatments when fed comprehensive LHR datasets. LHR-fed LLMs are poised to revolutionize biomedical research, accelerating discovery and improving outcomes.

Real-World Catalysts

Undiagnosed patients and caregivers like Courtney and her son understand the importance of managing their LHR data and leveraging LLM tools in search of answers. Similarly, rare disease communities, often underfunded and underserved, have long accepted and embraced their participatory responsibility in the absence of formal support.

Patients and caregivers, particularly those navigating and managing congenital or genetic conditions, quickly take proactive roles early in their diagnostic and care journey. These rare disease consumers are more than willing to participate in the limited existing research, grant unfettered access to their EMR data, and often take the lead in fundraising efforts.

A disease is classified "rare" when it affects fewer than 1 in 2000 individuals. Extremely rare diseases are considered ultra-rare if less than 1 in 50,000 are impacted, while hyper-rare conditions occur in fewer than 1 in 100,000,000 people [30]. Some nano-rare diseases are so uncommon that their mutations are unique to a single patient or known to affect fewer than 30 people [31].

Motivated to Share

Rare and undiagnosed patient communities offer demonstrative proof of how consumers manage and share health data in ways that significantly differ from other areas, such as finance, politics, religion, or shopping and commerce. Quite the contrary,

when facing mortality, data sharing becomes a survival strategy, and consumers willingly exchange privacy for insights in hopes of benefiting from more accurate diagnoses and better outcomes.

Most rare diseases are genetic in origin [32], and those living with them are among the most motivated health consumers. The rarer the disorder, the less likely patients will find expertise among their care team. As a result, patients and families often seek out the few specialists and researchers worldwide who focus on their specific orphan disease.

The most highly engaged patients and caregivers are those managing severe, chronic, congenital genetic diseases—particularly those with ultra- and hyper-rare categories. When parents and caregivers learn about their child's life-altering condition, they embrace an elevated responsibility, despite lacking formal medical training or experience. With aligned purpose and ample time, these communities significantly contribute to advancing critical understanding of the human genome and accelerating therapeutic discoveries.

Their efforts exemplify the promise of precision medicine. The study and tailored treatment of severe rare genetic diseases, driven by highly engaged, data-sharing consumers, represent the apotheosis of precision medicine and a roadmap for future advancements in biological understanding.

Shining Example

With little attention and funding for research, and no "magic" doctor or treatment, patients with rare diseases recognize their fundamental responsibility and critical contribution in advancing medical understanding by aggregating and consenting to share their health data. Investigators leading rare disease registries [33] rely heavily on this active patient participation to apply observational methods to expand disease knowledge.

For example, the Cystic Fibrosis Foundation Patient Registry (CFFPR), one of the largest congenital severe rare diseases [34], has operated since 1966. This registry actively engages patients to collect and contribute comprehensive clinical and genomic data to support collaboration with clinicians and researchers. Similarly, registries like DuchenneConnect, focused on Duchenne muscular dystrophy [35], now incorporate nonclinical and wearable technology data to track mobility, physical activity, and respiratory function.

As registries evolve to include exponentially growing sources of nonclinical data, such as wearable trackers, social determinants of health, monitoring devices, patient-reported outcomes, nutrition, fitness, behavioral metrics, family history, symptoms, and mobile health apps—they can become powerful platforms to produce real-world LHR datasets that complement and extend far beyond EMRs alone.

Powerfully Rare

The research funding and attention secured by a single severe congenital genetic rare condition are minuscule compared with support for common conditions, such as heart disease or cancer. However, despite individual rarity, rare diseases collectively affect over 10% of the US population—approximately 30 million people [36]. In 2019, the collective economic implications of rare diseases in the United States reached nearly US $1 trillion, making it one of the largest burdens on our health care system [37].

Today's environment, shaped by the 21st Century Cures Act, technology standards like FHIR APIs, and the motivated behavior of rare disease consumers, affords an optimal ideal landscape to pilot the collection of complete LHRs across an entire disease registry cohort. Equipping researchers with full LHR datasets for all registry participants would confirm the consumer-led data aggregation model and demonstrate the maximum potential benefit of AI in medicine. The most vital and immediate need to help this new paradigm is to design and refine an LHR aggregation infrastructure for one or several congenital genetic rare disease registries. This prototype can then be replicated across the broader rare disease ecosystem—and ultimately benefit all consumers.

AI-Enabled LHR Integration

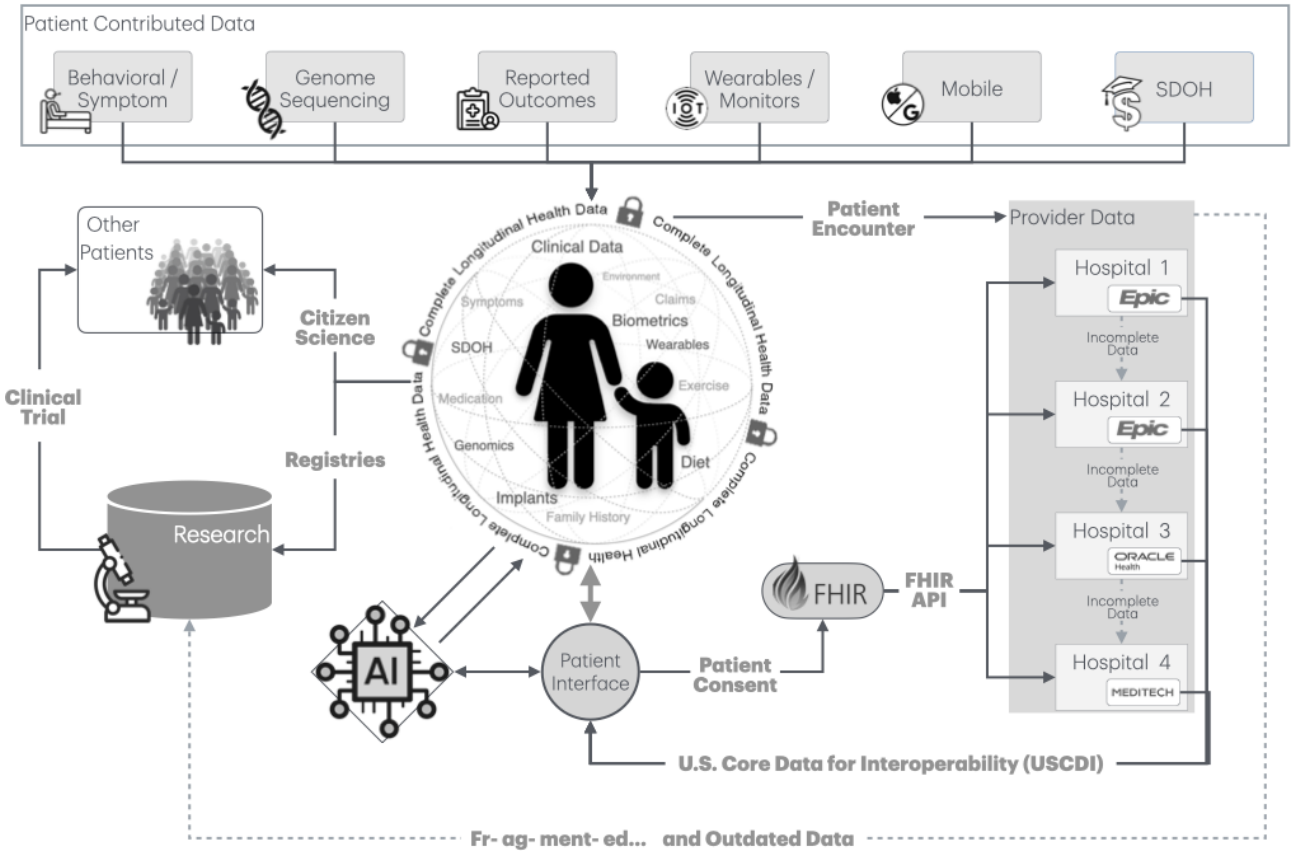
The following highlight steps to pilot AI-enabled LHRs (Figure 5):

1. Demonstrate the future universal participatory behavior. Despite variation in cognitive ability, creativity, and ambition, all individuals share the common and basic responsibility of aggregating and granting access to their health data.
2. Attend to health IT standards and policies. It is critical to identify gaps in access, accuracy, completeness, and enforcement of longitudinal health data. Aggregating LHRs for every participant in a congenital genetic rare disease registry will reveal limitations and discrepancies of legacy "point-in-time" frameworks (eg, C-CDA for HIM requests) and the real-time FHIR-enabled interoperability standard, as promoted by the ASTP.
    a. Leverage the 21st Century Cures Act Electronic Health Information (EHI) export rule. The EHI Final Rule, effective December 31, 2023, requires providers, health IT developers, and EMR vendors to ensure their systems can export complete EHI in a human- and machine-readable format.
    b. EHI exports additional data beyond what is included in the USCDI, such as full protected narrative notes including progress notes, consultation notes, discharge summaries, and other unstructured documentation; billing and claims information; Digital Imaging and Communications in Medicine (DICOM); complete medical history, including past surgeries, inactive medications, discontinued allergies, and previous diagnostic results; device and implant data; and detailed provenance information, such as the data source and the time it was recorded.
3. Ensure data harmonization to leverage comprehensive LHRs. Rare disease registries are perfectly aligned to demonstrate harmonizing nonclinical and wearable data with multiple EMR data sources. For example, storing harmonized LHRs in a graph database using nodes and edges will allow for semantic queries of data for both

humans and machine algorithms to provide better clinical care and research.

4. Optimize the value of using LLMs in health care. With comprehensive LHRs for an entire disease cohort, investigators can feed AI robust, real-world datasets to provide insights to complement their pretrained open data. This will help providers and researchers gain maximum insight and explore the upper limits of AI value. Knowing all available data are being considered frees providers to quickly iterate LLM prompt queries. Society can realize both limitations and power AI to augment clinical reasoning.
5. Establish a human custodian interface. Knowing consumers are at the center of translational science, the registry will provide a participant-focused (custodianship) interface. This can support data aggregation, a pipeline to experts, and research—enhanced by LLM analytics personalized for each user. A participant experience feedback loop will ensure optimal and ongoing participant engagement.
6. Formalize data ownership and consent frameworks. The participant interface will have a beneficial consent, access, and data ownership framework. This not only provides precision medicine capability for practitioners and research insights but also fuels access to data for unaffiliated clinical trials and population health studies. Ultimately, a data chain-of-ownership infrastructure will reshape the landscape and speed of research and drug discovery.
7. Rare disease registry proof of concept. Participants in rare disease registries serve as early adopters, using individual EHI exports for a comprehensive view of each patient's medical history, going beyond minimum data required by the USCDI. This approach ensures that all relevant patient information is accessible. Applying this method within a rare genetic registry can help ASTP shape future versions of the USCDI and support enforcement of information blocking policies.

Figure 5. Sociotechnical framework of consumer-driven longitudinal health data aggregation for precision and translational medicine. AI: artificial intelligence; API: application programming interface; FHIR: Fast Healthcare Interoperability Resource; SDOH: social determinants of health.



Where to Start?

Of the approximately 7000 rare diseases recognized by the US Food and Drug Administration [38], less than 20% [39] have dedicated patient registries. Unlike the more common conditions, such as cystic fibrosis or muscular dystrophy, ultrarare communities tend to be tightly knit, with higher levels of intimate involvement and familiarity. Capitalizing on this advanced participatory behavior, a well-established, highly active registry for an existing ultrarare congenital genetic rare disease provides an ideal use case to demonstrate the power of LHR aggregation.

Diamond Blackfan Anemia (DBA) is a severe, chronic congenital blood disorder that affects fewer than 1 in 200,000 live births [40]. Caused by 28 known gene deletions that impair red blood cell production in the bone marrow, treatments include blood transfusions, stem cell transplantation, and corticosteroid therapies.

The Diamond Blackfan Anemia Registry (DBAR) [41], established in 1993 by Dr. Jeffrey Lipton [42] and Dr. Adrianna

Vlachos [43] and operated at Northwell Health, is a premier example of a reputable rare disease infrastructure. Boston Children's Hospital, St. Jude Children's Hospital, Memorial Sloan Kettering Cancer Center, Children's Hospital of Philadelphia, and the University of Chicago Medical actively contribute to DBA research and treatment. These prominent institutions (and collaboration with other major research centers) bring vital expertise in genetic mutation, bone marrow failure syndromes, hematologic malignancies, pediatric oncology, stem cell transplantation, and gene therapies, making them valuable partners in DBA treatment strategies and novel discoveries.

The DBAR is unique in the rare disease registry realm, with an exclusive focus on collecting disease-specific longitudinal and genetic data. Like CFFPR, DBAR's narrow attention allows for a deep understanding of a single disorder; however, DBAR serves a smaller patient population, making participation in the community more personal and likely to occur. DBAR collaborates closely with the Diamond Blackfan Anemia Foundation (DBAF) [44], founded in 1994, to engage patients and families throughout the registry and research process.

The DBAF plays a critical role in raising awareness, connecting patients with expert providers, promoting initiatives to improve care and outcomes, and advancing research funding. They are a pioneering example of patient advocacy for rare disease, encouraging family participation in research and sharing real-world lived experiences. DBAR and DBAF's strong reputation in patient engagement fosters widespread participation and ensures that all efforts fully align with their community's needs and priorities.

DBA's severe and ultrarare environment offers a perfect opportunity to demonstrate emerging consumer-driven, participatory behaviors and prototype the aggregation of comprehensive LHRs. With a long history of trust and success, the DBAR and DBAF registries and networks provide a manageable sized cohort and setting to pilot data aggregation strategies, identify technology and policy needs, and demonstrate how LLMs can advance DBA knowledge and shorten the diagnostic odyssey for undiagnosed patients.

Significant Impact

By perfecting an LHR data aggregation framework—including nonclinical data, wearable inputs, and high-fidelity genomic tools, such as nanopore sequencing [45], and equipping DBAR with foundational and disease-specific LLMs, we can expedite insights into congenital hypoplastic anemias. More importantly, this refined DBAR-LHR model offers a scalable blueprint for all rare diseases, enabling dramatic improvements in outcomes, accelerating research, and potentially reducing the $1 trillion annual health care burden associated with rare conditions.

Major Shift

If we accept the principle that comprehensive data improves outcomes [46], we must also recognize that patients and caregivers are the only consistent provenance (source) and legal owners of Longitudinal Health Records. No health care system, business interest, or government entity will generate LHRs comprehensively. Thus, the pathway to leverage 60 Zettabytes of health data already collected for greater diagnostic accuracy and appropriate treatment depends upon consumer agency and AI collaboration.

Immediate Focus

We have the technology and the tools. We have the policy. Now we must use participatory behavior. No one cares as much as patients! Proving and scaling this participatory model is the most urgent priority.

The adoption of consumer-led LHR aggregation for rare disease will spearhead the inevitable paradigm shift. The administrative, participatory behavior, and technical foundations pioneered here will form the sociotechnical infrastructure needed for general health management and chronic and rare disease care to follow—transforming a US $13.1 trillion [47] health care industry and the health of 8 billion people on the planet.

Conflicts of Interest

None declared.

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Abbreviations

AI: artificial intelligence
ASTP: Assistant Secretary for Technology Policy
C-CDA: Consolidated Clinical Document Architecture
CFFPR: Cystic Fibrosis Foundation Patient Registry
DBA: Diamond Blackfan Anemia
DBAF: Diamond Blackfan Anemia Foundation
DBAR: Diamond Blackfan Anemia Registry
EMR: electronic medical record
FHIR: Fast Healthcare Interoperability Resource
HIPAA: Health Insurance Portability and Accountability Act
HL7: Health Level 7 International
LHR: longitudinal health record
LLM: large language model
ONC: Office of the National Coordinator for Health Information Technology
PCD: patient-contributed data
USCDI: United States Core Data for Interoperability
USMLE: United States Medical Licensing Examination

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Generative AI as Third Agent: Large Language Models and the Transformation of the Clinician-Patient Relationship

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Abstract

The use of artificial intelligence (AI) in health care has significant implications for patient-clinician interactions. Practical and ethical challenges have emerged with the adoption of large language models (LLMs) that respond to prompts from clinicians, patients, and caregivers. With an emphasis on patient experience, this paper examines the potential of LLMs to act as facilitators, interrupters, or both in patient-clinician relationships. Drawing on our experiences as patient advocates, computer scientists, and physician informaticists working to improve data exchange and patient experience, we examine how LLMs might enhance patient engagement, support triage, and inform clinical decision-making. While affirming LLMs as a tool enabling the rise of the "AI patient," we also explore concerns surrounding data privacy, algorithmic bias, moral injury, and the erosion of human connection. To help navigate these tensions, we outline a conceptual framework that anticipates the role and impact of LLMs in patient-clinician dynamics and propose key areas for future inquiry. Realizing the potential of LLMs requires careful consideration of which aspects of the patient-clinician relationship must remain distinctly human and why, even when LLMs offer plausible substitutes. This inquiry should draw on ethics and philosophy, aligned with AI imperatives such as patient-centered design and transparency, and shaped through collaboration between technologists, health care providers, and patient communities.

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KEYWORDS

artificial intelligence; large language model; generative AI; healthcare; empowerment; patient-clinician relationship; patient engagement

Introduction

The integration of artificial intelligence (AI) into health care has rapidly transformed various aspects of medical practice, from diagnostics to treatment planning. The emergence of generative AI, particularly large language models (LLMs) that can interact and communicate with humans in a personalized and empathetic way, heralds what some commentators have termed "relational AI," [1] with LLMs now functioning increasingly like "agents in the clinic" interposing themselves into patient-clinician interactions [2]. It is not yet clear if LLMs will act as facilitators—enhancing communication, supporting decision-making, and strengthening the clinician-patient relationship—or as interrupters, disrupting natural interactions, creating friction, or undermining trust. This paper explores patient and clinician perspectives on that question and proposes areas for inquiry when researching participatory medicine in an AI-enabled clinical relationship.

Patients have long sought medical information and support outside of traditional clinical settings, and since the advent of the internet, have often turned to online resources, listservs, and virtual communities [3]. The emergence of powerful and easily navigated search engines, followed by Web 2.0's digital and social networking platforms, amplified this trend, offering patients unprecedented access to medical knowledge and peer-to-peer platforms for sharing personal medical information and clinical experiences [4]. The rise of internet use for health information and self-diagnosis fueled a movement of e-patients [5] even as medical professionals raised concerns regarding the impact of "Dr. Google" on patient-clinician relations. The ship is sailed: as many as half of Americans seek health care information online for themselves or others, without evidence of negative effects on health outcomes or the patient-clinician relationship [3,6,7].

Legislative and technological developments have given new data and scope to the e-patient movement. More than 1 in 3

Americans now own a wearable or portable device that collects information about steps, sleep, blood pressure, heart rate, or other indicators of health or fitness [8]. The 21st Century Cures Act has required health systems to adopt information standards allowing data export and interoperability with other systems and mandated that patients have electronic access to their health information at no cost [9]. Advocates from the OpenNotes movement, which promotes trust-building through the sharing of medical records between health care providers and patients, have heralded these developments as key enablers of a shift to democratized, person-centric, and participatory health care [10,11]. If, as the e-patient movement suggests, data is power [12], then new types of data—and new ways of collecting and accessing it—can further empower patients. LLMs that allow patients and providers to organize health information, draw insights from it, and increasingly engage in iterative "prompting" with personal health data add a new layer to this already intricate landscape.

Building on the framing of LLMs as a "relational" technology, this paper focuses on their impact on clinician-patient relations. LLMs have been simultaneously hailed as a "turning point in patient power" [13] and as an unreliable, inconsistent, and unaccountable tool that is dangerous for medical use [14]. The degree to which LLM use will be acknowledged during a clinical encounter, and whether or not LLMs are a facilitator of or impediment to therapeutic alliance, are open questions. Writing from our perspectives as patient advocates, computer scientists, and physician-informaticists, we explore various potential roles for LLMs in the clinical exchange. We propose areas of research aimed at better understanding current attitudes toward and uses of LLMs, while moving us toward a collaborative use that could enrich therapeutic alliance and health outcomes.

Patient and Personal Care Team: The Rise of the AI Patient

Even before LLMs, patients regarded AI use in health care with ambivalence. Six in ten said they would be uncomfortable with their provider relying on AI in providing their care. A nearly equal number thought that using AI to diagnose disease or recommend treatment would make relations with clinicians worse. At the same time, a majority believed racial bias would be decreased if AI were used more to do things such as diagnose disease and recommend treatments for patients [15].

LLMs, and the associated ability of patients to move from passive objects of AI to more active users, may change the calculus. We join those patient advocates who see LLMs as a new and important tool in health care and self-care, particularly in addressing the gaps in access and communication that often plague the current health care system. Chat interfaces like OpenAI's ChatGPT have opened options previously unavailable to the e-patient, lowering the technology and language literacy barrier, allowing patients to ask questions in multiple languages, generating responses tailored to different audiences and responsive to requests for clarification or further elucidation. By synthesizing complex, highly technical health-related literature or multiple examination results into understandable summaries for a range of educational levels, LLMs have become valuable tools for participatory medicine. For patients and their families, these technologies facilitate a fundamental and empowering shift in the flow of information, moving from patients to doctors rather than the other way around [13]. If electronic medical records and the internet enabled the rise of the e-patient, LLMs are now driving the rise of the AI patient [16].

As a caretaker for his elderly father and a patient with a genetic heart condition, one of us (HdOC) relies on LLMs for various tasks, including preparing for appointments, organizing health information, weighing the pros and cons of different medical interventions, and summarizing medical notes for family members not fluent in English. HdOC's recent leveraging of LLMs to navigate his father's complex medical needs demonstrates the technology's potential to empower informed patients and bridge information gaps (Textbox 1). More generally, LLMs are already being used by patients and by the families and caregivers integral to their care to simplify and improve understanding of informed consent forms, to parse complicated communications from insurance companies or a medical note, to better understand laboratory notes, and to translate any and all of the above into different languages [17,18].

While all patients have the potential to increase their sense of agency and engagement in their health care, not all have the technological literacy to use LLMs to advance participatory medicine. AI may thus exacerbate existing health disparities and create a digital divide between those with internet access and those without, and between those who have or who lack the skills and resources to use AI tools effectively. Former Google CEO Eric Schmidt, speaking to Stanford students at a 2024 forum on AI's likely impact on global development, offered a prognosis relevant here: "the rich get richer, and the poor do the best they can" [19]. For example, the size of the "context window" that determines the amount of information that an LLM can take in is expected shortly to grow to more than a million tokens, or the equivalent of 750,000 words. This massive expansion, a 45-fold increase from earlier models such as GPT 3.5, will mean that those who can pay for premium LLM services will receive more personalized and contextualized answers. Those relegated to smaller-capacity, free LLM services will not. Even use of freely available tools will require understanding of multiple dimensions: English proficiency, medical literacy, numeracy, and technical and critical thinking skills to help them make informed decisions in an increasingly AI-mediated health care landscape [20].

Textbox 1. Case example.

One of us (HdOC) faced a challenging situation when his older adult father developed a severe pruritic rash, and the earliest available dermatologist appointment was months away. Drawing from his experience using large language models (LLMs) for his own health care, HdOC turned to various publicly available chatbots, including Anthropic's Claude 3 Opus, Perplexity AI's Perplexity, and OpenAI's GPT-4o, for counsel on his father's condition. He meticulously collected his father's medical records by downloading clinical notes from past clinical encounters and accessing blood test results (with permission) through his father's electronic patient record portal. Armed with these records, including laboratory results, recent clinical notes, and photos of the rash, HdOC then used multiple LLMs to analyze these inputs. The models provided differential diagnoses, recommended actions, and identified a potential link between the rash and his father's underlying chronic kidney disease.

HdOC then developed a multipronged treatment plan based on LLM recommendations. The plan included strict dietary adjustments to manage kidney function, reducing shower frequency and temperature to prevent skin dryness, aggressive moisturizing with fragrance-free products, and the application of topical corticosteroids to control itching and inflammation. HdOC also used the LLMs to translate this information into Portuguese, ensuring that HdOC's father could understand the proposed treatment plan and participate in the decision-making process.

By comparing outputs from different LLMs and validating AI-suggested interventions through online searches and email correspondence with medical professionals, HdOC implemented a care plan that significantly improved the rash within 10 days. By the time the appointment with the dermatologist arrived, the rash had mostly cleared up. Strategic use of the tools enabled an approach that transformed the traditional patient-clinician dynamic into a more equal partnership, correcting power and information asymmetry, and ultimately leading to better outcomes and enhanced patient satisfaction.

Prompts and outputs from LLMs are included in Multimedia Appendix 1.

While the use of an LLM as an ally or "doctor in your pocket" holds great potential, integrating LLM insights into the patient-clinician relationship remains a challenge. Just as the e-patient movement emphasized patient control over "our data," AI patients are likely to support LLMs for personal health use but may be wary of their adoption by institutions, health systems, or commercial entities. Comfort about when or if LLMs are used in the diagnostic and care pathway may vary by patient and condition: surveys of patients asked to consider AI use to augment or replace physician input in the years before LLM availability, for example, found significant differences in concerns about privacy and AI-assisted diagnosis among those with chronic or acute conditions, as well as variation in understanding of AI function by age and demographics [21]. Patients with rare diseases and their family members today, for example, are significantly more likely to use LLMs for health assistance than other patients [22]—we do yet know how this impacts their interactions with clinicians, or if it will positively impact their care. Diagnostic errors with general purpose LLMs such as GPT (OpenAI), Llama (Meta AI), or Gemini (Google LLC) are a particular area of concern—multiple studies show that while these models can answer examination questions or analyze clinical vignettes correctly, they often produce diagnostic conclusions or responses at variance with clinician recommendations when confronted with real-life, "noisy" medical data, and reproduce racial or gender biases and stereotypes adversely impacting diagnosis [23-27].

Usage transparency—knowing when and how LLMs are being used by any part of the health care system—is also likely to be key to patient trust. Patients discern whether medical professionals or health systems deem them worthy of enough respect to disclose when AI has been deployed in their care and to inform them of potential limitations [28]. A patient at a recent advocacy forum shared her experience with a clinic representative named Jennifer, with whom she had been messaging about medication refills and scheduling an appointment. Jennifer was helpful, kind, and friendly, even engaging in casual conversation about personal topics. But when the patient arrived for her appointment and asked to say hello to Jennifer, she was surprised to learn that Jennifer was a chatbot—not a real person (personal communication, 2024). Many patients express discomfort when an LLM is used to replace a genuine human connection. But is the discomfort arising from being misled, or does it stem from deeper existential concerns about forming relationships with a nonhuman entity? Can these qualms be overcome? And should they be?

Keyboard Liberation or Loss of Human Connection?

Promise and Pitfalls

For many patients and clinicians, the most immediate use case for LLMs is what Eric Topol famously termed "keyboard liberation," [29] reducing time spent feeding information into electronic health records (EHRs) and increasing opportunities for interaction. LLM-driven scribing systems, which listen to patient-clinician exchanges and automatically generate large parts of clinical notes and after-visit summaries, are increasingly deployed in well-resourced, AI-capable health care systems [30]. Early reports are that both patients and clinicians feel more connected when the clinician can shift attention from the keyboard [31]. By taking over rote administrative tasks and allowing clinicians to shift their focus from screens back to patients, the best-case scenario is that LLMs will free up clinicians to practice "at the top of their license," reducing clinician burnout and improving patient experience [32,33].

The same advances that promise liberation, however, may also bring unanticipated and undesired shifts in roles. For nearly a decade, analysts have debated whether various physician roles—from radiologists to primary care providers—will be needed at all in an AI-enabled future, or whether replacement with AI-enabled avatars could reduce the burden and increase health care delivery [34,35]. Current LLMs remain vulnerable to hallucinations, errors of fact or reasoning that make the elimination of a human in the loop inadvisable. Performance can be improved through human correction (eg, reinforcement learning through human feedback), and through the fine-tuning of smaller, more health care–focused models by supplementing their built-in knowledge with a connection to external medical databases and peer-reviewed literature. Whether this method—known as retrieval-augmented generation—will

improve LLMs to allow for unsupervised diagnosis remains uncertain.

The risk that LLMs will eclipse humans in the clinical encounter is a concern even when clinicians are present. Analysts have warned that as health systems increase their use of LLMs, human clinical skills may degrade over time, particularly as LLMs ingest AI-generated data for training, creating a self-referential and increasingly machine-driven learning loop [14]. Automation bias—the belief that the machine-generated insights are more authoritative than they actually are—is another concern raised by those analyzing the potential impacts of physician use of LLM-generated notes in the EHR [36]. The same bias may apply to patients using LLMs to organize and analyze medical information.

Finally, LLM recommendations may add moral injury to the clinical encounter. Managed care has for some time required physicians to play a dual and conflicted role in the health system, tasked both with protecting patient well-being and achieving cost containment or other health system priorities [37]. It is easy to imagine LLMs trained by payors or health systems mandating that clinicians adhere to algorithmically determined actions even when these conflict with their clinical judgment on what is best for patient health.

Strengthening the Human in the Clinical Exchange

LLM use has sharpened longstanding questions about which qualities in care are considered essentially human, and how these impact the patient-clinician relationship. On the one hand, LLMs have highlighted the patient view that human clinicians might benefit from their own "fine-tuning": in a study comparing physician and AI chatbot responses to questions on a public forum, patients rated the AI responses as more empathetic [38]. However, critics argue that such expressions amount to "artificial empathy"—a superficial simulation rather than a genuine recognition of patient worry or suffering [39]. Just as selecting the correct answer on a multiple-choice medical examination cannot replace a seasoned clinician's intuition or ability to recognize subtle patterns [40], an empathetic-sounding reply does not equal the deeper understanding of a patient's distress—or sensitivity to the moral and cultural values that shape appropriate response—that defines authentic human empathy in care.

What do patients value? Busch et al [41] conducted a meta-analysis of studies examining what patients and caregivers regarded as central to humanistic exchange in clinical encounters. They found that a majority highlighted 6 elements. Each raises questions about whether LLMs, regardless of their command of medical facts, will be able to reproduce these elements or fall short (Textbox 2).

Textbox 2. Key elements of humanistic care: the patient's view.

While competence in diagnosis and treatment is a key concern, many other factors also determine what patients and caregivers value in care. A meta-analysis by Busch et al [41] found that a majority identified the 6 elements below as key to humanistic care. Each suggests questions about how LLM use might facilitate or impede them.

1. Empathy. This extends beyond the clinical encounter to include genuine, emotionally engaged awareness of patient or caregiver experience outside the clinic, and clinician openness in learning more about the complexity of the patient's point of view [42].

2. Respect for patients' (and caregivers') dignity, uniqueness, individuality, and humanity. In addition to respectful care delivery in the clinical exchange, this includes attention to prevention and treatment in the context of the patient's life course, and a focus on individuals' (and caregivers') preferences and values [41].

3. Relationship bonding. Additionally referred to as therapeutic alliance, this is a shared sense between clinician and patient that affirms the collaborative nature of the relationship, shared emotional bond, and agreement on treatment goals and tasks [43].

4. Respect for patient autonomy and involvement. This includes creation of an environment where patients (and their caregivers) feel safe expressing their concerns, or disagreeing with or exploring alternatives to clinical recommendations [44]

5. Communication. In addition to clear verbal communication, this includes nonverbal communication—tone of voice, eye contact, and facial expressions, as well as things such as examination room characteristics, touch, interpersonal distance, and clinician clothing, gestures, and posture [45].

6. Patience and commitment. While these are difficult to define, both include care that allows time and interest in patient engagement during the clinic visit and beyond, without patients feeling rushed or dismissed and with a sense of clinician interest in patient progress over time [41].

LLM as Third Agent in the Clinical Encounter

Evolution of the Doctor-Patient Relationship

The doctor-patient relationship has historically been seen as the bedrock of medicine: even now, while the patient may have family caregivers and the clinician may practice within a clinical care team or health system, the direct, one-on-one human connection between patient and clinician remains an ideal. In this model, the doctor is a trusted confidante whose role as a medical and even moral adviser to the patient has moved some analysts to describe the doctor-patient relationship as similar to that of a parent and child [46,47].

Medical historians note that this idealized view of the family doctor was already out of date for much of the 20th century, even as it remained the dominant cultural narrative [48]. By the 1990s, the hallmarks of that relationship—physicians as carers for the whole family, and with freedom to act as they saw fit to safeguard patient health—were largely no longer in place. The growth of managed care, capitation, and other health system changes contributed to this shift. Changes in patient self-concept and advances in digital technology—including online medical information platforms, increased patient access to their own

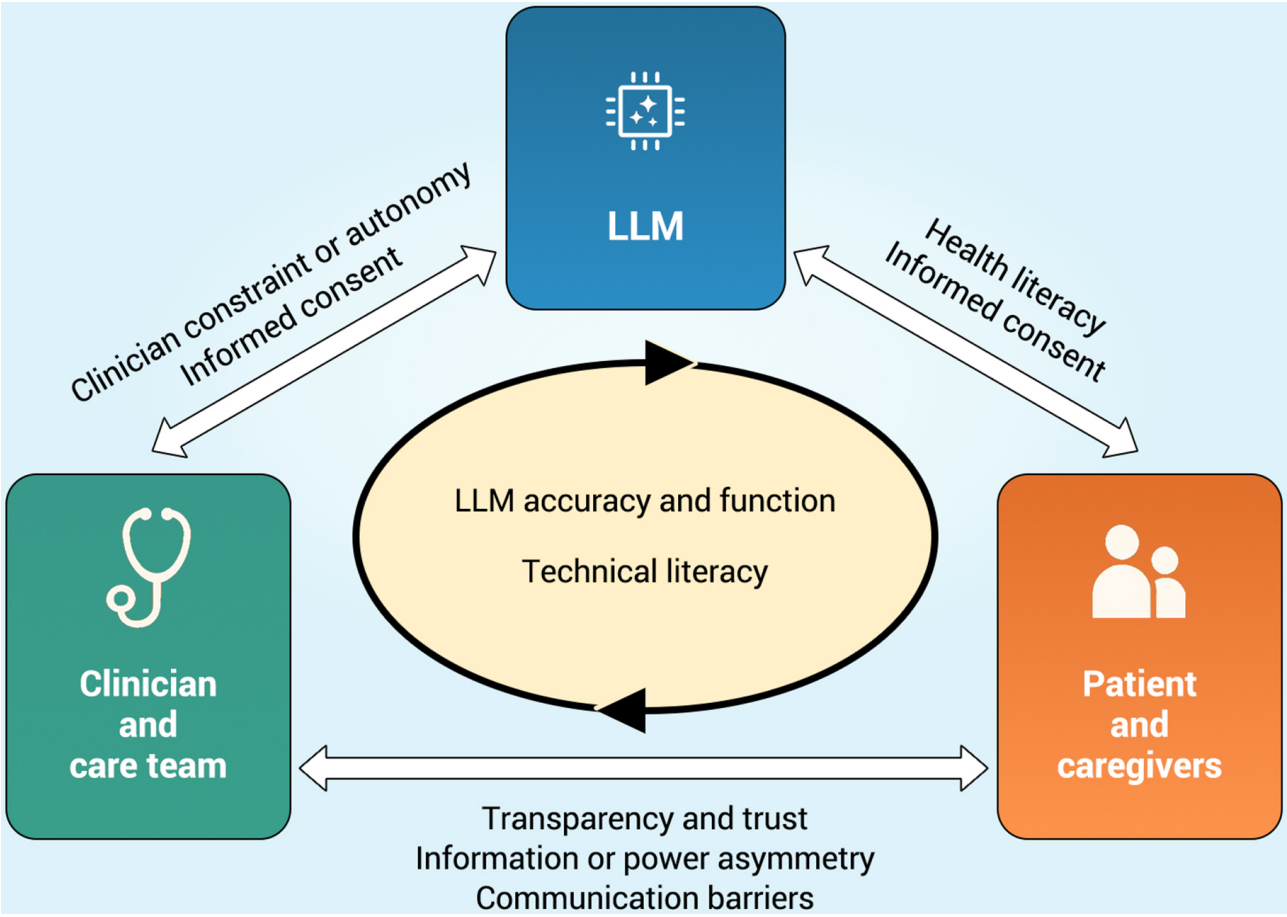
electronic medical records, and the overall movement for patient self-advocacy—further accelerated the transformation [37,49-51].

New Trilateral Framework

LLMs now introduce a new, third agent, shaping communication, understanding, and connection between patients and caregivers and their clinicians. We present a framework for describing and analyzing this new interaction, in which patients (and their surrogates) as well as clinicians at all skill levels avail themselves of the power of LLMs to review background information, secure diagnostic or therapeutic assistance, or navigate choices.

Figure 1 illustrates the current state of this new trilateral (3-sided) interaction. Each "corner" of the triangle represents an actor participating in the exchange of information. Two corners are inhabited by human actors: patients and their caregivers, and clinicians and clinical care teams. The third corner is now inhabited by LLMs, which are used by both clinicians and patients to generate content, analysis, and recommendations. Between these corners are "edges" representing interactions between humans and machines as well as between human actors.

Figure 1. Trilateral interaction framework—LLMs as a third agent in the patient-clinician relationship, and factors mediating exchange. LLM: large language model.



Accuracy of LLMs and the knowledge required to use them are factors that impact all dynamics, and so are at the center of the diagram. Other elements mediating the nature of the interactions are noted along each edge of the clinical exchange. For clinicians, LLM use may be constrained by the permissions or restrictions imposed by the system in which they work. For patients and caregivers, health literacy—including the ability to detect likely hallucinations or assess the reliability of cited sources—will impact both the use and usefulness of LLMs. Factors that have shaped clinician-patient relations since well before the LLMs remain relevant and are noted underneath the arrow indicating interaction between physician and patient, including power and information asymmetries, trust, and the quality of communication.

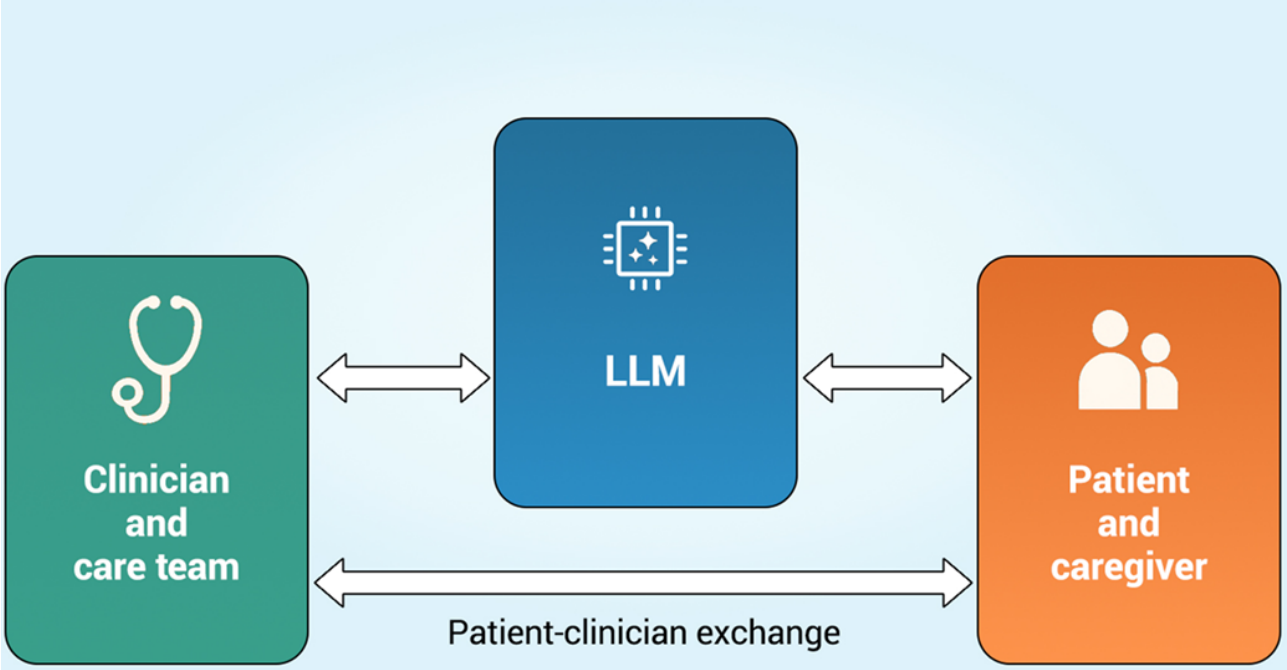
As LLMs currently play a limited role in generating direct communication between physician and patient, nothing links the LLM directly to the arrow representing doctor-patient exchange. While some health systems are deploying AI-generated "smart replies" to patients, these are generally only for routine matters such as scheduling of appointments, prescription refills, or the like, and only after clinician review and approval. A recent study of such AI-generated replies has found that clinicians deemed only 20% of drafts usable [52]. For their part, some "AI patients" have also begun to use LLMs to compose or clarify communications to clinicians, or to help raise the possibility of new diagnoses or course of treatment [53]. A paramount concern is how these trilateral interactions will impact patients' and clinicians' sense of their own agency and trust in other humans, and in the overall health care system.

LLM as Interrupter?

LLMs can expand capacity across a range of health care actors, delivering new knowledge, predictive insights, or recommendations to patients and their families, as well as to physicians, nurses, physician assistants, and pharmacists. As noted, although the multilingual translation capabilities of LLM-based chatbots have not been fully evaluated for medical accuracy or tested with non-English prompts, they are likely to improve comprehension in families where patients or caregivers are not native speakers.

This generative power, however, may diminish or interrupt humanistic exchange. As LLMs improve their capacity to generate communications without human supervision or refinement, it is not difficult to imagine health systems using them as a substitute for, rather than a facilitator of, human-to-human interactions (Figure 2). In some cases, the AI models—trained by health systems—may have goals that differ from those of doctors, leading to recommendations that prioritize cost saving over care, or that are insensitive to patients' moral or cultural values. Patient use of smartphone photos and LLMs for self-diagnosis of dermatological conditions, or use of ChatGPT to diagnose cause of stomachache or cough without consultation with medical professionals [6,54], represents present-day scenarios where the LLM, functioning as a "doctor in your pocket," is less a facilitator of exchange between patient and clinician than its interrupter [6,55].

Figure 2. LLM as an interrupter in clinician-patient interaction. LLM: large language model.



Reductions in human-to-human exchange risks loss of the therapeutic alliance, sense of shared purpose, respect, and connectedness that defines humanistic care. As noted in the anecdote above, where a patient had been interacting with an LLM without knowing it, this framework also suggests the need for new ethics governing trilateral, AI-involved medical exchange.

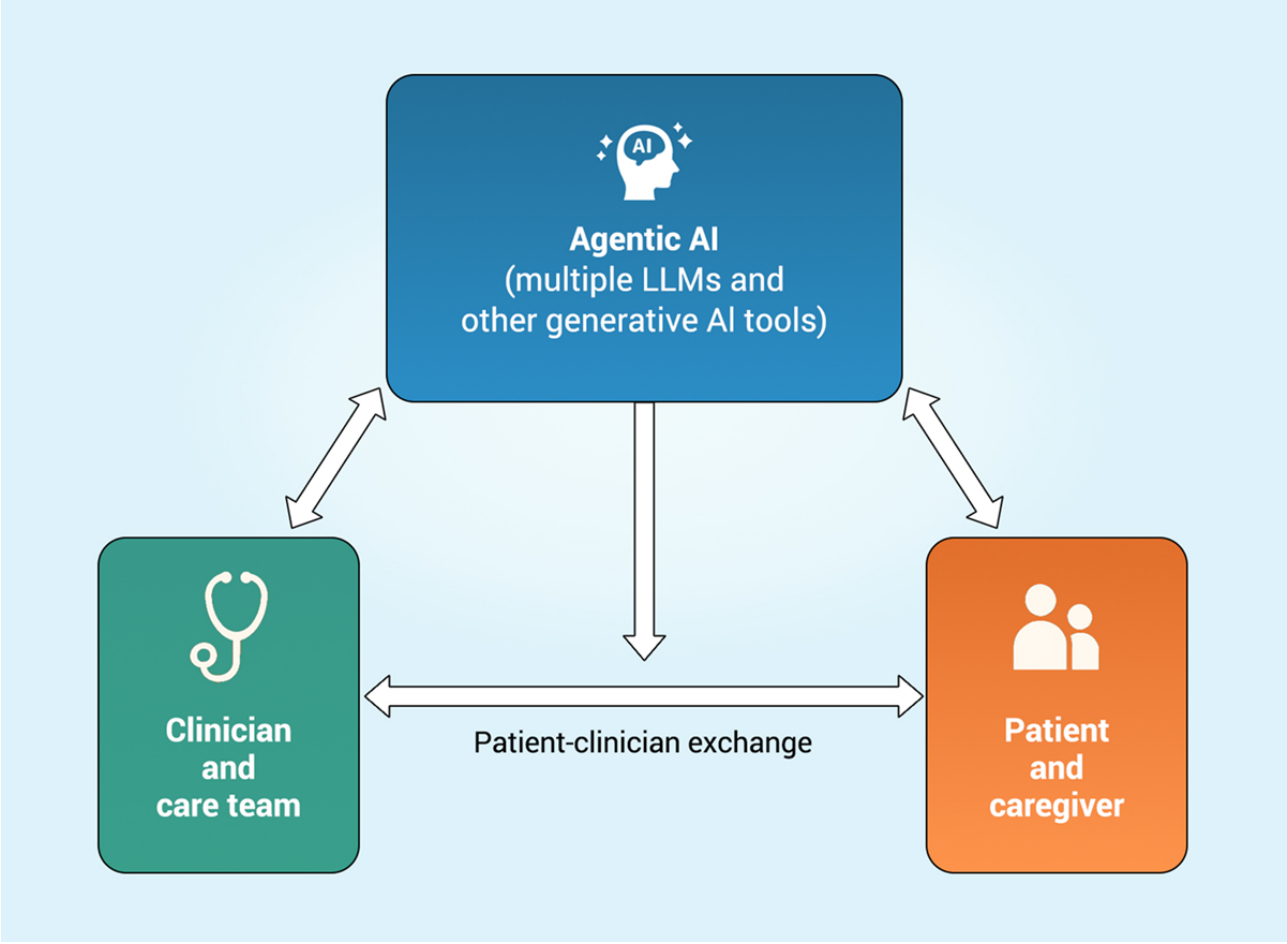
The health impact of this blurring of boundaries between human and machine and the diminution of human interaction is not yet clear. LLMs are evolving, and their power to simulate human relations raises the question of whether machine-generated therapeutic alliances might be as "good" in some practical sense as those created through human interaction. Might generative AI someday reproduce all the qualities in Textbox 2? Older adult Japanese patients have experienced decreased loneliness with therapeutic robot pets, such as small mechanical seals [56], and children with developmental difficulties have found benefit from robot playmates [57]. Generative AI may possess similar or greater powers of comfort. At the same time, as psychiatrist and medical anthropologist Kleinman [58] reminds us, caregiving is relational and reciprocal, including both a range of physical acts—touch, embrace, lifting, steadying, toileting, and more—as well as the way we look at another human being, receive their gaze, experience a quality of voice or physical presence as an expression of solidarity and moral support. For Kleinman and countless patients and families, these essential elements of human care had become mechanized and inauthentic in much of modern health care even before the advent of the LLM. The ineffably human dimensions of care—moments of connection, physical presence, deep empathy, and moral solidarity—are unlikely to be replicated by even the most sophisticated language models, no matter how well-prompted or finely tuned.

Longer Term: Agentic AI as Ally or Facilitator?

Generative AI is already evolving beyond prompted responses from chatbots to enable what is termed "agentic AI"—systems capable of initiating autonomous action in the virtual and physical world, potentially serving as loyal assistants while preserving human agency. In this scenario, AI can become allies for clinicians, patients, and their respective care teams, facilitating rather than replacing their essential partnership (Figure 3). Agentic AI is assisting in mediating communication

but is not eclipsing human exchange. Clinicians and computer scientists working with them have already begun discussion of agentic "AI teammates"—that is, tools to enhance decision-making capacity, parsing clinical records, initiating routine tasks such as prior authorizations, assessing medication interactions, and recommending treatment regimens or preventive strategies tailored to individual patient needs [59,60]. These scenarios, however, have tended to omit attention to patients and their caregivers, for whom agentic AI could similarly serve as a navigator and advocate, organizing clinical records and synthesizing data and medical knowledge, illuminating health determinants and advisable courses of action.

Figure 3. Agentic AI as a facilitator between clinician and patient. While clinicians and patients both use agentic AI, humanistic exchange remains robust. AI: artificial intelligence; LLM: large language model.



Agentic AI will represent an evolution beyond current LLM capabilities, joining a range of AI tools to initiate actions autonomously according to tailored parameters. Unlike today's LLMs, which primarily generate text in response to user queries, agentic AI systems will learn from patterns of use, anticipate needs, and act proactively. For example, they might autonomously organize clinical data, flag potential drug interactions, or offer unprompted suggestions or questions for patients and providers to consider in recommending or adjusting treatment regimens, preventive strategies, or diagnoses. AI agents may also autonomously carry out actions such as typing into a computer or clicking on buttons (called "computer use") [61]—for example, submitting a request for a prescription renewal, contesting the denial of an insurance claim, or changing the alert settings for a continuous glucose monitor.

Agentic AI will also help patients advocate for themselves, recommending strategies to increase patient independence or preferred approaches to address health challenges, while identifying attempts by health care or insurance systems to limit patient choice or impose unwanted treatment pressures. For physicians, AI agents could similarly be tailored or trained to their clinical preferences and style, drawing on lessons from experiences with particular patients and improving their ability to tailor both their communication and approaches to care. In this vision, both patients and clinicians may come to view their AI tools, implicitly or explicitly, as "theirs," that is, trained by them to serve their specific interests. The embedding of agentic AI in the clinical relationship could nonetheless align patient and clinician in working toward shared outcomes and improved health.

Generative AI for Participatory Medicine: Areas for Inquiry

LLM Use, Function, and Safety in the Clinician-Patient Exchange

The newness of generative AI as a third agent in the clinician-patient relationship raises multiple questions, as yet largely unanswered, on whether these new models are fit for purpose. How will patients or clinicians use "their" AI to

organize information before, during, or after a visit? How well or safely will the tools perform the tasks required? How will use vary? While answers are likely to change rapidly with field advances, key research directions can include:

Human Use of General-Purpose LLM Chatbots In Health and Health Care

Rapid uptake of these tools, and rapidly growing capacity to ingest images, PDFs, and increasing numbers of words, make understanding current and potential uses by patients and clinicians critical to understanding likely trajectories for off-the-shelf LLMs and those fine-tuned for health care applications. Key questions include patient assessment of intelligibility of LLM responses, including for those with different English language or educational levels, technical literacy, and assessment of accuracy of responses to patient queries, etc. What is the impact of biases or style embedded in particular LLMs, and how might those interact with patient need or preference? As with model training, research on LLMs as third agents will require diverse datasets and participants, including patients of different races, ethnicities, or gender identities, levels of English proficiency and education, health conditions, comfort with technology, and internet access, as well as varying preferences for communication and recommendations in health care.

Customization and Optimization of LLMs For Specific Clinical Purposes (eg, Diagnosis and Care Navigation) for Specific Users, Whether Clinicians, Patients, Or Caregivers

Research should examine both proposed solutions and methods development—including but not limited to pretraining of focused foundation models, incorporation of multiple forms of data (images, sensor data, or EHRs), quantification of uncertainty for estimates produced, and methods for fine-tuning and debiasing. Optimization work, with particular attention to retrieval-augmented generation, is already being carried out at a rapid pace in industry and academia, with industry likely to progress more rapidly given its disproportionate access to large-scale compute capacity. This raises collateral but related research questions on tensions or concordance between patient needs and health care market incentives, regulatory requirements in marketing and labelling of LLM applications to health, potential impact of use agreements between particular LLM or EHR vendors, and differentials in use or constraints to use varying by health care system (public vs private), budget, geography, etc.

Mediators in Generative AI Use: Health Literacy, Trust and Transparency, Clinician-Patient Power Dynamics and Beyond

Research Priorities

Participatory medicine emphasizes reducing information asymmetries and increasing trust as key to enabling patients and caregivers to become more effective partners in the clinical setting. The factors mediating relations between the agents in the trilateral framework of patient, clinician, and LLM in Figure 1 raise a range of research questions beyond assessment of the function of off-the-shelf or fine-tuned LLMs. Priorities for this research include approaches to health and technical literacy, informed consent and ethical use, transparency and trust, removal of communication barriers and gains in efficiency, clinician constraint and autonomy, and value of the human in care.

Approaches to Health and Technical Literacy

How does patient empowerment increase numeracy, critical thinking, or effective use of one or more LLM chatbots? Current versions of off-the-shelf LLMs do not cite sources or rank them by accuracy, leaving patients to distinguish between hallucination and reality, or between more and less authoritative sources of information. What strategies can be used to increase patient comfort with LLM use, comparison between models, and the ability to distinguish between recommendations based on low or high strength of evidence or rigor of sources. Literacy in data import or access is also variable—while all patients now have the potential to access medical records from across multiple health systems, knowing how to do that and how to feed results to LLMs will determine whether or not these tools significantly alter information asymmetry.

Informed Consent and Ethical Use

For patients, what is understood regarding privacy, informed consent, or the ability to opt out when their health data is used by health systems to train LLMs? When they upload their personal medical data via a chatbot, what do they understand about the uses that can be made of that information? ChatGPT is now used, with apparent success, to simplify informed consent forms for both clinical research and before surgical procedures [62]. But how informed are clinicians themselves about the potential use of their practice patterns to train generative AI, or about the training data or testing of LLMs in a clinical context? Guidelines urging AI that is “FAVES”—”fair, accurate, verifiable, effective, and safe”—or calls for centralized laboratories to evaluate health AI safety and effectiveness may be insufficient either to address such questions as the impact of LLMs drift in function over time, or to assess impacts of LLM use on patient or workforce morale at point of care.

Transparency and Trust

We cite the instance above of patient disappointment upon discovering that her interlocutor was in fact a chatbot rather than a human provider. What is the impact of disclosure by patients, physicians, and health systems of LLM use, or of not disclosing the use at all? One study of “smart replies” outside the health domain found that when participants think their communication partner is using AI-generated responses, they perceive them as “less cooperative” or “affiliative.” When AI’s role in authoring the responses was unknown, those receiving them judged their interlocutors to be more cooperative collaborators [54]. Whether or how patients and physicians reveal use of AI assistance, under what circumstances this is judged a positive or negative, and whether perception on the benefits of LLM use varies by patient or physician type, health condition, or health system are all questions of interest. Measurement of trust and partnership needs to begin with the

design stage, with inclusion of patients in the cocreation of research methods and aims central to research success [51].

Removal of Communication Barriers and Gains in Efficiency

With physician shortages projected to reach 86,000 in the United States within the next decade [63], how will LLM use allow existing clinicians to do more, or reduce the need for exchange with patients? How might patient use of these tools, or even of AI-generated summaries of key data points (including from different health systems, from wearable data inaccessible via the EHR, etc.) speed or improve communication with clinicians?

Clinician Constraint and Autonomy

Clinician priorities and commitment to care are not necessarily aligned with health system priorities. Whether generative AI's potential in the health system is realized depends in part on whether the cost of deploying and maintaining the innovations is offset by increased incoming revenue or decreases in the expense of replacing burned-out clinicians. Regulatory or liability concerns may also constrain health systems or physicians, leaving patients freer than clinicians in some instances to explore LLM-generated insights about their conditions. How or if limits on clinician autonomy impact the use of generative AI, physician sense of self-efficacy or cognitive load, and patient experience are all research questions of interest.

Value of the Human in Care

The importance to patients of human caring in health care in the age of generative AI, or the degree to which clinicians value their role or humanistic exchange as integral to a process of caregiving, is not yet known. This may vary by patient, condition, specialty or primary care, or health system and depend on patient access to or help from other human actors, including family and other service providers. As electronic, LLM-generated communication between patients and clinicians grows, or as patients or physicians turn to avatars or AI agents to represent them, the question of how much human exchange is needed and what is essentially human about such exchange will become increasingly central.

Conclusion

The LLM is a new change agent in the health care dynamic, and one with transformative potential for patients and clinicians. Clear-eyed research into both the function and use of LLMs can help bend the arc of that change toward mutual benefit. The key lies not in advancing LLMs as a replacement for clinician-patient interaction, but as a tool to augment it. By conceptualizing something closer to "assistive intelligence," we can leverage LLMs to enhance and facilitate human connections and collaboration, supporting sound clinical decision-making and improved communication. For patients, in particular, LLMs represent a powerful corrective to power and knowledge imbalances and may lead to a more effective clinician-patient partnership.

Understanding the impact of LLMs and agentic AI on clinician-patient relations will require social science and computer science, qualitative research, as well as quantitative analytics and software engineering. While a focus on clinician-patient interactions is insufficient to address the multiple incentives and forces that underlie the American health care system, understanding the dynamics of those interactions—and acting to design, train, and use LLMs in ways that reinforce humanistic collaboration—is possible and necessary. Adhering to the principles of engagement, cocreation, and ethics that have emerged from patient movements can create a future where AI serves as a facilitator of the communication and connection at the heart of human-centered and effective care.

Authors' Contributions

HdOC, DW, IS, and HL contributed to the research, framing, and writing of the text. HdOC, DW, and HL created the graphics.

Conflicts of Interest

None declared.

Multimedia Appendix 1
Prompts and outputs from LLMs. LLM: large language model.
[PDF File, 1741 KB - jopm_v17i1e68146_app1.pdf]

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Abbreviations:

AI: artificial intelligence
EHR: electronic health record
LLM: large language model

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Perception of AI Use in Youth Mental Health Services: Qualitative Study

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Abstract

Background: Artificial intelligence (AI) technology has made significant advancements in health care. A key application of using artificial intelligence for health (AIH) is the use of AI-powered chatbots; however, empirical evidence on their effectiveness and feasibility remains limited.

Objective: This study explored interest group perceptions of integrating AIH in youth mental health services, focusing on its potential benefits, challenges, usefulness, and regulatory implications.

Methods: This qualitative study used semistructured in-depth interviews with 23 mobile health stakeholders, including youth users, service providers, and nonclinical staff from an integrated youths' service network. We used an inductive approach and thematic analysis to identify and summarize common themes and subthemes.

Results: Participants identified AIH's potential to support education, navigation, and administrative tasks in health care, as well as to create safe spaces and mitigate health resource burdens. However, they expressed concerns about the lack of human elements, such as empathy and clinical judgment. Key challenges included privacy issues, unknown risks from rapid technological advancements, and insufficient crisis management for sensitive mental health cases. Participants viewed AIH's ability to mimic human behavior as a critical quality standard and emphasized the need for a robust evaluation framework combining objective metrics with subjective insights.

Conclusions: While AIH has the potential to improve health care access and experience, it cannot address all mental health challenges and may exacerbate existing issues. While AIH could complement less-complex services, it could not replace the therapeutic value of human interaction at this time. Co-design with end users is critical for successful AI integration. Robust evaluation frameworks and an iterative approach to build a learning health system are essential to refine AIH and ensure it aligns with real-world evolving needs.

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KEYWORDS

artificial intelligence for health; youth mental health; healthcare service delivery; digital health intervention; stakeholder perception

Introduction

Over the last decade, artificial intelligence (AI) has made significant breakthroughs in health care [1]. More advanced AI technologies, such as machine learning [2], natural language processing [3], and predictive analytics [4], have increasingly been introduced to diverse health care settings to support diagnostic capabilities, individualized treatment planning, administrative and clinical workflow development, and patient monitoring [5]. Using artificial intelligence for health (AIH), especially in the field of youth mental health, is in an exploratory phase. The current youth mental health landscape is often critiqued as fragmented and insufficient to meet the access and care needs of diverse youths [6,7]. AI offers a promising solution to augment existing services, with its low barriers to entry and resource-efficient nature, capable of enhancing existing services by providing real-time, data-driven support [8]. Recent advancements in generative AI, including large language models, further extend these possibilities by offering capabilities such as real-time emotional recognition, therapy-session summarization, crisis risk prediction, and personalized psychoeducation [9].

Given that youths (defined here as 12–24 years) are generally more receptive to new technologies than other age groups [10], they are uniquely positioned to lead the adoption of AI-based mental health services. The integration of AI into these services

not only has the potential to revolutionize care delivery but also to improve health outcomes and experiences, promote population health, reduce costs, and enhance both provider satisfaction and health equity, aligning with the goals of the quintuple aim [11]. However, these developments also introduce significant challenges, especially given the sensitive nature of mental health data and the critical importance of human empathy and therapeutic relationships in youths' care [9,12]. Therefore, the integration of AI into youth mental health services must carefully consider issues such as algorithmic bias, transparency, value alignment, and the potential loss of humanistic care elements.

Despite the challenges stemming from rapid advancements in this technology, there is a significant gap in evidence on how these AI innovations translate into successful AIH implementations. Perceptions of AI in health care remain mixed [8], especially in areas where AI is more embedded in digital health interventions, remote monitoring, and preventive care [13-15]. Stakeholders such as youth users, health care providers, technology developers, and policy makers hold pivotal roles in shaping the acceptance, regulation, and application of these technologies [16]. Their perspectives are critical in ensuring AIH solutions are tailored to the real-world needs of youth mental health services, rather than just performing in idealized experimental settings. This gap highlights the urgent need to engage with these stakeholders, whose insights are essential for fully understanding both the potential and the limitations of AI in transforming youth mental health care.

This paper explores the perceptions of key interest groups on the integration of AIH into youth mental health services. Specifically, we examine the (1) benefits and challenges of AIH integration, (2) perceived usefulness of AIH, and (3) strategies for evaluating and regulating AIH. By addressing these critical questions, this study sheds light on the factors influencing AI adoption in mental health care and offers actionable recommendations to support the responsible, equitable use of AI to improve care quality and accessibility for youths.

Methods

Study Design

This study used an inductive qualitative approach with semistructured, in-depth interviews to explore stakeholder perceptions of integrating AI-based tools (AIH) into youth mental health services. This study was situated within Foundry, a provincial network of integrated youth services (IYS) in British Columbia, Canada. Foundry offers youths aged 12–24 years access to mental health and substance use services, primary care, social services, and peer support. Foundry operates both physical centers and a virtual mHealth (mobile health) platform (the Foundry BC [British Columbia] app). Although Foundry does not currently offer AIH, its active digital infrastructure and dedicated mHealth team make it a potential setting for exploring the potential of future AI integration.

Three priority participant groups were included: (1) youth users, (2) service providers, and (3) nonclinical staff. These groups were selected to capture diverse perspectives across different stages of technology design, development, and implementation. Youths and service providers represent the primary users and deliverers of mHealth services, while nonclinical staff offer critical insights into the operationalization and governance of online health tools.

Ethical Considerations

Ethical approval was received from the University of British Columbia Office of Research Ethics Behavioural Research Ethics Board (#H22-03454). Study findings are reported in alignment with the COREQ (Consolidated Criteria for Reporting Qualitative Research) checklist for qualitative studies. Verbal and written consent was obtained from all participants prior to the interviews. Interviews lasted between 45 and 60 minutes, were audio-recorded with consent, and transcribed verbatim. Field notes were taken to aid data cleaning, capture nonverbal observations, and assist in contextual interpretation. Each participant was coded with a pseudonym for confidentiality purposes and anonymous presentation of results. Participants received a CAD $50 (US $36.30) honorarium after their session.

Study Sample

All recruitment and data collection took place between June 2023 and April 2024.

Youth Users

Youth inclusion criteria required participants to be aged 16 to 24 years (those 15 years and younger were excluded due to the need for parental consent), able to communicate in English, and have used mHealth to access services in the past year. Recruitment was conducted through recurring social media posts. To capture diverse experiences, no restrictions were placed on the frequency or purpose of mHealth use.

Service Providers

For this group, we recruited IYS service providers (eg, counselors, social workers, primary care providers) who have used mHealth to deliver care to youths (eg, virtual youths' counseling, remote info sessions, and online peer support groups). Most service providers were purposively recruited from Foundry centers that fully integrate mHealth into their clinical service workflows.

Nonclinical Staff

For this group, we recruited technology and implementation experts at Foundry who were engaged in the design, development, and implementation stages of the mHealth platform. We reached out to the Foundry communications team to share information about this study's opportunity to qualified nonclinical mHealth staff who met the inclusion criteria. This process was used to ensure the confidentiality of staff so they could make an unbiased decision to participate in the interviews.

Data Collection

We collected qualitative data through 23 participant interviews. We designed open-ended questions based on the participants' own perception and user experience with AI and AIH. To ensure a shared foundation for discussion, each interview began with a brief conversation about AI and AIH, helping to ensure that participants' understanding aligned with commonly accepted

definitions of these concepts. The major guiding questions were constructed based on the Technology Acceptance Model (TAM) [17-19]. TAM's core constructs informed the formulation of questions aimed at understanding participants' views on the potential integration of AI into youth mental health services. Interview questions probed stakeholders' beliefs about how AI could improve health care services (usefulness), their concerns about complexity or usability (ease of use). Specifically, TAM3 was taken into consideration because it further integrates broader factors such as trust, relevance, and ethical considerations that could influence acceptance in a youth mental health context. The semistructured interview format allowed participants to elaborate on topics of interest beyond the guiding questions (sample interview questions listed in Multimedia Appendix 1). Examples were offered when necessary (eg, "imagine using a chatbot to ask questions about anxiety or depression or to help you book a mental health appointment"). This framing helped participants consider the role of AI beyond general uses and reflect on potential health care applications, even if they had not personally used AI for mental health purposes.

Interviews were conducted via secure Zoom by the lead researchers (XD and SB) with qualitative research training and prior experience in the mHealth service setting.

Data Analysis

We used inductive thematic analysis [20,21] to identify, analyze, and report patterns and themes in interview data from 3 stakeholder groups [22]. Researchers XD and SB used an iterative approach to review the themes, ensuring they accurately represented the coded data and the overall dataset content. After identifying themes for each research question (RQ), the authors discussed and selected the most representative examples from the transcripts for each theme, presenting in-depth quotes alongside the group name and a pseudonym for each participant. To ensure rigor [23], the research team held weekly debriefs to review theme development and discuss discrepancies in interpretation. Reflexivity was maintained through memo writing and regular team reflection, particularly around the influence of positionality in interpreting different stakeholder perspectives. Themes were finalized once data saturation was achieved and no new codes emerged from subsequent transcripts.

Results

Participants

A total of 23 people participated in this study, with 12 youth users, 6 service providers, and 5 nonclinical staff who were deeply involved in the development of the mHealth services across the IYS network. Table 1 summarizes the demographic characteristics reported by the participants. Most participants self-reported using AI-powered tools in their daily lives, not limited to health contexts. Many had used AI tools, most commonly ChatGPT (OpenAI), for tasks related to school, work, and everyday problem-solving. Two youths reported they had used Snapchat (Snap Inc) for AIH-related counseling purposes. Most participants provided diverse and distinct insights on their perception of AIH IYSs, ranging from "it's scary and creepy" and "I am skeptical" to "it has potential" and "it is a positive trend." Only 1 participant in the youths group stated that they had never thought about using an AIH-related service and did not provide much information.

Through one-on-one interviews, participants shared their in-depth understanding of the current and future role of AI, specifically the integration of generative chatbot services in health care, based on their personal experiences. Thematically analyzed qualitative data will be presented in this Results section following the 3 research questions proposed: perceived benefits and challenges of AIH, intended usefulness of AIH, and how do we evaluate AI for regulation.

Table . Summary of demographic description of 3 groups (N=23).

	Youth (n=12)	Service providers (n=6)	Nonclinical staff (n=5)
Age (years), mean (range)	20.4 (18 - 24)	32.8 (23 - 45)	35.6 (29 - 46)
Self-reported gender, n			
Woman	10	4	3
Man	2	1	1
Nonbinary	0	1	1
Currently using AI in life, n (%)	11 (92)	5 (83)	4 (80)
Years of professional experience, mean (range)	N/A	4.2 (1.5-7)	14.1 (8 - 23.5)

RQ1: Perceived benefits and challenges of AIH

Perceived Benefits of AIH

Create a Safe Environment

When youths accessed virtual care, there were unique preferences for everyone. Some expected a real person on the other end of the screen, and some youths reported they have a strong fear of judgment, stigma, and social anxiety when facing a therapist. These participants reported that the lack of human interaction is beneficial in their help-seeking journey. This consideration can be particularly crucial in vulnerable groups, as the LGBTQIA (lesbian, gay, bisexual, transgender, queer, intersex, and asexual) community reported facing additional barriers when accessing mental health services.

> *The wall is my own struggling to trust. It's just my own wall that I don't want anybody to know what I'm struggling with. Because, like you say, it's an AI, so*

> *it's not a person who will know my struggle.* [Youth, July]

> *It feels wrong to suddenly question their attraction to the same sex, and I had a young person said that to me, 'I'm so embarrassed I could never tell my friends, I could never tell my parents, I could never tell anyone but I needed to tell somebody.* [Nonclinical staff, Sarah]

Mitigate Health Resources Burden

Participants reported that AIH is naturally perceived as affordable, resourceful, and available 24/7. It can provide immediate responses they need without having to go through a complicated registration and waiting process, compared to how you usually access a traditional therapy session. Some service providers optimistically suggested that AI could easily replicate certain therapeutic approaches that are relatively straightforward, such as the solution-focused brief therapy model and attention-deficit/hyperactivity disorder coaching. They proposed that AI could be designed to deliver appropriate responses at the right time. Participants suggested that if AIH can effectively and accurately handle less complex cases, it could alleviate the current shortage of health care resources. This would enable the system to dedicate more focus and resources to addressing higher-intensity situations.

> *Our clinical staff who worked at a help line reported that mostly people just want to talk to somebody, and who just feel like they need maybe some guidance or someone to listen to them, and this is the part that can benefit from a well-trained AI model.* [Service provider, Milo]

Perceived Challenges of AIH

Missing Human Element

As all participants have their AI experiences with generative AI chatbots, they largely envision using ChatGPT-like chatbots for therapeutic purposes. While the technology team showed confidence that AI has the capability of feeding the correct answer, most clinical staff and youths suggested that the value of talking to service providers is building empathetic relationships and connecting with the community. Current AIH cannot understand client facial cues, tones, raised voices, or body language, and to provide human-like empathetic responses ("You know they are crying, AI doesn't" [Nonclinical staff, Allison]). This perspective is particularly crucial when it comes to trauma counseling, crisis counseling, and suicide cases, since most participants stated AIH cannot handle extreme situations that require extra considerations and empathy. Moreover, both youths and service providers shared from their counseling experiences that clients often come in feeling vulnerable and seek to share that sense of vulnerability with another human being present in the same space. Sometimes clients are not here to hear the right words; they are here to feel heard and supported—"But you are not able to feel that from any robots" (Youth, John).

> *Your counselor is a human, they have human emotions, they make mistakes, they say weird things, too, and it's very reassuring to know that the person we're speaking with, despite being a professional counselor, they're also just living the human experience. Even if a counselor says the wrong thing, they were cursing with you that AI will never do, but you still know that they are there to support you.* [Youth, Rice]

In addition to the lack of empathy, service providers also reported that AIH lacks the clinical judgment ability and the power of uniqueness, so it is not personalized at all when facing different clients.

> *Two people could have the same issue. But then with an AI, if it's given the same prompt, it would probably have the same answer for both. But I feel like human therapist can change it up per person or being able to read the conversation better and make inferences during session.* [Youth, Sisi]

Worries About Technology

Participants from all 3 groups expressed concerns about the feasibility of implementing AIH services, particularly regarding the ability of health services to meet technological demands and address the evolving needs of youths. Participants also discussed equitable access to technology. Some participants noted that it is crucial to recognize there are rural and remote communities that do not have access to technology (eg, Wi-Fi), and some were not comfortable accessing the internet and remote services. While the AIH has a promising future, participants acknowledge that it is not the solution for every community, and the needs of each community need to be carefully scoped. As 1 participant noted,

> *It could be more harmful than good to do that [implement AIH] in communities where it's does not really aligned with how they live.* [Nonclinical staff, Lulu]

Participants also identified confidentiality and privacy as key concerns regarding the logistics of AIH. While these issues are common in all technology-based services, participants noted that they are particularly challenging in AIH because users often lack a clear understanding of who or what is managing the information they input into the "black box."

> *Will that be private, or will it go through some counselors I don't know or just to Google?* [Youth, July]

Some participants also perceived that AI in general can lack effectiveness and reliability, which is critical for delivering evidence-based services to youths accessing mental health services. Some perceived AIH as "impractical," and some participants reported highly negative experiences with AI chatbots, leading to a strong reluctance to see AI integrated into their health care experiences.

> *It's frustrating enough dealing with something as simple as Amazon customer service, let alone relying on AI for health-related matters. Anytime I can tell I'm talking to a robot, my first thing is to figure out how to get to the human.* [Nonclinical staff, Allison]

Risks

In addition to the general concerns toward using technology, participants also proposed more serious risks associated with integrating AIH into the health care system. Some stakeholders believed that at this stage, "AIH has more risks than what current knowledge can anticipate" (Service provider, Jacob).

> *I don't think people like the idea of getting therapy from a program.* [Service provider, Olivia]

Participants noted that unregulated AI tools can be maliciously trained, spread misinformation, and, more critically, lack empirical research evidence on the negative consequences resulting from such misconduct. All participant groups emphasized that each user interacts with AIH in unique ways, making it difficult to predict the specific information these tools provide.

It is important to note that nearly all participants expressed concerns about how difficult it can be to manage crises with AIH. This was identified as the most significant worry and the primary challenge when integrating AIH into youth mental health services. Participants specifically stressed the importance of exercising extreme caution with AI tools, highlighting the risk of these tools delivering triggering or harmful content that could lead to self-harm or suicide.

> *I worked with a couple of projects that was using AI to train particular counseling or training models. Right now I'm suspicious because you can make AI mad at you. I remember this…not ChatGPT, but a while ago I managed to convince the AI to tell me to kill myself and sent that back to somebody and …this is a no.* [Nonclinical staff, Allison]

Participants expressed a desire for AIH to be accompanied by a comprehensive crisis management plan that addresses the handling of sensitive information while prioritizing ethical and legal considerations. Finding a balance between data security and effective crisis management was described as a significant challenge for all groups.

> *To do a suicide rescue with somebody on AI is intense. Do you need to check for other things like do they have the modality? Do they have a plan? Is the plan imminent? So where is the line to necessarily get other people involved? If it looks like they're at a high risk for suicide, at that point somebody would need to know? But also there are also health laws there, somebody else would never be able to involve.* [Service provider, Flora]

RQ2: Current Intended Usefulness of AIH

Participants expressed 3 key functions where AIH could play to advance youth mental health service innovation.

Education

First, based on participant experiences with AI tools, participants felt that AI can serve as an effective educational resource to support the learning of health-related knowledge. AI can answer scientific questions without waiting times (eg, "What is an antidepressant?") and can provide tailored materials for diverse audiences, such as explaining medical concepts to youths in plain, accessible language. Additionally, it can update both health care providers and recipients with the latest knowledge and skills that are personalized to their specific needs. AI can help foster a more informed and knowledgeable support system and bridge gaps in health literacy.

> *If you're in need of realistic advice that you don't really need an appointment for, maybe AI can help. If I can get the solution right away. then [using AI to seek help] wouldn't be a concern for me.* [Youth, Kate]

Navigation

Second, participants reported that AI can be a navigation tool that directs users to the correct place to seek help. Participants suggested that AI chatbots can be used as screening tools to assist with identifying the type of support they need based on their symptoms or concerns and direct them to the suitable health care providers, facilities, or online resources. Participants proposed that AI can be trained with the stepped care model [24] and help triage users in specific communities by recommending whether they should seek immediate emergency care, schedule an appointment with a specialist, or explore self-management options. By navigating users across the complex health care system, AI has the potential to increase access to care, minimize delays, and mitigate stress for individuals in need of accessible services, especially those from vulnerable and marginalized groups, including youths.

> *I can definitely see to use it like find me a center near me, "okay, you have one x kilometers away," or "here is a substance use support station for you" and it would be cool. But I'm very against the idea of AI being my counsellor.* [Youth, Rachel]

Administration

Lastly, participants agreed that other than using AI for accessing health care, AIH has extensive value for assistive health administration purposes. Many youth users, especially those whose first language is not English, suggested that AI services can help overcome language barriers by accurately expressing their thoughts in their native language, often performing better than traditional translation tools. Service providers also highlighted that AI can handle administrative tasks such as appointment scheduling, billing, and managing patient records. This reduces the workload for health care staff, allowing them to focus more on providing personalized care. Additionally, AI can analyze health data to identify patterns in service use, track both short-term and long-term patient records, and support decision-making at the organizational level.

> *You can have AI store all the data and generate tables for like… what percentage of people accessed the app this month, and you will know the maintenance and other tech efforts you will need in the future.* [Nonclinical staff, Allison]

RQ3: Evaluation and Regulation of AIH in Youth Mental Health

All participants highlighted the importance of assessing the quality of care delivered by AIH and identifying effective regulatory measures to maximize its benefits for youths' mental health. At the beginning of this section, it is important to highlight that the prevailing view among stakeholders is that the success of AI-based health care services largely depends on how well AI can mimic human behavior. Many emphasized that AIH should incorporate human-like traits, especially empathy, to build trust and gain acceptance. The importance of having diverse personalities in AI was repeatedly emphasized by different participants, with some suggesting that users should be able to choose the different personalities of AI based on the specific service they are using. Stakeholders agreed that aligning AI with these desired qualities is key to its effective integration into youths' mental health care.

> *I would want to see whatever I can see in a real person, then it would actually be the same thing. If they didn't have this, then I wouldn't be satisfied. I want AI to be an active listener, so should be empathy! I want the AI chat to have empathy. I want it to be non-judgmental. I want the chatbot to challenge me in my thoughts and my patterns like a real therapist.* [Nonclinical staff, Alex]

Building on the overarching standard proposed by participants that AI services should mimic human behavior, 2 major categories of evaluation criteria were identified: objective measures based on quantifiable metrics, and subjective assessments based on user experiences.

The quality of care provided by AIH can be objectively assessed by tracking changes in symptom severity, using tools such as the GAD-7 (Generalized Anxiety Disorder 7-Item) and PHQ-9 (Patient Health Questionnaire-9 Item) scales to measure anxiety and depression levels in youths before and after the intervention. In addition to symptom severity, participants suggested other measurable factors that could be part of a comprehensive evaluation framework. These include the percentage of accurate information provided, response times, frequency of follow-up interactions, the number of successful referrals to appropriate resources, and even the reduction in years of disease burden at the population level.

> *Is it cutting down on the number of people who then go on to book an appointment? How effective it is in achieving individual health goals? Did it convince youth to take the next step to see a specialist? You can calculate some efficiency percentage here.* [Nonclinical staff, Jojo]

The other perspective is that you can measure the subjective individual user experience and level of satisfaction while using AIH. Participants noted that lived experiences are difficult to quantify and should not be categorized, as they often provide the best reflection of the unique perspectives, emotions, and challenges individuals encounter, shaped by their personal and cultural backgrounds. This part of the evaluation can include highly subjective feedback, such as: "Did I feel heard and understood? Did I receive the response I needed from this chat session? Did I feel empathy and validation? Did I feel safe talking to AI? Did I feel supported? Was the level of service consistent across sessions? Was I able to reach out to the kind of service I need?"

> [When I was typing something on Snapchat, and then it gives me something back… like a huge paragraph, and I read over, and I'm like, OH, you just completely got it in a wrong way. So I don't even have the energy to continue and to write to AI 'you're wrong'. So for me it did not give like a really good response and it was a waste of my time. Youth, Sunny]

Discussion

Principal Findings

The integration of AI into youth mental health services presents both opportunities and challenges. This study explored the perceptions of mHealth interest groups who are already familiar with mHealth services, offering critical insights into the benefits and challenges associated with integrating AIH in a real-world setting. Participants expressed the expectation that AIH could enhance care by improving health education, service navigation, and supporting administrative tasks. At the same time, participants proposed concerns about the loss of human empathy, lack of clinical judgment, data privacy risks, and the inability of AI to handle high-risk situations such as mental health crises. These findings emphasized the need for thoughtful AIH implementation that is more tailored to unique needs.

Previous evidence has highlighted the potential of using AI-powered health tools to address key barriers in health care, such as workforce shortages and financial constraints, by offering data-driven mental health interventions [1,25]. Some research has explored the use of AI in clinical decision-making, such as optimizing drug dosages and creating personalized treatment plans [26,27]. However, regarding implementing AIH to support mental health services, the American Psychiatric Association's *DSM* (*Diagnostic and Statistical Manual of Mental Disorders*) includes over 450 distinct definitions [28] of mental disorders, and current research does not have empirical evidence to support the use of AIH in all fields of mental health services.

In addition to these concerns, advancements in health technology often fail to engage end users effectively and neglect their lived experiences and needs [16,26]. While existing evidence showcases the capabilities of AIH, there is limited exploration of how service recipients perceive its use in a practical setting. This study investigated stakeholder perceptions, emphasizing the role of AIH, particularly AI chatbots, in supplementing traditional services. A key challenge identified was AI's inability to replicate human empathy, which aligns with some scholarly views [29], and this is especially crucial in critical situations requiring nuanced therapeutic responses. Recently, more research has focused on understanding the warmth and empathy conveyed by chatbots. Some showed empathy expressed by a chatbot may feel inauthentic [30], and users often prefer human-written stories over those generated by AI in mental health and social support settings [31]. Others, however, see potential in enhancing AI chat features and making them more

empathetic and responsive to patient experiences [32]. This reflects the ongoing scholarly debate around the topic of AI and empathy, leading to a contentious aspect of AIH integration.

Another recurring concern identified by participants in this study was the fear of AI mishandling sensitive data and spreading misinformation, particularly in high-risk situations for youths. Existing studies identified both technical and ethical risks associated with AIH, including the spread of misinformation about mental illness that contains factual errors, misleading claims, invented references, or advice that may be unsafe in crisis management and clinical contexts [33,34]. Literature underscores the importance of service providers acknowledging this risk and developing adaptive strategies for practice [33]. Some researchers have proposed using a "supervisor AI" to identify and correct misinformation, particularly on social media, but the feasibility of integrating such systems into AIH remains uncertain [35,36]. The study highlighted the need to expand evaluation criteria for AIH. While traditional measures, such as symptom reduction, remain important, there is increasing recognition of the complexity involved in measuring AIH tools [37,38]. Participants argued that a more holistic approach is necessary, focusing on evaluating meaningful, subjective recovery experiences, rather than solely relying on quantitative metrics. Lastly, participants emphasized the importance of efficiency and brevity in AIH interactions. Youths described disengaging after receiving lengthy and misaligned responses. This reflects a long-lasting usability issue in digital platforms [39,40], where users may feel that their time is "disrespected." As we are discussing AIH integration in youth mental health settings, it is essential to tailor responses to youths' cognitive load to sustain engagement and therapeutic value.

Limitations

For this qualitative study, the interview data came from a small sample within one youth service network, limiting the generalizability to broader contexts. Participants primarily shared perceptions of AIH integration based on their personal AI experiences, as they had limited direct experience with implemented AI-based health tools in a clinical youth mental health setting, which may have limited the depth of their insights.

Future Endeavors

Beyond the potential functions of AIH identified by participants, its effectiveness in health care can be enhanced by strategically integrating AIH applications with established care models, such as the stepped care model. This approach may allow AI to manage lower-complexity cases, enabling clinicians to focus on high-intensity, complex cases in youth mental health, thereby improving overall treatment outcomes. Moreover, to build trust and encourage widespread adoption in youth mental health, AIH must prioritize transparency, especially regarding data management and crisis intervention. Establishing robust ethical guidelines and regulatory frameworks is crucial to ensuring AI safety and addressing any potential risks. Most importantly, even as the technology matures, AIH solutions must be co-designed with end users, ensuring they are tailored to meet their needs and foster trust in the health care system. Given the current limitations of AIH integration reported by participants, there is a need for health care systems to adapt iteratively to the evolving needs of users, especially when it comes to vulnerable groups such as youths who usually face more barriers and challenges when accessing care. The future development of AIH should also prioritize continuous feedback and foster collaborative learning environments involving all interest groups. This includes groups represented in this study, as well as others not recruited, such as organizational leaders and policy makers. Our sample was small and predominantly composed of women who were relatively tech-savvy with mHealth tools but had limited direct experience with AI-powered health tools used in a clinical context. Broader representation across gender, background, and AI experiences may yield additional insights and ensure findings are more representative and actionable. While participants' perceptions offer valuable direction for early-stage design, future research should include more diverse and experienced stakeholders to inform equitable and tailored AIH development. This effort aligns with the call for a learning health system [41] that supports long-term interest groups' engagement rather than isolated, project-based approaches to break down silos among partners and to foster collaboration across AIH design, development, and implementation stages. Finally, it is crucial to recognize that while participants in this study mainly believed the current health care system is not yet prepared to fully integrate AI services, these perceptions are likely to evolve as technology and system development progress. As such, the establishment of a learning health system could provide the ongoing feedback and continuous improvement required to effectively integrate AIH, ensuring its adaptation and growth in alignment with the needs of youth mental health providers, service users, and technology developers.

Conclusion

This study underscores both the promising potential and significant challenges of integrating AI into youth mental health services. AI tools can be used for education, navigation, and administrative purposes. AIH can help create accessible environments and alleviate the burden on health care resources, yet its limitations cannot be overlooked. These include the unknown risks associated with current AI technology, the absence of essential human elements in care, the lack of effective crisis management plans, and the absence of a comprehensive regulatory framework for its integration into mental health systems. Additionally, there is a pressing need to develop a robust evaluation framework and establish ethical oversight to ensure AIH can adapt to the evolving needs of youth mental health services. Moving forward, it is critical to focus on building a learning health system for continuous improvement that encourages collaboration, ensuring AIH solutions are effective, equitable, and sustainable for future generations.

Conflicts of Interest

None declared.

Multimedia Appendix 1
Sample interview questions.
[DOCX File, 14 KB - jopm_v17i1e69449_app1.docx]

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Abbreviations

AI: artificial intelligence
AIH: artificial intelligence for health
COREQ: Consolidated Criteria for Reporting Qualitative Research
***DSM*:** *Diagnostic and Statistical Manual of Mental Disorders*
GAD-7: Generalized Anxiety Disorder 7-Item
IYS: integrated youths' service
LGBTQIA: lesbian, gay, bisexual, transgender, queer, intersex, and asexual
mHealth: mobile health
PHQ-9 : Patient Health Questionnaire-9 item
RQ: research question
TAM: Technology Acceptance Model

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Creating a Parent-Informed Pediatric Emergency Department Wait Time App: Human-Centered Design Approach to Creating an AI Health Care Tool

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Abstract

Background: Waiting has become an unfortunate reality for parents seeking care for their child in the emergency department (ED). Long wait times are known to increase morbidity and mortality. Providing patients with information about their wait time increases their satisfaction and sense of control. There are very few patient-facing artificial intelligence (AI) tools currently in use in EDs, particularly tools that are co-designed with patients and caregivers.

Objective: The aim of this study is to use insights from parents and health care providers to inform the design of an AI tool that provides personalized wait time and health information to parents during their child's ED visit.

Methods: The study followed a human-centered design methodology. The study was conducted in a large urban tertiary care academic children's hospital. Data were collected through demographic surveys, semistructured interviews, card sorting, structured observations, and prototype testing with parents and triage nurses. Quantitative data from demographic surveys and card sorting were analyzed using descriptive statistics, including means, medians, and interquartile ranges. Qualitative data from semistructured interviews and observations were analyzed using a thematic analysis. The thematic analysis informed the design criteria of the tool. The tool was implemented in the ED and improved through iterative rounds of usability testing.

Results: Between May 30, 2023, and August 30, 2023, a total of 64 semistructured interviews were conducted with parents in the waiting room. Five interviews were conducted with triage nurses. Parents primarily were mothers (38/64, 59%), were college/university graduates (37/64, 58%), and had a preferred language of English (51/64, 80%). All parents had a smartphone and 97% (62/64) used apps on their smartphone. Children were a median of 7 years old (IQR 4 - 12 years old) and had a median of 4 lifetime visits to the ED (IQR 1 to >5). The thematic analysis revealed 5 key themes that informed the development of the tool: (1) anxiety due to uncertainty, (2) feeling forgotten, (3) low health literacy, (4) not understanding the ED process, and (5) no indication of progress.

Conclusions: This study used a human-centered design approach to explore parents' experience waiting in the pediatric ED to develop an AI tool to improve the waiting experience. By prioritizing parents' experiences and insights, we created a solution that addresses the challenges of communicating wait times and contributes to a more compassionate and efficient health care environment. The implementation of this tool has given patients and families the control and certainty they were lacking by providing information about their wait time. Successful implementation of technology in health care requires a design approach so that solutions are clinically relevant, user-centered, and tested for acceptability and usability.

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KEYWORDS

emergency department; emergency room; wait times; human-centered design; design thinking; co-design; machine learning; artificial intelligence; algorithm; model; analytics; mHealth; mobile app; smartphone; digital health; digital technology; digital intervention

Introduction

Waiting has become an unfortunate reality of seeking care in the emergency department (ED), particularly for parents of pediatric patients [1]. Prolonged wait times in the ED are associated with increased morbidity and mortality in both pediatric and adult populations [2-4]. For parents, the waiting period presents numerous challenges, often marked by stress, anxiety, and uncertainty. When delays occur without accompanying information or updates, the experience can be especially frustrating and psychologically distressing [5]. The absence of communication regarding care timelines and expectations can intensify feelings of helplessness and, in some instances, contribute to aggressive or violent behavior directed at health care personnel [6]. Moreover, inadequate communication and expectations about the ED process can negatively affect the overall family experience and compromise the quality of care delivered to the child [7].

Despite these known challenges, a significant gap remains in how EDs manage and communicate wait times. In many settings, triage nurses are responsible for verbally updating families about delays, often interrupting their clinical duties to do so. Some EDs use static signage in waiting areas to communicate generalized information; however, this is frequently insufficient or inaccessible to patients [8]. In recent years, certain EDs have introduced digital wait time displays in the department to enhance transparency [9]. Some institutions have made wait time estimates available through websites or mobile apps, allowing access from both the ED and home [5].

The provision of wait time information has been shown to improve patient satisfaction and enhance individuals' perceived sense of control while in the ED [10]. Emerging patient-facing technologies, particularly those leveraging artificial intelligence (AI), offer an opportunity to address this unmet need. AI-based tools can generate personalized wait time predictions tailored to individual patients based on their clinical presentation and dynamic departmental factors, rather than providing a single generic estimate [11]. Such tools have the potential to enhance the experience of care, reduce patient frustration, and minimize interruptions to clinical workflows. By proactively setting expectations and offering transparency, personalized wait time information may empower families and decrease the incidence of disruptive behavior toward staff, allowing providers to focus on critical medical tasks.

Over the past decade, there has been a growing emphasis on patient-centered frameworks in health care delivery [12]. Engaging patients and families in the design and development of health technologies can lead to more effective, acceptable, and implementable solutions [13,14]. Human-centered design methodology emphasizes collaboration with end users, such as patients, parents, and health care workers, to ensure health care tools are informed by their needs, preferences, and lived experiences [12]. Nevertheless, there is a lack of research outlining best practices for applying patient-centered design principles to the development of advanced digital tools, such as AI applications, in clinical settings.

Given the known impact of wait time communication on patient experience and the importance of incorporating patient and caregiver perspectives into the design of health care technologies, the objective of this study was to use insights from patients, caregivers, and health care providers to inform the development of a patient-facing AI tool. The AI tool aims to provide parents with personalized wait time estimates and health education resources during their child's ED visit.

Methods

Design

The study followed a human-centered design approach, which is a prospective, iterative, and participatory approach to research and problem solving [15,16]. We used several design and qualitative research methods to gather and analyze data (Table 1 shows the techniques used).

Ethical Considerations

The study was reviewed and approved by the hospital's Quality and Risk Management Office and was therefore exempt from review by the research ethics board. All participants were provided with verbal and written information about the study prior to enrollment. Verbal informed consent was obtained from all participants before participation. The study adhered to institutional guidelines for informed consent and complied with local, national, and international regulations on the protection of personal information, privacy, and human rights. No financial compensation or stipend was provided to participants.

Table . Design research techniques.

Technique used	Description	Participants involved
Semistructured interviews	The first round of interviews focused on the waiting experience, other waiting environments, and a card-sorting activity. The second round of interviews focused on unmet needs while waiting and prototype testing. Interviews with triage nurses focused on commonly asked questions from parents in the waiting room.	64 parents (40 during round 1, 24 during round 2) and 5 triage nurses
Card sorting	Participants were given 8 cards with different data points and were instructed to sort the cards from most important to least important, for example, "How many children are waiting ahead of my child?" [17]	31 parents
Prototype testing	Prototype testing allows designers to gather feedback on a low-fidelity version of the product [18,19]. Prototype testing occurred during the second round of semistructured interviews. Parents were shown prototypes of the tool on a tablet device (Apple iPad) and asked for their feedback with structured questions.	24 parents
Structured observations	Structured observations using an AEIOU[a] Observation Tool (Multimedia Appendix 1) were conducted in the waiting room during two time periods by research assistants. Structured observations allow the research team to analyze the people, objects, and interactions in the space [20].	2 observation periods

[a]AEIOU: Activities, Environments, Interactions, Objects, Users.

Setting

The study was conducted in an academic tertiary care children's hospital that cares for patients from birth to 18 years of age. The hospital is in Toronto, Canada, a large urban area notable for its cultural, racial, language, and socioeconomic diversity. The annual census for the ED is approximately 90,000 patients per year. Interviews and observations were conducted in the waiting room of the ED.

Recruitment

Data were collected between May 30, 2023, and August 30, 2023. Participants were selected by convenience sampling. Participants were included if their child was waiting to be seen in the ED. Parents of unstable or acutely ill children (based on the triage nurse assessment) were excluded. Participants were approached to participate by one of two research assistants on the study team. Research assistants approached families who were in the waiting room with their child.

Two female research assistants conducted the interviews and observations. The research assistants were both undergraduate students with an interest in clinical research. The research assistants did not have any relationship to the participants prior to commencing the study.

Instrument Development

A semistructured interview guide was created by the research team (DS, SL, MM, ISK) after a review of relevant literature and consultation with subject matter experts (Multimedia Appendix 1). Interview guides were pretested with 3 research assistants who were not involved in the study and pilot-tested with 2 parents from the sample population. The research assistants further refined the interview script by conducting mock interviews with experienced research assistants prior to the start of the study.

Data Collection

Data were collected through demographic surveys, semistructured interviews, card sorting [17], structured observations [20], and prototype testing [18,19] (see Table 1 for techniques used).

Interviews and observations were conducted by research assistants while participants were in the waiting room of the ED. When the waiting room was crowded, research assistants brought participants to a nearby examination room for more privacy. Interviews lasted 20 - 45 minutes each. Interviews were conducted with participants verbally, with one research assistant asking the question and a second research assistant typing the participant's answers verbatim into a secure online form (Microsoft Forms). Research assistants recorded field notes and comments in the online form. No audio or video recordings were collected. Interviews were conducted in the participant's preferred language, using a telephone interpretation service when needed.

Two rounds of semistructured interviews were conducted with parents. The first round focused on the waiting experience in the ED; other waiting experiences with their child, such as at a restaurant, the airport, amusement park, or service center; and a card-sorting activity (see Figure 1 for an example of card sorting). The second round of interviews focused on parents' unmet needs while waiting and prototype testing. Parents were

shown wireframe prototypes of the wait time app on a tablet device (Apple iPad) and asked for their feedback with structured questions (see Figure 2 for examples of prototypes). In addition, brief (5 - 10 min) intercept interviews were conducted with triage nurses to corroborate commonly asked questions from parents in the waiting room. Both research assistants conducted one observation session in the waiting room. Observations were recorded on a structured observation chart (Multimedia Appendix 2).

The sample size was guided by the principle of data saturation, where participants were recruited until no new codes or themes emerged from the data. Although qualitative research does not require statistical calculations for sample size, an estimated range of 12 - 20 participants was initially planned based on similar literature and the scope of the research question [21]. Given the iterative nature of thematic analysis, data collection and analysis occurred concurrently, allowing for ongoing assessment of saturation. Recruitment ceased when additional data no longer contributed novel insights to the thematic framework.

Figure 1. Card sorting example.

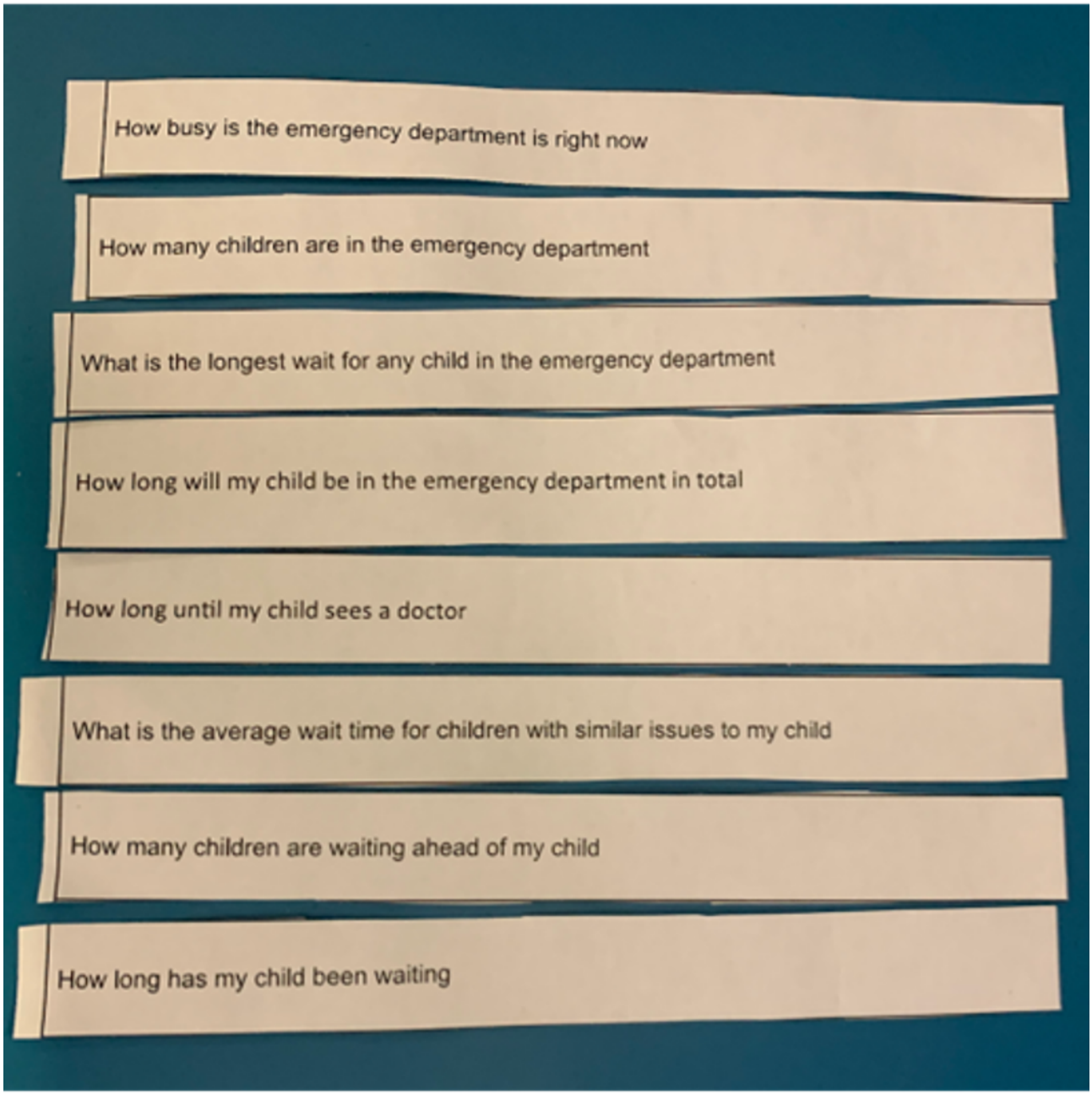
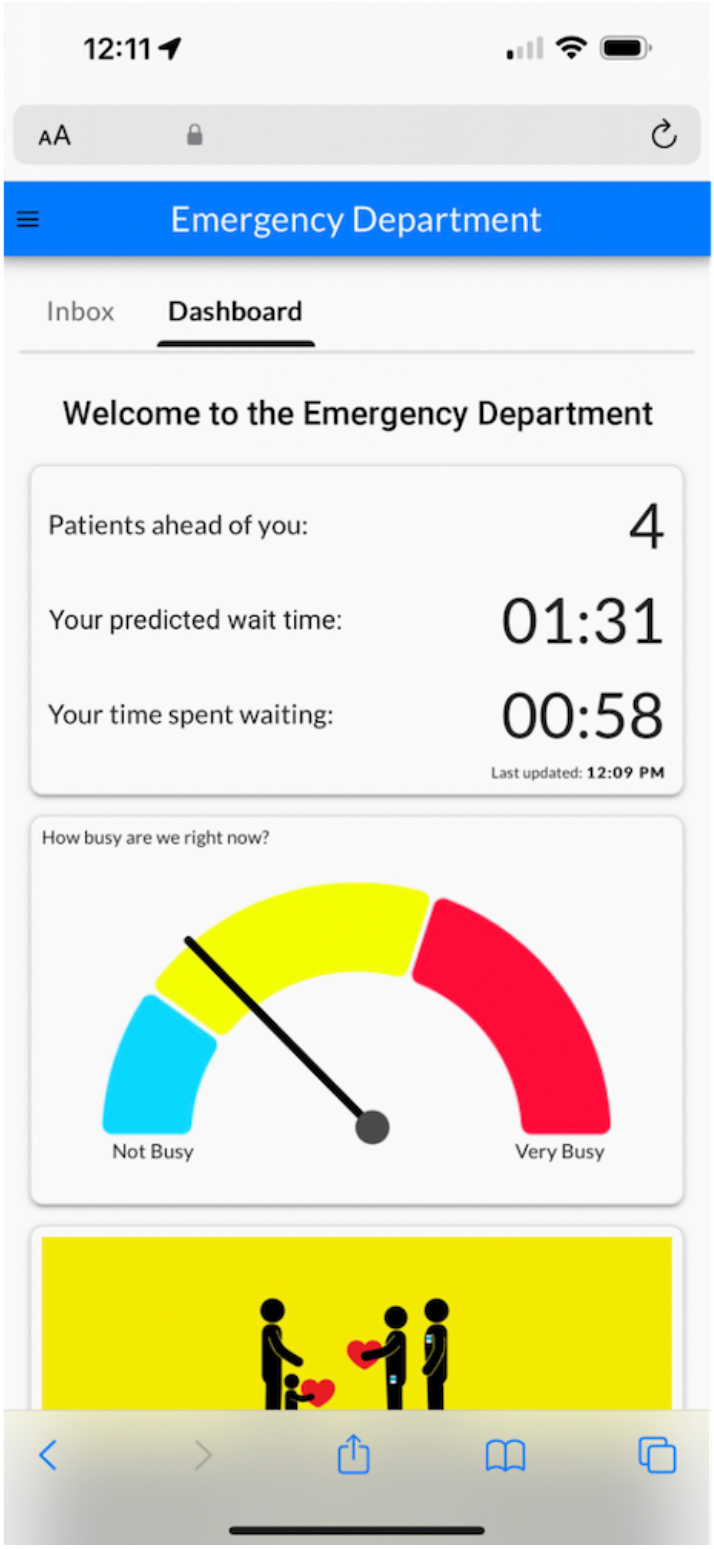


Figure 2. Example prototype.



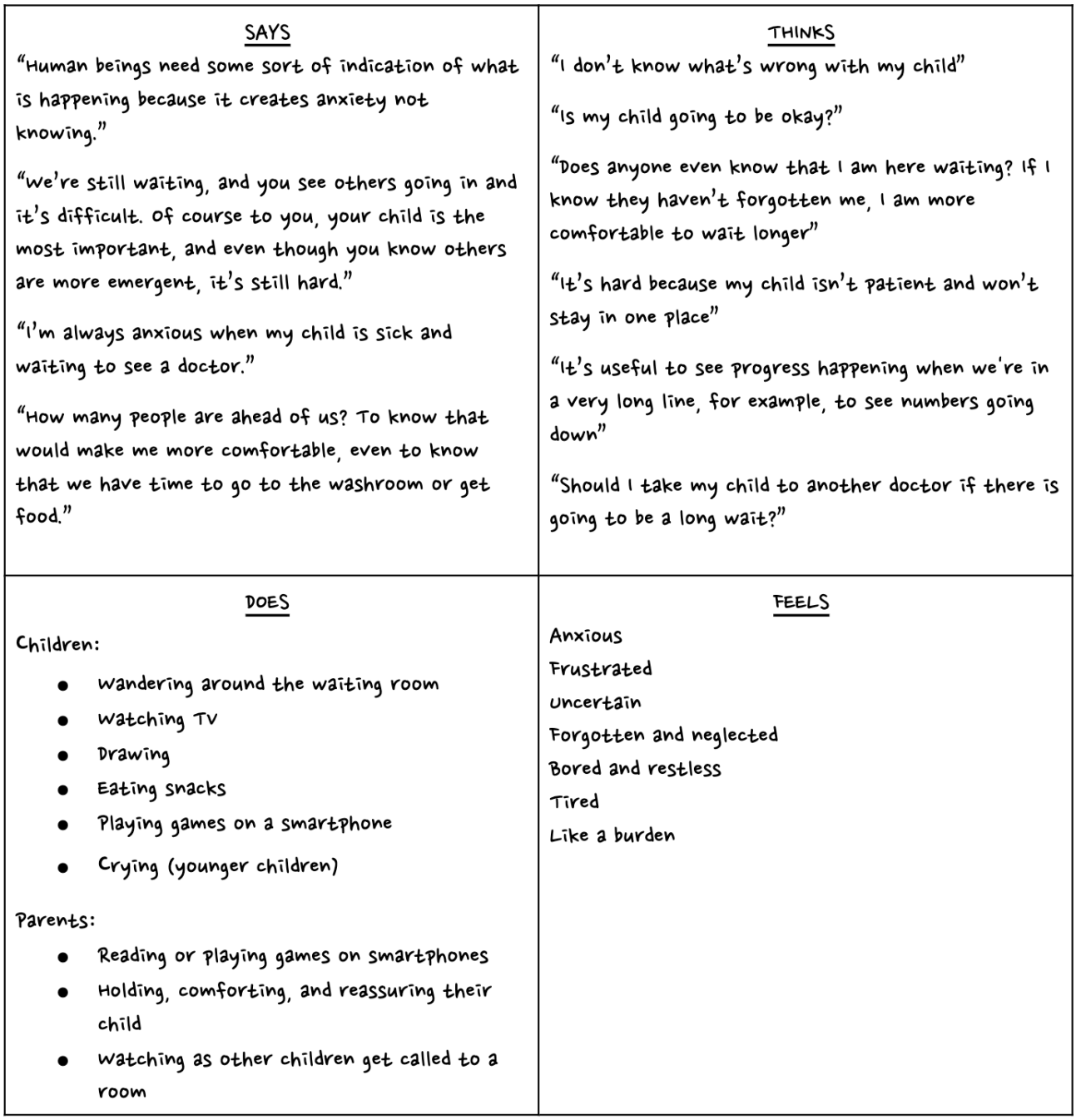
Data Analysis

Quantitative data from demographic surveys and card sorting were analyzed using descriptive statistics, including means, medians, and interquartile ranges. Data were not extracted or analyzed from the wait time app as the software was in development during the study.

Qualitative data from semistructured interviews and observations were analyzed independently by using a thematic analysis approach. Thematic analysis was conducted following Braun and Clarke's 6-phase approach [22]: familiarization, coding, theme generation, reviewing themes, defining and naming themes, and reporting. First, transcripts were read independently by three members of the research team (SL, MM, ISK) for familiarization. Initial codes were generated independently and then combined to discover other codes. Differences in codes were reviewed and resolved item by item by the three research team members to ensure consistency. Codes were then grouped

into potential themes based on patterns in the data. Themes were reviewed by the three members of the research team during team meetings. Data analysis was conducted iteratively, allowing for refinement as new insights emerged from ongoing interviews. Qualitative data were visually displayed in an empathy map (Figure 3). Data analysis and reporting were guided by the Consolidated criteria for reporting qualitative studies (COREQ) [23].

Figure 3. Empathy map.



To ensure the rigor and trustworthiness of the study, we adhered to the criteria of credibility, transferability, and confirmability [24]. Credibility was established through repeated rereading of the data and regular research meetings to discuss the data and by including new questions in ongoing interviews to validate findings with new participants. Transferability was supported by providing detailed descriptions of the research context, participant demographics, and thematic findings so readers can assess the applicability of the results to other settings. Confirmability was maintained through reflexivity, where researchers met to discuss their prior assumptions and potential biases prior to starting the study and as the data were collected and analyzed. These strategies ensured that the findings were grounded in the data and not influenced by researcher bias.

Results

Overview

A total of 67 parents were approached to participate and 64 enrolled in the study (96%). Semistructured interviews were conducted with 64 parents (40 in round 1 and 24 in round 2).

In addition, 5 interviews were conducted with triage nurses. Of the 64 parent interviews, 63 were conducted in English and 1 interview was conducted in Portuguese using a telephone interpretation service. All interviews took place on a weekday and occurred when the parent had waited less than 2 hours. Most parents were English-speaking and had a college or higher level of education. All parents owned a smartphone. Most children were under 10 years old and had previously visited the ED (see Table 2 for demographic data).

Table . Demographic data (N=64).

	Values
Time of day of interview (HH:MM), median (IQR)	13:55 (12:12-15:00)
Wait time at interview (hours), median (IQR)	1.0 (0.67 - 1.63)
Relationship to child, n (%)	• Mother: 38 (59) • Father: 22 (35) • Other (eg, guardian, grandparent): 4 (6)
Parent's age (years), median (IQR)	40 (37 - 44)
Parent's education level, n (%)	• Graduate/professional degree: 18 (28) • College/university: 37 (58) • High school: 7 (11) • Other: 2 (3)
Parent's preferred language, n (%)	• English: 51 (80) • Tamil: 2 (3) • Urdu: 2 (3) • Spanish: 2 (3) • Bengali: 1 (2) • Farsi: 1 (2) • Hindi: 1 (2) • Persian: 1 (2) • Tagalog: 1 (2) • Portuguese: 1 (2) • Punjabi: 1 (2)
Parent has a smartphone (yes), n (%)	64 (100)
Parent uses apps on their smartphone (yes), n (%)	62 (97)
Child's age (years), n (%)	• <1 year old: 3 (5) • 1 - 5 years old: 26 (41) • 6 - 10 years old: 22 (34) • 11 - 18 years old: 13 (20)
Child's total number of ED[a] visits, median (IQR)	4 (2 to >5)

[a]ED: emergency department.

Qualitative Analysis

Five key themes emerged from the qualitative analysis, from which the research team developed design criteria and solutions (Table 3). First, parents expressed significant anxiety due to the uncertainty surrounding their child's health condition and the lack of clarity about how sick their child might be. Second, although parents could see health care staff moving throughout the ED, they frequently reported feeling forgotten when long periods passed without any updates. Third, parents demonstrated varying levels of health literacy, which was influenced by factors such as educational background, cultural context, preferred language, and previous health care experiences. Fourth, a lack of education about the ED process contributed to confusion about triage and wait times. Parents often did not understand why some children were seen more quickly than others. Finally, parents described an absence of indicators showing where their child was in the queue, which contributed to a sense of stagnation and frustration during their wait.

Table . Themes, design criteria, and solutions.

Theme	Supporting quotations	Design criteria	Solutions
Anxiety due to uncertainty: parents have significant feelings of anxiety due the to uncertainty of waiting with their child in the ED[a].	• "I'm always anxious when [my] child is sick and waiting to see a doctor." • "Human beings need some sort of indication of what is happening because it creates anxiety not knowing." • "My child is a little anxious because she doesn't know what's to come."	The app must reduce uncertainty by giving parents information they can rely on.	The app will give parents more control over their time by providing their child's personalized wait time.
Feeling forgotten: parents feel neglected and forgotten in the busy rush of the ED.	• "I felt like an idiot asking for information." • "I felt like a burden." • "Knowing that people know we're here would make us more comfortable to wait longer."	The app must help make parents feel confident that they are being cared for.	The app will be available to parents throughout their stay so information is available when they want it.
Health literacy: parents report uncertainty about the severity of their child's health issue and what is the most appropriate place to seek care.	• "Is my child going to be okay? I don't know necessarily how bad his condition is." • "I want to know if my child needs to be in the ED. We don't want to wait 12 hours for a doctor to see her and say to take Tylenol, which is something we can do at home. Or if she doesn't need to be here but go see her pediatrician." • "A nurse coming up to check on my kid early on during the wait to give us a scope of how severe [her health condition] is, some information about waiting and knowing what's coming next was helpful."	The app must provide medical education to guide parents about their child's health issue.	The app will be designed to provide parents with relevant, personalized health information to read and watch as they wait.
Understanding the ED process: parents want to better understand the ED process, including the timing and order of steps in their journey.	• "Last time I waited 12 hours, no one came to check up on us and I couldn't get food for my child or myself." • "How many people are ahead of us, to know that would make us more comfortable to know what we have time for (the washroom or to get food)."	The app must give information to make the process of the ED more transparent.	The app will include a journey map that was cocreated with ED staff and parents. The journey map will have information about the steps in the ED process; the location of washrooms, food and drinks, prayer and reflection spaces, and breastfeeding rooms; and other important wayfinding information.
Indication of progress: parents perceive a lack of progress while sitting in the waiting room.	• "We want to know the progress of our child in the queue." • "How many doctors are working? I want to know if the doctors are in the ED and not in a clinic somewhere."	The app must provide parents with a sense of progress.	The app will show parents their child's spot in the queue. This number will decrease as their child moves up in the queue to show progress.

[a]ED: emergency department.

Tool Development

We developed a refined prototype through an iterative process of prototyping, software development, and redesign based on participant feedback and end user testing. Initially, a low-fidelity prototype was developed based on user needs identified during the thematic analysis. This prototype was tested with 24 participants in a controlled environment (in the ED waiting room with a research assistant observing), which allowed for the identification of usability issues and areas for improvement. Participants appreciated information about their child's wait time and were empowered by the idea of knowing what to expect so they could plan their time. Participants made suggestions to include an audio component to the alerts, for example, a sound

notification that their child was next to see a physician. Parents requested an inbox or chat feature so they could ask the health care team specific questions and receive personalized health information. Finally, parents wanted to be able to access wait time information from home so they could determine the optimal time to bring their child to the ED. Feedback from these sessions led to a series of redesigns, focusing on optimizing the data provided to parents, the user interface, and the interaction flow, based on observed participant behaviors and preferences (see Figure 2 for early prototypes). A point of disagreement emerged between triage nurses and parents. Triage nurses recommended including the data point "How long have we been waiting?" so they could refer to the app for objective data when parents expressed dissatisfaction about long wait times. Parents, however, found this feature unnecessary and even offensive to assume they might not know how long they had been waiting.

AI Integration

In final stages of usability testing, the app was made available more widely and offered to all parents who were waiting in the ED. Parents accessed the app via a QR code on posters in the waiting room. Initially, the app showed all users the longest current wait time in the ED. In parallel with the user experience research, the AI component was developed to generate predictive and personalized wait time estimates, enabling parents to access wait time predictions and relevant health information tailored to their child's presenting concern. The team developed machine learning and natural language processing algorithms to analyze free-text notes from the electronic medical record. The machine learning model analyzed several patient-specific and ED flow-related metrics to predict individual wait times. Patients were grouped into different categories based on what priority they would be expected to be assessed by a physician. The model analyzed key words from the triage note (eg, injury or fever) to deliver symptom-specific education. Metrics such as acknowledgment rates for education-based alerts and ED process-based alerts were tracked. The tool was tested in a validation phase for several months prior to being fully deployed. As of February 10, 2025, more than 7000 parents have used the tool.

Discussion

Principal Findings

The potential for technological innovations is rapidly evolving in health care. Many organizations have started to incorporate AI-powered tools into clinical practice. The use of AI to provide patients and families with individualized information has the potential to be highly beneficial. We propose a human-centered design methodology to ensure the needs of patients and families inform the design of the tools developed.

Comparison With Prior Work

Our findings align with previous qualitative studies examining the ED wait time experience for patients and families. In pediatric EDs, parents often lack a clear understanding of ED operations, triage and waiting in particular, which leads to distrust in the system. Many parents perceive their child's condition to be more urgent than other children's, which can create frustration and dissatisfaction. Extended wait times may prompt some parents to consider leaving the ED before being seen under the assumption that a "true emergency" would have warranted faster care [25]. Prolonged wait times and insufficient communication can negatively impact perceived quality of care and health outcomes [7].

Existing literature strongly supports providing wait time information to patients and families. Access to wait times helps families manage other responsibilities and fosters a greater sense of control during a stressful experience [5,8]. In transportation research, the presence of wait time displays led individuals to perceive shorter wait times, even if actual wait times remained unchanged, demonstrating the power of perceived experience [26]. Prediction models using AI have begun to explore how to improve patient care by better communicating information about wait times and processes to patients and families [11,27]. Despite these potential benefits, a recent scoping review revealed that only 9.3% of Canadian EDs currently offer public-facing wait time displays [9]. There are no data about how many EDs offer personalized, predicted wait time data or how they communicate this information to patients and families.

AI tools and systems can be developed to solve long-standing challenges in health care. AI systems can be tailored to meet diverse needs, offering features like multilingual support, culturally appropriate messaging, and accessibility options such as large text, video sign language, or voice-to-text software [9]. A critical gap remains in the development and implementation of AI technologies in clinical spaces: the human-centered design process. To be effective and widely adopted, these innovations must be grounded in clinical need, co-designed with patients and families, and tested with patients, families, and health care providers to ensure they are accessible, useful, and safe.

Principal Results

Participants in the study had wait times under 2 hours, which is typical for the overall lower patient volumes in the summer months. Most parents were English speaking, college educated, and all owned a smartphone. Most children were under 10 years old and had previous visits to the ED. Qualitative analysis of interviews and observations revealed 5 key themes that informed the development of the tool: (1) anxiety due to uncertainty, (2) feeling forgotten, (3) low health literacy, (4) not understanding the ED process, and (5) no indication of progress (see Table 3). Our exploration of the patient and parent experience informed the development of an AI tool that provides patients with personalized, predicted wait time and education information while they are in the ED. Prototype testing was crucial in refining the tool, ensuring that it was responsive to parents' needs. Initial prototype testing with interviews and wireframes guided initial design directions before launching the app to all parents in the ED. The AI component of the tool was tested in a validation phase for several months prior to being fully deployed. The tool is now available to all families who come to the ED with their child.

Limitations

There were some limitations to our data collection that should be noted. Interviews were conducted in the summer during

daytime hours on weekdays due to research assistant availability. Our findings may not fully capture the heightened frustration and stress that parents experience during the longest wait times, which are most often at night, on weekends, and through the winter months. As a result, the study may not reflect the full range of patient experiences. However, we suspect the results would be even more dramatic if we had included more participants with longer wait times, as they would report more frustration, anxiety, and lack of transparency.

Conclusions

This study used a human-centered design approach to explore parents' experience in a pediatric ED to develop an AI tool to improve the waiting experience. We found that it was feasible to collect information from parents and families in the waiting room about their experience. In fact, 96% (64/67) of parents we approached were eager to participate. Parents described the anxiety and frustration associated with waiting with their child in the ED and were grateful for any information about the wait time or process. Key factors that contributed to parental anxiety and frustration during long wait times included a lack of information about the ED process, a perceived lack of progress, and uncertainty about the urgency of their child's health issue. Receiving wait time and educational information that was personalized to their child was very appealing to parents. A key methodology in this study was the use of human-centered design to incorporate parents' insights and experiences in the development of the AI tool.

The study highlights the significance of engaging with and understanding the user's perspective in developing health care technologies. By prioritizing the parents' experiences and insights, we have created a solution that addresses the challenge of communicating wait times and contributes to a more compassionate and efficient health care environment in the ED. The next step of this study is to make the tool more accessible by adding translations to other common languages and purposefully testing the tool with specific users, such as those who have low literacy, health knowledge, and access to technology. Further research examining the impacts of the tool on repeated use of the ED, health outcomes, efficiency, and cost savings would be valuable.

The integration of AI and human-centered design in health care extends beyond the pediatric ED and has broad implications for improving patient care, efficiency, and provider workflow across various clinical settings. AI-driven tools have the potential to support triage, optimize resource allocation, and provide real-time patient updates, potentially reducing wait times and improving patient satisfaction in EDs, outpatient clinics, and inpatient units. Human-centered design ensures these technologies are intuitive, accessible, and aligned with user needs, fostering better adoption by both patients and health care providers. However, widespread implementation comes with challenges, including variability in digital infrastructure across health care systems, concerns about data privacy, and the need for carefully designed systems to avoid perpetuating biases present in health care data. Despite these challenges, the study's approach highlights the potential of combining AI with human-centered design to create scalable, patient-focused innovations that improve health care delivery across diverse settings.

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Authors' Contributions

DS and SL conceptualized the research. MM and ISK collected the data. SL, MM, and ISK analyzed the data and wrote the manuscript. All authors provided revisions to the manuscript.

Conflicts of Interest

DS is the CEO of Hero AI, a clinical artificial intelligence company that develops software for health care clients. The other authors declare no conflicts of interest.

Multimedia Appendix 1
Semistructured interview and usability testing guide.
[DOCX File, 18 KB - jopm_v17i1e66644_app1.docx]

Multimedia Appendix 2
Structured observation tool (AEIOU [Activities, Environments, Interactions, Objects, Users]).
[DOCX File, 15 KB - jopm_v17i1e66644_app2.docx]

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Abbreviations

AI: artificial intelligence
COREQ: Consolidated Criteria for Reporting Qualitative Studies
ED: emergency department

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Viewpoint

Patient Participation in AI for Health Curriculum

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Abstract

The adoption of artificial intelligence (AI) in health care has outpaced education of the clinical workforce on responsible use of AI in patient care. Although many policy statements advocate safe, ethical, and trustworthy AI, guidance on the use of health AI has rarely included patient perspectives. This gap leaves out a valuable source of information and guidance about what responsible AI means to patients. In this viewpoint coauthored by patients, students, and faculty, we discuss a novel approach to integrating patient perspectives in undergraduate premedical education in the United States that aims to foster an inclusive and patient-centered future of AI in health care.

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KEYWORDS

artificial intelligence; patient perspectives; experts by experience; premedical education; coproduction of knowledge; ethics

Introduction

The rapid uptake of artificial intelligence (AI) in health care has created a need for education of the clinical workforce on responsible, patient-centered use of AI [1,2]. Premedical college students, as the first generation of ChatGPT natives, are in a unique position to engage with innovative pedagogical approaches to health AI as foundational training for their future careers in health care [3,4]. As members of the National Academy of Medicine's Vital Directions for Health and Health Care: Priorities for 2025 initiative recently observed, "In the same way that training programs for physicians and allied health professionals require prerequisites of study in biology, chemistry, statistics, and anatomy, basic knowledge of AI and its applications is needed for all health care personnel" [5]. We designed an undergraduate course for premedical college students called "Responsible AI for Health" to begin to address this gap. Along with guest lecturers from health care and technology companies, the course included a patient advocate (AD) as an invited speaker. The visit sparked mutual recognition of a unique opportunity to bring our resources together and advance the work of patient advocacy while enhancing the education of the premedical college students. We developed a collaboration linking a subset of premedical students (WH, AP, TP, BT) and the faculty advisor (KO) with a larger group of patient advocates called The Light Collective (AD, VR) to support their work on the "Patient AI Rights Initiative" [6]. In this viewpoint coauthored by patients, students, and faculty, we discuss a novel approach to integrating patient perspectives on AI in undergraduate premedical education in the United States. By partnering with patients as coproducers of knowledge on health technology design and use [7,8], we pilot-tested a method for fostering a workforce trained in ethical, trustworthy, and patient-centered approaches to health AI [9,10]. This small-scale proof of concept may serve as a useful model for educators at

all levels to consider integrating patient perspectives on AI in their teaching.

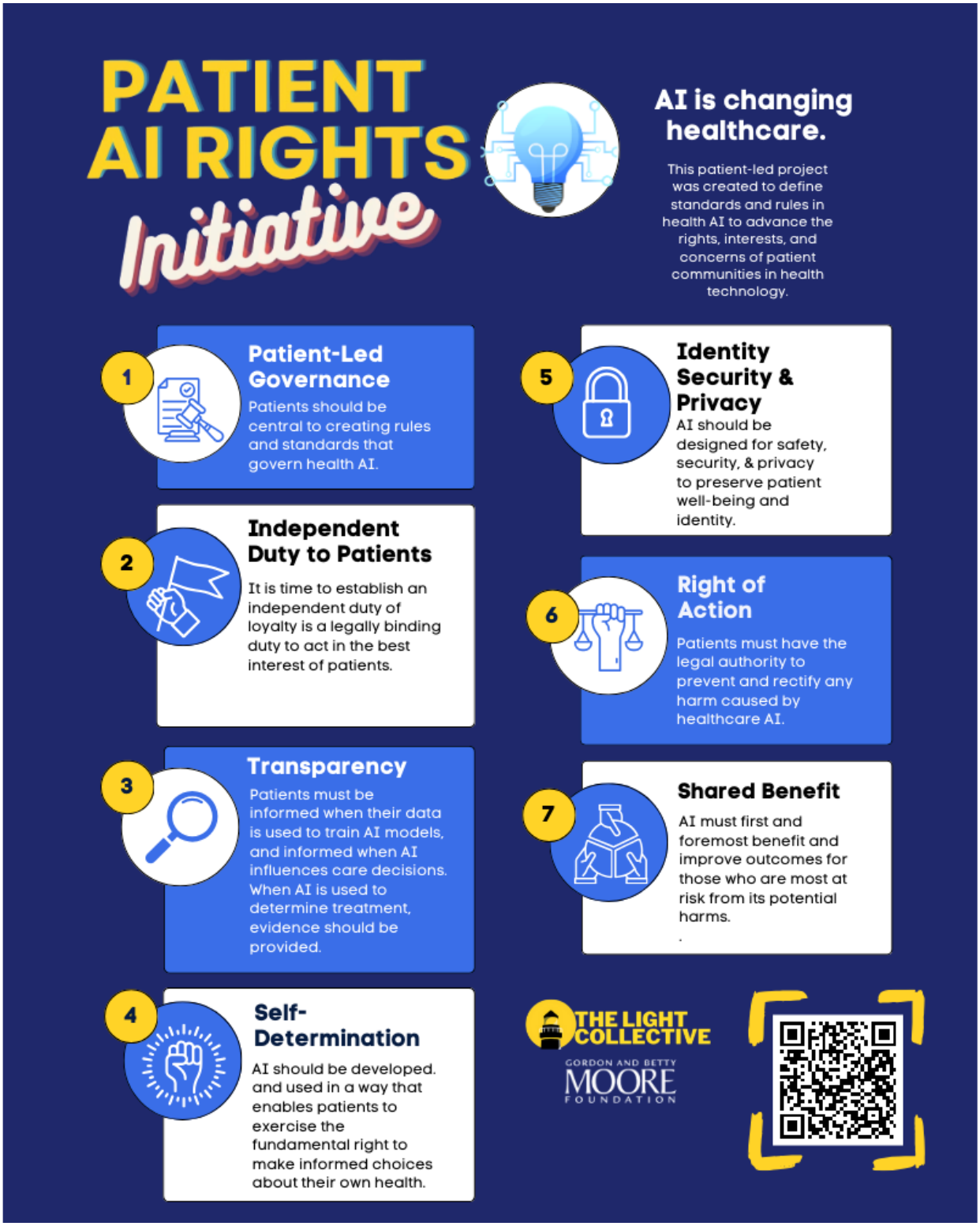
Patients as Coproducers of Knowledge: The Light Collective

The movement toward integrating patient perspectives into premedical education began decades ago, as modern medical ethics guidelines shifted away from framing patients as passive learning resources [11] to be studied by clinical experts [12]. In recent years, patients have begun to be recognized as essential partners in the knowledge creation process [13,14]. Starting in the early 2000s, a US-based group called the e-patient scholars working group played a pivotal role in identifying the transformative potential of emerging technologies such as the internet to empower and engage patients in peer-to-peer health care [15,16].

Building on that foundation, a group of patient advocates formed The Light Collective in 2018 [17] in the wake of the Cambridge Analytica data breach that exposed the private information of more than 50 million Facebook users [18]. Researchers and patient advocates recognized that health data may have been harvested and mined as part of the data breach [19]. AD, a founding member of The Light Collective, was a Facebook moderator for a support group of over 10,000 cancer previvors and survivors at the time. AD realized that similar lapses might put the privacy of all online communities at risk and began research on application programming interfaces, browser plugins, and developer tools for groups on Facebook's platform. This research led to the discovery of a security vulnerability that could potentially expose the sensitive personal data shared by members of all closed groups on Facebook. Through partnerships with cybersecurity experts, other patient activists, and legal experts, The Light Collective brought these complaints about Facebook to the Federal Trade Commission [20]. Despite an unsatisfactory Federal Trade Commission ruling on the case, the advocacy increased awareness among the public, the media, and health care professionals about the unique value of patient perspectives on health data privacy [21].

In 2023, when GPT-3 was released by OpenAI and rapidly adopted in health care, The Light Collective recognized an unmet need to bring patient community representation into the governance of AI, and the group launched the Patient AI Rights Initiative [6]. The initiative began with patient-led research in partnership with The Light Collective's diverse and growing coalition of patient advocacy organizations. They invited patient community stakeholders to share their thoughts through public comments and sought input from key stakeholders through private comments and combined these perspectives into a draft of the first patient-led framework for AI rights. Building on that framework, The Light Collective assembled a cohort of 12 participants to further explore patient perspectives on health AI. Each participant was not only an expert by lived experience, but also a person who had made significant efforts to drive change toward integrating patients as partners in clinical research. The cohort was tasked with sharing their knowledge with other community leaders, and biweekly meetings were held from December 2023 to June 2024 as a forum for discussion and debate about emerging priorities from the group. The cohort collaboratively authored a white paper enumerating 7 "Collective AI Rights for Patients," which was posted online along with an infographic summarizing the results (Figure 1) [22].

Figure 1. The Light Collective: 7-point summary of the patient AI rights initiative (June 2024; reproduced from The Light Collective [22], with permission from Andrea Downing, co-founder of The Light Collective). AI: artificial intelligence.



Patients as Partners in the Premedical Classroom: Proof of Concept

In fall 2023, a group of approximately 40 undergraduate college students were enrolled in one of the first humanities-based undergraduate classes in the United States on “Responsible AI for Health” [23], taught at Rice University in Houston, Texas. The 14-week course considered the social, cultural, and ethical issues related to the development and application of AI for health and explored the ways that technology can have unintended consequences that impact individuals and society and may increase existing health disparities. The instructor (KO) had been in conversation with members of The Light Collective dating back to the Cambridge Analytica data breach and invited a member (AD) to give a guest lecture in the class, drawing on their years of experience identifying risks and opportunities

related to patient health data sharing. AD presented The Light Collective's Patient AI Rights Initiative and discussed the 7 principles outlined in that document, focused on centering patient interests as a primary objective of health AI governance. The students who were in the class will enter medical training as ChatGPT natives, having used AI throughout their undergraduate premedical education. In their feedback on AD's lecture, the students commented that they found the patient perspective compelling and unique. In particular, students noted the contrast with the other perspectives presented through the class readings, which discussed health AI as a technical, ethical, or regulatory challenge, but not as a high-stakes personal opportunity or threat, as it was for the patient advocates.

In a follow-up to the class visit, the faculty member (KO) and advocate (AD) recognized a unique, mutual opportunity to advance the Patient AI Rights Initiative while also advancing the education of the premedical college students. The Light Collective wanted to document and disseminate the insights gained through the initiative; to do so, they partnered with the instructor and 4 premedical undergraduate student research assistants (WH, AP, TP, and BT) with support from the Rice University Medical Humanities Research Institute. The team undertook a structured process of recording and publicizing the narratives emerging from the patient cohort's learnings, working closely with 2 members of The Light Collective (AD and VR) to collaboratively create a set of video interviews showcasing the results of the Patient AI Rights Initiative [6]. This project brought together the principle of patients as partners with a coproduction of knowledge pedagogy. By participating in this process, the premedical student team learned how to engage in the cocreation of knowledge through a nonhierarchical team structure and methodology, where the questions, priorities, and output were guided by the patient-led cohort and not the academic researchers [24]. In contrast to the more hierarchical model of scientific laboratory work that was familiar to the students, this coproduction model promoted equal partnership between students, patients, and faculty, leading to novel insights that were captured in the students' reflections on the experience, including the following observations.

> *…I learned that patients, as the ultimate end users, not only provide invaluable perspectives and innovative ideas often overlooked by health care professionals and technologists but also show a strong commitment to putting in the maximum effort to make these tools as effective as possible, further emphasizing the critical need for their collaboration in developing AI-integrated health care technologies.* [WH]

> *…Interviews with advocates revealed the unique stories and backgrounds of patients that were often difficult to hear in typical health care facilities, underscoring the accountability our health care system should feel in bringing the narratives of each individual patient into medicine.* [AP]

> *…By truly listening to patients, we can ensure that health care becomes more responsive, inclusive, and better aligned with the real needs of those it serves.* [BT]

> *…As a researcher in the field of health AI, I am reminded by this work to consider qualitative, personal insights as data points that inform more humane technology solutions.* [TP]

The impact of coproduction with patients as teaching partners was evident in the experiences of the premedical student research assistants involved in this project (WH, AP, TP, and BT), who reported that partnership with The Light Collective profoundly shaped their understanding of the critical role that patient collaboration can play in the development of responsible health AI. The students noted that patients, as the ultimate end users, bring perspectives and innovative ideas that health care professionals and technologists might not consider. Several students found that The Light Collective members' commitment to ensuring that AI tools are as effective and patient-centered as possible further demonstrated the benefits of involving patients in every stage of the development process. Finally, The Light Collective's interviews with their diverse nationwide community of patient advocates revealed to the students that an understanding of individuals' unique lived experiences is often missing in traditional health care settings, highlighting the need to treat these qualitative insights with the same importance as clinical data. Through this partnership, the students voiced their appreciation of the patient-led team's involvement in shaping learning outcomes and capturing the voices of the community from a position of equity. The resulting output was a set of video interviews cocreated with The Light Collective cohort members discussing their views on health AI in their own words, which the students had reviewed, transcribed, and edited in full-length interview format and in short highlight reels. These videos are openly accessible through The Light Collective's Vimeo page [6].

Conclusion

The small-scale project we describe here took place in the US context of evolving debates about the role of patient perspectives in shaping policies related to health AI from tool design and piloting to education of the health care workforce. The Association of American Medical Colleges [25] and the American Medical Association [26], as well as numerous medical specialty organizations, have active working groups on the integration of AI into health profession education. These organizations provide resources to help their member institutions develop AI curricula, offer online courses on health AI, and convene virtual communities to discuss AI implementation. Although the American Medical Association acknowledges the importance of transparency regarding AI use in patient care, a shift toward a more patient-centered educational framework is crucial for adequately addressing these concerns within the medical field. The Association of American Medical Colleges' AI in Academic Medicine series only mentions patients in the context of patient care or patient records [25], not as sources of insight and expertise. An opportunity gap arises by not including patient perspectives to enhance the learnings and skills of clinicians. For example, patients could highlight how AI might contribute to patient self-care, information-seeking, peer-to-peer networking, trust in health care providers and organizations,

care interactions, and understanding of cultural contributors to communication.

Although we have described the benefits of integrating patient perspectives into premedical college student education, several challenges to integrating patients into AI medical education are worth noting. Some cultural attitudes within health care may lead to resistance based on differing levels of formally credentialled expertise. A coproduction model in which patients are partnered with clinicians may facilitate the cultural adjustments. Legal concerns related to liability, privacy, and confidentiality of patient data may arise. Explicit instruction in regulatory guidelines will be necessary to address any legal concerns. Logistical issues around already constrained medical schedules may arise. Scheduling issues may be overcome in part by adapting existing trainings to incorporate patient partners, rather than adding new, separate content that would require additional instructional time. Moreover, the opportunity to initiate this educational process at the premedical level warrants further exploration. Addressing these challenges will require thoughtful deliberation and planning to enable medical educators to find feasible methods for integrating patient perspectives.

This viewpoint presents a novel partnership between patient advocates and premedical college students that created a unique opportunity for the coproduction of knowledge about health AI. Based on our experiences, we recommend the integration of patients as partners in teaching as a timely and necessary evolution of the role of patients as research partners. We suggest that the framework presented by The Light Collective can be considered in dialogue with patient advisory committees that already exist at many hospitals and academic health centers to identify the concerns and priorities of local patient populations related to the use of AI in their health care. Nationwide efforts to develop new curricula on health AI have an opportunity to integrate patient perspectives by partnering with organizations like The Light Collective and learning from their work, to ensure the development of safe, trustworthy, and patient-centered AI for health.

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Conflicts of Interest

None declared.

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Abbreviations

AI: artificial intelligence

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