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Advancing the understanding and practice of participatory medicine among health care professionals and patients

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Contents

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
Supervision—AP
Writing—original draft: AP
Writing—review and editing: AP, MM, ME, RPD, ET, and PM

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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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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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

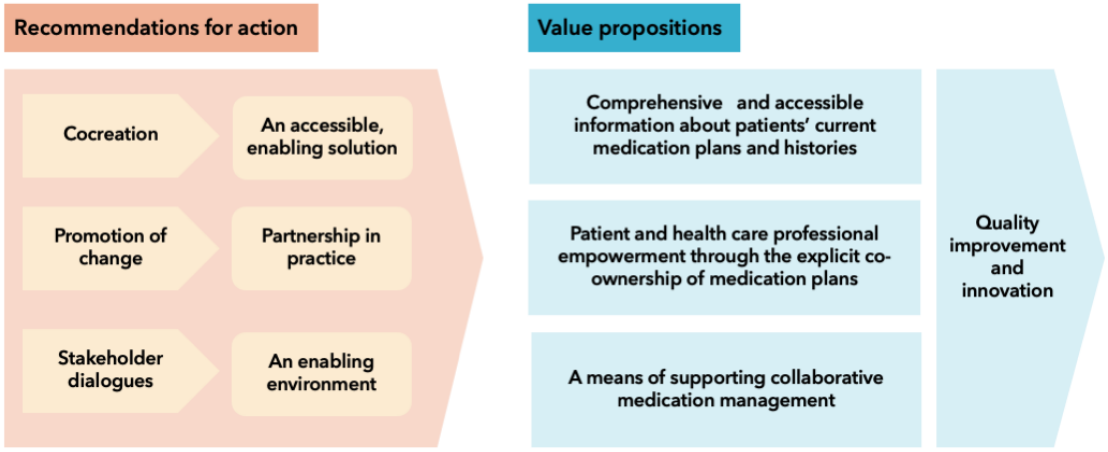
Principal Findings

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.

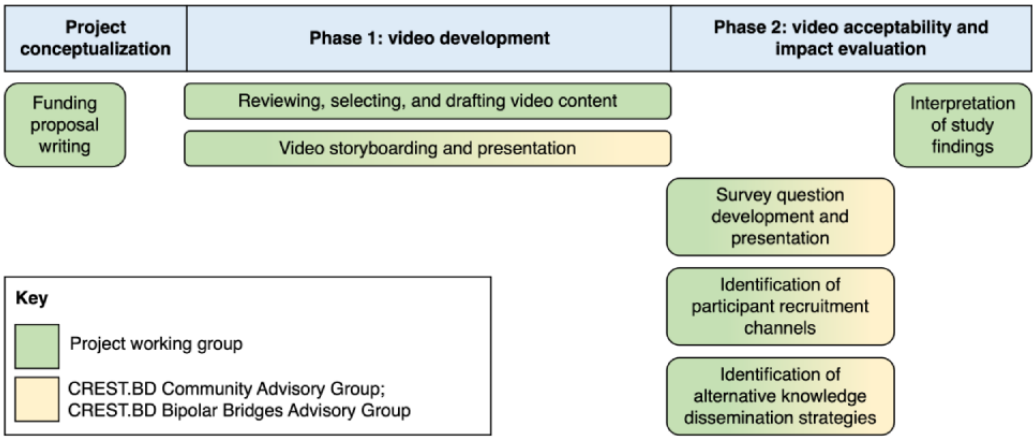
CBPR Framework

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)

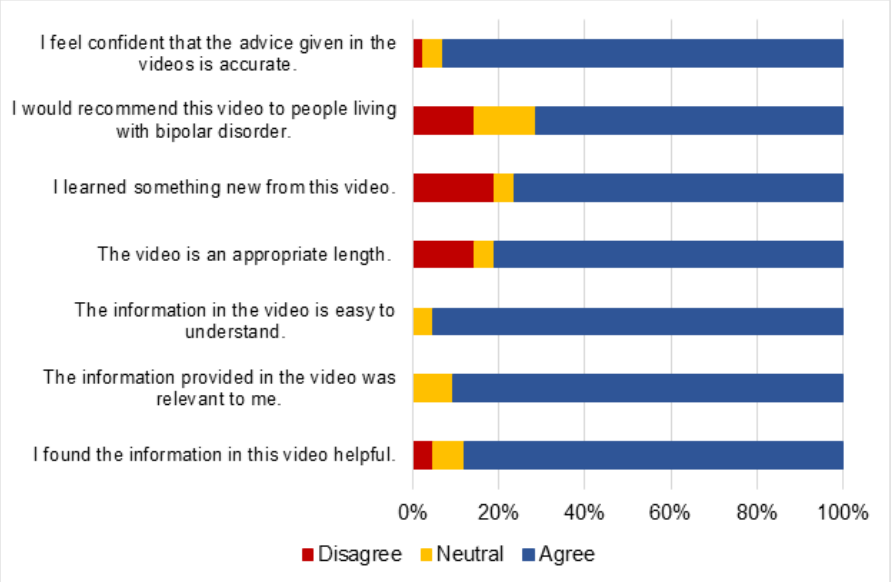
Demographic or clinical variable	Total sample (N=54)	Survey completers (n=42)
Other or do not know	4 (7)	2 (5)
Receiving treatment for BD, n (%)	50 (93)	40 (95)
Type of treatment, n (%)		
Pharmacological	48 (89)	38 (90)
Counseling or psychotherapy	28 (52)	25 (60)
Peer support	7 (13)	6 (14)
Other	2 (4)	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.

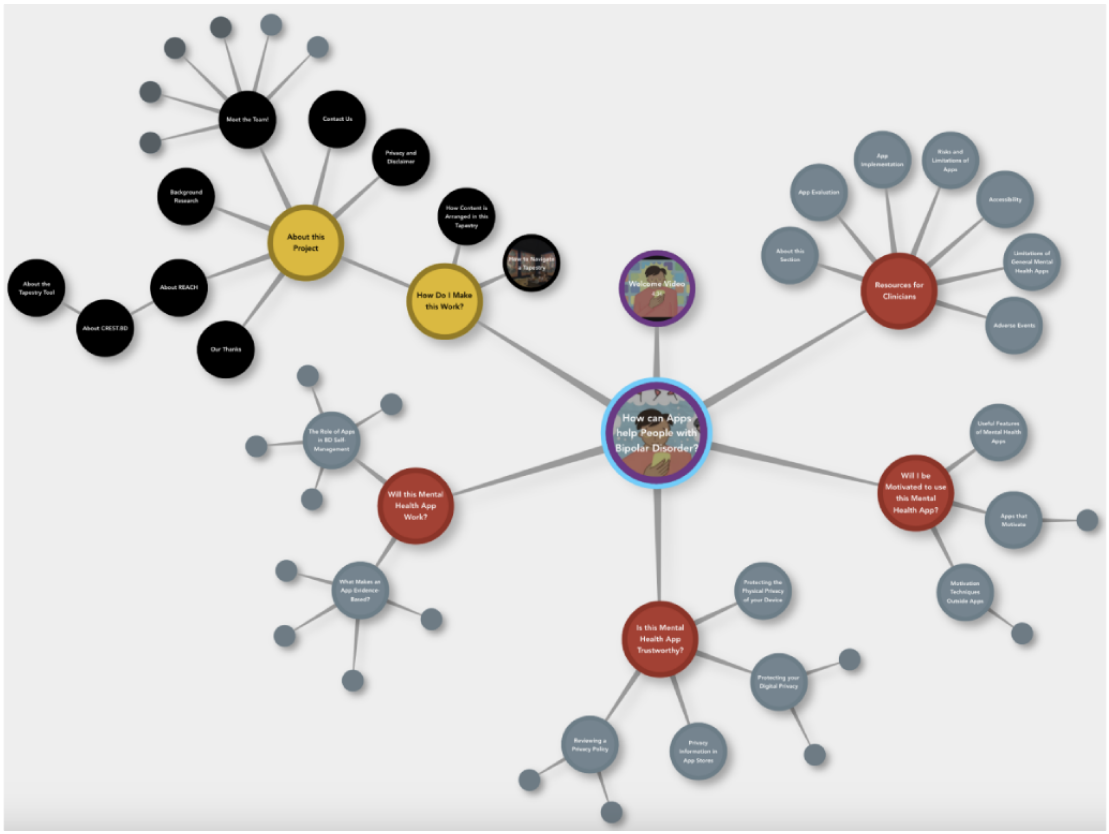
To complement the eHEALS, which is focused on digital health literacy more broadly, we also included some researcher-developed items to evaluate change in smartphone-specific competencies, such as searching for and evaluating apps. Positively, we observed improvements to some aspects of mHealth literacy, 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

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.

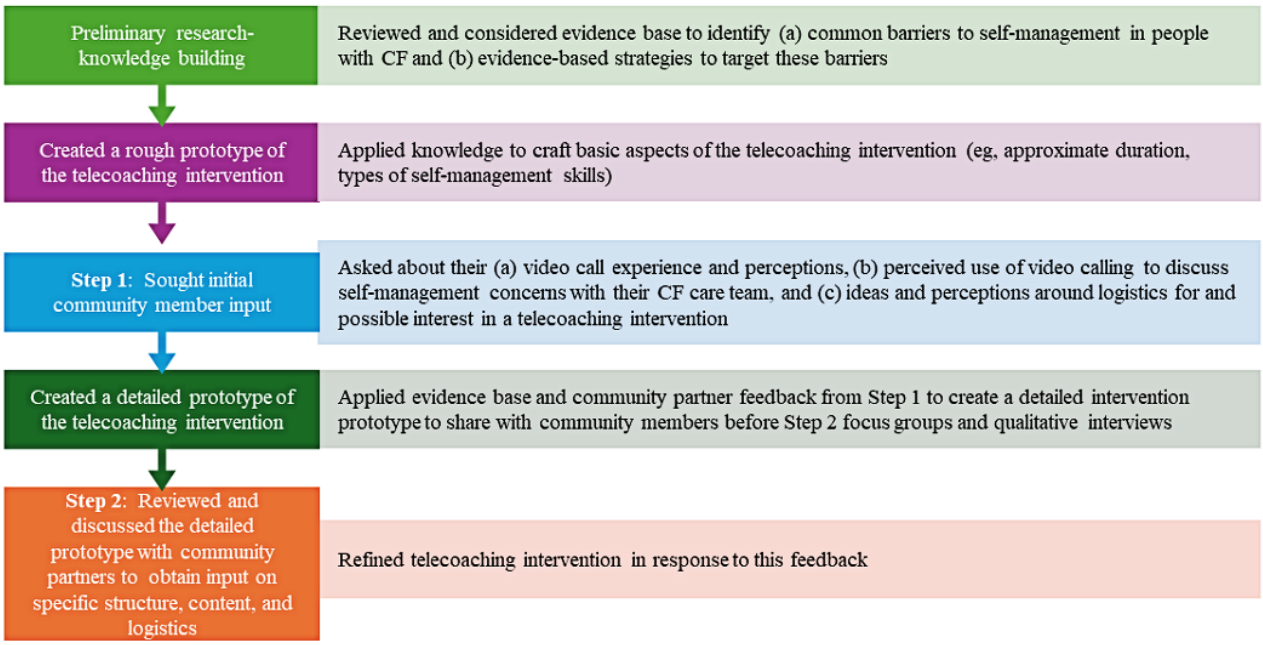
The goal of this study was to obtain and apply community partner feedback to develop (Step 1) and refine (Step 2) a novel and patient-tailored telecoaching intervention to enhance self-management in adolescents and young adults with CF (ages 14-25 years). In our subsequent line of research, the telecoaching 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."

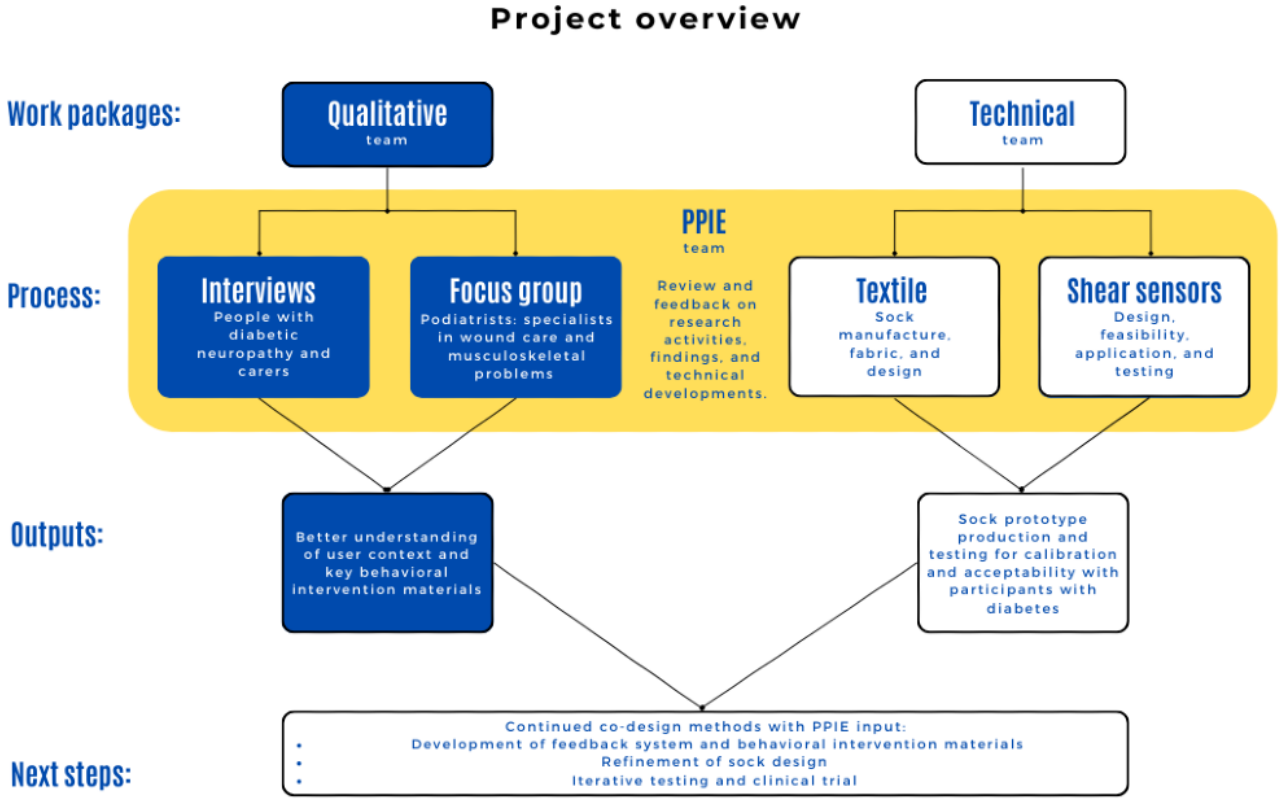
A semistructured interview guide with main questions and prompts was used and initially piloted and refined with the PPIE group (Multimedia Appendix 1). The interviews began by asking about the participants' experience with their foot care—previous issues, how they managed their foot care, and what they 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.

Trial Registration: ClinicalTrials.gov NCT06299566; https://clinicaltrials.gov/study/NCT06299566

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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.

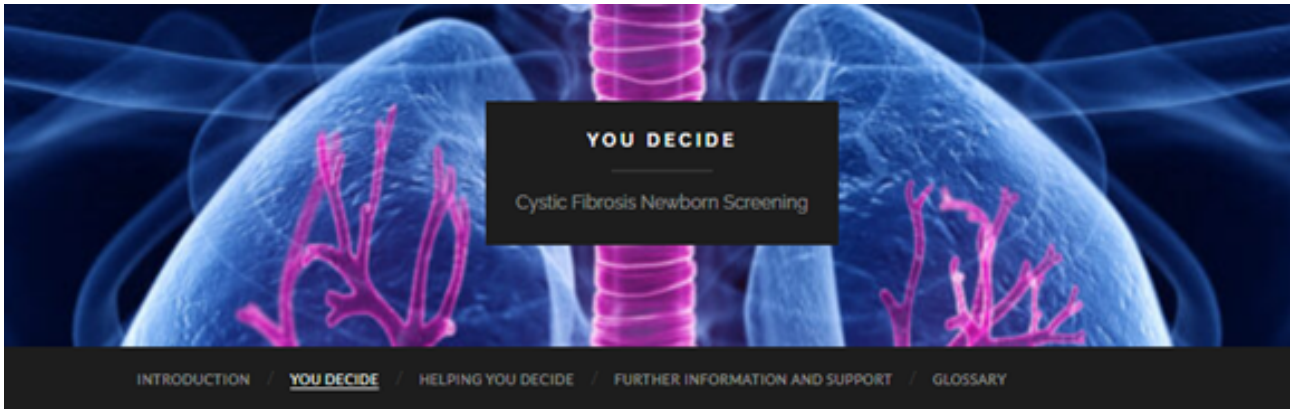
Production Considerations

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.



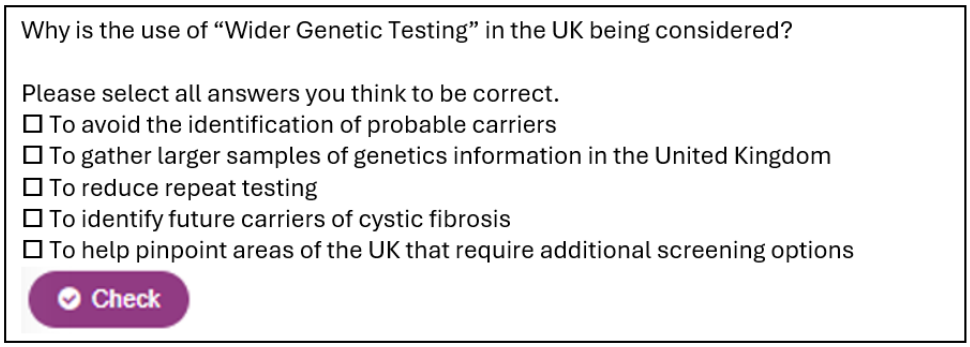
Presentation of Filmed Scenarios

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.

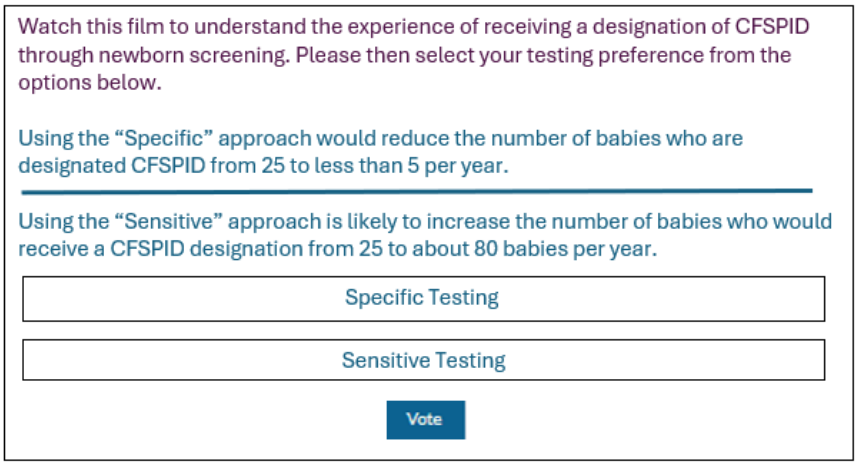
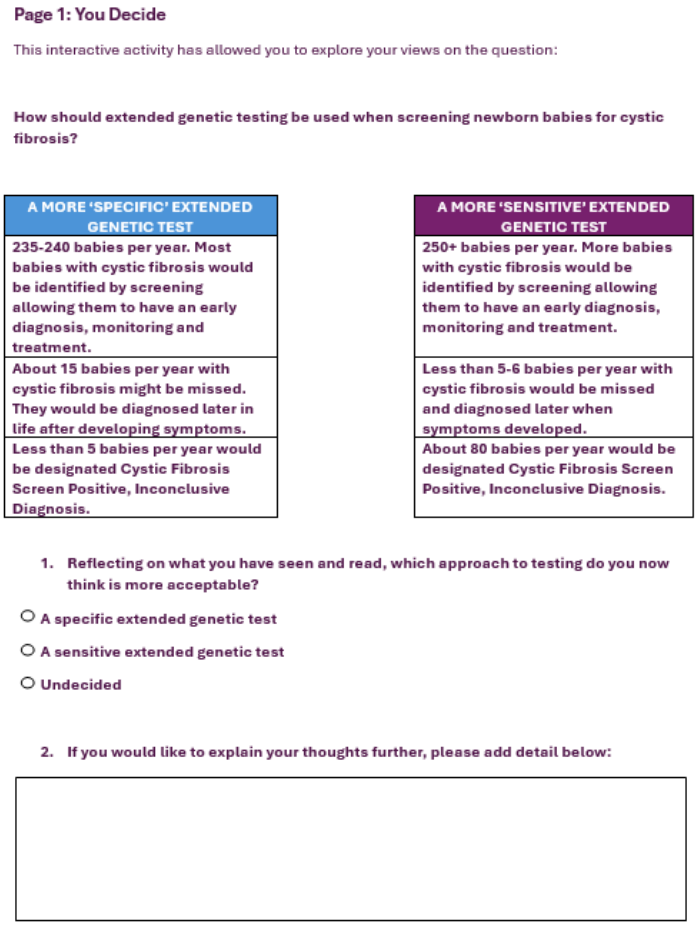


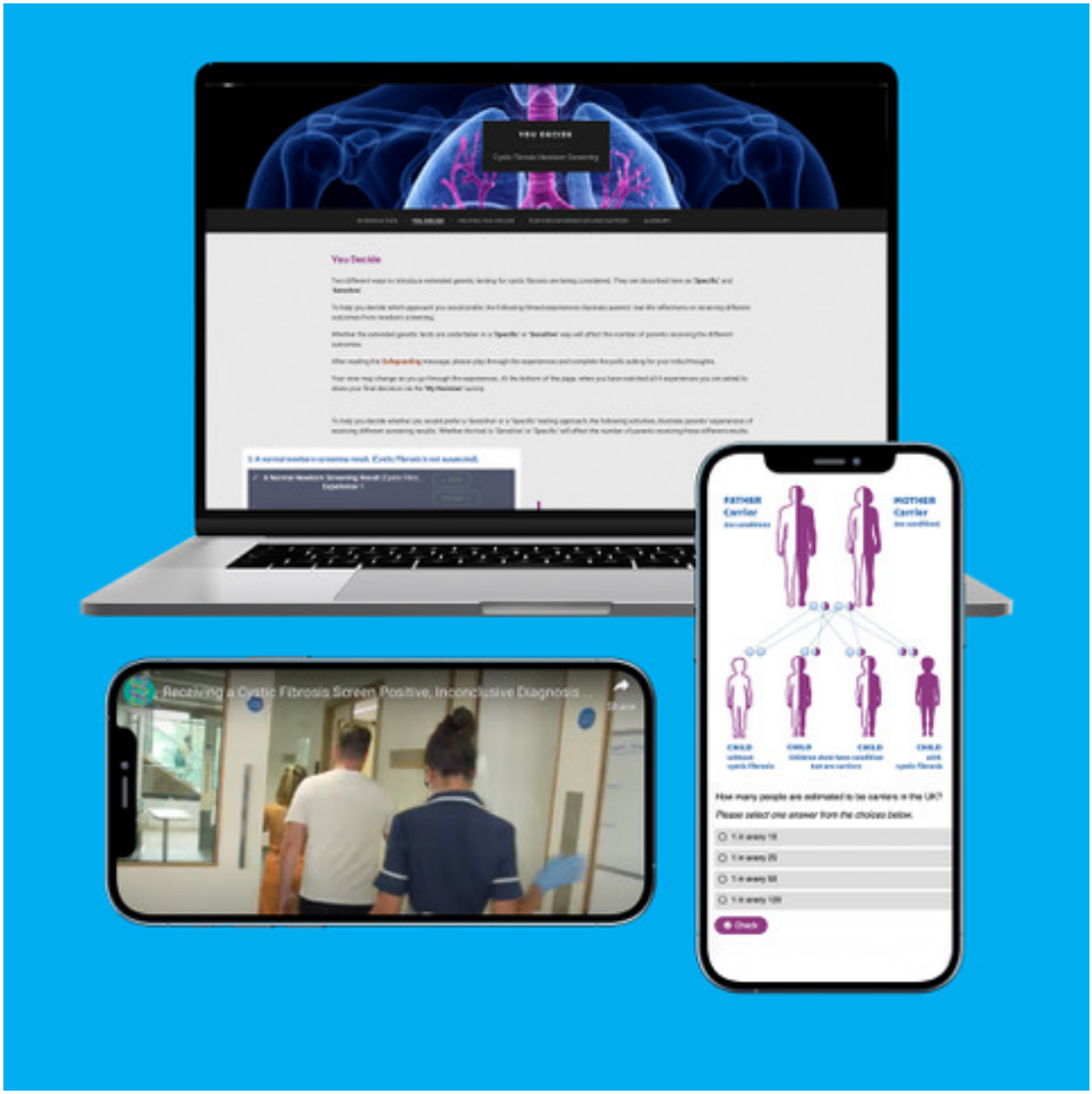
Figure 4. Question to gather a final view of the user on the question: "How should extended genetic testing be used when screening newborn babies for cystic fibrosis?" CFSPID: cystic fibrosis screen positive, inconclusive diagnosis.



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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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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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].

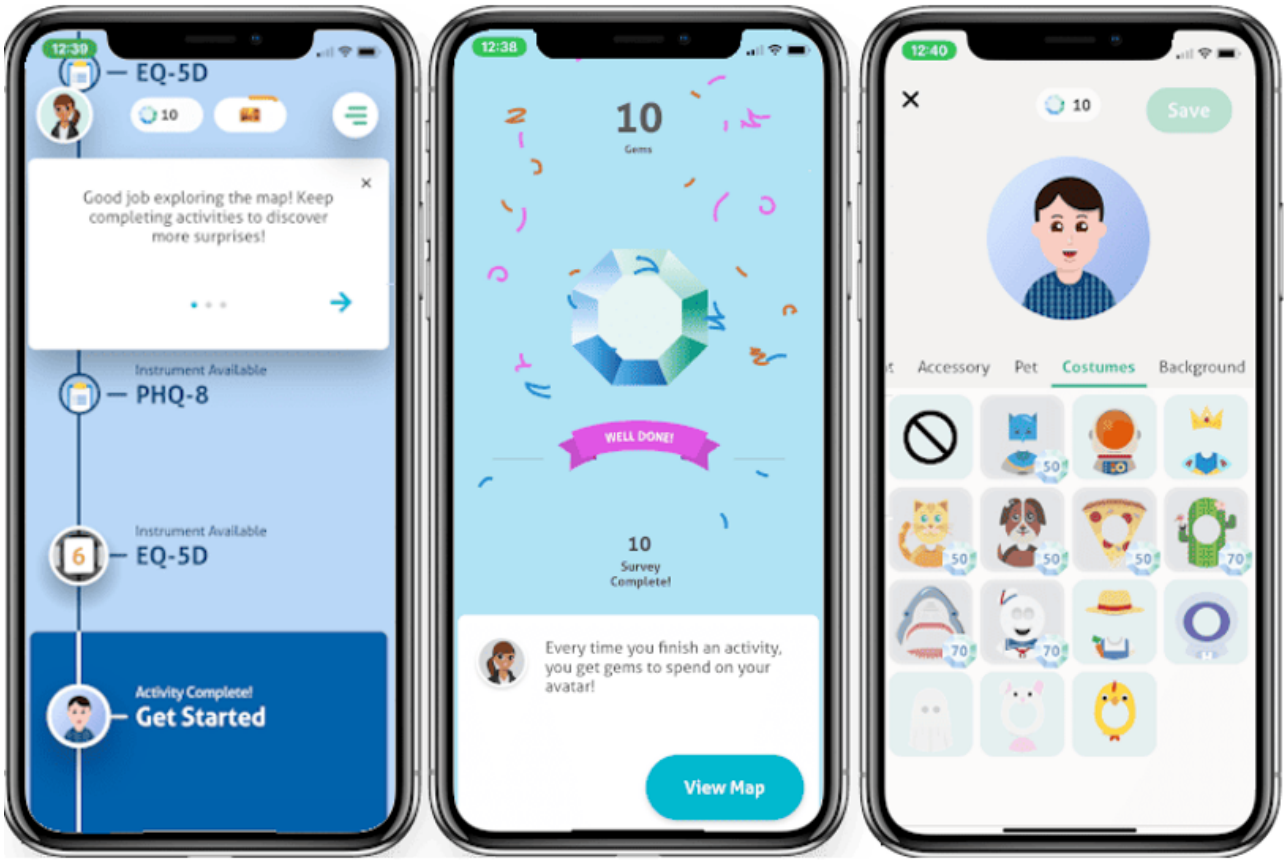
Researcher behavior and communication also impact participant retention. Retention increases with participants' positive attitudes toward study staff and the quality of their relationship with the study team [8,9]. Focusing on patient-centered communication and relationship building can therefore bolster 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

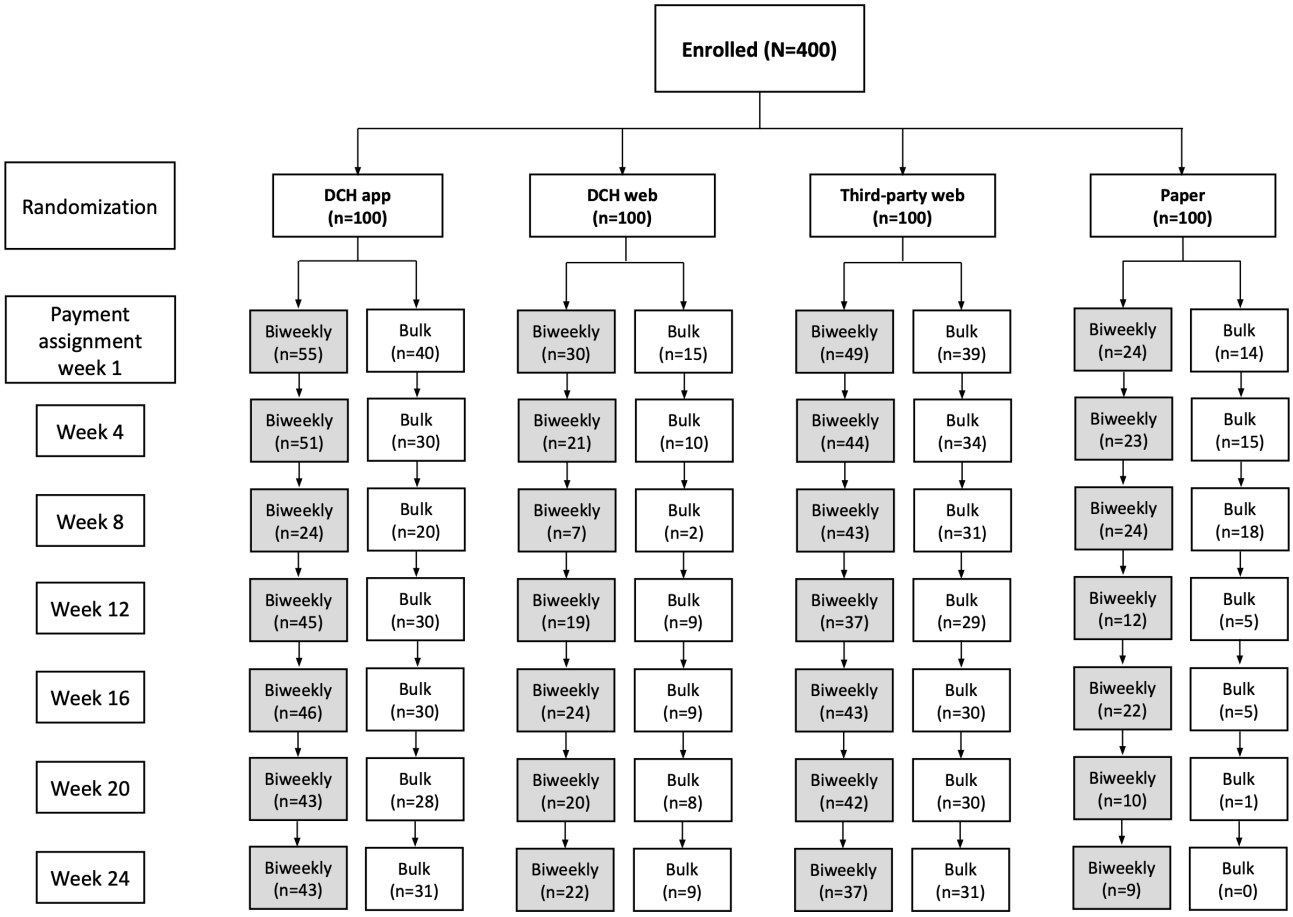
Descriptive statistics were evaluated for each of the 4 study arms. Multiple linear regressions with dummy coded categorical independent variables were performed to examine the effect of survey modality (DCH app vs DCH website vs third-party website vs paper), payment schedule (bulk vs biweekly), and 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.

Acknowledgments

This study was funded by Datacubed Health, Brooklyn, NY and conducted under institutional review board approval from the BRANY (Biomedical Research Alliance of New York). Generative artificial intelligence was not used for any component of this project including paper writing. The authors thank all user testers involved in developing the DCH app ("Linkt"), and especially participants in this study. Data collection occurred primarily during the COVID-19 pandemic, which the authors recognize as a chaotic and unpredictable time, and a particularly challenging time in which to participate in a longitudinal research study.

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).

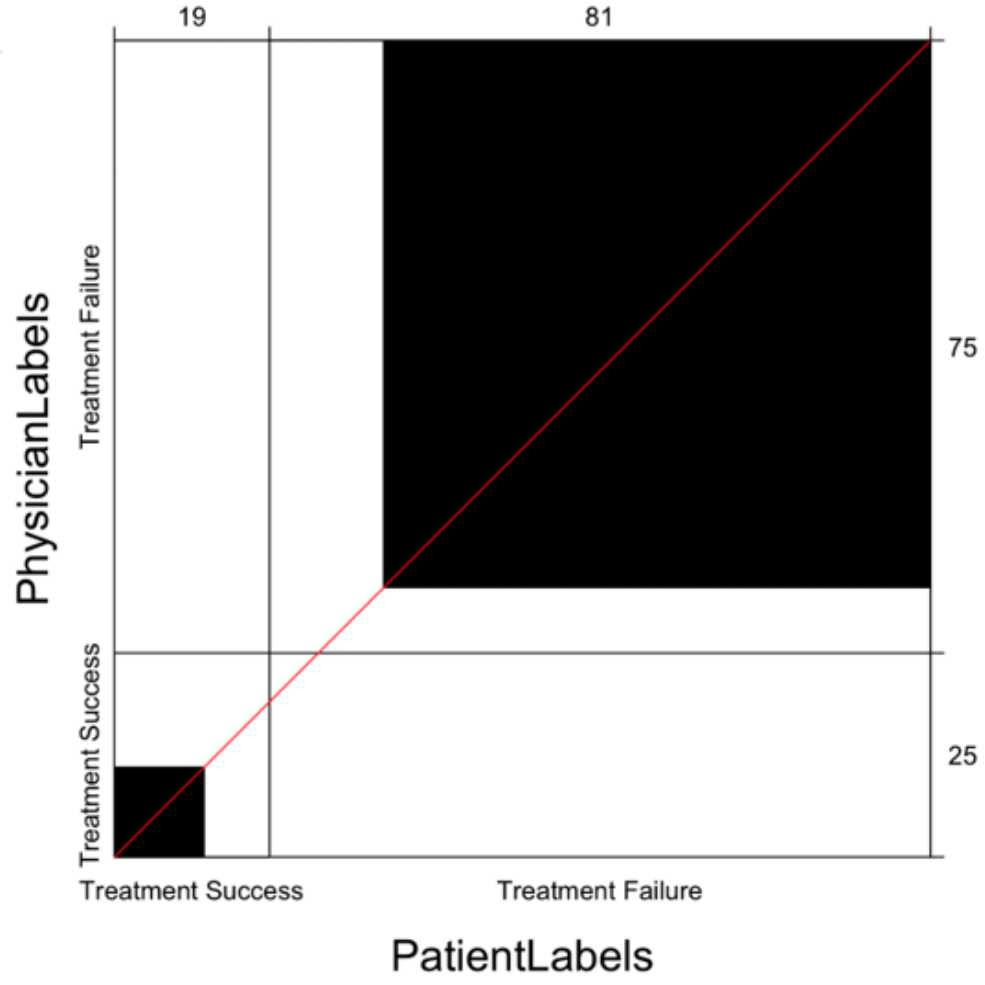
Physician labels	Patient labels			Agreement
	Success	Failure	Total	
Success	11	14	25	Fair (κ=0.32)[a]
Failure	8	67	75	
Total	19	81	100	

[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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