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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

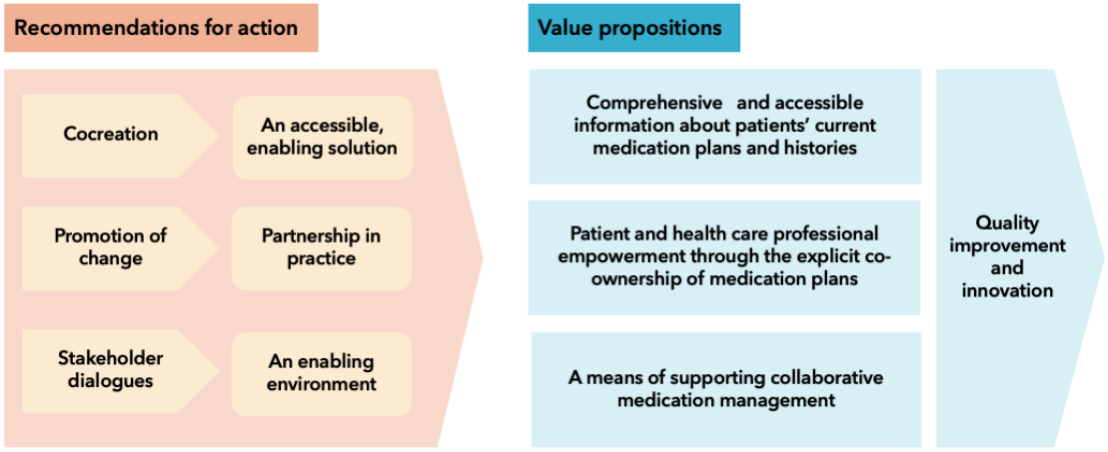
Principal Findings

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

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.

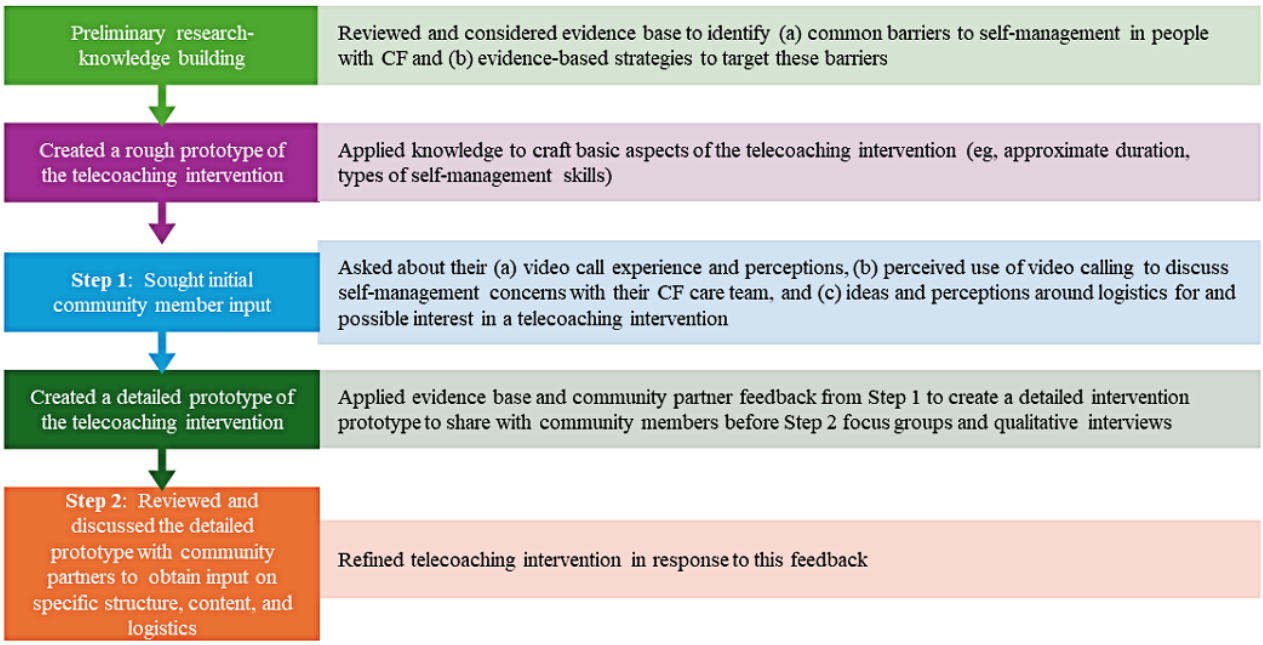
The goal of this study was to obtain and apply community partner feedback to develop (Step 1) and refine (Step 2) a novel and patient-tailored telecoaching intervention to enhance self-management in adolescents and young adults with CF (ages 14-25 years). In our subsequent line of research, the telecoaching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

Acknowledgments

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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."

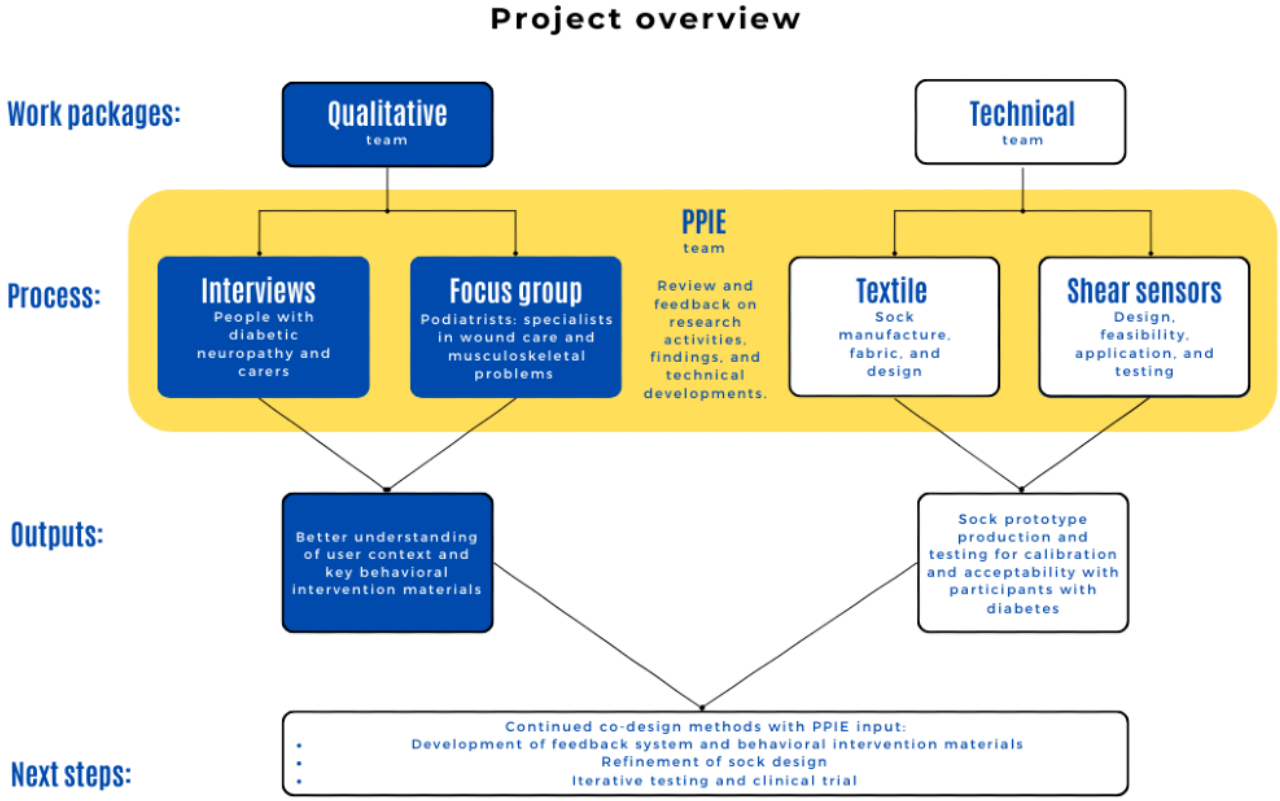
A semistructured interview guide with main questions and prompts was used and initially piloted and refined with the PPIE group (Multimedia Appendix 1). The interviews began by asking about the participants' experience with their foot care—previous issues, how they managed their foot care, and what they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

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).

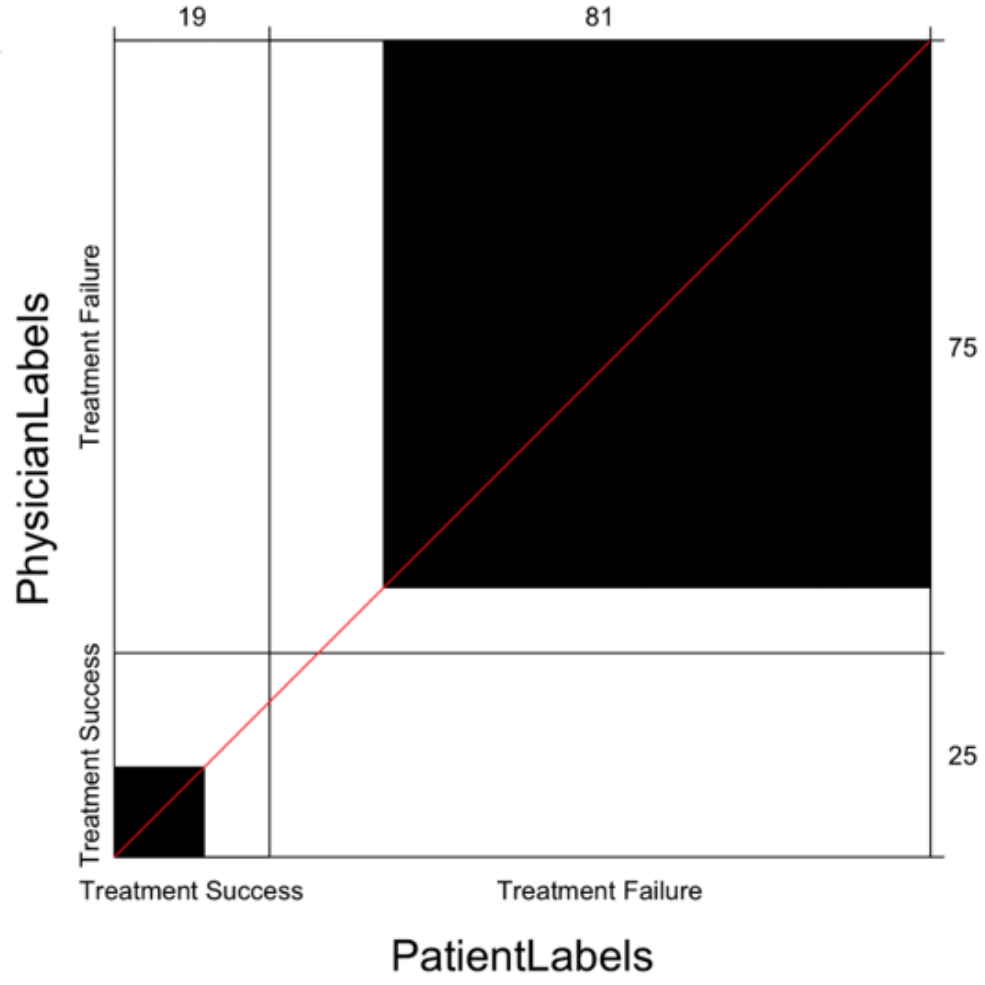
Physician labels	Patient labels			Agreement
	Success	Failure	Total	
Success	11	14	25	Fair (κ=0.32)[a]
Failure	8	67	75	
Total	19	81	100	

[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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