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Original Paper

Negotiating Tensions Between Theory and Design in the Development of Mailings for People Recovering From Acute Coronary Syndrome

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Abstract

Background: Taking all recommended secondary prevention cardiac medications and fully participating in a formal cardiac rehabilitation program significantly reduces mortality and morbidity in the year following a heart attack. However, many people who have had a heart attack stop taking some or all of their recommended medications prematurely and many do not complete a formal cardiac rehabilitation program.

Objective: The objective of our study was to develop a user-centered, theory-based, scalable intervention of printed educational materials to encourage and support people who have had a heart attack to use recommended secondary prevention cardiac treatments.

Methods: Prior to the design process, we conducted theory-based interviews and surveys with patients who had had a heart attack to identify key determinants of secondary prevention behaviors. Our interdisciplinary research team then partnered with a patient advisor and design firm to undertake an iterative, theory-informed, user-centered design process to operationalize techniques to address these determinants. User-centered design requires considering users' needs, goals, strengths, limitations, context, and intuitive processes; designing prototypes adapted to users accordingly; observing how potential users respond to the prototype; and using those data to refine the design. To accomplish these tasks, we conducted user research to develop personas (archetypes of potential users), developed a preliminary prototype using behavior change theory to map behavior change techniques to identified determinants of medication adherence, and conducted 2 design cycles, testing materials via think-aloud and

semistructured interviews with a total of 11 users (10 patients who had experienced a heart attack and 1 caregiver). We recruited participants at a single cardiac clinic using purposive sampling informed by our personas. We recorded sessions with users and extracted key themes from transcripts. We held interdisciplinary team discussions to interpret findings in the context of relevant theory-based evidence and iteratively adapted the intervention accordingly.

Results: Through our iterative development and testing, we identified 3 key tensions: (1) evidence from theory-based studies versus users' feelings, (2) informative versus persuasive communication, and (3) logistical constraints for the intervention versus users' desires or preferences. We addressed these by (1) identifying root causes for users' feelings and addressing those to better incorporate theory- and evidence-based features, (2) accepting that our intervention was ethically justified in being persuasive, and (3) making changes to the intervention where possible, such as attempting to match imagery in the materials to patients' self-images.

Conclusions: Theory-informed interventions must be operationalized in ways that fit with user needs. Tensions between users' desires or preferences and health care system goals and constraints must be identified and addressed to the greatest extent possible. A cluster randomized controlled trial of the final intervention is currently underway.

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KEYWORDS

user-centered design; codesign; medication adherence; health behavior; health education; myocardial infarction; secondary prevention; stents

Introduction

A heart attack is typically a major, frightening event in a person's life. It can be difficult for people to recover and get back to their previous activities. One challenge to full recovery is that many people are not able to follow or choose not to follow all medical recommendations, including taking 4 to 5 daily secondary prevention cardiac medications and participating in cardiac rehabilitation. Without these secondary prevention treatments, approximately 10 out of every 100 people who have had a heart attack or related event will die in the year following the event [1-3]. Taking all recommended medications and participating in cardiac rehabilitation reduces this 1-year mortality rate to approximately 2 in 100 [4-6]. In Ontario, Canada, the site of this study, up to half of patients who have had a heart attack are no longer taking all recommended medications a year after their heart attack [7] and two-thirds do not fully participate in cardiac rehabilitation [8].

There are a number of reasons why taking all recommended medications and participating in cardiac rehabilitation may be challenging for people. Some of these reasons occur at the system or societal level; for example, the timing and location of cardiac rehabilitation may present difficulties and social determinants of health such as income level may present barriers, even in a country with a publicly-funded health system [9]. Other reasons occur at the health care professional level, including family physicians who may lack resources to optimally care for a patient experiencing side effects from a medication prescribed by a cardiologist and pharmacists who may not have all the necessary information about a given patient. Finally, patients may not know whom to ask if they experience problems with a medication [10], may not have social support structures in place that facilitate better outcomes [11,12], or may face other barriers to implementing such changes within their already disrupted lives [13,14].

This study builds upon a prior study in which we aimed to address potential knowledge gaps relevant to medications at the patient, family physician, and pharmacist levels [15]. In that study, we iteratively revised letters that would be mailed to patients and their family physicians to improve comprehensibility. The patient's letter also included a letter to take to their pharmacist. Mailed letters have limitations but represent a feasible, scalable approach for a health care system like that of Ontario, with approximately 13 million enrollees and, as of yet, no system-wide electronic health record. The primary outcome in that trial—adherence to all recommended medications—did not change significantly, but we did find an improvement in other measures of adherence, patients reported that the letter was understandable, and the study demonstrated the feasibility of mailings in this context [16]. Prior research has likewise suggested that mailings can improve medication adherence among patients who have had a heart attack [17].

In this study, we aimed to build upon these previous findings by developing mailings with targeted content at different time points over the course of a year following a heart attack, focusing on communicating key information in an understandable, emotionally acceptable, and compelling manner. Our previous, smaller-scale intervention focused primarily on providing knowledge and was not designed to address potential additional barriers to taking medication. Thus, in this intervention, we also sought to address a range of determinants of adherence beyond a potential lack of knowledge and to do so at more than a single time point. As described in detail elsewhere [18], we identified determinants of medication adherence in this population to inform supplementary intervention content. Briefly, we conducted 2 studies to identify theory-based determinants. First, we conducted semistructured interviews based on the Theoretical Domains Framework [19,20] with 24 patients at 0-2, 3-12, 13-24, or 25-36 weeks after a heart attack. The interviews identified beliefs about consequences; memory, attention, and decision processes; behavioral regulation; social influence; and social identity to be key determinants. Second, we conducted a questionnaire-based study to assess the theory-based correlates of medication adherence with 201 patients at the same intervals after a heart attack as

the interview study. The questionnaires were based on the health action process approach [21] and findings showed that social support and action planning were associated with greater adherence, self-efficacy was related to adherence in the later time points after a heart attack, whereas action planning was related to adherence in the early phases after a heart attack. The analyses also showed that intention's relationship with adherence operated indirectly through action planning, providing a suggestion of how to bridge any potential intention-behavior gap. Intention to take medication was associated with greater self-efficacy and outcome expectations. Using different methods and theories, the findings nevertheless converged on key constructs to target as additional determinants of medication adherence beyond knowledge. This theory-informed approach indicated the need for the mailings to address factors including perceived risk, social support, memory, beliefs about treatment effects, self-efficacy, motivation, and planning. Drawing upon behavior change theory, we then identified key evidence-based behavior change techniques to address identified determinants and operationalized them within prototype mailings.

In this paper, we describe our development process and iterative design methods [22-24] used to operationalize the behavior change techniques targeting the identified key determinants of adherence. Our design aim was to efficiently produce high-quality materials as part of an intervention being evaluated in a pragmatic randomized controlled trial comparing the effects of mailings, automated phone calls, both, and neither (Clinicaltrials.gov NCT02382731). In describing our design process for the mailings here, we focus on issues that are likely to be generalizable to other teams who are developing theory-informed paper materials or digital media for patient use, specifically, design tensions we encountered and approaches we used to bridge such tensions.

Methods

Design of First Prototype

We gathered an interdisciplinary research team with experience in health behavior change, knowledge translation, cardiology, primary care, and the design and evaluation of evaluation of health communication materials. Based on our prior mixed methods work exploring psychological determinants of adherence among patients who have had a heart attack [18] and informed by studies testing similar interventions in the past [17,25], we identified a list of theory-based constructs that should be targeted by the intervention materials and behavior change techniques designed to develop motivation and to support translating motivation into action.

We used the Health Action Process Approach and Theoretical Domains Framework as a basis for identifying behavior change techniques linked to key determinants and the behavior change techniques taxonomy version 1 [26] to describe behavior change techniques in a consistent manner (see Table 1). Wherever possible, behavior change techniques were selected based on whether existing evidence demonstrated their effectiveness for changing health behavior. Further details of all behavior change techniques mapped to all intervention materials are available upon request.

Table 1. Behavior change techniques used.

Theoretical construct or domain	Behavior change techniques
Risk perception	Information about health consequences
Outcome expectancy	Information about health consequences
	Information about social and environmental consequences
	Credible source
	Comparative imagining of future outcomes
Self-efficacy	Verbal persuasion about capability
	Vicarious consequences
	Instruction on how to perform the behavior
Social support	Social support (practical)
	Social support (unspecified)
Intention	Goal setting (outcome)
Memory, attention, and decision processes	Prompts or cues
Action planning	Action planning
Coping planning	Problem solving
Behavioral regulation	Self-monitoring of behavior (optional)
	Adding objects to the environment (optional)
	Nonspecific reward (optional)

Researcher team members partnered with a design firm to engage in an iterative design process. The design firm's team included a person with significant lived experience as a patient who had served as a patient advisor to multiple organizations.

Designers worked with the research team to develop theme boards to guide the visual design of materials. The design firm also led additional user research, that is, research to better understand the needs, contexts, and goals of people who would use the materials. This user research informed the development of personas to guide the design of the content of materials to deliver intended behavior change techniques. Personas are archetypes—not stereotypes—of potential users [27]. Using personas may help to center design work around the people who will use the developed materials and have been used in other health communication contexts [28]. Working closely with the project's principal investigator (NMI) and consulting with other team members with expertise in user-centered design, health behavior change, and clinical support of patients in their recovery after a heart attack, the designers produced the content and first prototypes of study materials: mailings designed to be sent to patients 1, 2, 5, 8, and 11 months following a heart attack.

Recruitment

Cardiology team members (JDS, MN) identified potential participants from their cardiology practice roster in Southern Ontario that matched, to the extent possible, the various personas and recruited them to the study. A patient partner with design expertise (ENA) met with consenting study participants at Hamilton General Hospital. Patients were offered a Can $20 gift card to a common coffee shop chain in appreciation of their time and effort. This study was approved by the Hamilton Integrated Research Ethics Board (02-245).

User Testing

We used a think-aloud approach in which users were asked to articulate their thoughts as they used or reviewed materials [29,30]. Although think-aloud can demonstrably capture cognitive processes [31,32] and has been used with other static health communication materials [33,34], previous work using think-aloud to assess a booklet about a health topic (colorectal cancer screening) also reported some difficulties with the method, particularly among people with lower health literacy, who found the interview "intimidating and stressful" (p.9) [33]. Methods such as think-aloud that rely on verbal articulation may overlook important issues and may also privilege the views of people who are better able to find words to describe their reactions. Therefore, in addition to think-aloud, we also discussed the materials more broadly and asked clarifying questions of study participants to better understand their reactions to the materials. The interview guide for such discussions is shown in Multimedia Appendix 1.

Analysis and Subsequent Design Changes

We transcribed interviews verbatim, and the study team reviewed transcripts for key themes that could inform design changes using data from both think-aloud and interviews to develop interpretations based on users' verbal reactions to materials, researchers' observations of participants' nonverbal reactions, and participants' responses to questions about both their cognitive and emotional responses. Following each set of user testing sessions, the design team prepared a presentation for the larger research team. The whole team met to discuss usability or other problems identified during user testing sessions, assessing the severity of problems and the feasibility of different ways of addressing such problems and grounding these discussions in the context of other available evidence and the overall study goals.

Results

Recruitment

Out of the 15 eligible patients we attempted to recruit, 10 agreed to participate. The spouse of one of the patients also participated. Participants were thus 10 people who had had a heart attack within the past year (5 men, 5 women) and 1 spouse (a woman) of one of the patients. Patients' mean age was 57 years (range 31-70 years).

Key Tensions and Resulting Changes to Design

The user testing revealed key tensions to be negotiated during the design process. First, in a number of instances, users expressed a desire to remove operationalizations of behavior change techniques that have previous evidence of their efficacy. Second, the ethical imperative of supporting evidence-informed decisions aligned with the preferences and goals of each patient was sometimes at odds with the overall goal of encouraging particular behaviors. Third, logistical constraints made it infeasible to enact some of the changes requested by users. The full, final set of developed mailings is available in Multimedia Appendix 2.

Effectiveness Versus User Experience

One significant source of tension occurred when potential users' responses conflicted with evidence about what works to support behavior change. For example, we observed this tension around patients' responses to embedded problem-solving (coping planning) exercises within the mailings. This behavior change technique was operationalized to be consistent with the evidence supporting the use of volitional help sheets, which present prepopulated lists of barriers to action and solution to these barriers. Completion of a volitional help sheet involved users completing tasks such as drawing lines between a prespecified barrier (eg, "If I can't get to my pharmacy when it's open...") and solution that best applies to them (eg, "... then I will call about delivery options."). Problem solving and volitional help sheets have strong theoretical grounding and empirical evidence supporting their use [25,35-38]. However, a number of patients responded poorly to these; they found them silly and stated they would not do such an exercise, commenting, for example, "It seems useless...To me it's common sense...if you don't know this you have other problems." [Participant 2].

To address this tension, we analyzed and discussed user comments during testing and interviews to identify a potential root cause of the tension—users lacked a motivating reason to complete the exercise. We therefore highlighted the evidence supporting such exercises with brief explanations, "Research shows..." that connected the exercises to staying on track and thus avoiding dying due to a second heart attack (see Figures 1 and 2).

Figure 1. Final action planning and coping planning spread, patient booklet: month 1.

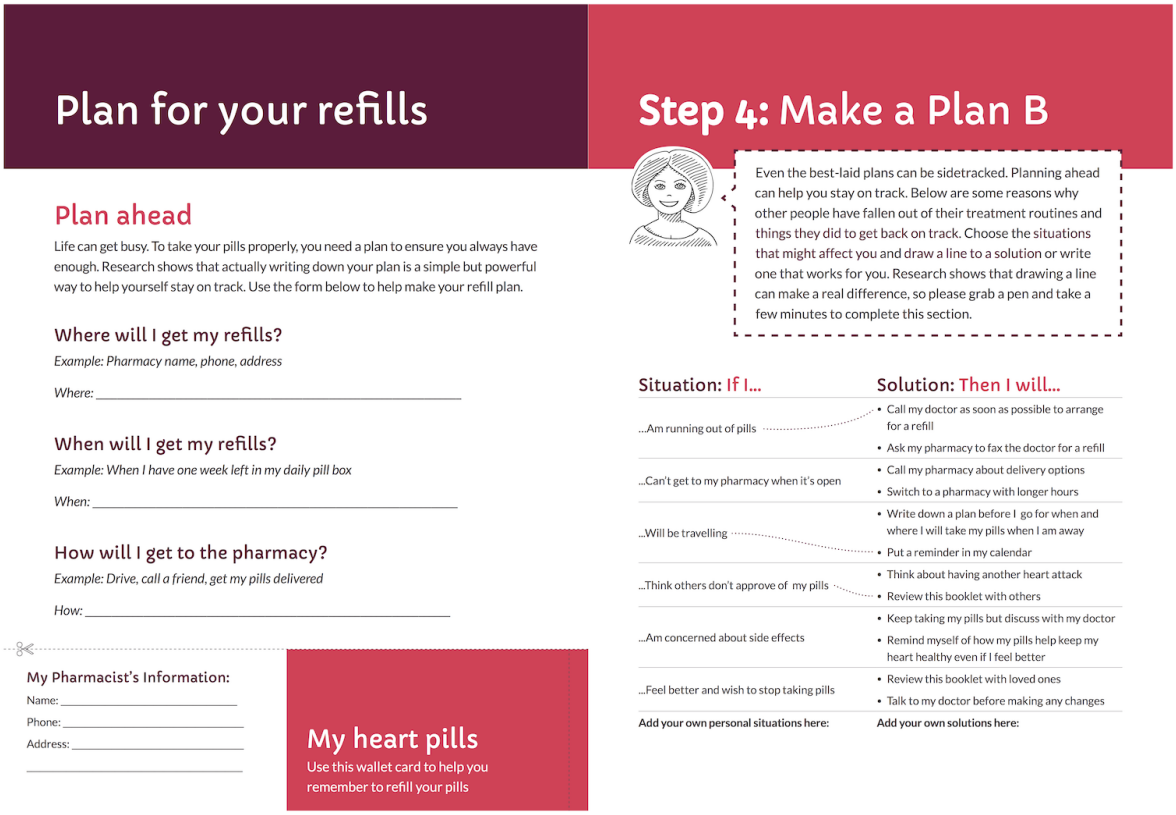
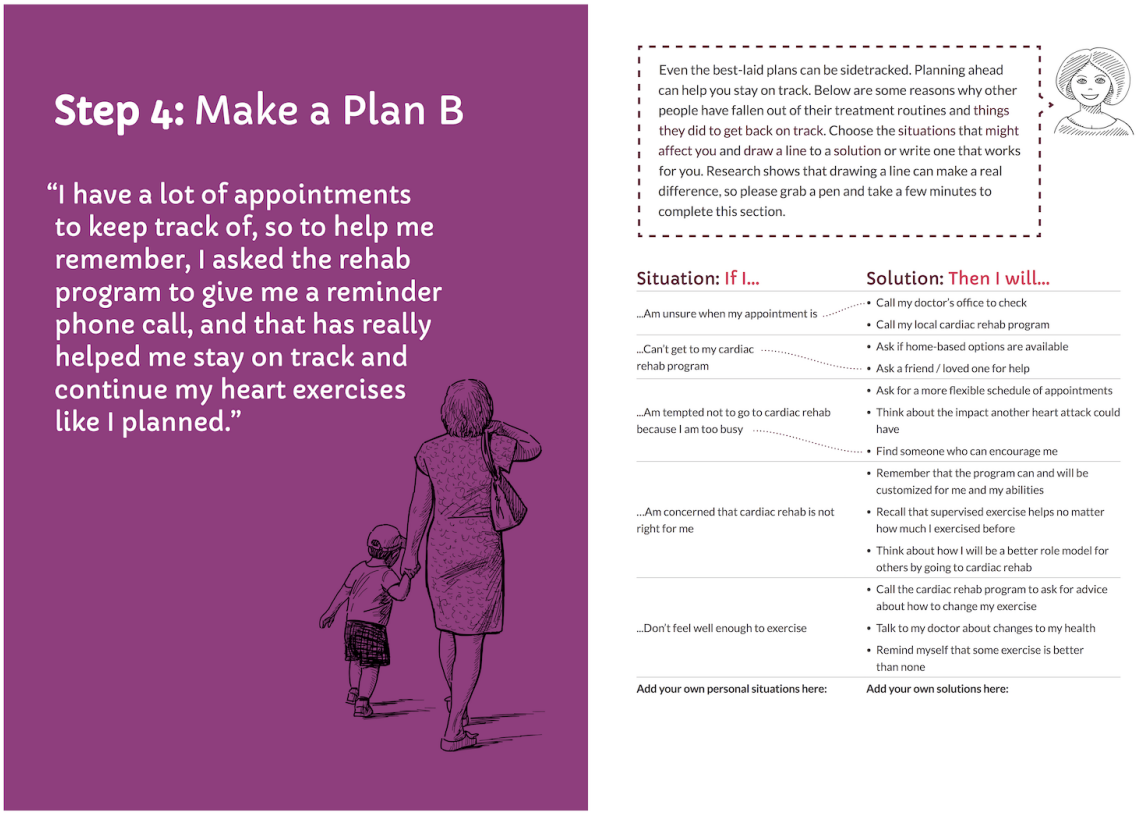


Figure 2. Final coping planning spread, patient booklet: month 5.



Informative Versus Persuasive Communication

The appropriate method for presenting information about choices, including their risks and benefits, depends on one's communication goals [39-42]. Informative communication has traditionally aimed to present all information in a balanced manner [43]. However, even tools such as patient decision aids, used primarily in situations of medical equipoise, are seeing application in situations in which there is often a medically preferable choice; for example, vaccinations [44-46].

Our initial designs were closer to the informative end of the informative-persuasive spectrum. As our design evolved and as the research team considered users' reactions to prototype materials, designs ultimately moved more toward persuasive communication. For example, we initially presented the choice to take medications or not to take them as somewhat visually equivalent by presenting 2 possible paths to follow (Figure 3). In contrast, our final design privileges the path of "new normal" by using a solid line, checking it off as the presumed default, and presenting returning to the old path as a dotted line deviation from the default (Figure 4).

The design team also initially attempted to convey statistics about mortality in the year following an acute coronary syndrome event using an abstract icon array with random dispersion of events (Figure 5). Users found this representation confusing and scientific team members confirmed that such a display was unlikely to be understandable [41]. By taking a more persuasive approach in the final design and focusing on the number of people whose premature death could be avoided, our final design allowed us to collapse a conditional probability into a single statistic that users reported as being both more compelling and also more understandable (Figure 6). Both initial and revised figures were deemed potentially frightening by some users, a worrisome finding, as it may not be effective to attempt to frighten people into healthy habits. However, our research team agreed that there was an ethical imperative to communicate this evidence to people whose lives could be affected by it.

Figure 3. Initial figure for path choice, patient booklet: month 1.

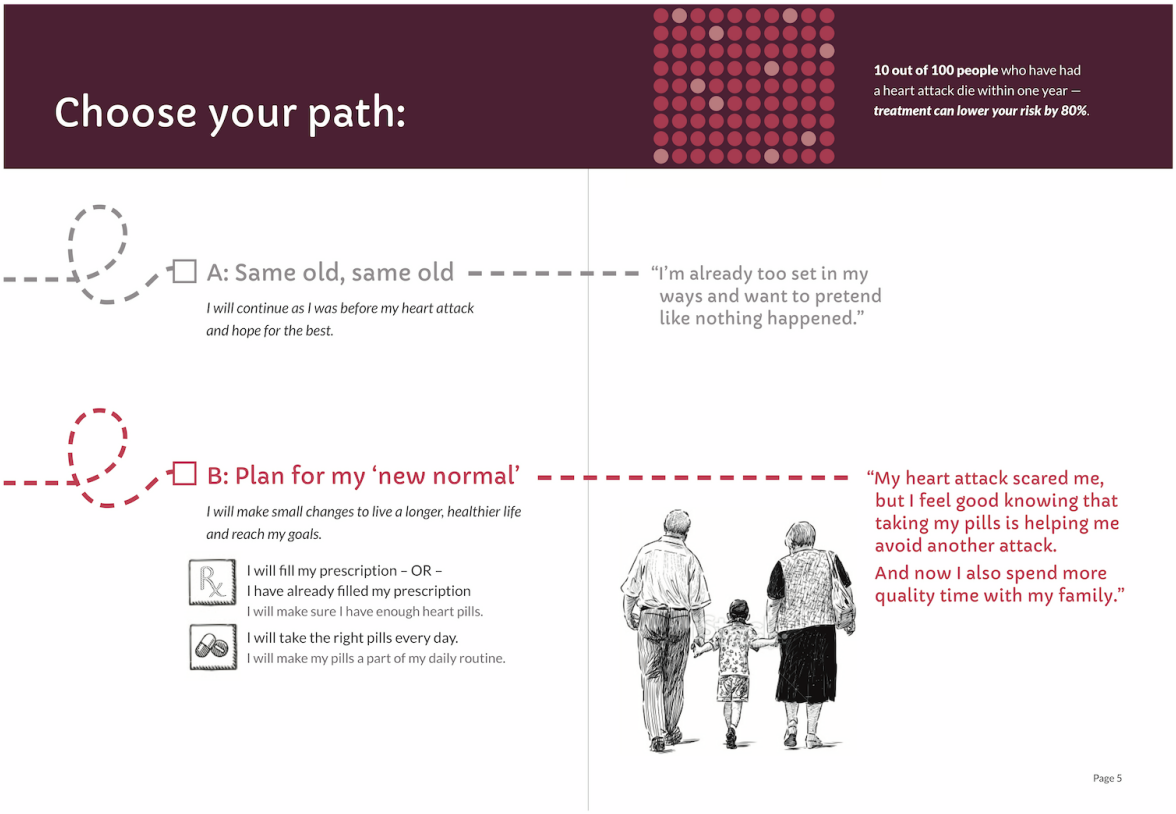


Figure 4. Final figure for path choice, patient booklet: month 1.

Figure 5. Initial figure (also see Figure 3 for full context) for mortality statistics, patient booklet: month 1.

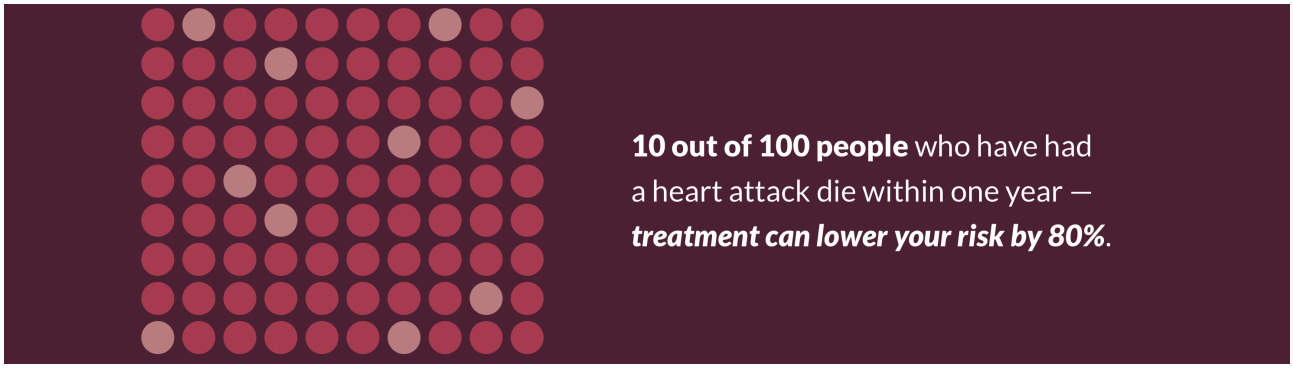
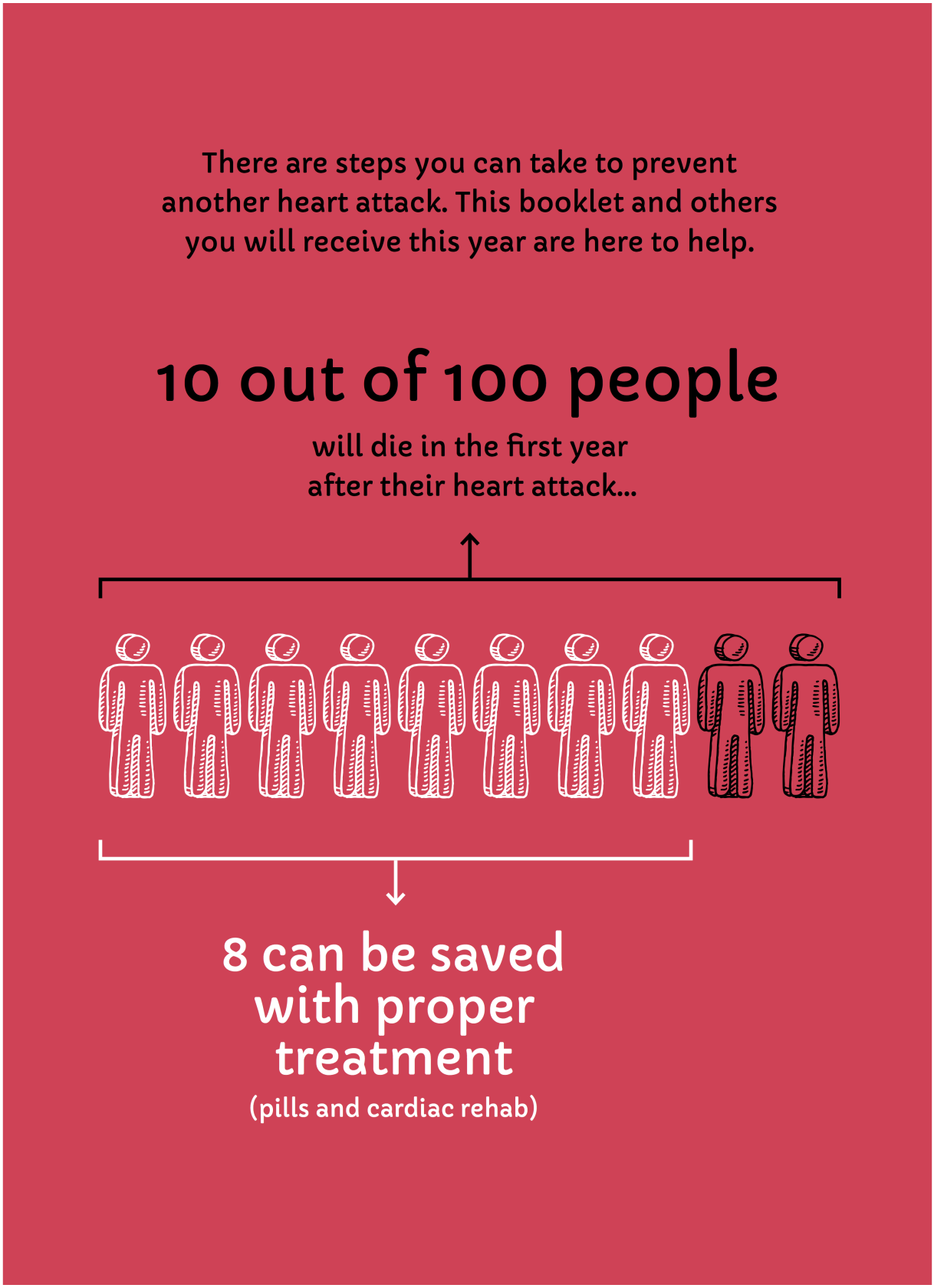


Figure 6. Revised figure for mortality statistics, patient booklet: month 1.



Feasibility of Meeting Users' Expectations

The nature of the planned intervention (standardized printed materials) and the context in which it was to be implemented generated some important tensions. Some expectations and needs related to imagery and content were able to be addressed or partially addressed, but others about the timing of the materials were not.

Designing static, paper booklets that could suit all potential users was a challenge when it came to imagery and other design

decisions. Many emerging methods that have been shown to optimally support comprehension of health information, informed choice, and behavior change involve digital tools [47-50] and translating such methods into static booklets is not always feasible. It was out of project scope to tailor images to match gender, age, race, ethnicity, and other characteristics. We therefore attempted to present images that were more abstract and less specifically representative of a single, identifiable person. Our initial images were intended to evoke ideas of life goals and plans (Figure 7) and moving on with one's life (Figure 8). However, users found the first of these confusing, questioning whether Figure 7 indicated that people are travelling somewhere in the rain and noting that it looked unpleasant: "Well, that's depressing." [Participant 1]; "Are they going back to hospital?" [Caregiver of participant 1]; and "Why are they walking in the rain? Who wants to walk in the rain?" [Participant 3].

Users also found Figure 8 not relatable due to a lack of match in perceived age. For example, participant 3 noted:

> *I think it should be more of a variety of people...you look at them and you know they're older people...maybe...it should be parent child and grandparent...so that it shows you that it's possible for anybody (to have a heart attack).*

While constrained by the inability to tailor images to individual users, we addressed the perceived discordance between intervention imagery and participants' self-image by changing the abstract human figures. In subsequent testing, revised figures were deemed more relatable and revised content more understandable (Figures 9-11).

User testing revealed an important missing element regarding the source of the mailings. Participants articulated their thoughts:

> *I'm wondering, who is this content from? One of the vital pieces of information for me, and I think probably other people, is more about who is sending me this? What's the organization/association/ hospital/cardiologistis it the Ministry of Health?* [Participant 5]

> *It could be the Heart and Stroke Foundation sweepstake thing* [Participant 7]

Participants revealed that when they receive mail with the logo of the hospital, they may assume it is a fundraising campaign and may not even open the envelope. We therefore added specific imagery (Figure 12) and a reference to a charitable foundation who partnered with us on the project (see Acknowledgments).

The early prototype for an introductory page (Figure 7) was also overwhelming to users, possibly due to inadequate introduction to a great deal of complex content. We therefore revised the introduction and added signposts to orient users as to where they were in a given booklet (Figure 9) and also in the series of mailings (Figure 13).

In contrast, some user needs and expectations could unfortunately not be addressed due to contextual factors including logistical constraints. For instance, many patients suggested that the first booklet should arrive at the time of hospital discharge, stating:

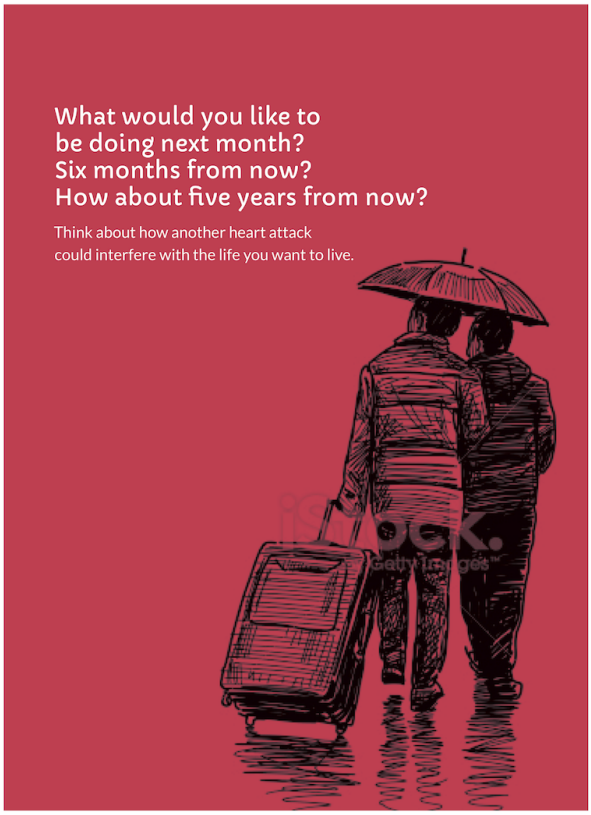
> *You need to hit the knowledge gap. This needs to come right after or in hospital.All of this would have been maybe useful right at the beginning* [Participant 5]

> *This comes too late (...) I got my pills the first day. You have to have that sorted* [Participant 3]

However, such timing was not technically feasible to implement at scale.

Furthermore, iteratively developing an intervention to the extent we believed would be ideal—including conducting multiple iterative cycles with users beyond a single site—would have left insufficient time to run the cluster randomized controlled trial within the 3 years allocated to the project. We partially addressed this by planning and undertaking rapid iteration and applying design findings from 1 set of evaluations across multiple mailings, increasing efficiency. For example, following potential users' responses to imagery in the first mailing, we adapted the images in all subsequent mailings as well.

Figure 7. Initial figure for opening pages of patient booklet: month 1.



Plan for the life you want to be living

Take a moment to discuss it
then write it all down.

In one month I want to...

(ex: Be active 3 or more times a week) _____

_____

_____

In six months I want to...

(ex: Travel) _____

_____

_____

Five years from now I want to...

(ex: See my grandchildren grow up) _____

_____

_____

Page 3

Figure 8. Initial figure for “new normal” path, patient booklet: month 1.

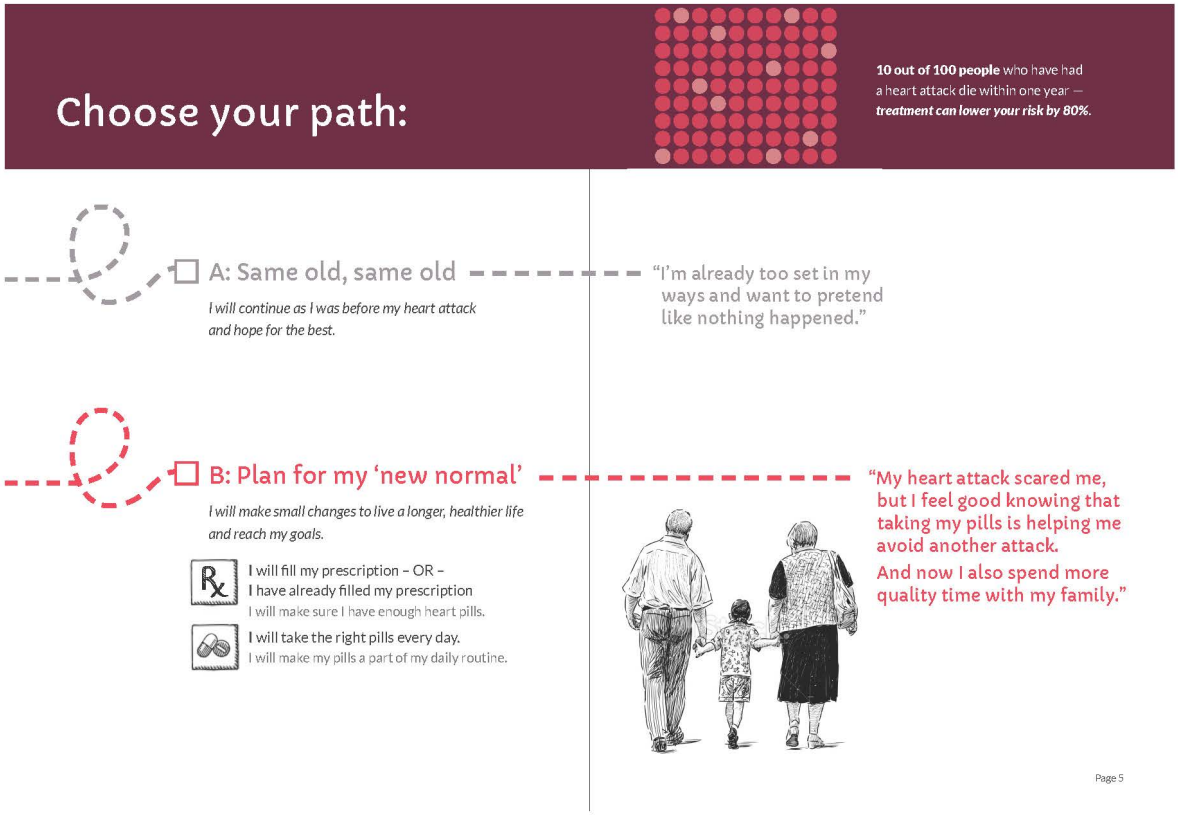


Figure 9. Revised figure for opening pages of patient booklet: month 1.

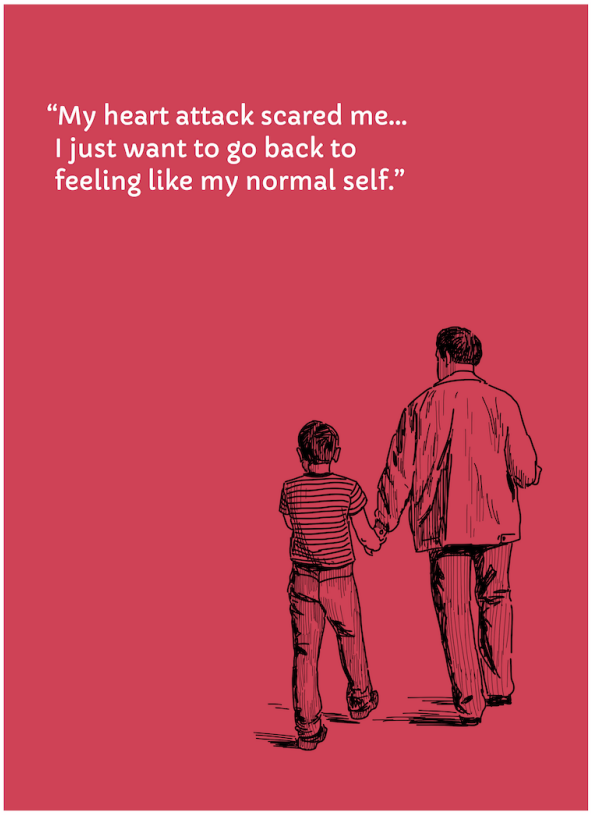


Figure 10. Revised figure for “new normal” path, patient booklet: month 2.

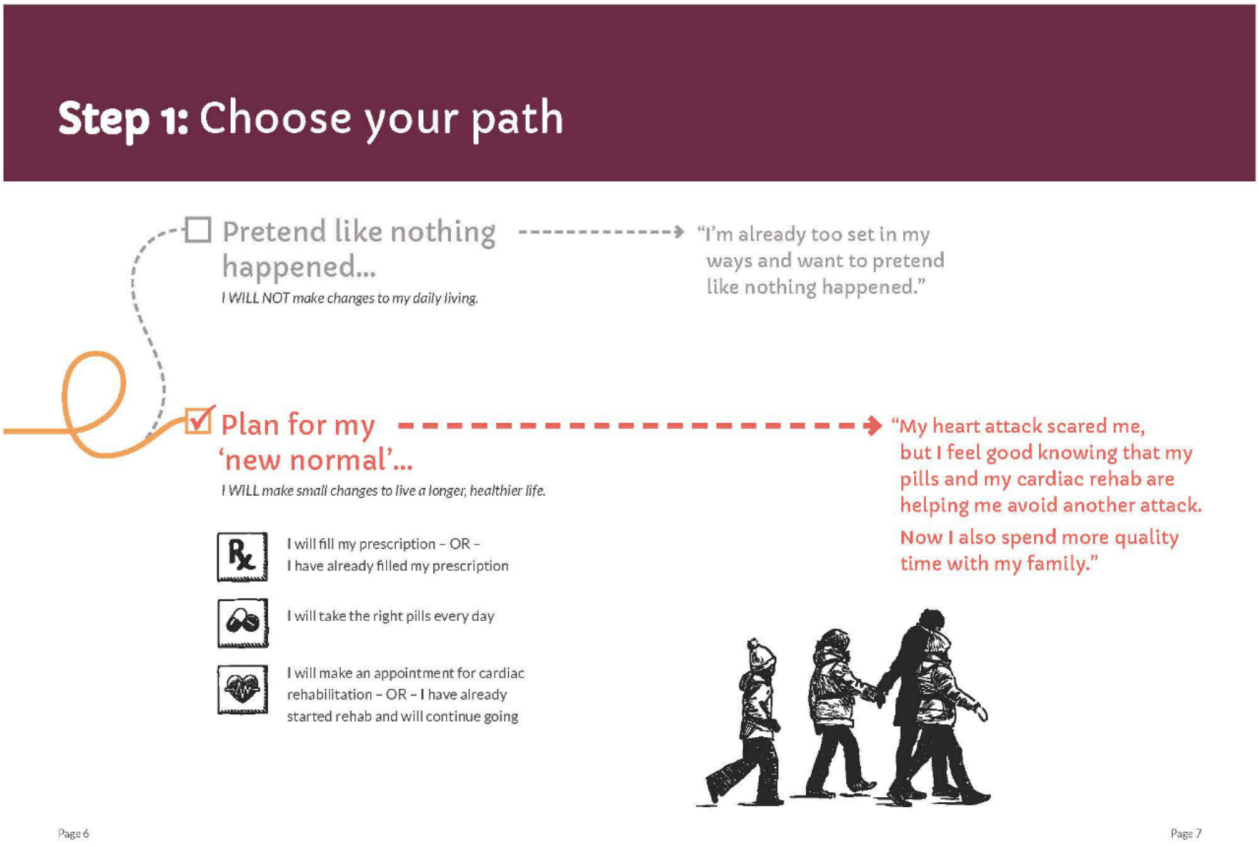


Figure 11. Final version of goal setting spread, patient booklet: month 1.

Figure 12. Envelope for first mailing at month 1.

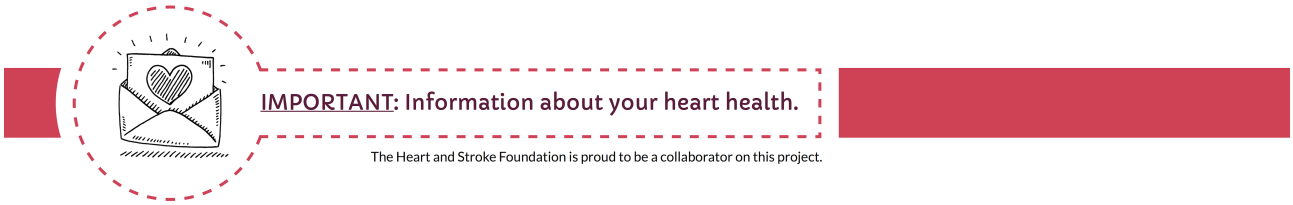


Figure 13. Signposts showing progress within series of mailings.

Discussion

Principal Findings

Relatively few quality improvement initiatives tested in trials are both theory-informed and formally user-tested [51]. In this design and development study, we collected and used patient input to refine our theory-informed intervention. Specifically, we encountered and addressed tensions within 3 themes that we believe may be relevant for others embarking upon similar projects.

First, we noted tension between users' assessments and evidence of effectiveness. This finding emphasizes that what people like and what works may not always be the same. The role of designers is not to automatically add every feature that users request, nor to automatically remove any feature that users dislike. Rather, design methods require carefully observing how people respond to a prototype—verbally, nonverbally, behaviorally, emotionally, and otherwise—analyzing those observations and making adjustments to the materials accordingly.

Second, tensions between informative communication and persuasive communication need to be addressed when designing any health communication materials, but particularly in cases in which a medically preferable option exists. This element of tension occurred even within our research team, as some team members are more oriented toward informative communication and others toward persuasive communication. Related to this, we recognized an ethical tension in using design approaches to address an external goal. Treatment adherence as a measure of quality of care is a metric that matters to health care systems, researchers, and health care professionals; it may or may not matter to the individuals who are assigned the task of adhering to the plan. Design methods are well-suited to optimize users' experiences according to their own individual goals, which may not be the same as goals externally imposed by a health care system. People may discontinue medications or not participate in cardiac rehabilitation for valid reasons. However, the demonstrated benefits of taking recommended medications and attending rehabilitation often align well with what matters to most people, namely, living longer with a higher quality of life. Therefore, we determined it was reasonable to suggest that if people are making a choice not to follow recommended practices, this choice ought to be fully informed by the available evidence, including evidence about ways that people can best implement behavioral changes in their lives.

Third, the tension between our initial imagery and patients' reactions to it highlight that people's acceptance of an intervention may depend on how well their self-perception is represented within it. For health communication materials incorporating visual depictions of potential users, user research should include issues of self-image, which may or may not be possible to address within the constraints of a research study. It remains a challenge to fit design approaches and methods within the bounds of feasibility of health care systems and health research projects. The lack of ability to deliver these materials when patients feel they would be most useful is a challenge to their ultimate effectiveness. Additionally, because design processes are not always predictable, fitting one within a tightly constrained timeline of a research project can present difficulties.

Although this work occurred in the context of paper-based mailings, the tensions presented here apply to design processes more broadly, including the design of Web-based applications. The challenge of finding the balance in responding to feature requests without falling into feature creep occurs regardless of format, as do the tensions of informative versus persuasive communication and adherence versus user experience. Although tailoring imagery to users is more technically feasible in a Web-based format, it requires, at minimum, a database of appropriate images, knowledge of each user's characteristics, and a matching algorithm. Such requirements can be technically or logistically difficult to fulfill.

We note that mailings, like Web-based applications, have advantages and disadvantages for users, health systems, and also for the design and development process. In this project, the advantages of mailings included their feasibility and relatively low cost within a large health care system that does not yet have widespread Web-based options for patients. Many patients within this system, particularly those who are older or who live in rural or remote areas, may lack reliable Internet access or be uncomfortable using computers or mobile devices. The disadvantages of mailings in this project included lack of tailored content and lack of accessibility for users who have literacy or vision barriers. Using paper as a medium is practical on many levels but also makes approaches such as universal design more difficult. Our trial in progress will help determine whether automated phone calls can help those users who receive mailings but who face barriers to using them effectively. Finally, although the delay in receipt of the first mailing is primarily a function of the transfer of administrative data—a barrier that would exist within this system regardless of format—the delay is arguably longer for a first mailing due to the time required for mail delivery.

Limitations

Our study has several limitations. First, all of our user testing took place at a single site, all in English, and with a small number of participants recruited by a study team member. Findings may or may not apply in other contexts or with participants who have no connection to the research team. Second, our randomized controlled trial evaluating these materials is currently underway and thus we do not yet know whether our approaches to the design tensions we identified resulted in materials that have desired effects. Third, the thematic groupings described here represent the authors' judgment and the ability to confirm saturation of key themes was constrained by project timelines.

Comparison With Prior Work

Tensions between research teams' evidence and users' views has been previously described, with 6 design approaches (participatory design, ethnography, lead user approach, contextual design, codesign, and empathic design) presented as offering different ways to address such tension [52]. Our approach of working to address users' concerns while also maintaining a design element that is both theoretically and empirically justified falls within participatory design in this framework. Others have also observed mismatches between what users like and what is demonstrably effective [53] and still other research teams have reported design challenges in developing health care tools due to divergent design specifications and described using similar methods to ours to help address them [54].

Our tensions between informative and persuasive communication are situated within a body of literature reflecting the different approaches that are recommended for risk communication to achieve these 2 different goals [39-42].

Particularly in a case such as ours, in which the goal is to help people achieve their own goals, it may be important not to lean too far on the persuasive side of communication to avoid people reacting negatively. However, persuasive elements may be effective in supporting positive health behavior change [55], and even in situations of clinical equipoise, it is acknowledged that in some cases it may be more ethically defensible to "nudge" users of materials toward a given choice [56]. Our persuasive framing of mortality statistics was also a simpler presentation; this "less is more" method of simplifying a risk statistic to its most salient points has been shown to be effective in other contexts [57,58].

Finally, our specific finding about the importance of self-image aligns with previous research demonstrating, for example, that people are more influenced by imagery that better reflects them [59].

Conclusions

Health care systems may not be optimally designed to support patients along their path to recovery after a heart attack. Our study explored whether health systems may be able to better support people in their recovery with a feasible, scalable approach: providing carefully designed educational booklets at specific time points. In designing such booklets by collaboratively working with patients as an interdisciplinary group of researchers and designers, our project revealed design tensions and possible ways to address those tensions. Teams developing similar materials may wish to use similar methods and may anticipate similar tensions requiring resolution. Particularly for teams developing interventions to encourage adherence, it is important to recognize that while the term adherence has largely replaced the previous term compliance, if the functional meaning of the word remains, "doing what others decide is best for you," nothing has truly changed. Teams must identify and address root causes of tensions and focus on ensuring and highlighting alignment between individual and health care system goals.

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Authors' Contributions

HOW prepared the first draft of this report. JP, EN, IJ, and NMI provided additional details to the first draft. All authors contributed intellectual content to subsequent drafts of this manuscript, reviewed, and approved the final submitted version.

Conflicts of Interest

None declared.

Multimedia Appendix 1

Interview guide.

[PDF File (Adobe PDF File), 48KB - humanfactors_v4i1e6_app1.pdf]

Multimedia Appendix 2

Final mailings.

[PDF File (Adobe PDF File), 8MB - humanfactors_v4i1e6_app2.pdf]

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Original Paper

eHealth Literacy: Predictors in a Population With Moderate-to-High Cardiovascular Risk

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Abstract

Background: Electronic health (eHealth) literacy is a growing area of research parallel to the ongoing development of eHealth interventions. There is, however, little and conflicting information regarding the factors that influence eHealth literacy, notably in chronic disease. We are similarly ill-informed about the relationship between eHealth and health literacy, 2 related yet distinct health-related literacies.

Objective: The aim of our study was to investigate the demographic, socioeconomic, technology use, and health literacy predictors of eHealth literacy in a population with moderate-to-high cardiovascular risk.

Methods: Demographic and socioeconomic data were collected from 453 participants of the CONNECT (Consumer Navigation of Electronic Cardiovascular Tools) study, which included age, gender, education, income, cardiovascular-related polypharmacy, private health care, main electronic device use, and time spent on the Internet. Participants also completed an eHealth Literacy Scale (eHEALS) and a Health Literacy Questionnaire (HLQ). Univariate analyses were performed to compare patient demographic and socioeconomic characteristics between the low (eHEALS<26) and high (eHEALS≥26) eHealth literacy groups. To then determine the predictors of low eHealth literacy, multiple-adjusted generalized estimating equation logistic regression model was used. This technique was also used to examine the correlation between eHealth literacy and health literacy for 4 predefined literacy themes: navigating resources, skills to use resources, usefulness for oneself, and critical evaluation.

Results: The univariate analysis showed that patients with lower eHealth literacy were older (68 years vs 66 years, P=.01), had lower level of education (P=.007), and spent less time on the Internet (P<.001). However, multiple-adjusted generalized estimating equation logistic regression model demonstrated that only the time spent on the Internet (P=.01) was associated with the level of eHealth literacy. Regarding the comparison between the eHEALS items and HLQ scales, a positive linear relationship was found for the themes “usefulness for oneself” (P=.049) and “critical evaluation” (P=.01).

Conclusions: This study shows the importance of evaluating patients’ familiarity with the Internet as reflected, in part, by the time spent on the Internet. It also shows the importance of specifically assessing eHealth literacy in conjunction with a health literacy assessment in order to assess patients’ navigational knowledge and skills using the Internet, specific to the use of eHealth applications.

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KEYWORDS

eHealth; socioeconomic factors; health literacy; cardiovascular system; chronic disease; Internet

Introduction

People are increasingly managing their health with the aid of electronic tools [1,2]. This requires an understanding of their condition as well as the skills to effectively use and navigate the devices available [1,3]. This skill is referred to as electronic Health (eHealth) literacy and is a growing area of research parallel to the increasing development and use of eHealth interventions. Although access to the Internet is fairly widespread [4], eHealth resources are constantly evolving and require an ongoing adaptation by their users [5,6]. To ensure that a patient is able to use the available resources effectively, it therefore becomes necessary to assess their eHealth literacy and identify its determining factors in order to improve access and usability.

Despite its increasing importance, to date there has been limited investigation into the demographic, socioeconomic, and technology use determinants of eHealth literacy. In healthy adults, lower age and higher education correlate to higher eHealth Literacy [1,7-9], as does higher Internet use and number of electronic devices used [2]. Likewise in younger adults, eHealth literacy correlates positively to education, electronic device use, and Internet use [9] with increasing age and duration of illness having a negative impact on eHealth literacy. In underserved populations, active Internet use and urban dwelling are associated with increased eHealth literacy, as is higher income [8], which is not the case in a general population study [9]. Conversely, a study examining the success of an eHealth intervention in elderly patients undergoing cardiac rehabilitation found that age and gender had no influence on eHealth literacy [10]. These diverging results demonstrate the difficulty in identifying generalizable predictors of eHealth literacy to all populations.

People with cardiovascular disease (CVD) are required to self-manage many aspects of their condition, and this requires a minimal level of health literacy. Health literacy is defined as the "knowledge, motivation, and competences to access, understand, appraise, and apply health information in order to make judgments and take decisions in everyday life concerning health care" [11]. In a population with CVD, poor health literacy was found to be associated with decreased health status [12]. Medication adherence is a strong determinant of health outcomes in patients with CVD and has been shown to improve through active patient education and electronically based reminders [13]. Likewise, eHealth interventions have shown promising results toward increasing health literacy [8,14]. How health literacy and eHealth literacy are correlated in a population with cardiovascular risk has not been examined. This was the first study to examine this relationship as well as the demographic, socioeconomic, technology use, and health literacy predictors of eHealth literacy in a population with moderate-to-high cardiovascular risk.

Methods

Design

People diagnosed with or at risk for CVD were assessed to explore the relationship between demographic characteristics, socioeconomic factors, use of technology, health literacy, and eHealth literacy. The sample consisted of 453 participants in the Consumer Navigation of Electronic Cardiovascular Tools (CONNECT) Study [15]. All participants provided written, informed consent, and ethical approval was obtained from the Human Research Ethics Committee (Project number 2013/716).

Recruitment

The CONNECT study methods and participant recruitment processes are detailed elsewhere [15]. In brief, CONNECT is an ongoing randomized controlled trial examining whether an eHealth strategy improves risk factor control when compared with usual health care in patients with or at risk for CVD. Participants were recruited via Australian primary care practices. The inclusion criteria were as follows: aged 18 years or older, have access to the Internet at least once a month, and have moderate-to-high risk for a CVD event. Moderate-to-high CVD risk was defined as (1) ≥10% 5-year CVD risk using Framingham risk equation; (2) a clinically high-risk condition (Aboriginal or Torres Strait Islander >75 years, diabetes and >60 years, diabetes and albuminuria, estimated glomerular filtration rate <45 mL/min, systolic blood pressure ≥180 mmHg, diastolic blood pressure ≥110 mmHg, total cholesterol >7.5 mmol); and (c) an established CVD diagnosis (ischemic heart disease, stroke or transient ischemic attack, peripheral vascular disease). Participants with an insufficient level of English proficiency or severe intellectual disabilities were excluded. At baseline, demographic and socioeconomic data were collected, and participants completed eHealth and health literacy questionnaires (HLQs).

Assessment of eHealth Literacy: eHealth Literacy Scale

The eHealth Literacy Scale (eHEALS) is one of the very few existing scales assessing eHealth literacy. It comprises 8 items scored on a 5-point Likert scale and aims to reflect the individuals' own perception of their knowledge and skills at using eHealth information [16,17]. The final result is the sum of all items ranging from 8 to 40 with higher scores reflecting a higher level of eHealth literacy. The validity and reliability of eHEALS has been demonstrated in various health conditions [14,18] and ages [5,19,20] and has been translated into many languages [21-23]. As recommended by the developers, 2 questions were added prior to the 8 items to capture the participants' opinion about the importance and usefulness of eHealth [7,14]. Following other studies with similar target populations, the cutoff for high eHealth literacy was set at 26 [2,7,9,14,21,23]. High eHealth literacy level (eHEALS≥26 out of 40) and low eHealth literacy levels (eHEALS<26) were thus

compared for predefined demographic and socioeconomic factors.

Assessment of Health Literacy: HLQ

The HLQ was used to assess health literacy. It comprises 9 independent scales that assess distinct aspects of health literacy and aims to measure an individual's capacity at effectively using health information and services [24]. Each scale is composed of 4 to 6 items and is scored on a 4- or 5-point Likert scale [24]. The score for each scale is the mean score of its items where higher scores indicate higher health literacy levels [24,25] with no fixed values distinguishing high or low levels. It was developed to provide a comprehensive assessment of health literacy compared with other existing tools [26], has demonstrated good construct validity, and has been widely translated [27-29].

Comparison Between HLQ and eHEALS

In order to examine the relationship between health and eHealth literacy, we undertook a process of matching HLQ scales to eHEALS items by grouping related items with similar themes (Table 1). eHEALS items 1, 2, and 3 related to Internet navigational skills and were thus grouped together. Likewise, items 6 and 7 both related to evaluation of resources found on the Internet. Items 4 and 5 represented distinct aspects of eHealth literacy and were therefore not grouped. Only item 8 of the eHEALS ("I feel confident in using information from the Internet to make health decisions") was excluded as there was no HLQ scale that comparably assessed the confidence related to using health resources. Four key aspects of eHealth and health literacy were thus defined, and mean scores for items or item groups were then derived for each patient. For "navigating resources" and "skills to use resources," the HLQ scales ranged from 1 to 5, and for "usefulness for oneself" and "critical evaluation," they ranged from 1 to 4. This process was performed iteratively and via consensus between experts in clinical practice, research, and statistical analysis (Table 1).

Table 1. Matching eHEALS (eHealth Literacy Scale) [16] items to the HLQ (Health literacy Questionnaire) [24].

Areas	eHEALS[a] questions	HLQ[b] subscales
Navigating resources	Item 1: I know what health resources are available on the Internet Item 2: I know where to find helpful health resources on the Internet Item 3: I know how to find helpful resources on the Internet	Navigating the health care system (range 1-5)
Skills to use resources	Item 4: I know how to use Internet to answer my questions about health	Ability to find good health information (range 1-5)
Usefulness for oneself	Item 5: I know how to use the health information I find on the Internet to help me	Having sufficient information to manage my health (range 1-4)
Critical evaluation	Item 6: I have the skills I need to evaluate the health resources I find on the Internet Item 7: I can tell high-quality health resources from low quality health resources on the Internet	Appraisal of health information (range 1-4)

[a]eHEALS: eHealth Literacy Scale.

[b]HLQ: Health Literacy Questionnaire.

Statistical Analysis

Univariate analyses were performed to compare patient demographic, socioeconomic, and technology use characteristics between the low (eHEALS<26) and high (eHEALS≥26) eHealth literacy groups. Chi-square test was used to compare the categorical variables, and independent *t* test was used to compare the means between the 2 groups. To determine predictors of low eHealth literacy, multiple-adjusted generalized estimating equation logistic regression model was used. Independent predictors included in the model were gender (female or male), age (<65 or 65-70 or >70 years), education (≤secondary or university or technical or vocational training), income (<Aus $1000 or Aus $1000-2000 or > Aus $2000 per week), CVD-related polypharmacy (active consumption of >3 medications related to CVD), private health care (yes or no), main electronic device used (desktop or laptop or mobile phone or tablet), and time spent on the Internet on any device (≤1 hour or >1 hour per day). These variables were included regardless of the statistical significance in the univariable comparison due to their clinical significance in relation to eHealth literacy. This analysis adjusted for the clustering effect of primary health care practices. The derived odds ratios (ORs) and corresponding 95% CIs were plotted in a forest plot. An adjusted analysis using the eHEALS score as a continuous variable was also done to see whether other predictors emerged. To test for the correlation between eHealth literacy and health literacy for the 4 literacy themes, multiple-adjusted generalized estimating equation linear regression models were used for each of the themes. The dependent variable, eHEALS score, was in a continuous form, and the corresponding continuous HLQ score was included in the model with the aforementioned covariates. Data were analyzed using SAS version 9.4 for Windows (SAS Institute Inc).

Results

Principal Findings

In total, 453 participants were included in the analysis; 1 was excluded due to an incomplete eHEALS (Table 2). The mean age of the sample was 67 years (range: 45-89; standard deviation, SD 8.0), 75.9% (344/453) were male, 89.0% (403/453) were white, and 80.4% (364/453) were either married or in a de facto relationship. The sample was overall well

educated (53.4%, 242/453; had undergraduate or postgraduate degree), and 81.0% (367/453) had private health insurance. Over half the sample stated that the Internet was useful or very useful to make decisions regarding health (n=257), and that it was either important or very important for them to be able to access health resources on the Internet (n=267). The mean eHEALS score was 27.2 (range: 8-40; SD 6.59), which was in the high eHealth literacy range (≥26). A total of 175 participants had an eHEALS score within half an SD value of 26. The HLQ scores were 4.12 (SD 0.53) and 4.07 (SD 0.54) out of 5 for "navigating the health care system" and "ability to find good health information," respectively and 2.92 (SD 0.46) and 2.79 (SD 0.51) out of 4 for "having sufficient information to manage my health" and "appraisal of health information," respectively. When we compared the cohort with low (n=154) and high (n=299) eHealth literacy, those with high eHealth literacy were more likely to be younger, have a higher level of education, and spend more time on the Internet (Table 2). The results were similar when using a continuous variable.

Table 2. Univariable comparison of demographic, socioeconomic, and technology use factors in eHealth literacy (analysis adjusted for the clustering effect of primary health care practices).

Variable	Low eHealth literacy (eHEALS[a]<26) (n=154), n (%)	High eHealth literacy (eHEALS≥26) (n=299), n (%)	Overall (N=453) n (%)	*P* value
Male	124 (80.5)	220 (73. 6)	344 (75.9)	.10
Age in years, mean (SD)	68 (8)	66 (8)	67 (8)	.01
Age <65 years, n (%)	49 (32)	121 (40.5)	170 (37.5)	.02
Age 65-70 years, n (%) 50 (32)	108 (36.1)	158 (34.9)		
Age >70 years, n (%)	55 (36)	70 (23)	125 (27.6)	
History of coronary heart disease, n (%)	49 (32)	92 (31)	141 (31.1)	.82
Taking >3 CVD[b] medications	30 (19)	73 (24)	103 (22.7)	.24
Education level, n (%)				
None, primary, or secondary	54 (35)	67 (22)	121 (26.7)	.007
Technical or vocational training	32 (21)	58 (19)	90 (20)	
Undergraduate or postgraduate	68 (44)	174 (58.2)	242 (53.4)	
Income (in Aus $ per week), n (%)				
<1000	30 (19)	56 (19)	86 (20)	.55
1000-2000	54 (35)	126 (42.1)	180 (39.7)	
>2000	45 (29)	82 (27)	127 (28.0)	
Private insurance, n (%)	118 (76.6)	249 (83.3)	367 (81.0)	.09
Main device used to access the Internet, n (%)				
Desktop computer	62 (40)	132 (44.1)	194 (42.8)	.53
Laptop	59 (38)	100 (33.4)	159 (35.1)	
Mobile phone or tablet	31 (20)	67 (22)	98 (22)	
Spends >1 hour on Internet per day	56 (36)	179 (60.0)	235 (55.8)	<.001
eHEALS score, mean (SD)	19.89 (4.909)	30.96	27.2	<.001

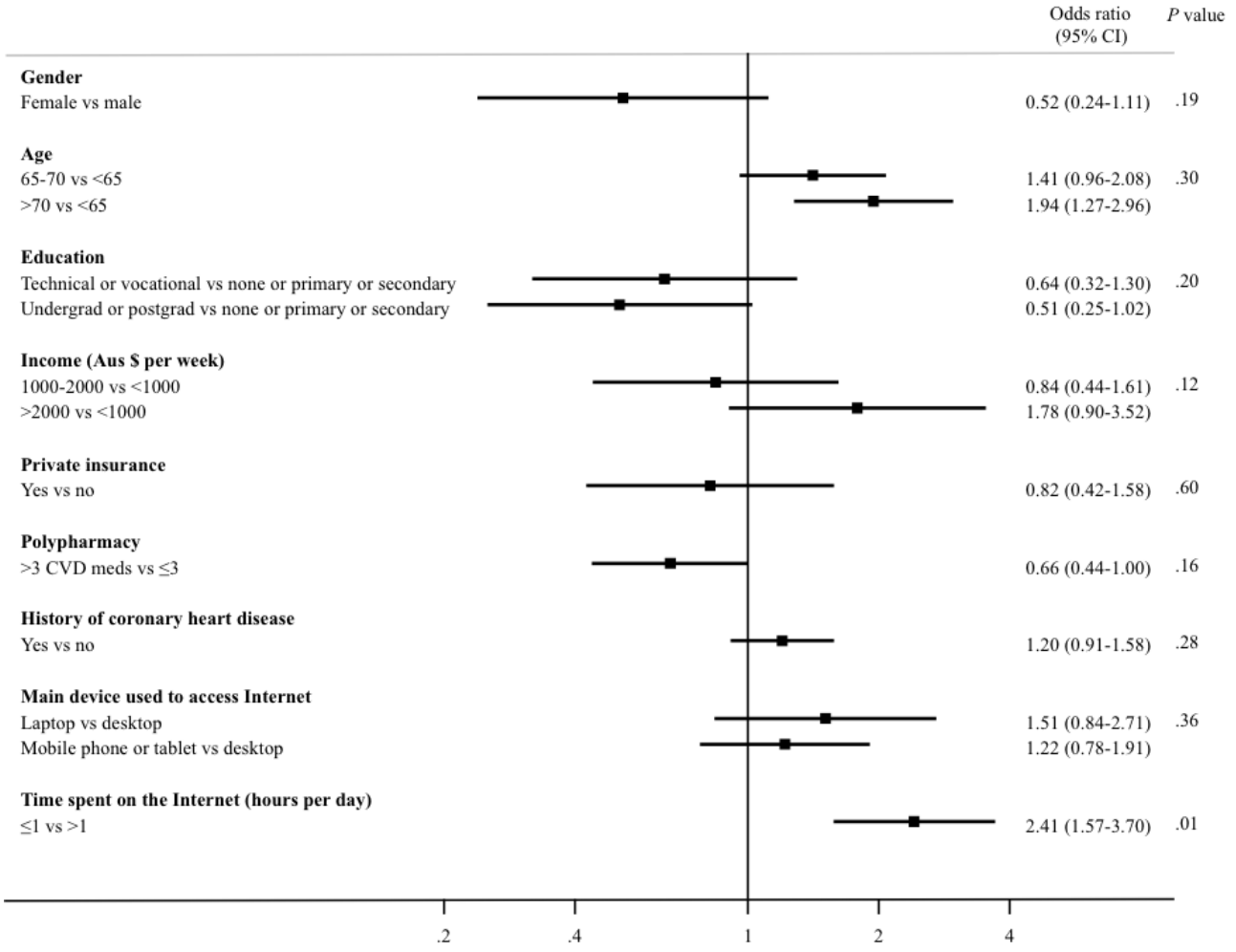
[a]eHEALS: eHealth Literacy Scale.

[b]CVD: cardiovascular disease.

Predictors of Low eHealth Literacy

The univariate analysis showed that patients with lower eHealth literacy were older (68 years vs 66 years, *P*=.02), had lower level of education (*P*=.007), and spent less time on the Internet (*P*<.001; Table 2). Gender, CVD-related polypharmacy, history of coronary heart disease, income categories, and main device used to access the Internet numbers were similar between the 2 groups. After adjustment for demographic, socioeconomic, and technology use, only the time spent on the Internet (*P*=.01) was associated with the level of eHealth literacy (Figure 1). Participants who spent less than or equal to 1 hour on the Internet per day were 2.45 times more likely to have low eHealth literacy compared with those who spent more than 1 hour per day. Conversely, age (*P*=.26), gender (*P*=.18), education (*P*=.19), income (*P*=.15), CVD-related polypharmacy (*P*=.22), private insurance (*P*=.47), and main device used to access the Internet (*P*=.30) did not achieve statistical significance.

Figure 1. Predictors of low eHealth literacy (defined as eHEALS score <26 out of 40; analysis adjusted for the demographic, socioeconomic, and technology use predictors). CVD: Cardiovascular disease; eHEALS: eHealth Literacy Scale.



eHEALS Versus HLQ

After adjustment for demographic, socioeconomic factors, and technology use, a positive linear relationship was found between the eHEALS items and HLQ scales for the themes "usefulness for oneself" (*P*=.049) and "critical evaluation" (*P*=.01; Table 3). For every point gained in the HLQ scale "Having sufficient information to manage my health" (range 1-4), there was a gain of 0.5 in eHEALS item 5 ("I know how to use the health information I find on the Internet to help me"). Similarly, an increment of every point in the HLQ scale "appraisal of health information" (range 1-5) corresponded to an increment of 0.80 increase in items 6 and 7. However, for "navigating resources" (*P*=.08) and "skills to use resources" (*P*=.06), the 2 scales were not well correlated.

Table 3. Comparison between eHealth Literacy Scale (eHEALS) [16] and the Health Literacy Questionnaire (HLQ) [24].

Themes[a]	Beta coefficient of HLQ[b] score (SE[c])	*P* value
Navigating resources	0.3117 (0.0970)	.08
Skills to use resources	0.4108 (0.0977)	.06
Usefulness for oneself	0.5222 (0.1439)	.049
Critical evaluation	0.7955 (0.0844)	.01

[a]The analysis was adjusted for the demographic, socioeconomic, and technology use predictors.

[b]HLQ: Health Literacy Questionnaire.

[c]SE: Standard error.

Discussion

Principal Findings

In this sample of participants with moderate-to-high CVD risk, over half felt that the Internet was useful for health, and that access to health information via the Internet was important to them. With regards to the demographic and socioeconomic predictors, age, gender, education, income, CVD-related polypharmacy, private insurance, and main device used to access the Internet were not statistically significant. Only the total time spent on the Internet per day, the only modifiable predictor that was tested, significantly determined eHealth literacy level, independently of the device used. These results implied that the level of eHealth literacy was directly correlated to the time spent on the Internet and was independent of nonmodifiable personal or socioeconomic characteristics. With regards to the relationship between eHealth and health literacy, only participants' perceptions of the usefulness of electronic resources for themselves and their critical evaluation were associated; navigation skills and confidence were not.

Comparison With Prior Work

Prior studies using the eHEALS have shown conflicting results regarding the demographic and socioeconomic determinants of eHealth literacy. Increasing age, for example, was found to predict lower eHEALS scores in healthy older adults [2] and underserved populations [8], whereas it was not found to be predictive in people with lung cancer [14] and rheumatic disease [23]. Similarly, education level was shown to increase eHealth literacy in older populations [2,8] and in people with lung cancer [14]. However this finding was not shown in other studies examining populations with chronic diseases [23,30]. Findings on the socioeconomic determinants of eHealth literacy are also contradictory with gender, marital status, and income being unrelated to eHEALS scores in older populations [2] but influential in a population with colorectal cancer [30]. The sole predictor in most prior studies using the eHEALS, [7,8,14,19,23], as in this study, was frequency of the Internet use. As for the relationship between eHealth and health literacy, a systematic review found that lower health literacy was predictive of lower eHealth literacy levels [8].

Given the diverging findings in prior studies with chronic diseases, the results of this study supported that the demographic and socioeconomic predictors of eHealth literacy were largely population dependent. Furthermore, this study provided further evidence that increased Internet use predicts higher eHealth literacy. The 2 aspects common to both the eHEALS and HLQ were "usefulness for oneself" and "critical evaluation," which both related to a patient's personal interpretation of the health information they were confronted to. This interpretation is independent of the knowledge and skills needed to effectively use electronic resources, which are very specific to eHealth and not necessarily addressed in a health literacy scale. The findings of this study reinforced the importance of evaluating patients' knowledge and access to electronic information through an eHealth literacy assessment alongside a health literacy assessment. By assessing these 2 types of literacy before implementing an eHealth intervention, participants who had a low level of eHealth literacy could thereby benefit from education in using electronic resources.

Strengths

This was the first study to examine demographic, socioeconomic, and technology-related determinants of eHealth literacy in a population with moderate-to-high CVD risk. By identifying patient characteristics that influence access to eHealth resources, health management and patient empowerment could be improved when using electronic resources. Although most predictors such as age, gender, education, and income are not modifiable, this study showed that the prevailing predictor of eHealth literacy was total time spent on the Internet, consistent with prior eHealth literacy research. Other studies do, however, underline that it is specifically time spent using Web-based health-related resources that increases eHealth literacy and not the time spent on the Internet in general [8]. Assessing time spent on the Internet is a simple and efficient way of determining the potential appropriateness of an eHealth intervention for a given patient. This was also the first study correlating an eHealth literacy scale with a health literacy scale. This comparison demonstrated the differences in these 2 related yet distinct types of literacies and the importance in assessing them individually and simultaneously. Although a patient may have access to the Internet, they require the skills to use it in an effective and beneficial way [7,14]. Further research with different scales and study populations is required, but this study nonetheless highlighted the importance of evaluating eHealth literacy aspects, which are not necessarily covered by a health literacy assessment. Future research is also needed to explore the health (including quality of life) outcomes associated with varying levels of eHealth literacy and the amount of time patients spend using the Internet. In addition, future research could clarify the value and importance of assessing eHealth literacy on a validated scale compared with asking the question of time spent on the Internet at baseline. Although we chose to use specific assessment tools for health literacy, this is a growing area and future research can also make comparisons with alternative tools.

Limitations

This study had several limitations. First, the study population was largely male (75.9%, 344/453), white (89.0%, 403/453), and well educated (53.6%, 243/453; had a graduate education), and all had access to the Internet. Furthermore, people who agreed to participate were likely to be more motivated and interested in their health management, which might have introduced an element of selection bias. Although this limited the generalizability of the findings to all populations with and at risk for CVD, an ongoing Australian CVD registry found 70% of male prevalence [31] and that 86% of Australians had access to the Internet in 2014-2015 [32]. Second, this study did not ask participants the purpose of their using the Internet in the time they spent on it. The increasing use of Web-based resources for professional reasons could constitute a considerable portion of the time spent on the Internet, even in this older population. This is particularly relevant because, as previously mentioned, it is the frequency of use of health-related information that increases eHealth literacy. Furthermore, this

study did not assess patient's ability to determine the quality of Web-based resources, and a recent study looking at the quality of health information related to weight loss found that the content of more readily available information on search engines was suboptimal [33]. Another limitation was that the eHEALS reflects self-perception of eHealth literacy and not actual skill. This is particularly relevant, as the only study that examined the relationship between the eHEALS score and health-related Internet skills in a sample of people with rheumatic disease found that they were not correlated [23]. It remains, however, the only study to demonstrate this finding, and further research is required to investigate it more fully. Finally, to truly assess the importance of an eHEALS score, intervention studies to increase eHealth literacy should be conducted to assess their impact on clinically important outcomes.

Conclusions

As Internet-based eHealth interventions are increasingly being developed to facilitate patients' health management, it becomes essential to gain an understanding of their eHealth literacy and identify its predictors. If users do not have an adequate level of eHealth literacy, certain Internet-based eHealth interventions could be compromised. This study has shown the importance of evaluating patients' familiarity with the Internet, as reflected, in part, by the time spent on the Internet, to improve their eHealth literacy. It has also shown the importance of specifically assessing eHealth literacy in conjunction with a health literacy assessment in order to assess patients' navigational knowledge and skills using the Internet. Although related, eHealth literacy requires knowledge of electronic resources and abilities to use them, which are distinct from purely an understanding of health or health literacy.

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Conflicts of Interest

None declared.

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Abbreviations

CONNECT: Consumer Navigation of Electronic Cardiovascular Tools
CVD: cardiovascular disease
eHealth: electronic Health
eHEALS: eHealth Literacy Scale
HLQ: Health Literacy Questionnaire

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Original Paper

A Human-Centered Design Methodology to Enhance the Usability, Human Factors, and User Experience of Connected Health Systems: A Three-Phase Methodology

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Abstract

Background: Design processes such as human-centered design, which involve the end user throughout the product development and testing process, can be crucial in ensuring that the product meets the needs and capabilities of the user, particularly in terms of safety and user experience. The structured and iterative nature of human-centered design can often present a challenge when design teams are faced with the necessary, rapid, product development life cycles associated with the competitive connected health industry.

Objective: We wanted to derive a structured methodology that followed the principles of human-centered design that would allow designers and developers to ensure that the needs of the user are taken into account throughout the design process, while maintaining a rapid pace of development. In this paper, we present the methodology and its rationale before outlining how it was applied to assess and enhance the usability, human factors, and user experience of a connected health system known as the Wireless Insole for Independent and Safe Elderly Living (WIISEL) system, a system designed to continuously assess fall risk by measuring gait and balance parameters associated with fall risk.

Methods: We derived a three-phase methodology. In Phase 1 we emphasized the construction of a use case document. This document can be used to detail the context of use of the system by utilizing storyboarding, paper prototypes, and mock-ups in conjunction with user interviews to gather insightful user feedback on different proposed concepts. In Phase 2 we emphasized the use of expert usability inspections such as heuristic evaluations and cognitive walkthroughs with small multidisciplinary groups to review the prototypes born out of the Phase 1 feedback. Finally, in Phase 3 we emphasized classical user testing with target end users, using various metrics to measure the user experience and improve the final prototypes.

Results: We report a successful implementation of the methodology for the design and development of a system for detecting and predicting falls in older adults. We describe in detail what testing and evaluation activities we carried out to effectively test the system and overcome usability and human factors problems.

Conclusions: We feel this methodology can be applied to a wide variety of connected health devices and systems. We consider this a methodology that can be scaled to different-sized projects accordingly.

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KEYWORDS

human-centered design; user-centered design; usability testing; user interface design; connected health; human factors; mHealth

Introduction

Background

Connected health is a term used to encompass health care concepts such as eHealth, telehealth, telemedicine, and mHealth, and refers to the use of health technology to deliver health care to patients remotely [1]. Connected health products include blood pressure and heart rate monitors; diabetes management devices; thermometers; weighing scales; and, increasingly, fitness, diet, and activity trackers. All of these are characteristic of the *quantified-self* movement, a modern trend whereby individuals seek to track their own physical, behavioral, or environmental information [2]. These devices, systems, and services, when combined with an appropriate clinical-based information and communications technology infrastructure, can allow users to take control of their own health and wellness in their homes while maintaining contact with a health care professional. This model can do the following: support continuous health monitoring for both individuals and for whole groups; encourage healthy behaviors to prevent or reduce health problems; support chronic disease self-management; reduce the number of health care visits; and provide personalized, localized, and on-demand interventions [3].

An increasing focus on reducing health care costs for patients of all ages has spurred the growth of the connected health care market. In a Geisenger Health Plan study, it was found that postdischarge use of connected health monitoring for heart patients reduced readmission to hospital by 44% [4], while a similar study by Agboola et al reported similar decreases in heart failure-related readmissions of 48% in the first 30 days postdischarge [5].

Many connected health devices share common features; they are typically compact, electronic modules that carry out at least one specific health care function. These devices generally have buttons, switches, touch or nontouch screens, speakers, and wearable clips or belts; in addition, they are generally designed to measure some aspect of a person's health status [6]. Connected health devices, such as wearable heart rate or blood pressure monitors, can be synced to mobile phones with the mobile phone acting as a data storage, data transmission, and interaction platform.

Connected health devices have various characteristics that make them unique compared to other health or medical devices that may be utilized in hospital, clinical, or surgical settings [7]. Connected health devices are designed to be used in an unsupervised manner in the home by users who may not be specialists in health care. Connected health devices have user interfaces (UIs) that require some level of human-computer interaction and they comprise software and hardware elements. Due to the likely use of these devices by disabled, elderly, or infirm users, connected health devices require UIs with good usability characteristics. There may be different levels of interaction required, in terms of both complexity and regularity, across a range of devices.

The UI features of connected health devices can place demands on users that are incongruent with their capabilities [6]. It has been observed that many otherwise excellent products have failed in the marketplace due to poor interface design, while mediocre products have flourished due to attractive and user-friendly interface design [8]. Therefore, an important consideration in the design of connected health devices is the usability and human factors characteristics of the device interfaces and, hence, the user experience they provide for the user.

Usability is defined by the International Organization for Standardization (ISO) as "the extent to which a user can use a product to achieve specific goals with effectiveness, efficiency and satisfaction in a specified context" [9]. The term *human factors* is described by the American National Standards Institute and the Association for the Advancement of Medical Instrumentation as "the application of knowledge about human capabilities (physical, sensory, emotional, and intellectual) and limitations to the design and development of tools, devices, systems, environments and organizations" [10]. User experience is defined as the perceptions and responses of users that result from their experience of using a product or service [11]. Both the Food and Drug Administration (FDA) and the Agency for Healthcare Research and Quality have called for usability and human factors evaluation of medical devices and systems during the design process [12,13], with the FDA requiring evidence of end user involvement during the design process when reviewing market presubmissions [14].

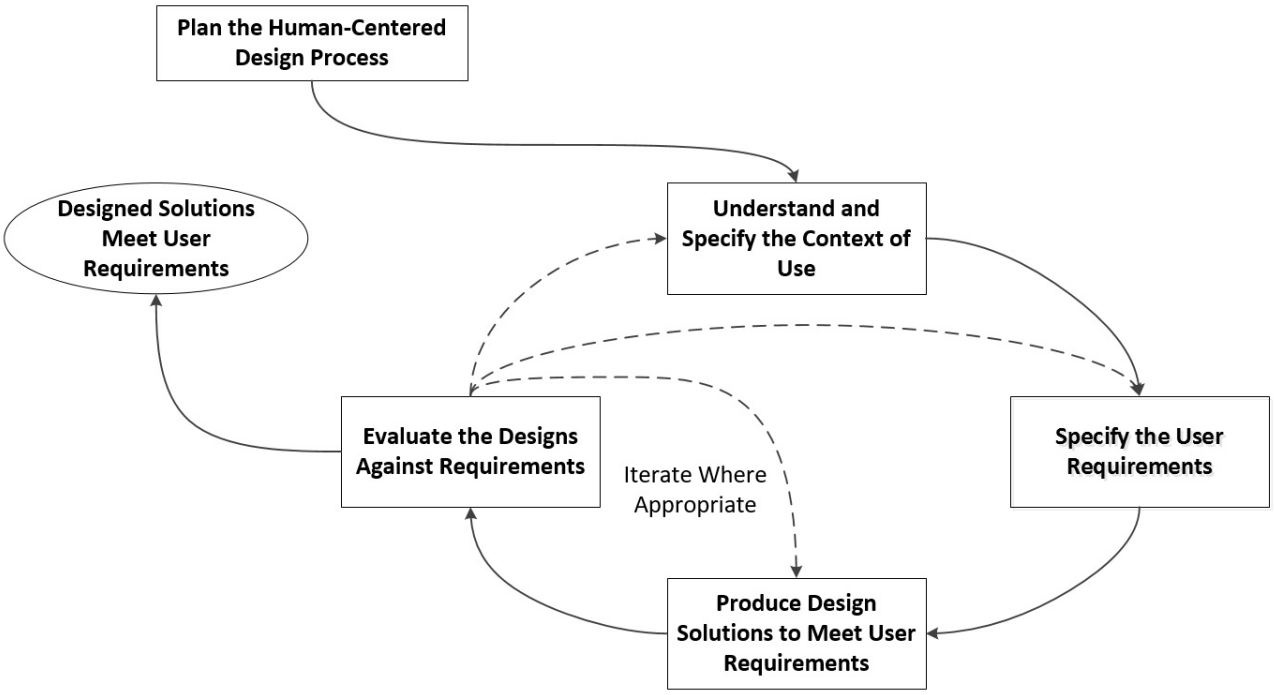
User- and Human-Centered Design

User-centered design (UCD) is a design philosophy that seeks to place the end user at the center of the design process. The term was coined in the 1980s by Donald Norman [15] who put forward guidelines that designers could follow in order for their interfaces to achieve good usability outcomes. From that point on, many designers, researchers, and policy makers have proposed various methodologies and techniques that seek to involve the end user in the design process, with the end user being defined as the "person who will ultimately be using the product." In their 2010 standard ISO 9241-210, the ISO extended the definition of UCD to "address impacts on a number of stakeholders, not just those typically considered as users," referring to the design approach as human-centered design (HCD) [11]. As such, we will refer to UCD as HCD from now on in this paper. The ISO 9241-210 standard defines human-centered design as "an approach to systems design and development that aims to make interactive systems more usable by focusing on the use of the system and applying human factors/ergonomics and usability knowledge and techniques." The standard also describes the potential benefit of following a design approach that improves usability and human factors:

"Usable systems can provide a number of benefits, including improved productivity, enhanced user well-being, avoidance of stress, increased accessibility and reduced risk of harm." Putting the user at the core of the design process is also the guiding principle of a philosophy related to HCD, that of *universal design*. The aim of universal design is to create accessible products, environments, and services for all users regardless of their physical or cognitive abilities [16]. It must be noted that this goal is not always the main goal of HCD, which may try to make a product accessible to a specific target group of end users, rather than all user groups [17]. HCD has four defined activity phases: (1) Identify the user and specify the context of use; (2) Specify the user requirements; (3) Produce design solutions; and (4) Evaluate design solutions against requirements. HCD has roots in the field of *requirements engineering* in that it seeks to document the user requirements and how they are being met by the design at each stage of development [18,19]. The main goal of HCD is to increase the usability of the product in order to create maximum user satisfaction and increase the safety performance of the device. The process model of HCD as defined in ISO 9241-210 is illustrated in Figure 1.

As well as the steps outlined above, there are six requirements which are described in ISO 9241-210 that a process must meet if it is to be considered an HCD process. Our methodology before meeting any other requirements must meet these six requirements. We will refer to these requirements as Requirements 1-6, which are as follows: (1) The design is based upon an explicit understanding of users, tasks, and environments; (2) Users are involved throughout design and development; (3) The design is driven and refined by user-centered evaluation; (4) The process is iterative; (5) The design addresses the whole user experience; (6) The design team includes multidisciplinary skills and perspectives.

Figure 1. Human-centered design has four main activity phases: (1) Specify the user and the context of use; (2) Specify the user requirements; (3) Produce design solutions; and (4) Evaluate designs against requirements.



Human-Centered Design for Connected Health Devices

So far, we have discussed the increasingly important role of connected health devices in health care globally [20]. We have established that various connected health devices have interface characteristics that could cause problems for older adult users or users with disabilities [6]. We have also established that as medical devices, connected health devices and systems are unique in terms of context of use and UI requirements [7]. Finally, we have outlined the technical aspects and requirements of HCD. This leads us to the question, "Why is all of this important for connected health system design?" In the context of what has just been discussed, we think there is a need for a customized HCD methodology for the design of connected health devices; we will now further explore why we think this is necessary by highlighting three specific needs.

The Need for Descriptive Detail and Standardized Structure for Human-Centered Design Methodologies Within Medical Literature

We must make it clear that various HCD approaches to the design of health care technology have been described in the literature. For example, Vermeulen et al described a multiphase HCD methodology for the design of an older-adult activity monitor, with the phases including the following: analysis of users and their context, identification of user requirements, development of the interface, and evaluation of the interface in the lab [21]. Schaeffer et al employed an HCD methodology where they used surveys and focus groups to gather user requirements and create interface prototypes for an insulin pump [22]. Castilla et al described an HCD process for a telepsychology app, where they presented end users with icon and interface concepts in the first step of their design process,

before moving on to a cognitive walkthrough methodology to evaluate the navigation of the interface. These and many other examples like them [23-25] show the wide variance in the application of HCD to health devices and systems. It also exhibits the broad range of usability and human factors testing activities available to engineers and designers to gather feedback. Many of these activities are not new; many of the most well known testing and evaluation techniques had been developed by the late 1980s [26-29]. However, we feel that in a lot of the connected health literature, there is a lack of descriptive detail of the activities carried out within the design process, particularly in regard to ISO 9241-210, and a lack of reporting on how successful or unsuccessful these activities were.

The Need for a Methodology That Allows for Rapid Development Cycles

Additionally, the connected health industry is seen as a fast-moving, highly competitive industry [30], highlighting a need not only for devices that achieve adequate levels of usability, but also for devices that can have rapid development cycles associated with them. This need is punctuated by the association of connected health technology with mobile devices, such as mobile phones. The phones themselves typically act as collection, transmission, and storage platforms for the health data, while the mobile phone apps provide users with an interface to their data or to an external device. In 2015, over 100,000 mobile health apps were available for download between the Google Play Store and the Apple App Store [31]. By 2016, over 500 million people are expected to be utilizing mobile health apps to some degree [32]. This proliferation of mobile health devices and apps means that these devices and their apps can become relatively obsolete in a short period of time [33], with a consequent need for shorter and shorter product lifecycles as was previously experienced in the software industry. This can mean that companies may not be able to incorporate a full HCD methodology into their product development cycle. In light of this observation, it is the authors' opinion that presenting a detailed, comprehensive description of an HCD methodology is warranted, one that is in line with ISO 9241-210 and is optimized for use with connected health devices through the streamlining of the different steps in the HCD process.

The Need for a Guided Approach That Emphasizes Planning and Documentation

It has been previously observed that developers of connected health solutions are in many cases more engaged with the technical innovation in these systems rather than with their usability [7,34]. More recently, it was identified that there is a need for guidelines on how to conduct the design and development process for connected health devices in terms of usability [35]. Finally, in the development of medical devices, appropriate documentation of the design process is critical, particularly if the device is to adhere to a standard such as that from the International Electrotechnical Commission (IEC), IEC 62366-1. The FDA requires evidence of end user involvement during the design process when reviewing market presubmissions [14].

Therefore, as well ensuring our methodology adheres to the six guiding principles of HCD as outlined in ISO 9241-210, we will add three more requirements that our methodology must meet. We will refer to these three new requirements as Requirements 7-9, and they are listed below:

1. Requirement 7: Our methodology will follow the steps outlined by ISO 9241-210 as closely as possible and give a detailed description of activities carried out and outcomes achieved in each phase.

2. Requirement 8: Our methodology will utilize activities that allow for rapid prototyping, testing, and development.

3. Requirement 9: Our methodology will emphasize planning activities in advance and generating the appropriate documentation.

In this paper, we will describe a three-phase methodology which follows the same process as outlined in ISO 9241-210 (see Figure 1), which adheres to the six requirements it outlines as well as the three additional requirements we have just derived. In the following section, we will provide a detailed description of our activities and the justification for them. We will also provide an example of the application of the methodology to a connected health system. This paper will not provide the results of this application as those results will appear in a related publication.

Methods

Overview

The methodology, which will be described in this section, now has nine requirements that must be fulfilled. These are listed below with appropriate elaboration:

1. Requirement 1: The design is based upon an explicit understanding of users, tasks, and environments. In the first phase of our methodology, we will establish context of use, user requirements, and user profiles.

2. Requirement 2: Users are involved throughout the design and development. We will involve end users and expert users as much as possible in each phase.

3. Requirement 3: The design is driven and refined by user-centered evaluation. We will use evaluation techniques at each phase to achieve measurable results.

4. Requirement 4: The process is iterative. We will have multiple phases where design changes can be made after each phase; the process can revert back to a previous phase if necessary.

5. Requirement 5: The design addresses the whole user experience. Use cases developed in the first phase will address all aspects of use and will be used as reference points before and after each phase.

6. Requirement 6: The design team includes multidisciplinary skills and perspectives. We will incorporate multiple perspectives from disciplines within the design team, from stakeholders, and from experts. Here we define stakeholders as any person involved in the project who is affected by the activities or outcomes related to the product in question. An

expert is defined as any person with an expert knowledge of the product, the end user, or of usability and human factors.

7. Requirement 7: Follow the steps outlined in ISO 9241-210 and provide details of suggested activities and their expected outcomes within each phase. Our phases will be structured to conform to the phases outlined in ISO 9241-210 and will outline which activities should be carried out in each phase.

8. Requirement 8: Perform rapid development and testing while maintaining clear structure. The early phases of our methodology will designate activities that allow for rapid prototyping and evaluation.

9. Requirement 9: Our methodology will be well planned with all activities, outcomes, and design changes properly documented. Our methodology will seek to embed the documentation of all activities, design, and developments.

Based on these requirements, we will now describe a three-phase methodology that will fulfill these requirements. These three phases are labeled as follows:

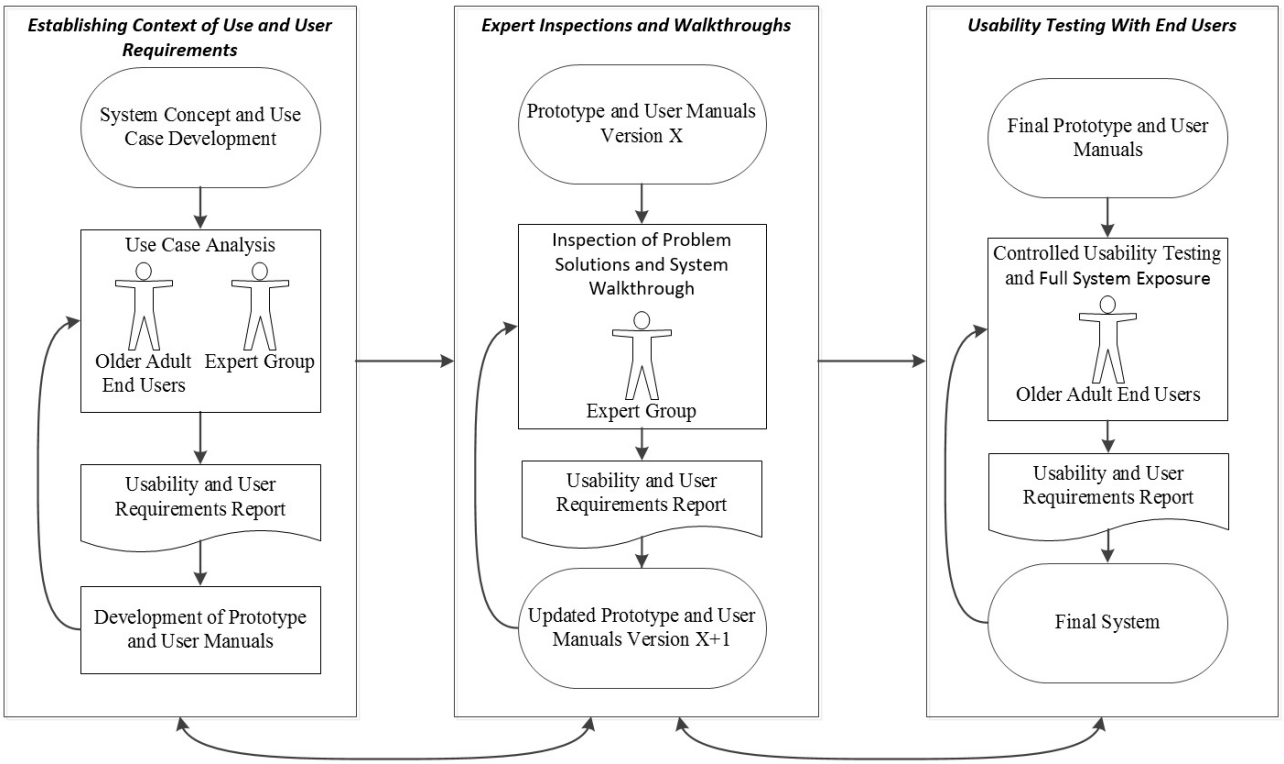
1. Phase 1: Establishing Context of Use and User Requirements

2. Phase 2: Expert Inspections and Walkthroughs

3. Phase 3: Usability Testing With End Users

The full methodology is illustrated in Figure 2 and then described in further detail within the text.

Figure 2. Our human-centered design approach to a connected health app.



Phase 1: Establish Context of Use and User Requirements

Overview

This phase establishes the context of use of the device and the requirements and needs of the target end user. Usually in early phase testing, to understand the needs of the user, activities such as interviews [36], surveys, and ethnographic observations are carried out [37,38]. This can be resource intensive and difficult to document properly. In our methodology, we attempt to gain an explicit understanding of users, tasks, and environments (Requirement 1) through the immediate construction of a use case document. Constructing use cases is a commonly used method to analyze user requirements and user preferences [39,40,23]. Starting with the system concept as reference point, the use case document should be made up of flow diagrams, storyboards, screenshots, interface mock-ups, paper prototypes, and descriptive end user profiles. The document is designed to be interactive and descriptive; it is designed to provide a common platform for project stakeholders to communicate their vision for each component's and user's role within the system and the interactions they have with each other, thereby attempting to address the whole user experience (Requirement 5). User profiles should be drawn up within the use case document of potential users, describing capabilities, requirements, and preferences.

Suggested Activities

These use cases can be exposed to a group of experts with knowledge of the system and/or usability (Requirement 6) and to a group of end user representatives (Requirement 2) [41]. At various points in the document, questions can be put to the reader or they can share their insights; in this way, the use case analysis acts like an interview, survey, and ethnographic exercise all in one, allowing for more rapid turnaround of information related to user requirements (Requirement 8). In the early phase of the design process, designers could pursue many different

possible solutions and concepts. Within the use case, or as an accompaniment to it, paper prototypes, wireframes (essentially a skeletal framework of an interface, usually a website), and mock-ups should be exposed to the users [42-45]. Likert scales can be used to query the reader's agreement with aspects of the prototypes (Requirement 3).

Outcomes

A usability report and a list of user requirements, backed up by quantitative and qualitative data, are produced (Requirements 3 and 9). Semifunctioning prototypes or mock-ups that fulfill as many of the uncovered requirements as possible should now be built and made available for testing in Phase 2. The first user manuals, if required, should also be ready for inspection in Phase 2. This phase fulfils Requirements 1-3 and 5-9.

Phase 2: Expert Inspections and Walkthroughs

Overview

The testable prototype should now be exposed to a controlled formative test that takes into account usability, human factors, and overall user experience characteristics, as well as testing the overall functionality of the prototype (Requirements 3, 5, and 6). This can be done using so-called discount usability techniques to ease the burden on time resources and to forgo expensive recruitment of end users (Requirement 8). The testing is carried out with reference to the use case and the requirements generated from Phase 1. Problems uncovered by the tests need to be prioritized and addressed in turn by the development team, with testing repeated if necessary (Requirement 4).

Suggested Activities

Evaluation and inspection methods could be carried out. Usability inspection involves a multidisciplinary expert group (Requirement 6) inspecting the interface and attempting to identify usability and human factors problems [23]. This can be in the form of a heuristic evaluation where the interface is compared to a set of predefined design guidelines [45,46] or a cognitive walkthrough [47,48]. In a cognitive walkthrough, the expert group can carry out a task by way of task analysis of the interface while focusing on cognitive processes that the task requires, documenting where they encounter problems. Usability inspections are commonly used as a precursor to formal end user testing [49-51] because they are seen as low cost and easily implementable techniques than can garner quick and concise feedback [52]. Their flexibility and quick feedback lend themselves well to the evaluation of almost any type of system or device. In addition, usability inspections have been used to assess the usability of electronic health record systems [53], Web-based interfaces for telemedicine apps [54], online educational websites [55], infusion pumps [56], pacemaker programmers [57], instrumented insoles [51], and mobile phone apps [58].

Outcomes

An updated usability report is produced (Requirement 9). A now-advanced prototype with almost full functionality with accompanying user manuals should now be ready for testing with end users. This phase fulfils Requirements 1 and 3-9.

Phase 3: Usability Testing With End Users

Overview

The now-advanced prototypes are exposed to end users in summative user testing (Requirement 2). The test can be carried out in controlled settings like a lab, but it is more useful to carry out field-testing with end users, such as in their homes. Problems uncovered by the tests need to be prioritized and addressed in turn by the development team, with testing repeated if necessary (Requirement 4). Test cycles should be kept short with a low number of participants in each cycle if possible.

Suggested Activities

User testing should be carried out; it has been greatly described in the literature [59-61] and involves monitoring users while they interact with the system interface. This monitoring can be carried out in different environments, with laboratory sessions allowing for more control over the experiment and more robust data, albeit with the loss of real-world fidelity. Observing users in a more natural use environment can lead to richer data, but the data can be harder to quantify effectively. In early instances of user testing, the administrator will often ask the subject to think aloud, allowing the observer to gain an insight into the train of thought the user is employing as they encounter and attempt to overcome usability and human factors problems [62,63] (Requirements 1 and 5). Cameras, audio recorders, and note taking are employed to record the user behavior. Scales such as the Quebec User Evaluation of Satisfaction with Assistive Technology, the System Usability Scale (SUS), the After-Scenario Questionnaire (ASQ), the NASA Task Load Index (TLX), and the Visual Analogue Scale, as well as 5-point Likert scale questionnaires [64], are utilized to record and quantify user satisfaction (Requirement 3). An example of a Likert questionnaire item might be "I can read the text on the screen without any difficulty"; a user will then rate their level of agreement or disagreement with the item on a scale of 1-5. Efficiency and effectiveness are measured by recording time taken to complete tasks and error and completion rates [65].

Outcomes

A very advanced prototype that can be subjected to further user testing or expert inspection can be carried out if required. This phase fulfils Requirements 1-5 and 7-9.

Within each phase, activities can and should be repeated if necessary (Requirement 4). After each phase, all problems are recorded and documented in structured usability and human factors reports, or another form of presentation, so that all stakeholders are aware of the problems and all problems and changes are documented (Requirement 9) [66].

Application of Methodology to a Connected Health System

Overview

This methodology was applied to assess and enhance the usability, human factors, and user experience of a connected health system known as the Wireless Insole for Independent and Safe Elderly Living (WIISEL) system, a system designed to continuously assess fall risk by measuring gait and balance

parameters associated with fall risk [67]. The system is also designed to detect falls. The architecture of the system is illustrated in Figure 3 and it is described in further detail below.

It is proposed that the system can be used in the home by a user for a period of time in order to identify specific gait and balance patterns that may be affecting a user's fall risk. The system is targeted at older adults who represent a high-fall-risk group. The system consists of a pair of instrumented insoles worn by the user and a mobile phone carried by the user. Data collected by embedded sensors in the insoles are sent to the mobile phone, where they are then uploaded to a server in a clinic for processing and analysis. The mobile phone represents a major interface in the system, as this is how the home user will primarily interact with the WIISEL system with the WIISEL app allowing the user to check the system status, sync with the insoles, send data to their local clinic, and monitor their daily activity.

Phase 1 Activities

The process of Phase 1 is summarized and illustrated in Figure 4.

Figure 3. The Wireless Insole for Independent and Safe Elderly Living (WIISEL) system.

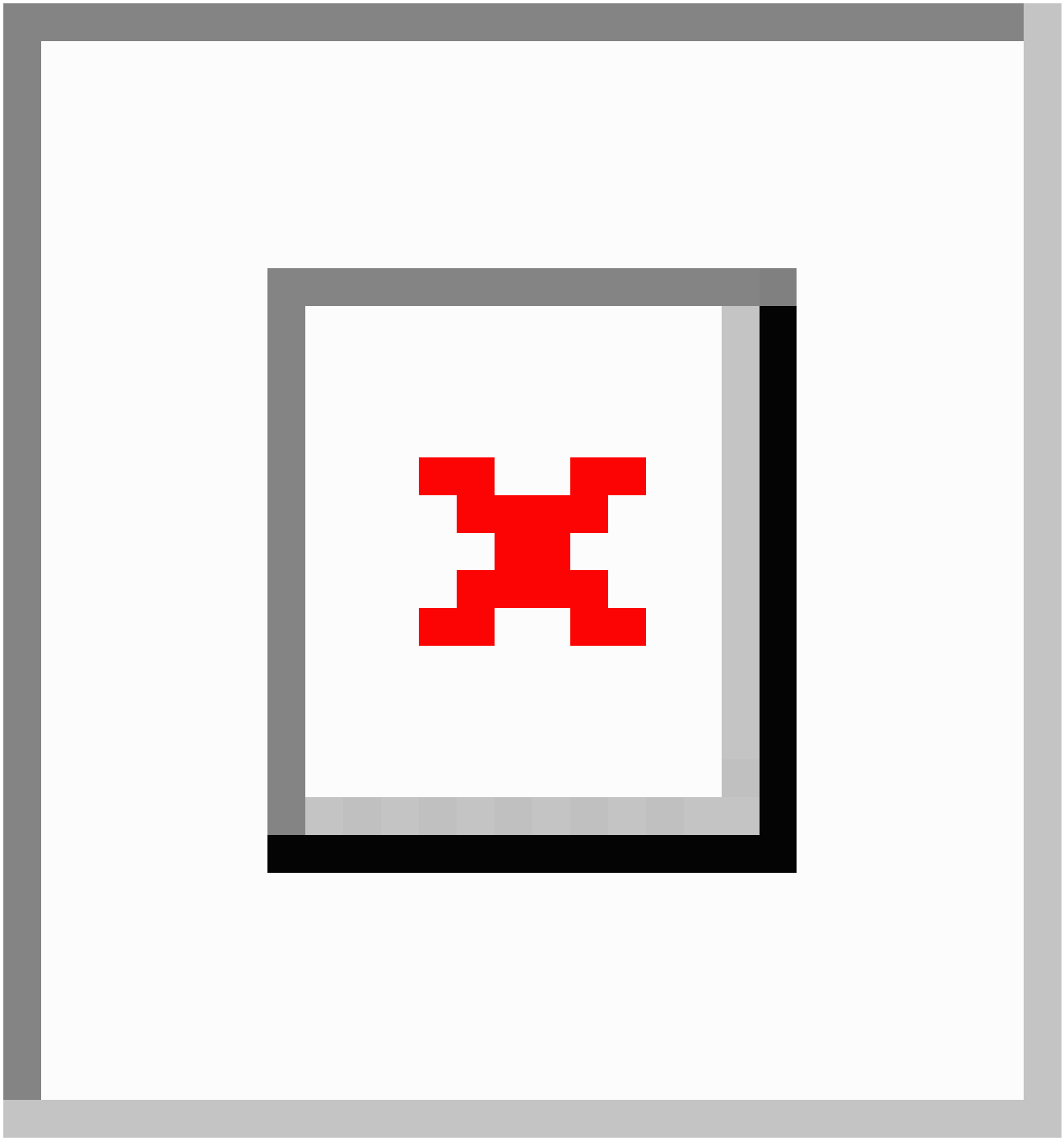
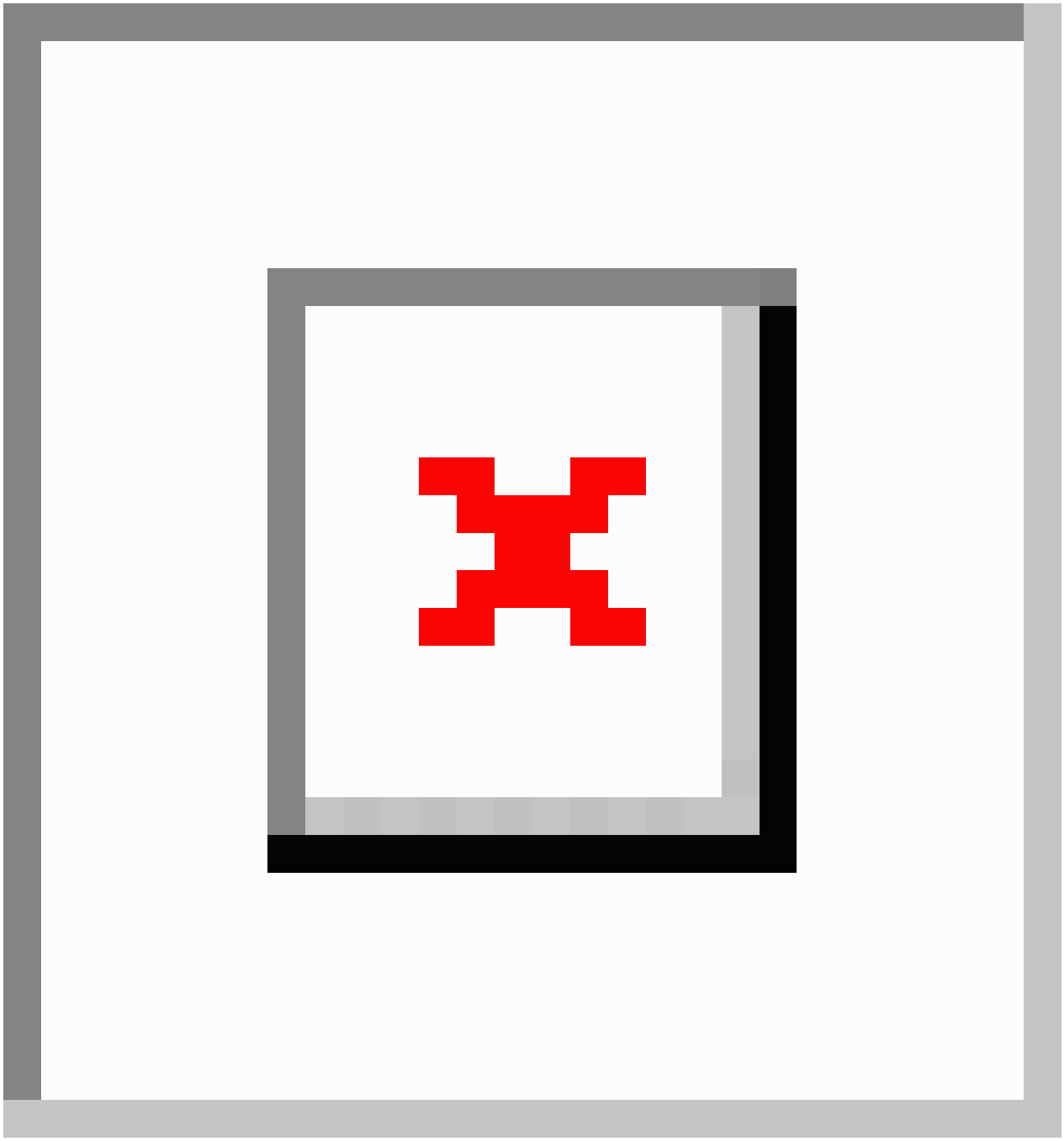


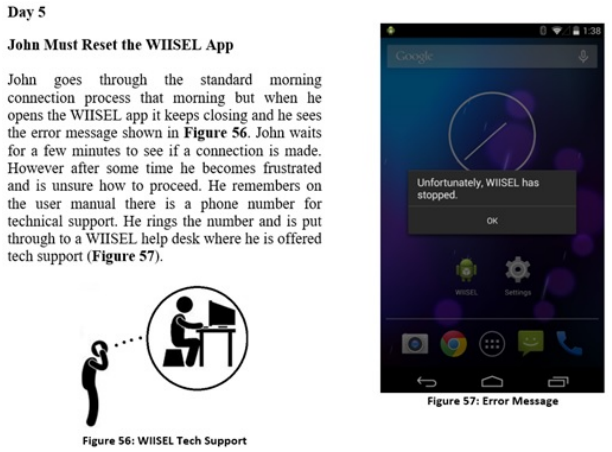
Figure 4. Phase 1 activity flow.

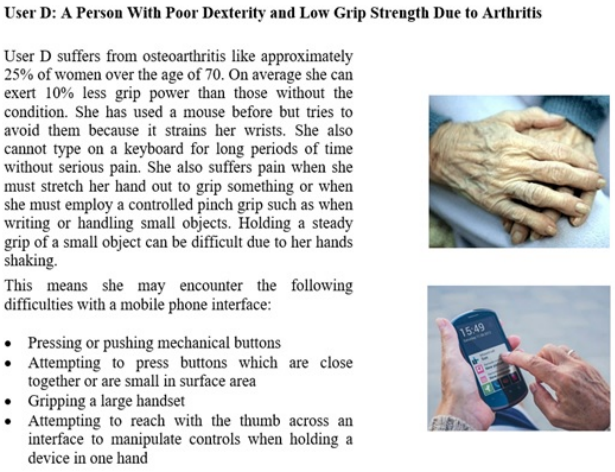


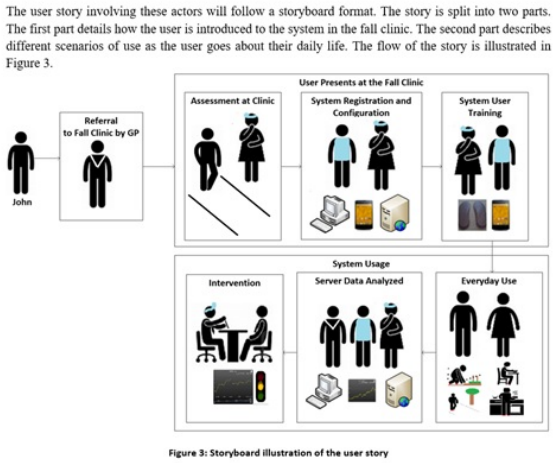
Use Case Creation

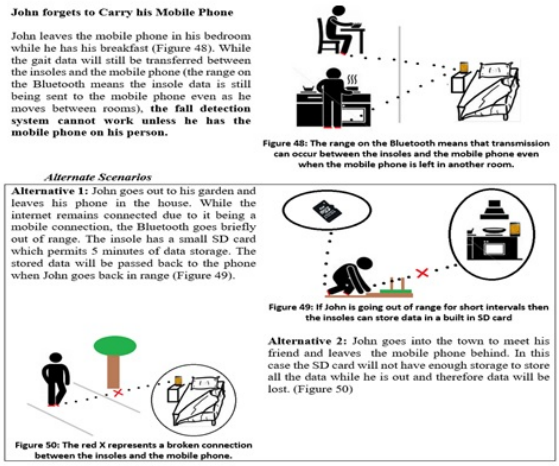
The use case document was constructed with inputs from all project stakeholders, who were able to share their opinions on how the system would work and what it would be used for. Scenarios were described in the document, which identified the tasks the user must carry out with the system, the order the tasks were carried out, and the context in which the tasks were carried out. Potential risks that the user might encounter through their interaction with the system were also identified (using ISO 62366 as a reference guide). Examples of the information included in the WIISEL use case are illustrated in Figure 5.

Figure 5. Examples of the information included in the WIISEL use case. (A) A scenario presented in the use case where the user, John, must carry out a troubleshooting sequence with the app; a life-size color screenshot of the mobile phone interface is shown. (B) A section of the use case that profiles typical physical capabilities of the target user and how this might affect their interaction with the mobile phone. (C) A storyboard at the beginning of the document summarizing the whole process, from when the user is prescribed the system to when they return to the clinic having worn it for a period of time. (D) A scenario in the use case where it describes what might happen to the phone while the user is doing daily home chores. WIISEL: Wireless Insole for Independent and Safe Elderly Living; GP: general practitioner.









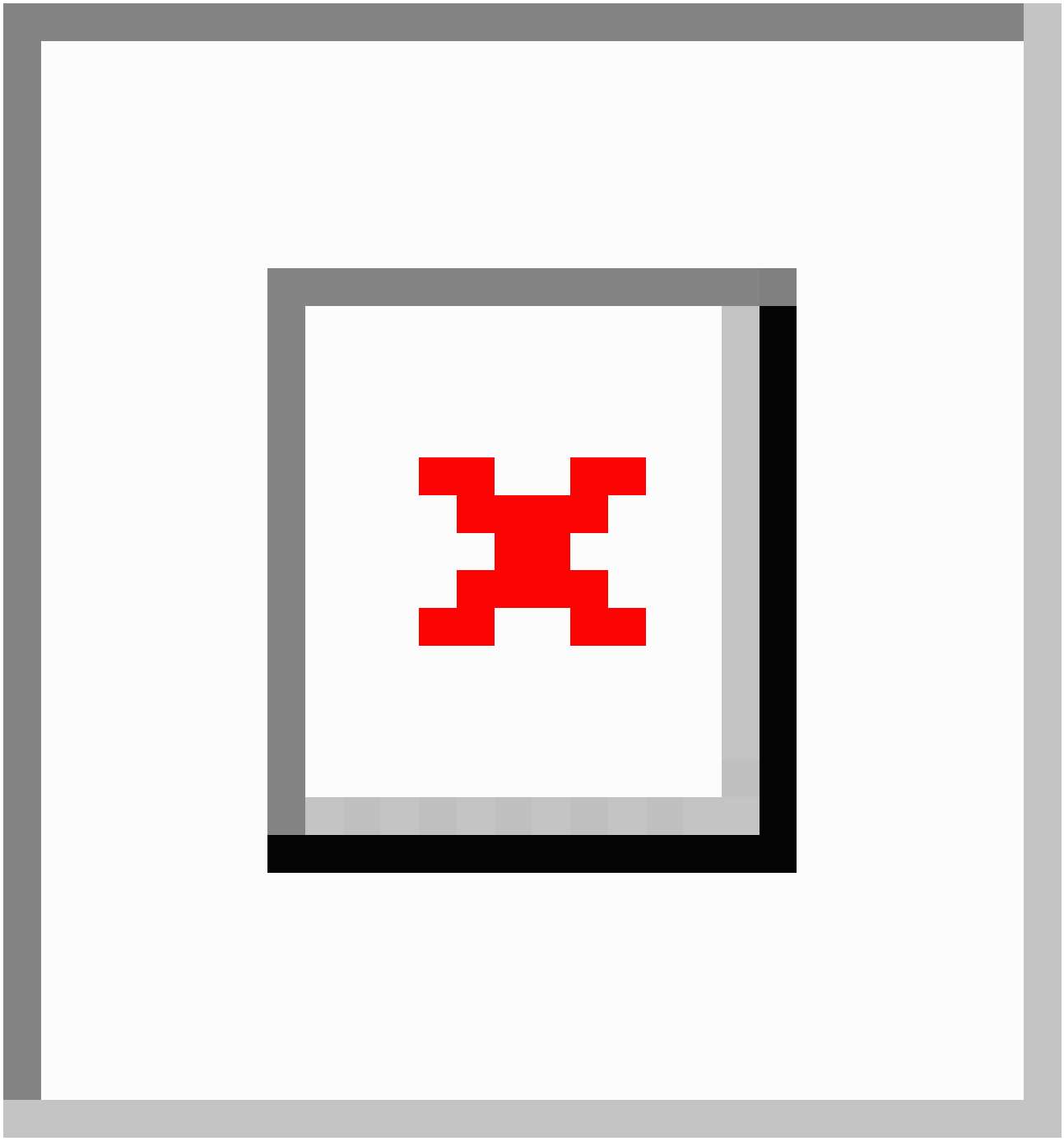
Use Case Analysis

The use cases were examined by a series of stakeholders, which included target end users—older adults and health professionals—and people with relevant expertise who may not necessarily be end users but who have experience in the design of similar systems. The reader examined the scenarios one after another. After each scenario of the use case, the reader was interrogated on their thoughts on what they had seen using tick-box Likert scales which were embedded in the document.

For example, in the case of the use case describing the use of the WIISEL mobile phone, the user filled out Likert scales that queried their opinions on color schemes, text size, button size, and screen navigation flows as observed from high-definition color screenshots. Examples of end users interrogating use cases and filling out the appropriate scales are shown in Figure 6.

Apart from the set scales the reader filled out, the think-aloud protocol was also employed by the reader so that they could elaborate on any potential problems and digress if necessary to related problems not explicitly presented in the use case.

Figure 6. Older adult participants analyzing and providing feedback on the use cases.



Problem Classification

There are a number of methods to classify usability problems [68-70]. Many of these methods, such as clustering, heuristic evaluation, and Nielsen's classifications, prove effective in identifying how likely an identified problem is to affect the user's interaction with the system. Because the use case is not representative of the fully interactive system, it is not possible to carry out a traditional classification by observation and evaluation; rather, we used the transcripts and the scoring from the Likert scales to predict potential problems. A three-step process was employed:

1. *Clustering Identified Problems*: Using the compiled transcripts from the think-aloud protocol, we grouped explicit identification of problems on a scenario-by-scenario basis. Problems can be grouped according to a set of heuristics, making the problems easier to classify and track throughout the design cycle. In the case of the WIISEL mobile phone use case, the following set of heuristics (a-e) was used [70]:

(a) *Consistency/Clarity of Task Structure*: The flow of the task or the interface may cause confusion or may be hard for a typical user to follow.

(b) *Completeness and Sufficiency of Task Meaning*: Feedback obtained when the user carried out an action, or was required to carry out an action, was unclear or may cause confusion.

(c) *Noticeability*: An element on the interface that is important to the completion of the task is difficult to notice.

(d) *Discernibility*: Physical interface characteristics such as text size, button size, and color scheme—each of which is a subcategory—may make it difficult for the user to complete the task.

(e) *Cognitive Directness*: The user was required to carry out an action that did not result in the expected outcome.

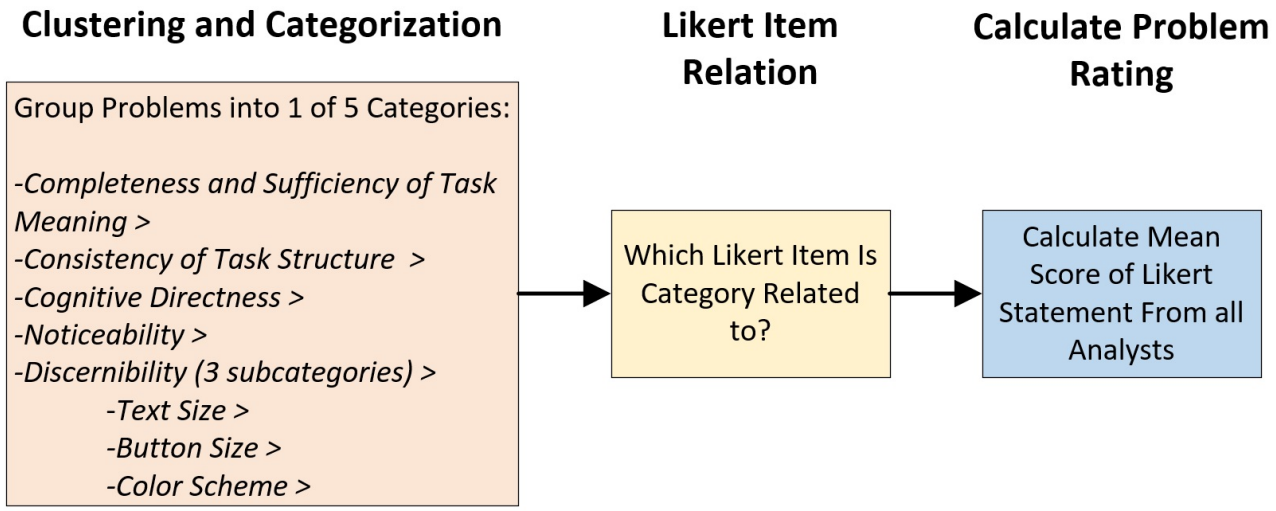
2. *Relate Problem to Likert Item*: The identified problems were related to one of the Likert items put to the participants at the end of each use case scenario. The Likert items are related to each of the categories above.

3. *Calculate Severity Rating*: The median score was calculated for the Likert item (adjusted range 0-4, with 0 considered a perfect score and 4 considered the most severe). This provided a problem rating for the problem.

The methodology, illustrated in Figure 7, is sometimes referred to as bottom-up clustering because it groups together similar problem descriptions from first principles.

This list of problems can be dealt with straight away, as most of them will be aesthetic and superficial, while more complex problems, such as ones related to concepts and flow, can be further explored in functioning prototypes.

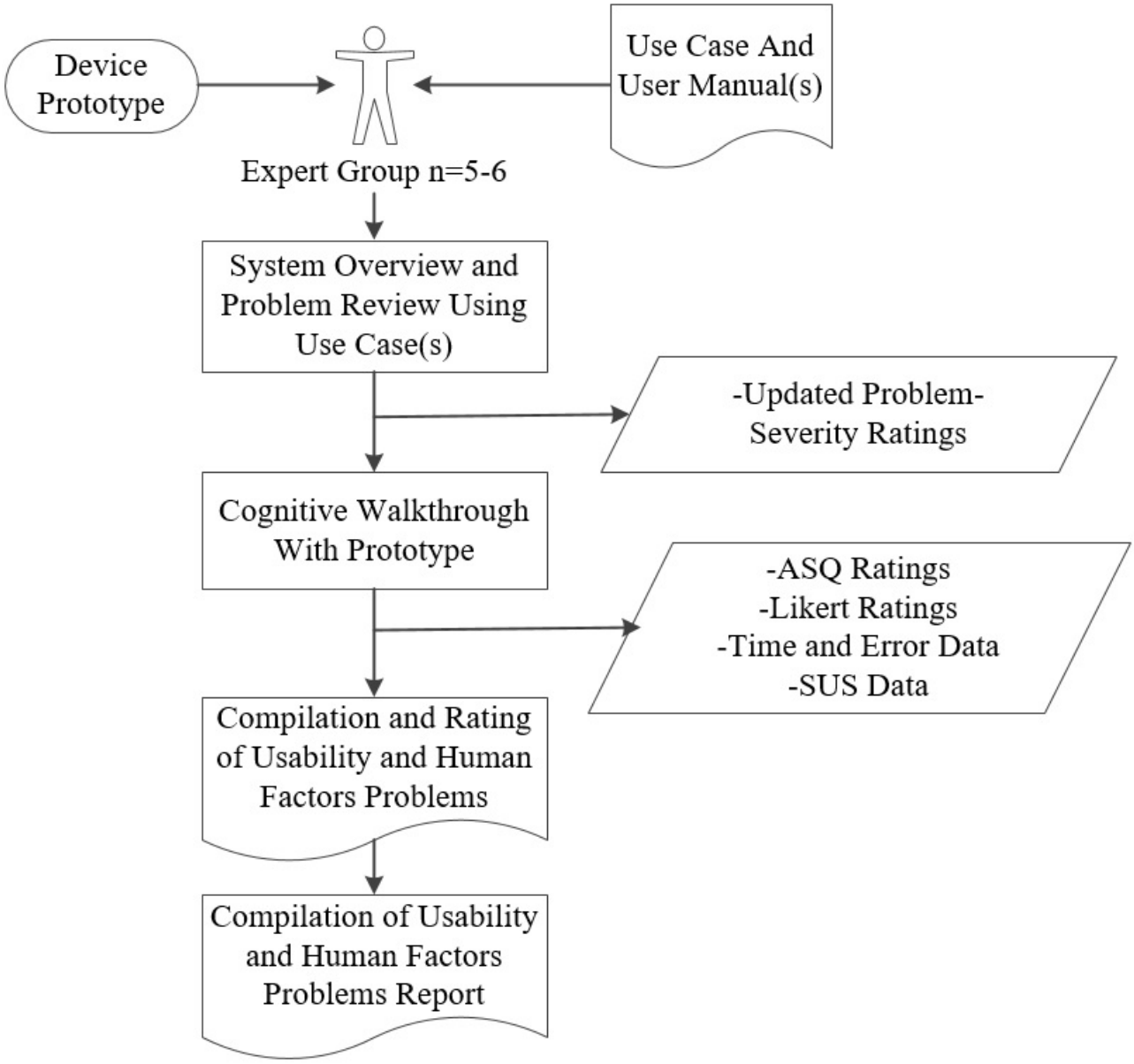
Figure 7. Structured process for prioritizing usability problems.



Phase 2 Activities

The Phase 2 activity flow is illustrated in Figure 8.

Figure 8. Phase 2 activity flow. ASQ: After-Scenario Questionnaire; SUS: System Usability Scale.



Inspection of Updated Use Case

In response to the feedback from Phase 1, a semifunctioning WIISEL mobile phone app prototype was also developed with accompanying user manuals—Working Prototype Version 1—and made available for expert walkthrough. An updated use case was also created to accompany the inspection—Paper Prototype Version 2. The original experts from Phase 1 carried out a two-part usability inspection. First, the experts inspected the solutions to the problems they had identified in Phase 1 using the new version of the use case—Paper Prototype Version 2—as a guide. This use case only presented the problems that the experts identified in their original analysis and showed how the problems had been addressed. Second, they inspected the physical app—Working Prototype Version 1—utilizing a walkthrough methodology.

The use case inspection consisted of four steps:

1. The expert was presented with the original use case scenario—Paper Prototype Version 1—in which they originally identified the problem. This provided the problem context.

2. The expert was presented with a description of the problem they identified within the scenario with, where possible, an annotated screenshot of the interface outlining where exactly the problem was identified.

3. The updated interface—Paper Prototype Version 2—was presented to the expert, which has sought to address the problem.

4. The expert was asked to mark the relevant Likert item for the purpose of calculating a new problem rating.

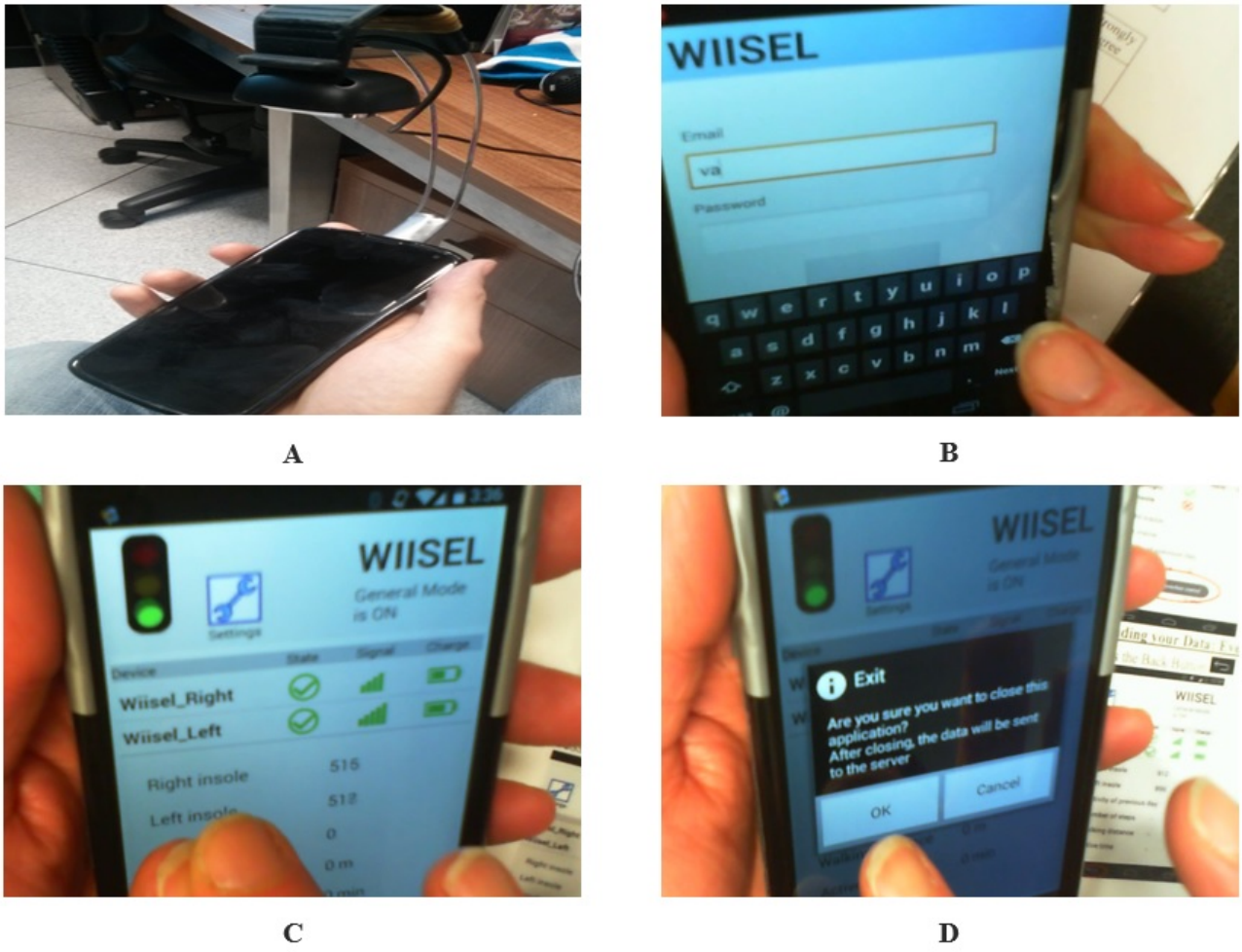
The expert was notified before proceeding that they could still reject any changes to the interface as being either inadequate or not being what they had suggested. The new problem ratings calculated from the Likert items filled out in Step 4 were then compared to the original ratings.

Cognitive Walkthrough With Manuals

In order to give the expert a chance to fully analyze the physical app and transition from a high-fidelity paper prototype to a functioning physical prototype, the app was presented to the expert following a cognitive walkthrough methodology. The cognitive walkthrough method is employed as a means of identifying usability problems in interactive systems, with a primary focus on determining how quickly and accurately new users would be able to complete a task with a system. A lightweight overhead camera (Microsoft Life HD+Mic) was attached using a wire cradle to the phone handset, which captured all interactions with the phone screen interface (see Figure 9).

The experts were walked through the user manuals and the app by the researcher as if they were a first-time user and were then asked to carry out a number of scenarios. They could consult the user manual at any time, but were not prompted by the administrator. They were encouraged to think aloud as they carried out each task. A number of usability metrics, such as time taken to complete task, errors made, and completion rate, were recorded during the walkthrough and captured using the overhead camera. The ASQ was employed after each scenario. The ASQ is a 7-point scale where a score of 7 indicates strong disagreement and 1 indicates strong agreement; a lower score indicates increased satisfaction with the interface. It seeks the user's agreement on three statements related to key usability metrics: "Overall I am satisfied with the ease of completing this task," "Overall I am satisfied with the amount of time it took to complete this task," and "Overall I am satisfied with the support information (online help, messages, documentation) when completing this task." All observed problems were again recorded and compiled in a usability and human factors report.

Figure 9. Phone screen interface. (A) The experts walk through each scenario in the user manuals with the phone; the cradle camera captures all of their interactions with the mobile phone. (B) An expert attempts to log in to the mobile phone app. (C) An expert follows the connection sequence from the user manual. (D) An expert carries out the data upload sequence.



Phase 3 Activities: User Testing

The process of Phase 3 is summarized and illustrated in Figure 10. In this phase, a now-advanced functioning prototype complete with user manuals where necessary was exposed to end users in controlled summative user testing. Any major problems with the system identified in the expert inspection should have been addressed by this time, particularly any problems that could adversely affect the health of the end user. The new manuals and updated interface—Working Prototype Version 2—were exposed to 10 older adults who had previously analyzed the use case. The testing was carried out in the home of the participant. The procedure was as follows:

1. The participant was asked to complete all tasks defined in the original use case.

2. Each task was carried out three times.

3. Before the testing began, the participants were guided through the task by the researcher using the user manuals. Allowing the participant to become familiar with the interface is important to separate genuine usability problems from mistakes due to unfamiliarity with the interface or device.

4. The overhead camera was attached and the screen interaction was recorded. No prompts were given to the participants, who were expected to complete the task using only the user manual as a guide (see Figure 11).

The same usability metrics were captured as in Phase 2 and the users were also interviewed posttest to get their general feelings on the device and interface. The feedback from user testing was used to generate the first working system complete with user manuals. Another usability report was compiled for the consumption of all stakeholders.

Figure 10. An example of Phase 3 activities. ASQ: After-Scenario Questionnaire; SUS: System Usability Scale.

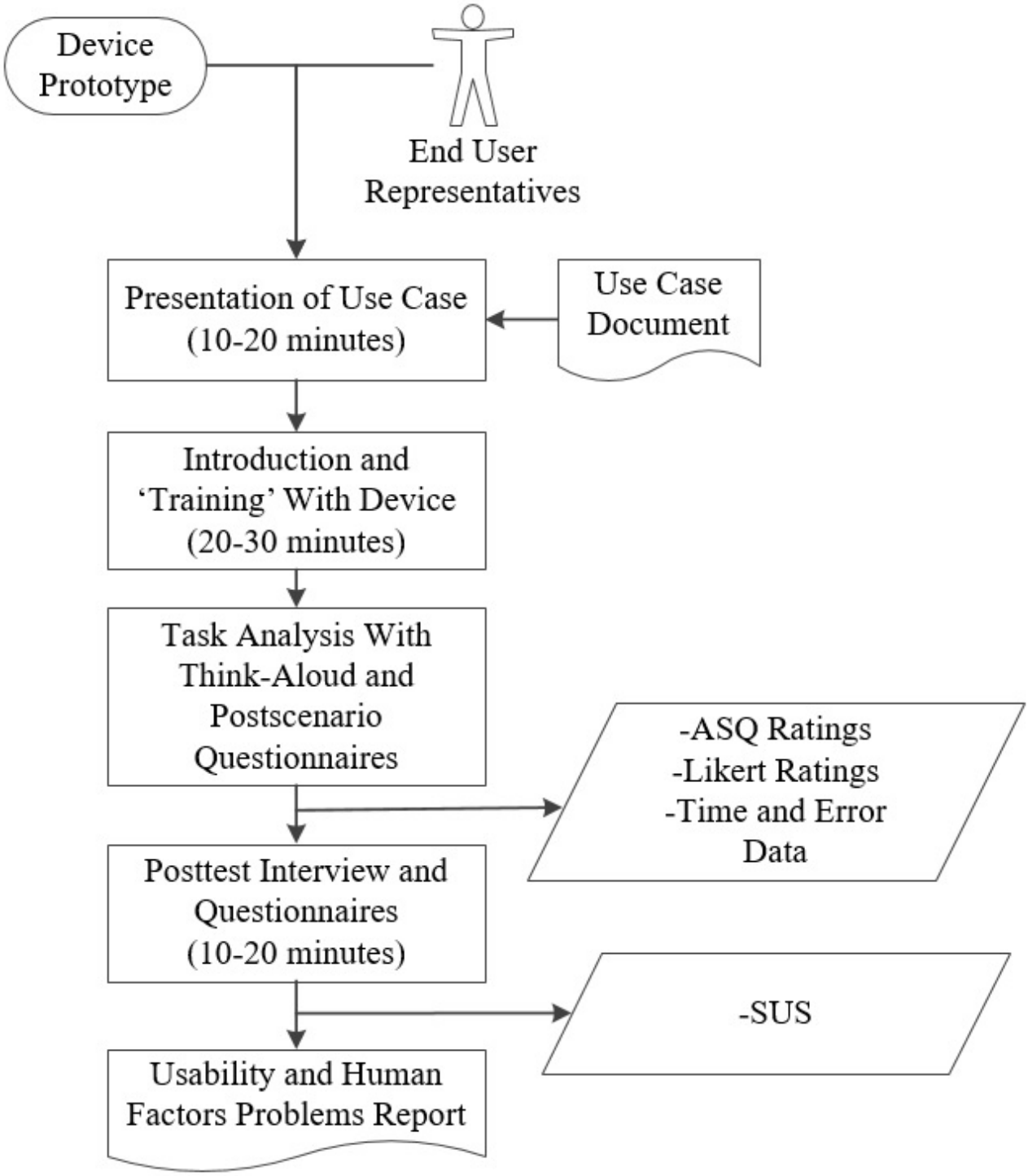
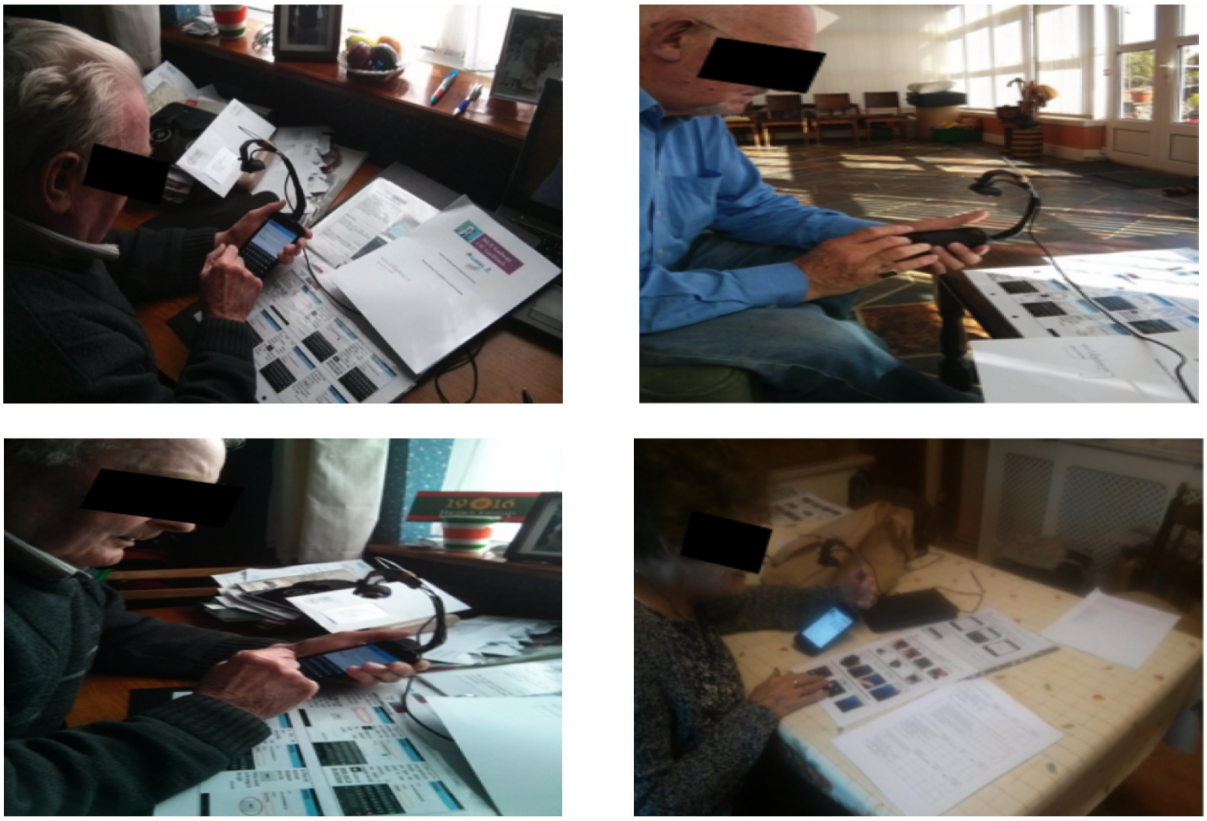


Figure 11. Older adult users carrying out tasks using the user manual as a guide during the user testing phase.



Method Overview

The complete methodology, with a breakdown of each phase, is illustrated in Figure 12.

Figure 12. An overview of the complete methodology and all the suggested activities in each phase as applied to the Wireless Insole for Independent and Safe Elderly Living (WIISEL) system. ASQ: After-Scenario Questionnaire; TLX: Task Load Index.

Discussion

Principal Findings

We have presented in detail the HCD methodology we consider to be a sensible and robust approach to designing interactive connected health devices. We will now review our proposed methodology and its example application to the WIISEL system by comparing the outcome to the nine requirements that were originally derived.

Did Our Methodology Meet Our Requirements?

In terms of the first six requirements, we implemented a three-phase methodology that followed the flow of ISO 9241-210. The three phases allow for design iteration and can be repeated if necessary. The phases where iteration is most likely to occur are Phase 2 and Phase 3 [51], as these are the major testing phases with measurable outcomes, where outcome metrics can be compared when tests are repeated after prototypes have been updated. The methodology began with a phase that sought to gain an explicit understanding of users, tasks, and environments and tried to address the whole user experience by constructing a use case. This use case allowed for end users and multidisciplinary experts to become involved and evaluate the system concept, prototype screens, and the user task flow. The use case we developed for WIISEL contains information regarding the typical capabilities of the user, possible risks a user may encounter (eg, using ISO 62366 or ISO 14971 as a reference), what might happen if an error arises, and how often they would be expected to interact with the system. These aspects of system use were then explored in more detail in Phases 2 and 3, using the original use case as a reference point.

The target end user was involved in Phase 1 and Phase 3. The end users in Phase 1 were able to provide accurate feedback on their user profiles and the context of use in which they would use the system, as well as provide early feedback on interface concepts and task flows. In Phase 3, we were able to closely observe them performing the system tasks that had been carefully designed in the previous two phases. In total, 22 end users were involved in our process. We successfully integrated multidisciplinary inputs into our design, utilizing experts from various backgrounds such as computer science, medicine, nursing, gerontology, psychology, and design. The experts should be chosen based on the type of system being designed and who the target end user is. In our case, the input of gerontologists and nurses with experience in technology for older adults was invaluable. If the necessary experts are not available, then generic inspectors should inspect the prototype using pre-established heuristics.

In terms of the three further requirements that were derived to add to the original six, ISO 9241-210 was used as a guiding source by following the principles and steps outlined within it to fulfill Requirement 7. To fulfill Requirement 9, before the process began we set out exactly what testing and design activities we were going to carry out. While there are many activities usability engineers can employ to test products, it is never necessary to try to use all of them in the same project. We felt it was best to choose what activities would best suit our particular device and project. It is important to plan and document the activities in a design file, particularly if the device is to adhere to a standard such as IEC 62366-1. Regular meetings were carried out among stakeholders and developers to discuss upcoming activities and design changes. After each activity, all

results and findings were placed into presentable formats, such as PowerPoint slides, so they could be disseminated among team members and stakeholders. Methodologies for activities were also disseminated such that changes could be made before activities took place. To fulfill Requirement 8, in Phase 1 we carried out a well-planned and choreographed use case analysis activity that was designed to allow for rapid idea and concept exchange. The use case analysis acted like an interview, survey, and ethnographic exercise all in one because it was addressing the whole user experience and allowed end users, experts, and stakeholders to participate in the formation and analysis of concepts and ideas, as well as providing validation on user profiles and context of use. We utilized paper prototypes extensively in Phase 1 and usability inspections with small expert teams in Phase 2. This use of so-called discount usability engineering methods again allows for rapid turnaround times on prototypes and quick feedback to be sent to the design team. The use cases can be constructed in a matter of days, while a full use case analysis can be carried out with an end user or expert in an hour. The data are easy to process because all the data—the Likert data and think-aloud transcripts—are at hand from the one analysis and are relatable directly to the context of use.

Final Comments and Limitations

We can say on a preliminary basis that all the objectives we originally outlined for this methodology have been successfully met. We feel that our proposed methodology, and the examples of its implementation in this paper, will provide prospective designers with a methodological blueprint to follow an HCD process that adheres to a standardized structure, but also allows for rapid development cycles.

We have also recognized some possible limitations in our methodology that need to be addressed. In Phase 2, we only tested the prototypes with experts from various disciplines. There are a number of reasons for this. First, as a matter of principle in terms of ergonomic quality control and safety, we feel it is important to not expose a prototype to a potentially vulnerable user group, such as older adults in this case, until it has been fully inspected and walked through by experts. The example of a mobile phone app may not seem necessary to warrant this level of caution; however, we want this methodology to be applicable to all kinds of connected health devices, some of which may have greater levels of risk than others. Second, the expert input in Phase 2 allowed for a fresh third-party perspective on the system and brought a level of expertise in areas of usability, human factors, and interface design, something that the target end user themselves may not have experience in. Finally, end user recruitment can be expensive, therefore Phase 2 acts as a way to remove many of the usability problems, however simple or complex they may be, before the prototype reaches end users. Experts may also be expensive to hire or recruit; however, within a research group or enterprise, usability inspection groups can be formed from stakeholders, designers, and developers who may already be involved in a project or related projects. Those not experienced in usability can be trained in how to analyze prototypes using heuristics.

One of the requirements of the methodology was to create an emphasis on rapid prototyping and evaluation, which is made possible in the methodology by introducing paper prototyping activities in Phase 1 and so-called discount usability engineering techniques in Phase 2. This emphasis on rapidity may lead to depreciation in quality. However, our methodology emphasizes the need for documentation and review after each phase. This will ensure that changes that have been recommended are disseminated, prioritized, and implemented before the next phase begins [71]. Ultimately, the quality and design of the testing and evaluations will dictate the quality and efficiency of the user feedback and what changes need to be made; this is why having a dedicated usability engineer on a design team is important [72].

In terms of measurability, how do we know our methodology has provided any improvement or is measurably better than other methodologies? This is hard to measure and would only be realistic if we applied different methodologies to the design of the same product. In this paper, we have identified many different methodologies that have been applied to the design and development of connected health and other similar medical devices. However, we identified a lack of standardized and guided approaches. Therefore, we wanted to derive a methodology that was guided by the principles and steps described in ISO 9241-210 and that has explicitly described steps and activities that other designers and engineers can follow. If this methodology is used in the future and is adopted by others, then we can start to measure its true effect and measure what its shortcomings may be, leading to improved HCD methodologies in the future. The application of the methodology to the WIISEL system and the subsequent results of this application will be explored in more detail in a separate paper.

Conclusions

We conclude that our methodology brings a simple yet robust structure to HCD and development, while maintaining a rapid approach that will suit modern design and usability engineering teams in fast-paced and competitive industries. We have described in detail the activities that can be carried out in each phase. We have also presented our justification for this methodology and why we consider it to be a flexible and useful methodology, particularly for improving the usability, human factors, and user experience of devices and systems to be used for medical purposes.

Acknowledgments

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Authors' Contributions

The methodology for this study was conceived and designed by RH, LQ, and GÓL. The experiments were carried out by RH with the support of LG, TS, and ARM, each of whom contributed both usability and medical knowledge to the testing. The data were compiled and analyzed by RH, LQ, and GÓL and reviewed by LG, ARM, and PB. All authors contributed equally to the introduction and discussion sections of the paper. The paper as a whole was reviewed and edited where necessary by all authors before submission.

Conflicts of Interest

None declared.

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Abbreviations

ASQ: After-Scenario Questionnaire
CACP: Center for Advanced Communications Policy
CÚRAM: Centre for Research in Medical Devices
FDA: Food and Drug Administration
FP7: Seventh Framework Programme for Research
GP: general practitioner
HCD: human-centered design
IEC: International Electrotechnical Commission
ISO: International Organization for Standardization
SUS: System Usability Scale
UCD: user-centered design
UI: user interface
TLX: Task Load Index
WIISEL: Wireless Insole for Independent and Safe Elderly Living

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Original Paper

Mobile Phone Apps for Smoking Cessation: Quality and Usability Among Smokers With Psychosis

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Abstract

Background: Smoking is one of the top preventable causes of mortality in people with psychotic disorders such as schizophrenia. Cessation treatment improves abstinence outcomes, but access is a barrier. Mobile phone apps are one way to increase access to cessation treatment; however, whether they are usable by people with psychotic disorders, who often have special learning needs, is not known.

Objective: Researchers reviewed 100 randomly selected apps for smoking cessation to rate them based on US guidelines for nicotine addiction treatment and to categorize them based on app functions. We aimed to test the usability and usefulness of the top-rated apps in 21 smokers with psychotic disorders.

Methods: We identified 766 smoking cessation apps and randomly selected 100 for review. Two independent reviewers rated each app with the Adherence Index to US Clinical Practice Guideline for Treating Tobacco Use and Dependence. Then, smokers with psychotic disorders evaluated the top 9 apps within a usability testing protocol. We analyzed quantitative results using descriptive statistics and *t* tests. Qualitative data were open-coded and analyzed for themes.

Results: Regarding adherence to practice guidelines, most of the randomly sampled smoking cessation apps scored poorly—66% rated lower than 10 out of 100 on the Adherence Index (Mean 11.47, SD 11.8). Regarding usability, three common usability problems emerged: text-dense content, abstract symbols on the homepage, and subtle directions to edit features.

Conclusions: In order for apps to be effective and usable for this population, developers should utilize a balance of text and simple design that facilitate ease of navigation and content comprehension that will help people learn quit smoking skills.

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KEYWORDS

mHealth; mobile apps; smoking cessation; schizophrenia; psychotic disorders

Introduction

Over half of the people with psychotic disorders such as schizophrenia smoke (45-80%) [1,2]. Evidence-based cessation treatments for tobacco use disorder are effective in people with schizophrenia [3]—combined psychosocial treatment with medication to treat nicotine dependence (nicotine replacement, bupropion, or varenicline)—increase the likelihood of quitting more than twofold over placebo [3]. Unfortunately, most of these treatments are not available to people with psychotic

disorders. Strategies to increase access to cessation treatment are needed.

A growing number of treatments developed for smoking cessation are delivered via the Web [4], telephone, and text [5], and more recently through mobile apps [6], increasing access to interventions for smoking cessation. Our research group recently found that typical cessation websites were not usable by people with schizophrenia [7], who have cognitive impairments and less experience with technology. Websites constructed with the Flat Explicit Design Model (FEDM) is most usable by this group [8,9]. This model includes (but is not limited to) a flat design (no more than 2 levels), descriptive labels (vs succinct, without abstract symbols), and text written at a low reading level [10].

When carefully designed, mobile apps may also effectively deliver interventions to clinical populations [8-14]. One app was recently developed and tested for symptom management in people with schizophrenia [13]. In this pilot study, 87% used the mobile app daily for a month, and the majority of participants reported that the mobile app was useful (ie, helped them manage their symptoms) and usable (ie, it was easy to find the information they needed). Whether smoking cessation apps are usable by smokers with psychotic disorders who have cognitive impairments and lower mobile phone experience is largely unknown. One recent study examined the long-term use of a smoking cessation app in 5 adults with severe mental illness and found the usability to be below average [15], indicating that off-the shelf apps may fair poorly for this population.

Although only a few apps have been tested in research studies [15-17], many apps for smoking cessation are publicly available. Abroms et al [18,19] completed two reviews of content and quality of smoking cessation apps: one of iPhone apps in 2009 and one of both Android and iPhone apps from 2012. Both studies found that overall the content of publicly available smoking cessation apps had a very low adherence to clinical practice guidelines [18,19]. The more recent review found that none of the apps connected users to a Quitline, few assisted with a quit plan, and overall recommendations to use medications or to refer to other relevant treatment was poor to nonexistent [18].

Although apps have been assessed for content, we are not aware of any research evaluating many smoking cessation apps for usability among disadvantaged populations who are most likely to smoke and have difficulty accessing cessation interventions. This study begins to fill this gap. In this study, experts evaluated and characterized a large random sample of smoking cessation apps. Then, smokers with schizophrenia and other psychotic disorders assessed the highest quality apps regarding usefulness (ie, does the app have the potential to help someone quit smoking) and usability (ie, it is easy to use).

Methods

App Selection

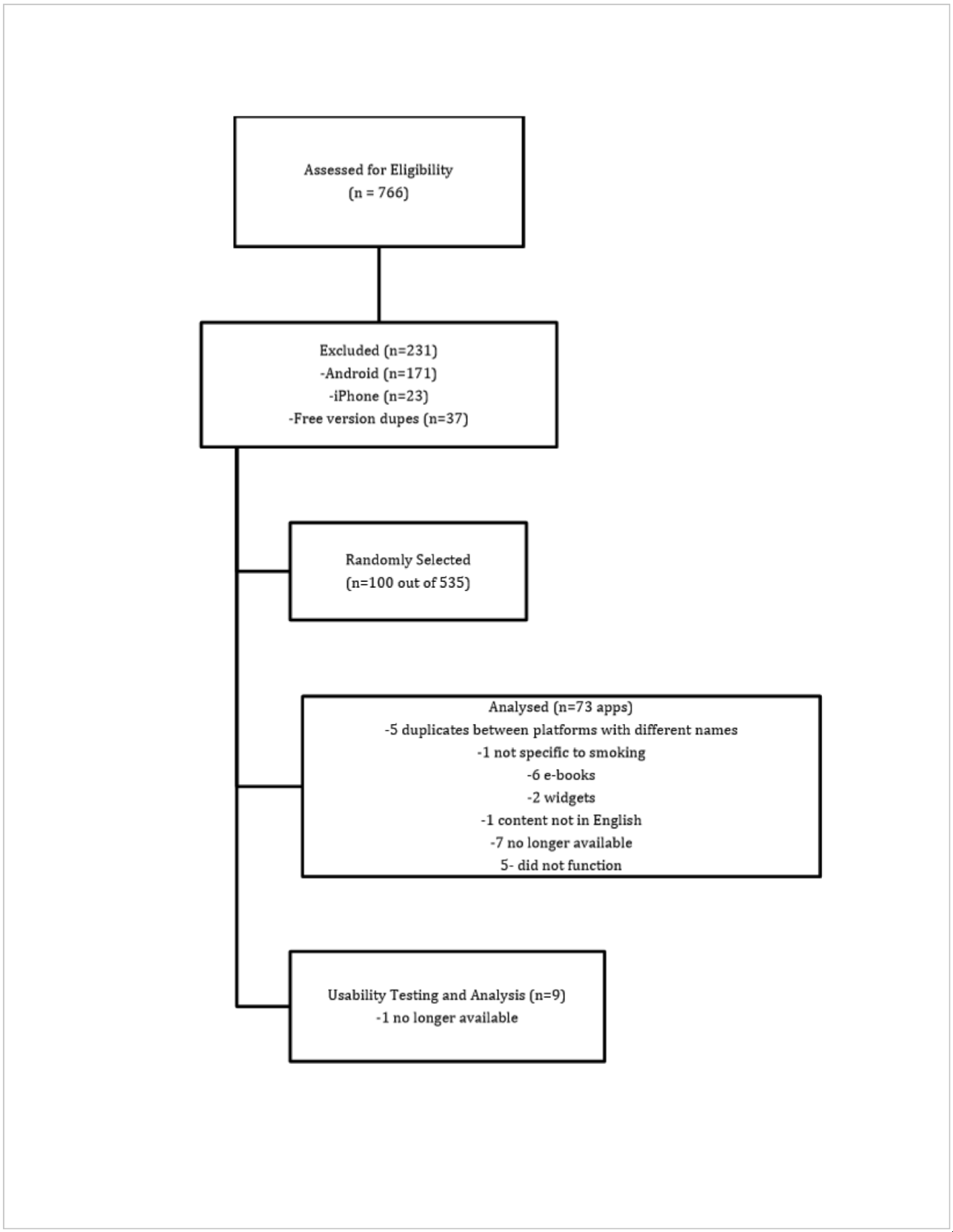
We identified all available smoking cessation apps in 2013 and randomly selected 100 for review. The top rated apps were then tested for usability and usefulness among 21 consenting smokers with psychotic disorders who were stable in mental health treatment. Although being videorecorded, each person used 2 randomly selected apps within a structured semiqualitative usability protocol, which lasted an average of 1 h. Videorecordings and text were analyzed to assess usability and usefulness of each app. State and University Institutional Review Boards approved and monitored the study.

First, using the search term “quit smoking” in both iPhone (iTunes App Store; sampled on July 15, 2013) and Android (Google-Play; sampled on July 11, 2013), we identified 479 app results from Android and 287 from iPhone. To be included in the review, the mobile app had to specifically address smoking cessation behaviors in English. On the basis of their brief written descriptions, we excluded apps based on the following findings: In the iTunes App search, 23 were excluded; of which, 8 were not in English, 8 were not related to smoking, 3 were books, 2 were about behavioral change but not specific to quitting smoking, and 2 were videos of burning cigarettes. In the Google Play search, 171 were excluded. Of the 171, 26 were marijuana related, 34 were widgets (eg, a component of an app, wallpaper, or other effects), 12 were videos of burning cigarettes, 17 were about acupuncture but not specific to smoking cessation, 42 were unrelated, 13 were generic for “bad habits,” 3 were books, 1 was specific to chew tobacco, 3 were videos, 12 were about hypnosis but not specific to smoking, 3 were not in English, 2 were mp4 files only, and 3 were stores selling tobacco using an app interface. A sample of 264 iPhone apps and 308 Android apps (572 total) were further assessed as follows (Figure 1).

Next, we match-merged the Android and iPhone files by name and publisher to discover overlapping mobile apps between platforms. We did not find any overlapping apps based on name of the app and publisher. Within platforms, many mobile apps were available in 2 versions (free version and upgraded version available for sale). We omitted the 37 free versions, maintaining the upgraded versions in the final group of 535 usable apps.

We randomly selected 100 apps for detailed review and rating. Upon detailed examination, we discovered 27 additional apps that were not eligible. These apps fit into the following three categories: (1) they were duplicates between platforms with different names (n=5); (2) they did not meet our study criteria—not specific to smoking (n=1), ebooks (n=6), in a different language — although title was in English (n=1), and widgets (n=2); or (3) they were not ratable because they were no longer available (n=7) or they did not function (n=5). The remaining 73 eligible apps are listed in Multimedia Appendix 1.

Figure 1. Mobile app screening flowchart.



Expert Assessments of Mobile Apps

We used the National Tobacco Cessation Collaborative rubric to define the type of the app (mobile app: calculators, calendars, hypnosis, rationing, and mixed types) [18]. Calculators were defined as a tool to compute how much money one spends on cigarettes per time period. Calendars were defined as a tool to track number of cigarettes smoked per day over time and to set quit dates. Hypnosis apps contained audio recordings of a person providing a hypnosis method. Rationing apps allowed users to set alerts to indicate when they can smoke each of their allotted

cigarettes throughout the day. Mixed types perform two or more of the aforementioned functions. If the app did more than the functions specified within this classification system, the app was typed in the "other" category. We then performed a content analysis to identify subcategories within the "other" category—we found 9 additional types of apps: education, brain waves, motivation, games, virtual cigarette, virtual smoke, magic spells, graphic pictures, and social media (described in detail in "Results" section).

We used the 20-item Adherence to Practice Guidelines for Treating Tobacco Use and Dependence Index (ie, Adherence Index) [19]. Four responses were possible for each item (0=none; 1=minimal; 2=adequate; and 3=fully present). Two raters reviewed and rated each of the 73 apps (JF&PG). Interrater reliability was assessed with Cohen kappa and found to be excellent, .914 (SE .033), $P<.001$. We used an average of the two scores.

We then divided the Adherence Index into clinically relevant subindexes; each had adequate scores on Cronbach alpha. The first subindex, *Assessment of current use and attitudes* (Cronbach alpha=.61; 3 items) contained items such as, "Ask for tobacco use status." The second subindex, *Enhancement of motivation* (Cronbach alpha=.87; 4 items) included items such as "Enhance motivation to quit with rewards." The third subindex, *Advise every user to quit* (Cronbach alpha=.93; 4 items) contained items including, "Advise every user to quit with personalization." The fourth subindex, *Assistance with quit plan* (Cronbach alpha=.89; 5 items) had items such as, "Assist with quit plan—used practical counseling." The last subindex, *Referral to smoking cessation resources* (Cronbach alpha=.71; 4 items) included items such as "Refer to recommended treatment."

App Usability Assessment

As recommended by usability design experts [21], each app was assessed for usability by 3-5 users. In formative usability trials, use by a sample of 5 identified 80% of usability issues [22-24]. This study was designed to find out whether available cessation apps would be usable by a particular target population, not to identify all of the problems in the app, thus 3-5 was felt to be a parsimonious approach.

A total of 21 smokers with psychotic disorders provided informed consent. After brief assessment, researchers then guided participants through the usability assessment protocol. We provided a brief training on how to use a mobile phone. Using a basic weather app, participants were taught how to swipe, click, scroll, enter text, and get back to the homepage. When participants were able to complete these activities, they started the usability testing procedure on a sequence of two randomly selected smoking cessation apps. Following guidance from usability engineering [21], researchers instructed participants to use the mobile apps "as if they were trying to quit smoking" while "telling us what you think." During this activity, participants were prompted to say their thoughts out loud [25]. The interviews were videorecorded with a focus on the participant's hands and the screen of the mobile device. After using the apps, researchers used the Perceived Usefulness and Ease of Use scale [26] to assess participants' perceptions of each app. It was found that 5-6 participants tested each app.

Assessments—Participant Characteristics

During a structured interview, trained research assistants obtained participant demographics (age, level of education, race, ethnicity, and marital status), history of mobile phone use, and smoking activity. We assessed overall symptom level with the modified Colorado Symptom Index (CSI) [27], a 14-item questionnaire that measures psychiatric symptoms. The CSI has been found to be reliable and valid in people with mental illness and/or substance use disorder [28]. We obtained DSM-IV-TR psychiatric diagnosis from the medical record. We assessed level of nicotine dependence with the Fagerström [29] with scores from 0 to 10 (no to high dependence). After using each mobile app, participants responded to the Perceived Usefulness and Ease of Use subscales. This scale is an adapted 15-item questionnaire [26] and was used to gather reactions to and satisfaction with each app. The perceived usefulness subscale contains 11 items with a range from 11 to 55 with a higher score indicating better usefulness. The Ease of Use subscale contains 4 items with a range from 4 to 20 with a higher score indicating better ease of use (see Multimedia Appendix 2).

Assessments—Usability and Usefulness

During the think-aloud protocol, researchers took field notes on usability issues (ie, difficulty with touch screen, typing, other) and usefulness (ie, opinions about if, how the app would, or could be used). Researchers also recorded observations on app use behavior through videorecording the participant's hands, whereas they used each mobile app and wrote extensive field notes during and after each usability session. Researchers used the Flesch–Kincaid grade level scale within Microsoft Word to determine reading level for the text-heavy apps. This scale is standardized and uses word and sentence length to determine grade level [30].

Analyses Plan

Basic descriptive statistics were used to describe both the mobile app sample and the participant user group (using SPSS v19). We used *t* tests to evaluate the differences between the types of app on the Clinical Guideline Index scores. We assessed the usability of the apps by evaluating usability themes within the videorecordings and field notes. We watched, transcribed, and coded the videorecorded data and field notes from each participant. We pulled quotes emblematic of users' experience on each app. We developed themes that emerged from the data and found three categories of usability problems. Finally, we contrasted users' qualitative descriptions of usefulness by deriving themes from quotes regarding apps that scored high on the usefulness scale and contrasting them to themes derived from apps that scored low.

Results

Expert Assessment of Mobile Apps

The 73 apps were categorized with the National Tobacco Cessation Collaborative rubric. Within the prespecified categories, nearly one-fifth of the apps were categorized as

calculator (18%, 13/73), followed by hypnosis (12%, 9/73), mixed-type (combination of the descriptive categories; 10%, 7/73), rationing (5%, 4/73), and calendar (1%, 1/73). Over half of the apps fell into the "other" category (54%, 39/73).

Within the "other" category, almost half of the apps featured educational content (46%, 18/39) and a few had an additional interactive questions and. Many of the "other" category apps contained motivational content (20%, 8/39) with quotes or pictures aimed to help the smoker remember why they want to quit. Some apps claimed to change users' "brain waves" with sounds (8%, 3/39), contained graphic pictures of smokers' diseased organs (10%, 4/39), were virtual cigarettes or smoke (7.5%, 3/39), were games (3%, 1/39), were virtual "magic spells" (3%, 1/39), or contained elements of social support (8%, 3/39) either through social media or chat rooms.

Average scores of expert ratings on the Adherence to Clinical Practice Guidelines for Treating Tobacco Use and Dependence Index are shown in Table 1. Over two-thirds (about 69%) of the apps scored at or below 10 on a 60-point scale (Mean 11.47, SD 11.8, Range 0-51). Average guideline scores did not differ by platform (Apple vs Android). The average score was significantly higher for apps in the "other" category compared with the remainder of the types of apps (categories were collapsed due to small sample sizes; t_{71}=2.21, P<.05). Within the "other" category, the education subtype of app scored higher than the other subtypes (t_{37}=4.04, P<.001). The education apps also scored higher than other apps on the subindexes in every domain (Table 1).

Table 1. Mean scores on guidelines subscales in educational apps versus other.

Subtype	Total sample mean (SD)	Education mean (SD)	Other mean (SD)	*t* test	Degree of freedom	*P*
n	73	18	55			
Assess	5.5 (2.6)	6.6 (2.3)	5.2 (2.7)	−2.14	33	.04
Enhance	2.7 (3.1)	5.5 (4.2)	1.8 (2)	−3.54	20	.002
Advise	2.2 (3.5)	5.1 (4.5)	1.3 (2.6)	−3.48	21	.002
Assist	1.7 (3.2)	5.2 (4.3)	0.6 (1.5)	−4.42	18	<.001
Refer	0.6 (1.8)	2.4 (2.9)	0.1 (0.5)	−3.35	17	.004
Total scale score[a]	11.5 (11.8)	23.2 (15.9)	7.7 (6.9)	−4.03	19	.001

[a]Unequal variances assumed.

A minority of apps contained content in 2 domains: (1) *assisting with a quit plan* and (2) *referring or connecting to recommended treatments*. In terms of *assisting with a quit plan*, about 19% (14/73) provided "practical counseling"—mostly by way of offering quit tips like, "Drink water when you have a craving for a cigarette." Only 3 of them have provided instruction to perform a skill to help with quitting. For example, the app, Quit for Two, provides a picture of a baby blowing up a balloon in order to model deep breathing. Specific to *referring and/or connecting to recommended treatments*, 21% (15/73) of the apps mentioned smoking cessation medications and only 1% (1/73) recommended use of both medications and psychosocial treatment. It was found that 11% of the apps (8/73) referred participants to a Quitline.

The average cost per app was US $0.76 (SD US $1.21, Range: US $0 to US $4.99). Most apps were free (n=44, 60%). There was no relationship between the cost and Adherence Index scores (r=−.02, P=.88).

Participant Characteristics

Most of the 21 participants were white (81%, 17/21) and male (81%, 17/21). Over three-quarters of the group (76%, 16/21) was diagnosed with a schizophrenia spectrum disorder; the remainder were diagnosed with bipolar disorder with psychotic features or psychosis not otherwise specified. The average amount of completed education was 12 years (SD 2) and most participants were unemployed (76%, 16/21). CSI scores indicated a moderate degree of mental illness symptoms (Mean 18, SD 12). Most participants were severely dependent on nicotine as measured by the Fagerström Nicotine Dependence scale (Mean 7, SD 2) and, on average, smoked 26 cigarettes per day (SD 9). Many had tried to quit in the past month (41%). Regarding use of phones and technology, most of the sample (81%, 17/21) owned a cell phone, 62% (13/21) owned a mobile phone, 43% (9/21) played electronic games, and 33% (7/21) of the group used social media.

Usability

Through the think-aloud protocol, open-ended questions, and observations of participant's use of the apps, 4 main themes emerged, of which 3 are related to design and 1 is related to content. First, one group of mobile apps were easy to use but were unappealing because they were text-heavy with minimal interactive features. A second group of apps were difficult to navigate due to main menus that featured abstract symbols, jargon, or one-word labels that the users did not understand. Third, many apps had subtle directions on how to use their interactive tools that users either failed to notice or did not understand. Finally, all but one of the apps were missing concrete directions on how to use quit smoking skills; although most suggested other things to do instead of smoking. We will expand on these themes and provide illustrative examples below.

Text-Heavy Design

Three of the apps consisted predominantly of text. These text-heavy apps seemed to be the easiest to use, but participants reported that they were boring and unengaging. For example, although expert reviewers rated Smoking Cessation Srior highly for breadth of smoking cessation information, participants had problems reading and understanding the text, which was at Flesch–Kincaid grade level (FCGL) 12. Two other apps consisted of a book-like format with easy to understand text (Quit Smoking Easily, FCGL=8.3 and You Can Quit Smoking, FCGL=6.4). Participants found them useful and easy to use, but boring, as exemplified by the comments "I'm getting tired of this app" and "I am bored." Users indicated that they were unlikely to use this type of app.

Difficult Navigation

In contrast, many of the apps that held easily understandable, interactive content were difficult to navigate. The main menus of 4 apps (NCI QuitPal, San Francisco Stop Smoking, Quit for Two, Call it Quits) consisted of abstract symbols and one-word descriptions of each section (NCI QuitPal) or jargon-laden descriptors (Call it Quits). For example, Call it Quits called their homepage a "Dashboard," which confused participants. When participants attempted to use these apps, they often did not know what the homepage buttons meant, requiring research staff assistance to continue. The abstract homepage titles and symbols were also poorly understood. Participants guessed as to section contents and were unable to find the information they sought.

Subtle Directions

Three apps featured subtle directions to use app features (Quit for Life, Smoke Free, and Call it Quits). These apps typically provided small buttons with symbols or one-word instructions as cues for how to use app features. Cue placement also impeded use; sometimes, the cues were off to one side of the page, which made them more obtuse. Participants experienced problems with subtle directions on how to enter their reasons for quitting, select quit tips, and choose motivations to quit. Many participants voiced frustration over these functions and said things like, "I can't get this to work. How do I do this?" One participant stopped using the app, Call it Quits, because he could not get it to save the quit smoking tips he had selected, suggesting that subtle directions may be difficult to learn by this group.

Lack of Smoking Cessation Skills Training

Only one app provided content designed to help the user learn a cessation skill while using the app, whereas all the other apps simply provided brief instructions to do something different instead of smoking. The Quit for Two, Quit for You App illustrated deep breathing with a cartoon of a baby slowly inflating a balloon, providing in the moment instructions an effective skill to cope with craving.

Table 2. Participant ratings of app perceived usefulness and ease of use for top apps.

App Name		Perceived Usefulness	Ease of Use	Adherence Index	Text	Subtle	Difficult
	n	Mean (SD)	Mean (SD)	Score	Heavy	Directions	Navigation
NCI Quit Pal	5	42 (4.8)	18 (1.1)	51	0	0	x[a]
You Can Quit Smoking	5	39 (5.1)	16 (5)	49.5	x	0	0
San Francisco Stop Smoking	5	37 (7.8)	16 (4.4)	43	0	0	x
Quit Smoking Easily	5	36 (3.7)	16 (4.2)	40	x	0	0
Quit For You – Quit For Two	3	43 (5)	15 (1.7)	39	0	0	x
Quit For Life	5	38 (6.6)	15 (3.8)	36	0	x	0
Smoke Free – Stop Smoking Now	5	32 (7.8)	11 (5.9)	34	0	x	0
Smoking Cessation – SRIOR	6	31 (7.9)	14 (2.4)	31.5	x	0	0
Call It Quits	5	31 (11)	11 (4.6)	29.5	0	x	x

[a]x indicates the presence and 0 indicates the absence of usability issues.

Perceived Usefulness and Ease of Use

Usefulness and ease of use scores are shown in Table 2. App usefulness ratings correlated with app quality (Adherence Index scores; *r*.34, *P*.01). Participants rated NCI Quit Pal and Quit for Two highly for usefulness. Participant comments provided examples on how they found the apps useful, including, "I would use Facebook to connect with friends and would personalize the settings to remind me what I'm saving for," and "Use the tracking, savings goals, facts and tips for urges and quit lines (to quit smoking)." With the Quit for Two App, one person commented that it, "gives you tips that you can practice" and another said that it, "reminds you of your money saved and gives you good tips plus there are games to keep you busy."

In contrast, the lowest rated apps on the usefulness scale were Call it Quits and Smoking Cessation Srior, which both scored 31. Participants stated, "You know what it (nicotine) does but that doesn't help (with quitting)," "It's like a book, you can only use the content once." Call it Quits had more interactive tools, and participants commented that they would use the quit tips and reminders within this app, but most of them could not figure out how to do this because of the subtle instructional cues, which undermined the apps' usefulness.

Discussion

Principal Findings

In this study of expert-rated quality and user-rated usefulness and usability, we identified multiple barriers indicating that currently available smoking cessation apps may be inaccessible or ineffective for most smokers with psychotic disorders. Although the top 9 apps scored moderately high on expert-rated quality, they performed poorly during user testing. We found 3 primary design flaws: text heaviness, subtle directions, and abstractions on the homepage.

A myriad of smoking cessation apps are available, leading to a high level of consumer choice, but we found several indicators likely to cause consumer confusion. First, we found that descriptions of 25% of the 100 randomly sampled apps were inaccurate. Second, we found that most apps scored low on content quality. Similar to Abroms's results [18,19], the apps evaluated in this study performed best on the assessment of user smoking behaviors and poorly on all of the other subindexes of adherence to treatment guidelines. Much like Abrom's findings, most apps did not inform users about smoking cessation medication or Quitlines (which are universally available in the United States), and strikingly, most apps did not provide adequate quit skills training. Since apps on the market do not have any indicator of whether they contain evidence-based content, consumers have no way to find and select the minority of apps with effective content. Concrete guidelines for app evaluation could ameliorate this situation [31].

Similar to previous research of website usability [7,9,10,32], we found that smokers with psychotic disorders had difficulty using apps. Although we found similarities with Rotondi's work on usability of websites among people with schizophrenia [9], we also found differences. Rotondi [9] has suggested that scrolling is more usable than paging in this population, but users in this sample did not perform poorly with paging. Additionally, Rotondi has suggested that hyperlinks should be used. In this sample, most users did not understand hyperlinks. Also, apps with subtle directions scored lowest on the Adherence Index by the experts and were frustrating for users. Previous work on website usability [10,32] indicates that explicit instructions improve usability for people with psychotic disorders.

Several study design issues warrant further discussion. A small number of participants rated each app. The sample size of 3-5 users is supported by recommendations of usability design experts [21] and, in formative usability trials, a sample of 5 was found to identify 80% of the usability issues [22-24]. Our usability findings are supported by our quantitative data and other researchers' findings [10], indicating that the sample utilized here provides a reasonable assessment of the apps. However, a larger sample would likely have found additional problems. Additionally, the scope of our usability study was limited to short-term use; the next steps in usability testing should include long-term use. Further, we did not evaluate efficacy. Efficacy testing in user populations with the highest rates of smoking is sorely needed.

Conclusions

In summary, this study provides an updated evaluation of smoking cessation app quality, indicating ongoing poor quality of most apps and suggesting need for a system to inform consumers about whether apps contain content that is likely to be effective. This study also suggests that adults with psychotic disorders are unlikely to be able to use the highest quality apps. In order for apps to be effective for populations who have cognitive impairments, future app content should provide (1) motivational enhancement exercises and information, (2) recommendations about smoking cessation medications and other relevant support, and (3) information and instruction on how to cope with withdrawal and urges to smoke. App designs should utilize a balance of text and simple designs that facilitate ease of navigation and content comprehension. Smokers with schizophrenia may then obtain adequate, accurate, and useful information about their smoking and learn methods to quit.

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Conflicts of Interest

None declared.

Multimedia Appendix 1

Random sample of smoking cessation apps.

[PDF File (Adobe PDF File), 25KB - humanfactors_v4i1e7_app1.pdf]

Multimedia Appendix 2

Perceived Usefulness and Ease of Use subscales.

[PDF File (Adobe PDF File), 14KB - humanfactors_v4i1e7_app2.pdf]

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Abbreviations

CSI: Colorado Symptom Index
FEDM: Flat Explicit Design Model

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Original Paper

A Self-Regulation Theory–Based Asthma Management Mobile App for Adolescents: A Usability Assessment

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Abstract

Background: Self-regulation theory suggests people learn to influence their own behavior through self-monitoring, goal-setting, feedback, self-reward, and self-instruction, all of which smartphones are now capable of facilitating. Several mobile apps exist to manage asthma; however, little evidence exists about whether these apps employ user-centered design processes that adhere to government usability guidelines for mobile apps.

Objective: Building upon a previous study that documented adolescent preferences for an asthma self-management app, we employed a user-centered approach to assess the usability of a high-fidelity wireframe for an asthma self-management app intended for use by adolescents with persistent asthma.

Methods: Individual interviews were conducted with adolescents (ages 11-18 years) with persistent asthma who owned a smartphone (N=8). Adolescents were asked to evaluate a PDF app wireframe consisting of 76 screen shots displaying app features, including log in and home screen, profile setup, settings and info, self-management features, and graphical displays for charting asthma control and medication. Preferences, comments, and suggestions for each set of screen shots were assessed using the audio-recorded interviews. Two coders reached consensus on adolescent evaluations of the following aspects of app features: (1) usability, (2) behavioral intentions to use, (3) confusing aspects, and (4) suggestions for improvement.

Results: The app wireframe was generally well received, and several suggestions for improvement were recorded. Suggestions included increased customization of charts and notifications, reminders, and alerts. Participants preferred longitudinal data about asthma control and medication use to be displayed using line graphs. All participants reported that they would find an asthma management app like the one depicted in the wireframe useful for managing their asthma.

Conclusions: Early stage usability tests guided by government usability guidelines (usability.gov) revealed areas for improvement for an asthma self-management app for adolescents. Addressing these areas will be critical to developing an engaging and effective asthma self-management app that is capable of improving adolescent asthma outcomes.

(JMIR Hum Factors 2017;4(1):e5) doi:10.2196/humanfactors.7133

KEYWORDS

mHealth; asthma; mobile; usability

Introduction

Asthma is the most common chronic condition among youth in the United States, affecting 8.6% of children under the age of 18 years (10.1% of males and 7.0% of females) [1]. Prevalence rates in youth are higher than those for adults, which are 7.4% overall (5.1% of males and 9.6% of females) [1]. The negative impacts of asthma for youth include decreased quality of life [2], nearly 10 million missed days of school a year, a half million emergency department visits annually [3], and limited ability to engage in normal daily activities, such as taking part in physical activities (eg, sports and exercise) and other outdoor activities and extracurriculars [4]. For many adolescents, self-management behaviors such as medication adherence, trigger avoidance, monitoring symptoms, and communication with health care providers and family members can prevent or reduce the negative impacts of asthma [5-7]. Unfortunately, patient-provider communication about self-management behaviors among adolescents is often inadequate [8-11], which may partially explain why adherence to asthma controller medication is low (50%-70%) for adolescents [12-14].

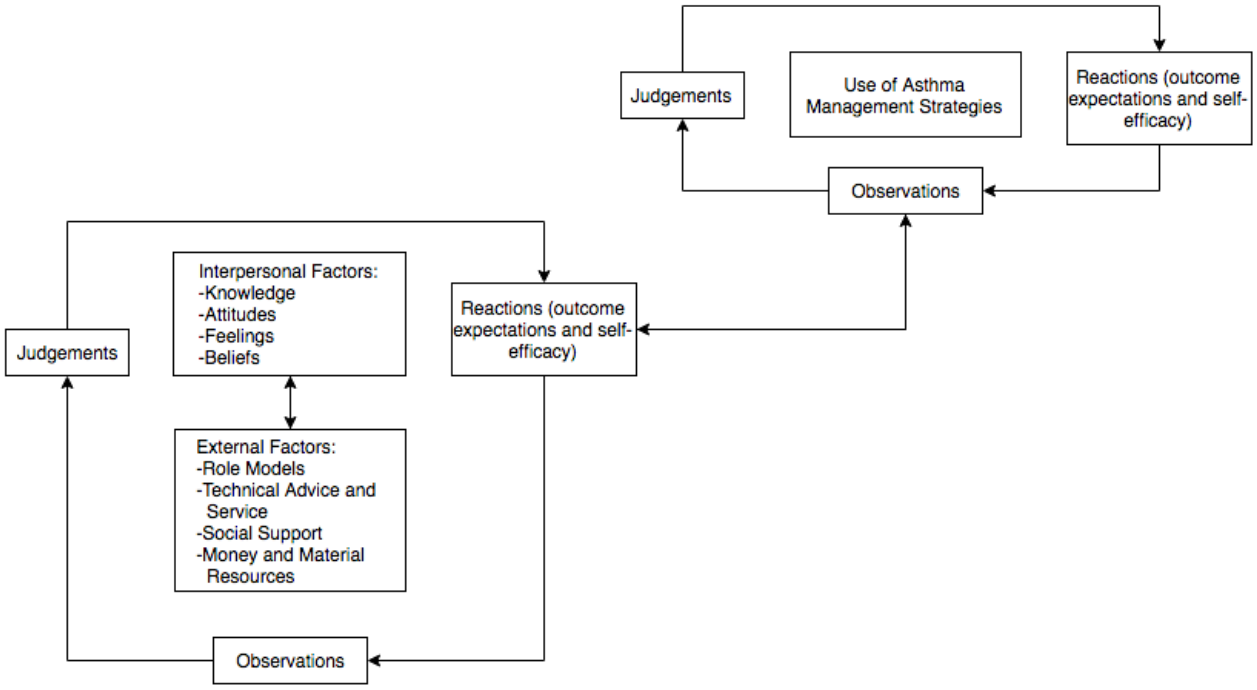
Self-regulation theory (SRT) posits that one possesses the ability to influence his or her own behavior by being observant, making judgements about behavior, and reacting accordingly based on those observations and judgments [15]. This process (presented in Figure 1) can be achieved in several ways, including through self-monitoring one's own behavior and behavioral feedback or information about a task intended to improve performance [15]. Smartphones are now capable of facilitating self-regulating health behaviors, and mobile-based interventions are increasingly capable of addressing barriers to medication adherence [16]. In fact, several mobile apps exist to manage asthma, which is important since text messaging is a preferred method for communicating asthma information among 12 to 17-year-olds [17]. Unfortunately, although smartphone adoption rates for teens aged 13 to 17 years are on the rise (73%) [18], only 8 of 147 (5.4%) existing asthma apps target children or young adults [19]. Furthermore, to our knowledge, the theoretical pathways through which existing asthma apps operate to influence self-management behaviors have only been reported in 1 study [20,21]. A 2013 Cochrane Review located only 2 randomized controlled trials (RCTs) that tested the effects of asthma self-management apps. However, these RCTs did not link app features to asthma outcomes, which led the authors to suggest that future apps should have theory-based features and study designs that allow researchers to identify which components (ie, app features) of the intervention are effective [22].

According to Usability.gov, benefits of a user-centered design for mobile apps include improved performance (eg, fewer user errors) and credibility (eg, user satisfaction and trust of the app) [23]. These benefits are particularly important when it comes to managing asthma symptoms, triggers, and medication. The approach to app development used in this study adheres to mobile app development and design guidelines outlined by Usability.gov, which provides guidance for ensuring mobile apps are useful, usable, desirable, and accessible and consist of content relevant to the user that is also credible [23]. Usability tests are an important part of determining if such guidelines are met throughout the app development process. This study is a formative test of an app wireframe, which is an important step in the usability lifecycle [24]. Results from this study will guide subsequent efforts to develop an app for adolescents that optimizes performance for the user while providing an experience that both engages and encourages asthma self-management.

In a previous study, we examined the theoretical pathways through which asthma management apps promoted self-management for adolescents [20,21]. Specifically, we asked adolescents (n=20) aged 12 to 16 years to use 2 existing asthma self-management apps and conducted semistructured interviews to identify specific app features that promoted self-observation, self-judgment, and self-reaction (key components of SRT). Our findings identified several potentially useful app features that align with key components of SRT, including features that promote self-observation and self-judgement (monitoring symptoms, triggers, and medication) and features that promote self-reaction (viewing charts based on data from logging medication adherence, symptoms, and triggers and asthma control quizzes). Results were used to inform the development of a high-fidelity asthma app wireframe described here.

The purpose of this study is to assess the usability and user-centeredness of a high-fidelity wireframe for an asthma self-management app intended for use by adolescents with persistent asthma. We employed a user-centered approach [23] in developing the wireframe by conducting interviews with adolescents to test its usability, including usability of specific self-management features such as logging medication and setting medication reminders. To do this, we posited several research questions to ascertain the visual aspects of design (Do participants like or dislike how the app looks and feels?), the app's intended functionality (Do participants understand the desired functionality of different app features?), areas for improvement (Are there any changes participants would make to the app?), expectations of the app (Does the app appear to perform the tasks they would expect from an asthma self-management app?), and behavioral intentions related to app features (How do participants anticipate using the app and its specific features?). These data can be used to guide the development of adolescent self-management features that are theory-based, user-centered, and perceived as useful by adolescents.

Figure 1. The self-regulation process as it relates to use of asthma self-management strategies [15].



Methods

Participant Recruitment

A purposive sample of 8 adolescents was recruited from 3 pediatric medical practices in North Carolina and via word of mouth. Adolescents were sampled to maximize racial/ethnic, age, and gender diversity. Eligible participants were between the ages of 11 and 18 years, spoke and read English, had a self-reported diagnosis of persistent asthma, and owned either a smartphone or tablet. Parents or guardians provided written consent, and adolescents provided written assent.

Data Collection Procedure

A research assistant (AS) trained in usability test methods conducted all 8 in-person exploratory usability tests using semistructured interviews [24,25]. Each interview lasted approximately 45 minutes. Participants first verbally answered demographic questions as well as general questions about mobile app and Internet use. Participants were then presented with an electronic PDF wireframe of a mobile app for managing asthma. The wireframe consisted of 76 screenshots representing different sections of the app and different app features, including log-in and home screen (2 screens); profile set-up (17 screens); settings and app information (4 screens); an asthma control quiz (5 screens); gamification (quizzes and badges) (10 screens); logging medications, symptoms, and triggers (19 screens); charting (7 screens and 2 separate printed charts); and notifications, reminders, and alerts (11 screens). A detailed description of each feature, the number of screenshots for each feature, and the associated questions and measures for each feature are presented in Multimedia Appendix 1. Example screenshots of each feature shown to participants are also included in Multimedia Appendix 1. Following a complete review of the wireframe, summary questions were asked. Adolescents received a $25 gift card incentive upon completion. The research protocol for this study was reviewed and approved by the institutional review board at the University of North Carolina at Chapel Hill.

Measures

Prior to commencing the usability tests, participants were asked their age in years, gender, race (white, black, other–specified) and ethnicity (Hispanic, non-Hispanic), how many hours they use the Internet per week (open-ended), and how many hours they use mobile apps per week (open-ended).

An interview protocol was developed to guide the usability tests [24,25]; the questions are presented in Multimedia Appendix 1. Participants were asked to evaluate several aspects of the app: whether they liked or disliked features (yes/no), what they liked or disliked about the features (open-ended), if there was anything about the feature that was confusing or missing (yes/no), if there is anything they would do differently to improve the feature (open-ended), and if customization (ie, allowing user-specific changes to the app) was mentioned (yes/no). Several open-ended questions were also used to obtain user input about the look and feel of the log-in and home screen (eg, colors, logos, and organization), how often they would take an asthma control quiz, and how they would like to be reminded to use medications (eg, regularly or only when missed). Participants were also encouraged to provide any additional feedback not specifically solicited by the interviewer.

Participant preferences for information visualizations within the charting feature were also assessed. Specifically, participants were asked to review 2 types of charts: (1) a line graph plotting asthma control over time with dots indicating logged triggers, symptoms, and medication adherence and (2) a bar chart using only dots to show the same information. Each type of visualization showed identical information about asthma control,

controller medication adherence, symptoms, and triggers over a 7-day period. Participants were asked to rate the asthma control of the person represented in the charts on a 4-point scale (1=very uncontrolled to 4=very controlled). Participants were then asked to choose which of the 2 charts they would prefer to use to see their own data.

Finally, after having reviewed the entire wireframe, participants were asked several summary questions about the app. These included open-ended questions such as overall likes and dislikes and the top 3 things participants liked and disliked about the app. Participants were also asked to rate their likelihood of using the app to manage their asthma on a 5-point scale (1=not at all likely to 5=very likely).

Data Analysis

Interviews were audiorecorded for coding and analysis. Unique IDs were assigned to each participant to deidentify responses. Two independent coders (AS and CR) listened to the audiorecorded interviews and coded responses for each section or set of screenshots representing different app features. The first coder (CR) coded all 8 interviews, while the second coder (AS) coded 4 randomly selected interviews. Multimedia Appendix 1 summarizes how data for each feature were coded (yes/no, scale, or open-ended). Whether a participant liked or disliked a feature was coded as yes/no, and questions soliciting open-ended responses were transcribed verbatim and assessed for common themes.

To assess interrater reliability, separate Cohen kappa coefficients were calculated using a random selection of 50% of coded items for each feature, questions on previous app and Internet usage, and summary questions. Interrater reliability scores ranged from good (.70-.90) to very good (.90-1.0).

Results

Sample Characteristics and Adolescent Technology Use

Table 1 summarizes the demographic characteristics and self-reported technology use of the study participants. The sample included 4 males and 4 females, with an average age of 14.2 years; 4 participants were white, 3 were black, and 1 was Hispanic. Participants reported using the Internet on any device an average of 26 hours per week and reported using mobile apps (on a smartphone or tablet) an average of 24 hours per week. The types of mobile apps participants reported using most were games (n=5) and social media (n=3).

Table 1. Sample characteristics.

Characteristics	N=8
Age, years, mean (SD)	14.2 (2.5)
Male, n (%)	50 (4)
Race/ethnicity, n (%)	
Non-Hispanic White	50 (4)
Non-Hispanic Black	38 (3)
Hispanic	13 (1)
Hours using the Internet per week, n, median, range	26, 19, 2-70
Hours using mobile apps per week, n, median, range	24, 12, 3-60

Initial Impressions

All participants liked the overall look and feel of the app citing the colors and that it looked clean and professional.

> *I really like the design of it; I like the color scheme; it looks real clean. Not too much busy-ness going on.* [Female, white, 15 years]
>
> *It is appealing to the eye.* [Male, black, 15 years]

Profile

The profile consisted of 17 screens, which demonstrated steps for setting up the profile: (1) uploading an asthma action plan document, (2) adding medications (type and dosage), (3) adding allergies and triggers, (4) setting goals, (5) creating an avatar, and (6) adding and editing personal information and emergency contacts. Half of the participants (4/8) mentioned a desire for customization of certain aspects of the profile, such as the option to manually enter medications, symptoms, triggers, and goals that are not included on existing dropdown lists.

Of the 8 participants, 5 liked the idea of having an avatar, although a few were less enthusiastic. This did not differ by age.

> *If [the avatar] is going to teach me about asthma, I don't really care.* [Male, white, 12 years]

Settings and Information

A total of 4 screens showed settings and information for the app, which displayed where additional educational information could be found (eg, video tutorials and informational websites), as well as notification on/off buttons and volume controls. When asked if something were missing or if they would do something differently, only 1 participant suggested a change, citing it would be useful to have an in-app search function that directed to Internet resources rather than just listing links to informational websites. No participants found the settings or educational information confusing.

Participants were asked to indicate whether providing information (eg, links or videos) on 7 different topics would be useful to include in the app. Participants found the following

useful: how medications work in the body (8/8), how to avoid triggers (8/8), how to tell the difference between a rescue inhaler and control medication (7/8), how to tell when your asthma is not well controlled (7/8), how to talk with your doctor about your medication (5/8), how to use your inhaler (4/8), and how to remember to take your medication (3/8).

Gamification

The wireframe components included a gaming feature consisting of 11 screens, which presented a mock asthma knowledge quiz and badges awarded for (1) scoring well on the quiz, (2) adhering to medication, (3) consistently logging medication, (4) consistently logging symptoms, (5) consistently logging triggers, and (6) having well-controlled asthma. Overall, the idea was well received with 7 of 8 saying they liked the idea of games and 5 of 8 liking the idea of badges. However, open-ended feedback was not very enthusiastic. A participant stated a badge seemed interesting "but you can't use it towards anything" [Female, white, 11 years].

Asthma Control Quiz

The asthma control quiz showed 5 screens with 3 example questions. The example questions displayed the question text (eg, How is your asthma today?) with the following response options (very good, good, bad, very bad). Corresponding emoji faces were also depicted along with each response option. A total of 5 of 8 participants indicated that an asthma control quiz would be useful. Participants indicated they would engage more with an asthma control quiz if it were shorter and more accessible. A participant stated that they would use a quiz "if it was kind of short, maybe every day, maybe every week, maybe every few days" [Female, white, 11 years]. In response to the emoji faces, participants were accepting of them but did not see them as necessary.

> *[The faces are] not absolutely necessary but I guess they help.* [Female, white, 11 years]
>
> *I don't think they're necessary but I think they're cute.* [Female, white, 15 years]

Logging Medications, Symptoms, and Triggers

There were a total of 19 logging screens, which detailed the processes for logging medication use, symptoms, and triggers. The logging feature was generally well received. A participant found the logging feature useful "because I usually forget stuff like that" [Female, Hispanic, 17 years]. Participants found using and navigating the logging feature to be intuitive, but 4 of 8 participants commented that some form of customization would improve the feature. A common suggestion for customization included adding one's own symptoms and triggers (ie, not from a dropdown list). A participant offered a suggestion that might improve engagement, citing she would like the app to "go more quickly" [Female, white, 15 years] by making the logging process more simple because logging information is not fun, and that in doing so more people might use the app.

Charting

Participants were presented with 7 screens that depicted the progression through the charting feature. These screens included menu items to view information about the user's asthma control, medication adherence, symptoms, and triggers, followed by a chart with all information over a 1-week period in a single visualization. Feedback from participants about the charting feature was generally positive.

> *A lot of people are visual learners. . . they will understand things better.* [Male, black, 14 years]

Multimedia Appendix 1 presents the 2 chart types presented to participants. Interestingly, all participants rated the bar/dotted chart as more controlled than the line graph for asthma control despite them depicting the same level of control. When asked which data visualization they preferred (line graph vs bar chart), 7 of 8 participants preferred line graphs. Feedback suggested that charting information longitudinally is appropriate for the target user age group (adolescents).

> *I prefer seeing the graph, honestly. If you could have a line graph for every one of them, that would be my preference, because it's easier to kind of watch how it goes up and down. . . It's really easy to see visually what's going on.* [Female, white, 15 years]
>
> *I like [the line graph] better because it shows throughout the week how it's progressed over time.* [Male, black, 15 years]

Notification, Reminders, and Alerts

Participants were shown 11 screens related to notifications, reminders, and alerts for medication (medication reminders and notifications of missed doses), doctor's appointments (reminders set in a calendar view), and triggers (alerts and notifications). All 8 participants said they would use the feature to remind them to use their inhaler, 7 of 8 participants said they would use the feature to alert them of triggers, and 6 of 8 said they would use the feature for doctor's appointment reminders. An older participant (aged 18 years) pointed out the doctor's appointment reminder would be useful.

> *So let's say you go out of town, right? Let's say you give your medication to like someone in your family so they can hold on to it. And then you forget about it, that you even have it with you. You have a reminder that tells you 'hey don't forget to take your medication.'* [Male, black, 15 years]
>
> *I think the alerts are good because I want this app to alert me when to take my medication.* [Female, Hispanic, 17 years]
>
> *I like the reminders. I use my calendar a lot, so it's nice just for doctor's appointments and medications and stuff like that. So yeah, I would use it. . .often.* [Female, black, 18 years]

Feedback about how and when reminders, notifications, and alerts should be delivered indicated that these features should be customized to individual users. Smartphones have several options for delivering notifications, including sound, vibrations, and visual cues, and they have even more specialized settings (eg, types of sounds, banner notifications, and text message notifications) for each type of notification. Furthermore, the rules dictating when a notification, reminder, or alert is sent can vary (eg, every day or when a dose is missed). Customization

was mentioned by 7 of 8 participants, so it appears a one-size-fits-all approach may not be ideal for optimal user engagement.

> *I want it to pop up on the screen like a text message.* [Female, Hispanic, 17 years]
>
> *I might get a little annoyed at the notifications.Male, white, 12 years]* [Male, white, 12 years]

Final Questions

Following the review of the wireframe, participants were asked what they liked and did not like about the app. Feedback was generally positive.

> *I like how it was user friendly, looks professional, stuff like that.* [Male, black, 14 years]
>
> *It seemed pretty organized, which is, I like that a lot.* [Female, Hispanic, 17 years]

All 8 participants said they would find an app like this useful and reported they would be likely to use the app (mean 4.06, SD 18). Among the top 3 things participants liked about the app were notifications/reminders/alerts (5/8), quizzes and badges (5/8), charts (4/8), logging medications (3/8), and tracking triggers (3/8). Among the top 3 things participants did not like about the app were the bar charts (2/8), lack of customization (2/8), some of the labeling in the app (eg, specific graphics or icons) (1/8), and games (1/8). Some participants (3/8) did not designate any dislikes about the app.

Discussion

Principal Findings

To our knowledge, few asthma self-management apps exist that target adolescents [19], although ongoing studies address this research gap including the MyAirCoach project [26] and the CompAir trial [27], which seek to develop mobile-based asthma education and self-management technologies. This project seeks to do the same using a theory-driven approach. To our knowledge, no currently publicly available apps are based on any health behavior theory. This study is an important step in addressing this gap. In a previous study, we examined the theoretical pathways through which an asthma management app for adolescents is capable of improving self-management behaviors [20], which allowed us to assess the needs and requirements for the app and its features and incorporate them into a high-fidelity app wireframe. In this study, we examined the usability of the self-management features based on SRT and solicited feedback on the visual appearance and overall impressions of a wireframe of the app. The results from the usability tests provide an important understanding of how users expect to interact with an asthma management app, as well as their preferences while doing so. Specifically, our results suggest that users prefer the ability to customize a wide range of features including charting, notifications, reminders, and alerts.

In a previous study, a mobile asthma management app was shown to improve asthma control [28]. When surveyed postintervention, patients reported that the app was easy to use, relevant and personalized to their asthma, and provided helpful asthma-related information. By obtaining user feedback on our wireframe early in the development process, we believe we have identified key ways to integrate user-centered design into asthma self-management features to further increase an app's ability to prompt better behavioral outcomes such as medication adherence, that can, in turn, lead to better asthma control. In our study, overall feedback regarding the look and feel of the app was positive. In particular, participants reacted positively to the aesthetics, including the colors, logos, icons, and organization. After the adolescent has decided to engage with the app, it then becomes important not to overlook aspects of the app that are not essential for carrying out the primary functions of the app but can improve or impede engagement. For instance, profiles are an important mechanism for customizing the user experience, and avatars, games, and badges may provide additional incentives to use the app. While not necessary for the app to function and complete necessary asthma management tasks (eg, logging medications or delivering cues to action), they may provide enhancements to the primary functions of the app in ways that promote engagement.

Promoting continuous engagement with a health app can be difficult, particularly with adolescents. Gamification is one way to promote engagement [29]. For example, rewarding positive behaviors (eg, medication adherence and regular logging of medication, symptoms, and triggers) with badges or trophies, improving asthma knowledge through quizzes, and unlocking avatar customization features (eg, dressing and accessorizing an avatar) as a reward for consistent app use are possible ways in which games or gamification can promote app engagement. However, where some features such as games and quizzes might be optional approaches to increase engagement, other necessary features require a certain level of effort by the user, which could negatively impact engagement. App developers should be cognizant of this. For instance, asthma control quizzes and logging medications, symptoms, and triggers are necessary tasks for self-managing one's asthma, but the burden of doing so should be minimized. This can be accomplished in several ways, including minimizing the number of questions to accurately determine asthma control, allowing easy access to certain features (ie, limiting the extent to which drilling down into the app is required to reach certain features), and reducing the number of steps needed to complete tasks (eg, logging medication).

The primary focus of the usability tests was ascertaining feedback on the self-management features themselves, their functions, and how likely users envision incorporating them into their own asthma self-management behaviors. Of all the features, the charting feature and the notifications, reminders, and alerts feature received the most feedback, which was generally positive. However, there were also important suggestions that may improve the app's usability. Like usability guidelines would suggest [23], we found that adolescents preferred a more personalized experience by customizing many features of the app. Both the charting feature and notifications, reminders, and alerts feature should provide a level of customization that both accomplishes its intended purpose (eg, providing visual feedback through patient data visualizations, or providing cues to action) without causing undue burden on the user.

For charting health data, customization might take the form of allowing individual charts and graphs (eg, separate charts for medication adherence, asthma control, symptoms, and triggers) as well as charts and graphs summarizing all logged information, allowing for custom colors and custom periods of time (eg, weekly vs monthly views). Developing a useful charting feature is important because charting improves self-judgement, which is key to promoting asthma self-management [20]. In our study, almost all participants preferred line graphs to display longitudinal information for asthma control, medication adherence, symptoms, and triggers. This finding is what we would expect considering common data visualization standards [30] and suggests that adhering to these standards and reaffirming the appropriateness of their application in communicating health data to a patient is important for ensuring optimal usability for mHealth applications. When designing such data visualizations, it is important not to burden the user with too much visual information in 1 chart or graph, as this may limit the comprehension of the information that is being communicated [31]. To address this, app designers should seek creative solutions that allow the user to comprehend information while adhering to data visualization standards [30].

The customization of notifications, reminders, and alerts can also take many forms. For instance, users might choose to be notified daily to take their medication or only when a dose is missed. Individuals can be prompted by notification when medication was not logged for the day. The frequency of notifications and how they are displayed is also customizable. For example, reminders can be linked to the native iPhone reminders or calendar app, sounds can be turned on and off, notification indicators can appear on the app icon and/or inside of the app itself, and notifications can be shown as banners or alerts that can either be dismissed or in the form of a prompt allowing the user to access the app from the notification itself. Trigger alerts can also be set by linking environmental triggers from weather alerts (eg, pollen, dust, smoke/fire, and temperature) to the app and can further be customized by location tracking.

Limitations

This research is not without limitations. A convenience sampling method was used to purposively sample adolescents in order to ensure representation from males, females, different adolescent ages, and racially and ethnically diverse participants; however, these adolescents may not be representative of the broader population of adolescents with asthma. For the purpose of this study and the stage in the app development process where a high-fidelity wireframe was used, the sampling method and interview process was sufficient to obtain data on perceived usability of app features. Results from these assessments will be incorporated into a functional app, allowing for more summative usability testing in the future [24]. Given the one-on-one informal atmosphere of the usability tests, it is possible participants provided socially desirable responses. In an effort to prevent this, we told participants that we understand there may be things about the app they may not like and may find confusing. We described that the purpose of the interview was to obtain their feedback on the app wireframe, including what could be improved. We encouraged them to speak openly and honestly about the app. However, while several features or sections of the wireframe, including the profile, games, badges, settings and information, and logging medications, symptoms, and triggers received positive feedback overall, feedback on how to improve the app was limited. This may be a result of the format of the wireframe (PDF), and a functional prototype may have allowed users to understand the features and the tasks related to each feature better. For instance, the PDF wireframe used in this study presented several screenshots for logging medications, which allowed the participants to see the steps in the process. However, getting a true sense for the level of effort (eg, number of screen taps to complete a task) is limited by using a wireframe not capable of interaction.

Conclusion

Our study is an important step in developing a useful and useable asthma management app for adolescents. Adhering to usability guidelines and ensuring adequate and appropriate usability testing throughout all stages of the app development cycle is important, especially when theoretical concepts of behavior change are integrated into a design in novel ways. The results from this study will be incorporated into a functional app intended to significantly improve asthma self-management for adolescents. A fully functional app will enable us to assess usability using quantitative experimental methods and sampling techniques that allow for a more representative sample of the target patient population (ie, all adolescents with persistent asthma owning smartphones or tablets). Finally, a fully functional app would provide a necessary intervention tool that would allow for comparisons of the effectiveness of existing asthma self-management apps and the theory-based and user-centered asthma self-management app currently being developed.

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Conflicts of Interest

None declared.

Multimedia Appendix 1

Semistructured interview questions and example screenshots used during usability tests.

[PDF File (Adobe PDF File), 1MB - humanfactors_v4i1e5_app1.pdf]

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Abbreviations

RCT: randomized controlled trial
SRT: self-regulation theory

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Original Paper

Design and Usability of a Heart Failure mHealth System: A Pilot Study

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Abstract

Background: Despite the advances in mobile health (mHealth) systems, little is known about patients' and providers' experiences using a new mHealth system design.

Objective: This study aimed to understand challenges and provide design considerations for a personalized mHealth system that could effectively support heart failure (HF) patients after they transition into the home environment.

Methods: Following exploratory interviews with nurses and preventive care physicians, an mHealth system was developed. Patients were asked to measure their weight, blood pressure, and blood glucose (if they had diabetes). They were also instructed to enter symptoms, view notifications, and read messages on a mobile app that we developed. A Bluetooth-enabled weight scale, blood pressure monitor, glucometer, and mobile phone was provided after an introductory orientation and training session. HF nurses used a dashboard to view daily measurements for each patient and received text and email alerts when risk was indicated. Observations of usage, cases of deterioration, readmissions, and metrics related to system usability and quality of life outcomes were used to determine overall effectiveness of the system, whereas focus group sessions with patients were conducted to elicit participants' feedback on the system's design.

Results: A total of 8 patients with HF participated over a 6-month period. Overall, the mean users' satisfaction with the system ranked 73%, which was above average. Quality of life improvement was 3.6. Patients and nurses used the system on a regular basis and were able to successfully identify and manage 8 health deteriorations, of which 5 were completely managed remotely. Focus groups revealed that, on one hand, the system was beneficial and helped patients with: recording and tracking readings; receiving encouragement and reassurance from nurses; spotting and solving problems; learning from past experiences; and communication. On the other hand, findings also highlighted design issues and recommendations for future systems such as the need to communicate via other media, personalize symptom questions and messages, integrate other health tracking technologies, and provide additional methods to analyze and visualize their data.

Conclusions: Understanding users' experiences provides important design considerations that could complement existing design recommendations from the literature, and, when combined with physician and nurse requirements, have the potential to yield a feasible telehealth system that is effective in supporting HF self-care. Future studies will include these guidelines and use a larger sample size to validate the outcomes.

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KEYWORDS

mHealth; telehealth; heart failure; human factors engineering; self-management

Introduction

Heart Failure

According to the American Heart Association's "Impact on Heart Failure (HF) Report," the number of individuals with HF is estimated at 5.7 million. As the incidence of HF increases with age, over 8 million individuals are expected to have HF by 2030. Moreover, the cost of care is also projected to increase 127% from an estimated US $30.7 billion in 2012 to around US $69.7 billion in 2030 [1]. HF is one of the main reasons for hospitalization in patients' ages 65 years and older [2]. It is also the leading cause of death for men and women in the United States [3].

Managing HF presents a challenge for patients and providers. Patients have to spend extra time and effort for self-care. The self-care process starts with monitoring, then recognizing and evaluating symptoms, and goes from treating symptoms to evaluating treatments [4]. It is complex especially when comorbidities exist. In addition, it requires behavior and lifestyle changes such as losing weight, limiting sodium consumption, and adhering to medications. Individuals are capable of behavior change when they have the motivation, ability, and appropriate triggers in place [5]. To support HF patients, the American Heart Association recommends patient education and close supervision [6].

However, with the growing number of HF cases and limited clinical resources, exacerbations that occur after the transition of care are problematic for health care providers due to increasing costs and reimbursement restrictions. Although nurse-led HF support programs exist, more effective strategies are needed to identify and support patients at-risk.

mHealth and Health Outcomes

mHealth systems have the potential to be beneficial to both patients and providers, and studies evaluating their impact on HF health outcomes have been rising rapidly. On one hand, a recent review articulated that interventions that used automated devices to collect vitals from patients resulted in a 35% decrease in all-cause mortality and a 23% reduction in the risk of HF-related hospitalizations [7]. On the other hand, a recent multisite randomized control trial found that telehealth intervention had a significant improvement on quality of life but did not reduce readmissions [8].

The various design approaches and inconsistent findings have resulted in the need to understand what features are effective and how users' interaction with the system impacts adherence to the HF self-care process and, consequently, health outcomes [7,8]. This study aimed to fill this gap in research by describing the design of a HF mHealth system and the users' experiences with it. Effective features, in this context, are system design features that are useful in identifying patients at-risk of deteriorations that might require emergency hospital admissions. Users' interaction with the system is demonstrated by observations of usage frequency and the feedback received from users regarding the systems' role in supporting self-care, usability problems, and suggestions for future designs. This study was conducted at Loma Linda University Medical Center (LLUMC), which is an academic medical center with an International Heart Institute that provides a cardiac rehabilitation program and clinic to support patients with HF. Two HF nurses manage patients after the transition of care.

Methods

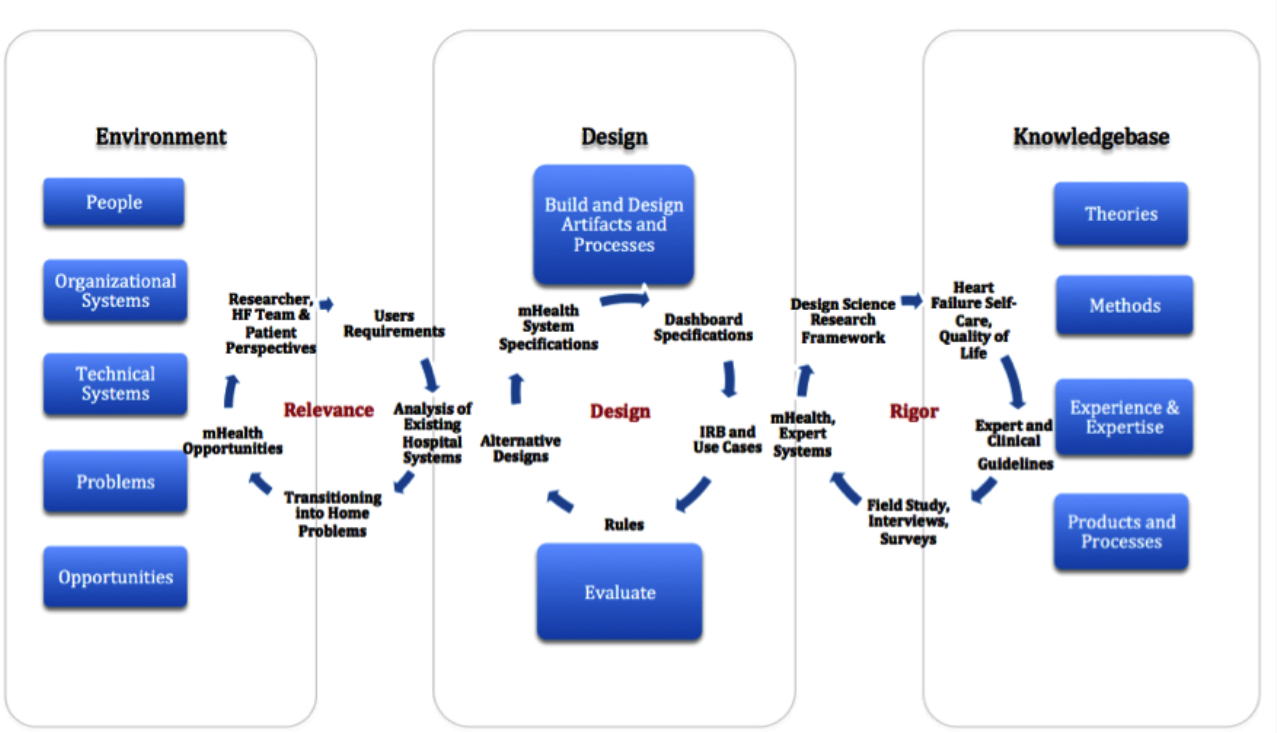
System Design and Build

A design science research (DSR) approach was used [9]. DSR is well established in information systems research and mainly consists of 3 iterative cycles: relevance, design, and rigor. The relevance cycle is where designers incorporate specific context requirements into the design, whereas the rigor cycle is where they draw on the literature and experiences to inform the design as well. The design cycle is where artifacts are built and evaluated to test efficacy and usefulness.

According to DSR, the relevance cycle starts when the problem, opportunity, and the acceptance criteria for evaluation are identified. This began with an exploratory open-ended interview with the director of cardiovascular health and wellness at LLUMC on October 24, 2012 and lasted for 60 min. The interview highlighted the gap in care that occurs when the patient transitions from the hospital to the home environment and the need for a solution to bridge this gap because it is leading to an increased number of readmissions. Further, preliminary needs for a mHealth system were acquired from the HF team to ensure that the system is relevant to the context, and to confirm its potential impact. The requirements included (1) providing patients with devices to measure their weight, blood pressure, and blood glucose since HF patients often had diabetes as a comorbidity, (2) communicating the patient's measures and symptoms to providers and support the clinicians in identifying individuals that need attention the most, and (3) educating the patient about maintaining a healthy life style (eg, nutrition and exercise).

In the rigor cycle, we adapted concepts from the HF self-care theory, behavior change model, and related work to further inform the design [4,5,10,11]. Furthermore, qualitative and quantitative techniques were selected in this cycle to understand the participants' experience and evaluate outcomes. These techniques are presented in the next section. Finally, the design cycle combined the context requirements with outputs of the rigor cycle to build the system as shown in Figure 1.

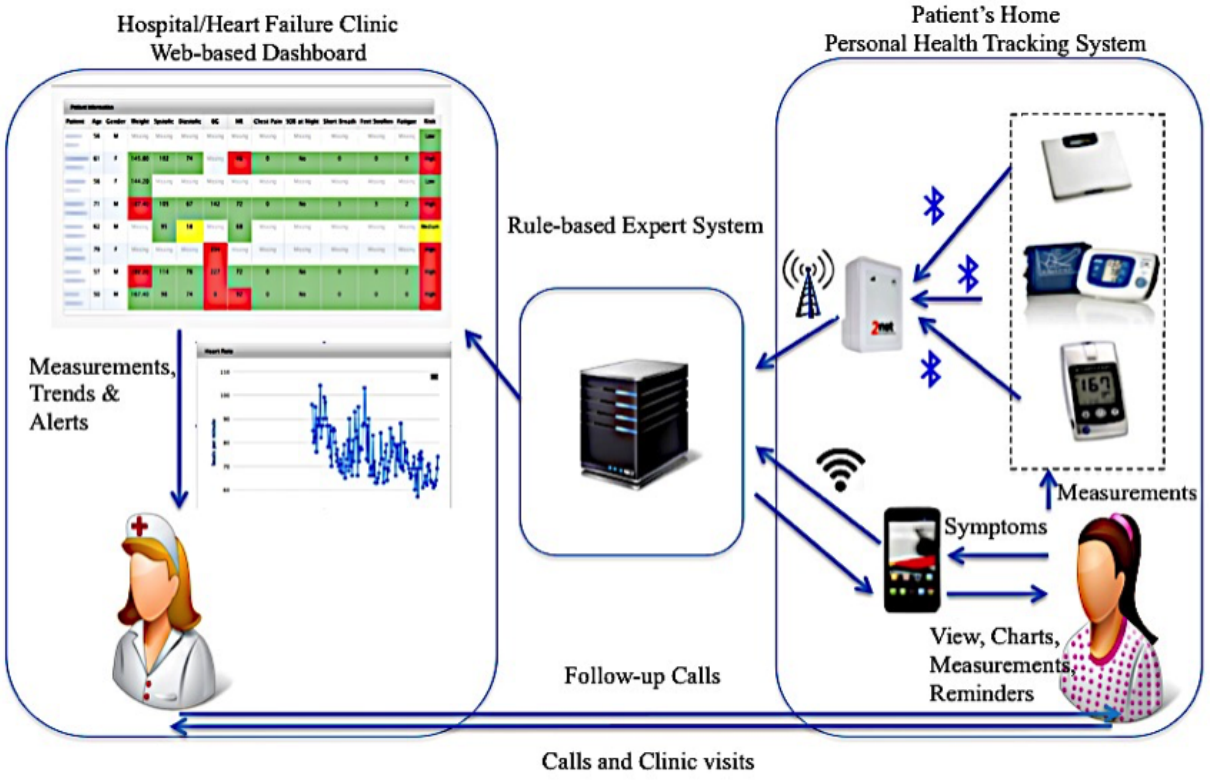
Figure 1. Design science research cycles, adapted from [9].



System Overview

Overall, the system consisted of 3 components: (1) a personal health tracking system for each patient, (2) a rule-based expert system that collects and processes patients' data, and (3) a dashboard view for HF nurses to view transmitted measurements. Figure 2 depicts the components and the following sections provide a brief description for each one.

Figure 2. mHealth system components.



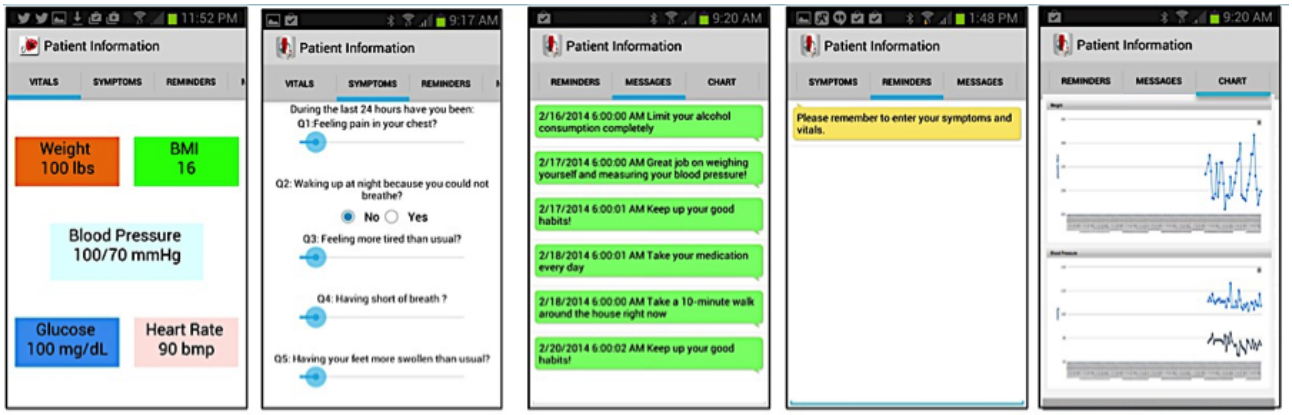
Personal Health Tracking Component for Patients

First, the health tracking devices (Entra Health System, San Diego, CA, USA) included a wireless weight scale (A&D UC-321PBT), wireless blood pressure monitor (A&D UA-767PBT) with medium cuff, Bluetooth-enabled glucose meter with test strips and lancet supplies (MyGlucoHealth), and a hub with data service (Qualcomm 2net). Patients were also provided a mobile phone (Alcatel ONETOUCH Evolve 3G) with a custom app, called MyHeart, which was designed with continuous feedback from the HF team.

Figure 3 shows screenshots from the mobile app. The app consisted of 6 tabs for biometrics, symptoms, reminders, messages, blood glucose, and trend charts. The symptoms section of the mobile app used a set of questions adapted from [10,12] as requested by the HF team and included the following: In the past 24 h have you been: (1) feeling chest pain? (2) waking up at night because you could not breathe? (3) feeling more tired than usual? (4) having shortness of breath? (5) having your feet more than usual? (6) feeling fatigue? A sliding scale from 0 to 10 was used for questions 1, 3, 4, and 5 because patients were already familiar with a pain scale, whereas a "yes" or "no" reply was used for questions 2 and 6 because a patient was considered at high-risk if he or she could not breathe at night.

In addition, a pool of motivational and educational messages was elicited from the preventive care physician. Examples of these messages included: "limit your total sodium intake today to no more than 1500mg," "replace your salt shaker with fresh lemons," "Today, make the healthy choice the easy choice." Overall, patients received two types of notifications; reminder messages, and motivational and educational messages. Reminders were for missing data, whereas motivational and educational messages were allocated randomly and sent to patients daily.

Figure 3. Screenshots from the mobile app.



Expert System Component for Data Collection and Processing

This was a cloud-based app. Rules, shown in Table 1, were practice-based and implemented to determine whether a patient was at high- or medium-risk for exacerbation that requires emergency care or hospital admission. Rules were based on the criteria used by the HF team. A patient was at high-risk if any of the measurements were in the high-risk range. Alternatively, a patient was at medium-risk if none of the measurements were in the high-risk range but at least one measurement was in the medium-risk range. This component also sent reminders and messages to patients and alerts to nurses. When data was missing for a day, the system sent a reminder notification to the patient. The nurse also made a follow-up call to determine why measurements were not received.

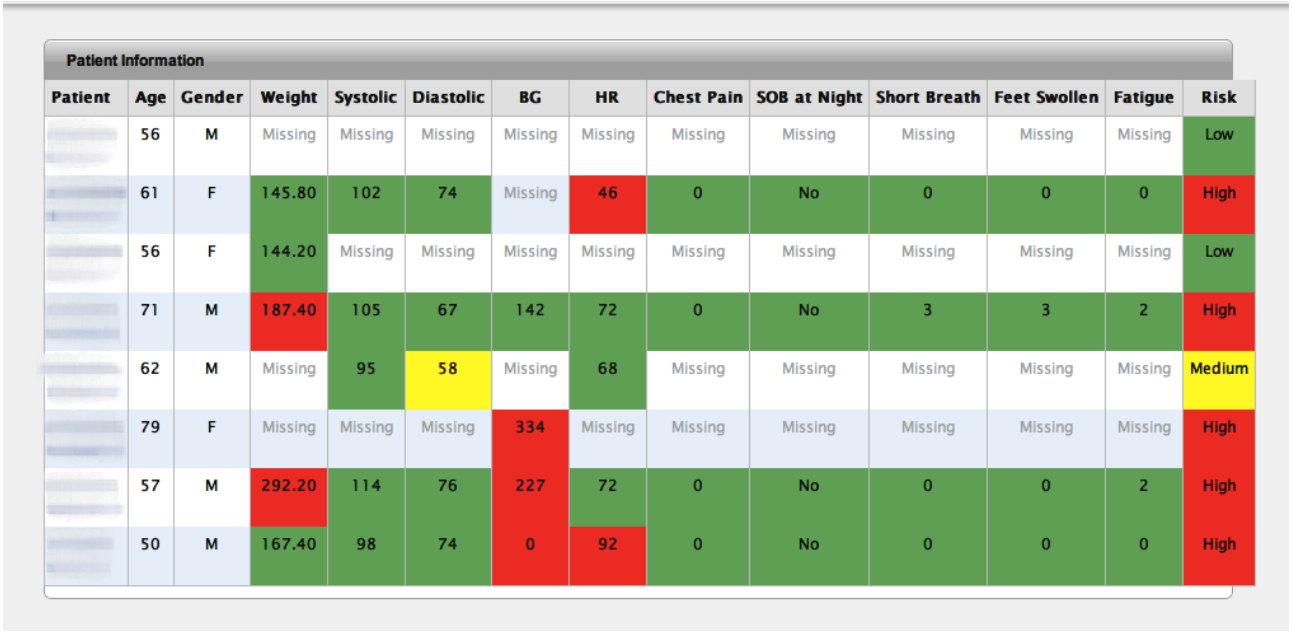
Table 1. Risk-classification rules.

Risk classification	Normal	Medium-risk	High-risk
Measurements			
Heart rate	60-79	50-59 80-99	49 or below 100 or above
Blood pressure systolic	90-129	80-89 130-139	79 or below 140 or above
Blood pressure diastolic	60-79	50-59 80-89	49 or below 90 or above
Weight	Gain or loss of 1 pound	Gain or loss of 1.5 pounds	Gain or loss of 2 pounds
Blood glucose	70-200	51-69 201-249	50 or below 250 or above
Symptom Q1: Feeling pain in your chest? Scale (1-10)	0-3	4-8	9-10
Symptom Q2: Waking up at night because you could not breathe? Yes or No	No	-	Yes
Symptom Q3: Feeling more tired than usual? Scale (1-10)	0-3	4-8	9-10
Symptom Q4: Having shortness of breath? Scale (1-10)	0-3	4-8	9-10
Symptom Q5: Feet more swollen than usual? Scale (1-10)	0-3	4-8	9-10
Symptom Q6: Feeling fatigue?	No		Yes

Dashboard View for HF Nurses

HF nurses accessed a Web-based app to view a dashboard containing patients' data. The patient list was displayed in a table as shown in Figure 4. Each value was color-coded to indicate the status of the transmitted measurement: green for normal, orange for medium-risk, red for high-risk, and no color for missing data. Nurses also received text and email messages that alerted them when a patient was at-risk. Implementation details, including rules and security, were discussed in the previous publication [13].

Figure 4. Patient list view on dashboard.



Evaluation

Setting and Sampling

We conducted a field study at LLUMC where the participants used the system for a 6-month period to evaluate health outcomes and usability. The HF team used purposive sampling to recruit participants from the outpatient clinic or via phone. Participants were selected to include individuals of different genders, a range of ages, socioeconomic backgrounds, and health histories. Patients were eligible if they were 21 years or older, had a clinical diagnosis of HF and one or more HF-related hospital admission in 2012, their expected survival was over 1 year, ejection fraction in the last 6 months was between 45% and 70%, and they were willing and able to use a mobile phone.

Patients were excluded if they were less than 21 years old, had comorbid conditions that may limit life expectancy to less than 1 year, unable to read text on a mobile phone due to vision disability, unable to perform self-care due to anxiety, depression, or decreased cognitive function, unable to use the monitoring equipment due to an impairment, demonstrated insufficient compliance to monitoring equipment or study visits, and had prior participation in another clinical study. Institutional Review Board (IRB) approval was obtained from LLUMC (IRB# 5130208).

In total, 12 patients were selected and invited to an orientation session at the Cardiac Rehabilitation Center conference room at LLUMC where they were informed about the purpose of this study, of which 8 patients agreed to participate and provided their consents. Reasons cited for not participating included privacy concerns.

Procedures

Observations

Two technical researchers conducted an individual hands-on 30-min training session with each patient and caregiver (if present) at the Cardiac Rehabilitation Center conference room at LLUMC. The researchers collected baseline demographics during this meeting. After that, patients returned home with their health-tracking devices, manuals, and technical support contact numbers. The measurements and usage patterns were observed daily. Hospital admissions and deteriorations were also noted when they occurred.

Questionnaires

Patients were asked to complete the Minnesota Living with Heart Failure Questionnaire (MLHFQ) to evaluate quality of life and the System Usability Scale (SUS) to measure satisfaction with the system. MLHFQ is a 21-item questionnaire with responses from 0 to 4. It includes 4 dimensions: global, physical, emotional, and economical. MLHFQ was selected because it has been widely used in HF studies and was accepted by the HF team as an outcome measure. The SUS questionnaire is a 10-item questionnaire with 5 response options ranging from “strongly agree” to “strongly disagree.” SUS was chosen to measure usability from each patient’s perspective because it is simple, validated, and suitable for small sample sizes. The goal was to complement other techniques, link experiences with outcome measures, and to provide additional information in a standardized format rather than to generalize the findings.

Focus Groups

There were 4 focus groups (3 exploratory and 1 confirmatory) held at the Cardiac Rehabilitation Center conference room at LLUMC. Focus group lasted between 1 and 2 h. The exploratory focus groups were planned to be conducted monthly to gather feedback from the patients and the HF team as they became more experienced with using the system, and to provide additional training and technical support when needed. However, due to conflicts in schedules, some group meetings were delayed but all were conducted during the study period. A confirmatory meeting, conducted at the end of the study and after saturation of concepts was reached, aimed to share the findings with participants and validate their relevance. Details for each focus group meeting are as follows:

- Focus Group A (exploratory)—2 patients, 1 nurse, 2 IT researchers—May 9, 2014
- Focus Group B (exploratory)—4 patients, 1 nurse, 2 IT researchers—May 16, 2014
- Focus Group C (exploratory)—4 patients, 3 nurses, 1 physician, 1 IT researcher—July 30, 2014
- Focus Group D (confirmatory)—4 patients, 1 nurse, 1 IT researcher—October 23, 2014

A single researcher made notes of the interviews, focus groups, and participant observations, and coded the data. Although it is recommended that two or more researchers code the data in the analysis phase and compare codes, findings were discussed with participants and other researchers to confirm validity.

Data was entered into NVivo 10 (QSR International Pty Ltd), a software package that is designed to manage unstructured qualitative data. Grounded theory coding strategies were used for analysis. Data were organized through open coding and categorization. Themes were developed and revised from emerging codes. Saturation was determined when no additional themes for users’ experiences emerged.

Results

Observations

Users

In total, 5 male and 3 female (N=8) patients with HF with a mean age of 61.5 (SD 9.3) participated in this study. It was found that 5 of the participants, 4 males and 1 female, also had type-2 diabetes. Patients also reported other health issues such as renal failure, gastroparasis, anemia, and a history of multiple heart attacks. All 8 patients were classified as stage III or IV as per the New York Heart Association (NYHA) classification. Table 2 shows patient demographics.

Table 2. Patient demographics.

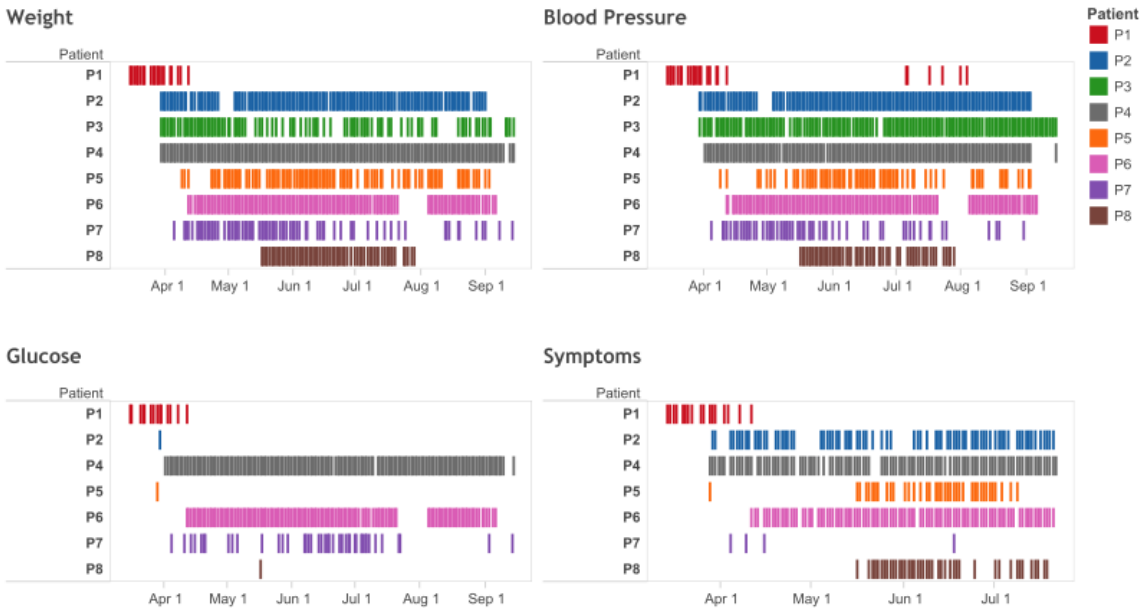
Patient	Gender	Age in years	Has type-2 diabetes?
P1	Male	56	Yes
P2	Female	61	No
P3	Male	62	Yes
P4	Male	71	Yes
P5	Female	56	No
P6	Male	57	Yes
P7	Female	79	Yes
P8	Male	50	No

Usage Patterns

We observed patients use of the system on a daily basis, between March 14, 2014 and September 14, 2014, and found that they had different usage patterns. For example, 3 patients (P2, P4, and P6) used the devices consistently everyday except when camping or hospitalized, whereas 2 patients (P1 and P8) started using the system but stopped later due to changes in health providers and health coverage issues. The remaining 3 patients (P3, P5, and P7) used the devices occasionally. P5 and P7 found it challenging to remember using the system on a daily basis, whereas P3 encountered technical difficulties, with the phone connectivity and the glucose meter, that did not allow him to report blood glucose and symptom values.

Figure 5 shows the usage patterns for weight, blood pressure, blood glucose, and symptoms reported by the patients. Overall, automatically transmitted measurements (ie, weight, blood pressure, and blood glucose) occurred more frequently than the manually entered measurement (ie, symptoms).

Figure 5. Usage patterns for weight, blood pressure, blood glucose, and symptoms.



Deteriorations and Admissions

A total of 8 deteriorating cases were detected and managed. Alerts that were effective in identifying these cases were all high-risk alert events triggered by the heart rate, blood pressure, weight, and shortness of breath values. None of the medium-risk alerts were helpful in identifying patients at-risk of deterioration or admission. HF nurses were able to manage five of these conditions by calling patients and advising them to take missed medications, increase diuretics, and reduce salt intake. For example one nurse explained:

> *There was actually two times when it alarmed me… He's been on the road and out and about and didn't take his diuretic in 4 days… and I said your weight is up so much and then he dropped 8 to 10 pounds.*

We also noted three HF-related admissions and no mortalities. P2 had two emergency admissions due to flu symptoms and a HF nurse guided P7 into a hospital admission when her heart rate could not be managed at home. A high-risk heart rate alerted the HF team to both patients.

Questionnaires

Usability Outcomes

It was found that 6 patients 75% (6/8), who were actively using the system, responded to the SUS questionnaire. The mean SUS

score was 75 (SD 17.4). A raw score of 75 converts to a percentile rank of 73% meaning that the system has higher perceived usability than 73% of all products tested [14]. This result indicates that the usability of the system was above average [15].

Quality of Life Outcomes

As for quality of life, 5 patients 62.5%, (5/8) who attended the first and last focus group meetings responded to the questionnaire. The baseline mean was 20.2 (SD 14.6) and the after-trial mean was 16.6 (SD 7.2). The decrease in the mean score from 20.2 to 16.6 suggests an improvement of 3.6 in quality of life. Although the overall improvement was not clinically significant because it was less than 5 [16], we noted that one patient had an improvement of 12, which was considered clinically significant.

Focus Groups

Patients' Experiences

On one hand, patients expressed that the system was useful and helped them. The following 5 themes emerged:

Recording and Tracking Readings

Patients stated that the system was instrumental for tracking measurements they did not track before. For instance, P4 stated that he used to track his weight and blood glucose but not his heart rate. However, he found that monitoring his heart rate helped because he had atrial fibrillation. He recalled a time when his heart rate "went wild" and he was able to watch it and call the nurse when the problem persisted. Patients also found the charts very useful and more convenient than keeping paper records.

Receiving Encouragement and Reassurance From Nurses

Patients were happy to receive follow-up calls from the nurse. P5, for instance, reported that the nurse monitored her measurements and called her to tell that she was doing a great job. P6 also expressed that he knew when he had a problem but the nurse called him and reassured him that he was doing what he needed to do.

Spotting and Solving Problems

Weight gain was often problematic for patients. P4 used the system to watch his weight to determine when fluid retention begins because he usually has shortness of breath after that. He commented: "This system of taking measurements permits me to determine when I'm building up fluid and what action I can take."

Learning From Past Experiences

Patients expressed that when using the system, they started realizing how past experiences impacted their condition. For example, P1 stated that, during Easter he ate more than usual and did not pass water for days. He recalled that Easter was a time he would have been in the hospital but using the devices helped him manage his symptoms, from the "arm chair in his living room," through laxatives and diet adjustments.

Communication

Patients also articulated that using the system helped them communicate with doctors and nurses especially since it was very difficult to call them directly. P2 and P5 also reported that they shared the tracked measurements with their cardiologist and that helped them make evaluations on the data. Adding a feature for the patients to text the nurse was strongly desired especially since patients sometimes knew what caused a high-risk alert and were able to manage it independently.

On the other hand, patients also pointed out areas of concerns such as reliability of the equipment and limited availability of technical support for detecting failures and resolving them immediately. Specific problems that patients experienced while using each system component are summarized along with suggested opportunities for improvement (Table 3).

Table 3. Usability problems and opportunities for improvement—patients' feedback.

Component	Usability problem	Suggested opportunities for improvement in future design	Examples of patient feedback on problematic experience
Weight scale	Family members use scale	Establish validation measures for weight variations	*(The nurse) found out a problem when one of my friends used the scale and she is so tiny so the weight is 106 and then my husband used it once because he thought it's not working and he weighs 195! So, (the nurse) was so scared and she called right away and said what happened? So, I said my friend used it and then my husband. So, it's good. (The nurse) is the best nurse, she is always taking care of her patients*
Blood pressure monitor	Cuff usage	Include possible error in reading in training	*Sometimes you get a reading that is not a reasonable range, and, usually it is my mistake... you have to be extremely careful in how you put the cuff on...There are things that you can do wrong. You can have the tube pointed the wrong way in which point you will certainly get the wrong answer*
Blood glucose meter	Complex process to transmit readings	Allow manual entry of blood glucose values	*The blood sugar is not as easy to use as the other instruments because you have a multistep procedure to make it read properly...it is not intuitive that you first press the button to see the number visually and then you watch the countdown and then you see the thing.*
	Accuracy of readings	Test the accuracy of each device with the user before home monitoring	*The glucometer I got from you was reading me 50 points higher...well I use my own glucometer because it was a lot nicer to me in the morning because I average about 130-150 fasting*
Hub	Connectivity	Use phone as hub to verify connectivity status	*I get situations where it is not going in right...the normal procedure is to see one light blink green, the other blinking green, and then the top blinks blue. When it is red I unplug and plug-in*
App: symptoms	Redundancy in reporting symptoms everyday	Submit symptoms only when present	*It got to the point where I was just no, no, no, done…Maybe rather than having that everyday, there would be a place where we could push that symptom...if you are having it*
	Questions about symptoms do not match the patient's personal symptom	Provide personalized symptom questions	*My symptoms aren't the same as others... Today my eyes are drooping that is my symptom of retention of fluid so is my belly. My hands and feet are skinny*
App: messages and reminders	Not personalized	Customize messages	*I thought they were impersonal*
App: charts	Charts on the mobile app were too small and had no printing or customization capabilities	Improve chart visualizations (filtering and zooming) and provide printing and customization functions	*P2 stated that her afternoons are more problematic than her mornings and created charts on paper to show the need for a larger view and overlapping heart rate and blood pressure measurements*

Nurses' Experiences

Nurses also expressed their viewpoints, which were also categorized into 5 areas:

Identifying Individual Patterns and Personalized Rules

Nurses highlighted that each patient had an individual pattern of measurements that require personalized rules.

Guiding Admission

Nurses reported that the system helped them guide admissions. One nurse described a situation when her patient's heart rate went out of control and they were not able to manage it while she was at home, the nurse arranged her admission so the treatment was made earlier and no emergency room visit was required.

Recommending Treatment

Viewing daily measurements allowed nurses to recommend treatments such as taking extra diuretics.

Communication

Nurse-to-patient communication increased especially since the nurses contacted patients when the measurements indicated high-risk or when data were missing. They also used the charts produced from the system during the clinical visit to discuss how patients can improve their trends. The feedback, which nurses provided on each system component, is shown in Table 4.

Table 4. Usability problems and opportunities for improvement—nurses' feedback.

Component	Usability problems	Suggested opportunities for improvement in future design	Example of nurse feedback
Rules	Can not customize rules to include each patient's dry weight	Add customization capability to include dry weight	*they have to have a dry weight...having the patient know a weight that is optimal where they are not overloaded or too dry*
	Changing standards	Add customization capability to change rules according to new standards	*There are also shifts from research…we've been using weight gain of 2 to 3 pounds for years...they decided that is really not helpful...they are still looking at weight change but if it is 4 pounds or more...*
Dashboard: all patients	Anomalies	Allow edits or deletes	*The nurse highlighted a spike in one patient's weight explaining that it was not real because he was weighing himself with his cat so there is a need to delete anomalies*
	Gaps in data	Improve the process to prevent gaps in data	*with it (data) not always being downloaded everyday, I see this big jump and I go what am I to do with that?*
Dashboard: individual patient views	Identifying uncontrolled cases	Control charts	*if you do a control chart, there is a pattern that starts appearing before hand and then you can see what's going on and pay more attention*
Alerts	False positives	Add rules to reduce False Positives	*I would like to trust that text is something I need to look at… because about 95% of the time the alerts have been normal…*
			or we wanted that to happen so we get an alert for the weight drop and we wanted the weight to drop but it comes up as a high-risk

Discussion

Principal Findings

This paper presented the design and use of an mHealth system for HF. The aim was to identify what features are effective and how users' interaction with the system impacts adherence to the HF self-care process and health outcomes. In this context, we focused on user engagement and user interaction. We explored the system usability aspects of our solution and how it benefitted both patients in achieving better health outcomes, and caregivers in providing a better way for remotely monitoring their patients. One lesson learned was that, even in spite of motivational messages and reminders, there were gaps in adherence to using the system to support self-care.

Effective features included blood pressure, heart rate, weight, and symptom monitoring as high heart rate, blood pressure, weight gain, and shortness of breath were all events that occurred and were managed immediately.

With personal health tracking features for patients and monitoring capabilities for nurses, the use of the system was correlated with an overall improvement in quality of life and detection of 8 deteriorating cases. Patients' experiences with each system component highlighted challenges and opportunities for design improvements.

Although the HF team was a key in engaging patients to use the system, benefits that were articulated included support in recording and tracking readings, receiving encouragement and reassurance from nurses, spotting and solving problems, learning from past experiences, and communication.

In total, 3 patterns of patient usage emerged: frequent, occasional, and abandonment after initial use. These patterns emphasize the need to account for various scenarios when planning future systems to maximize the impact and reduce the cost of the system. Given that technical difficulties and remembering to take measurements were cited as reasons for occasional use, focused training, technical support, and different modes of communication could help remedy this problem. On the other hand, users who completely stopped using the system in this context, did so for two reasons: one was due to changes in health care insurance coverage which resulted in the patient becoming ineligible to continue care at the hospital. Another reason was change of health care provider as one patient transferred to another hospital because he needed a specialized service that was not offered at this setting. More research is needed to address the reasons behind system abandonment.

The following lessons were learned from the design and evaluation of the system:

Lesson 1: One Size Does Not Fit All

There is a need to include features that allow users to customize the mobile app and rules within the expert system for each individual case. For example, patients requested personalized messages, symptom questions, and integration with other personal medical devices and systems to overcome irrelevancy and redundancy in the mobile app. We found that some patients did not understand why they were asked about swollen feet when their swelling occurred in their stomach or eyelids. They also expressed that their expectations for messages tailored to their specific situation and lifestyle rather than a prefixed pool of messages. Some patients also articulated the need to incorporate and monitor data from other devices to track their health (eg, Implantable Cardioverter Defibrillator [ICD], Prothrombin Time and International Normalized Ratio Monitor [PT and INR], and Continuous Glucose Monitor). Nurses, on the other hand, pointed out that they need to enter a dry weight

for each patient so that they can determine if the weight change is desired or not. They also requested the ability to change the rules for the expert system to keep up with changing standards.

Lesson 2: Visualizations Are a Valuable Feature for Patients and Nurses

Patients and HF nurses repeatedly articulated how the trend charts helped them in tracking and managing their health. Two additional features were suggested: adding control charts to help predict at-risk cases on the dashboard, and adding print and Web access capabilities for patients to customize their charts.

Lesson 3: Logging Mechanisms Could Be Effective When Incorporated in the Design

Patients envisioned that the ability to log known reasons behind abnormal readings on the mobile app and sending a message to inform the nurse that the problem is being treated, or is an error, would be beneficial. Nurses also preferred to have a log to indicate how each case was addressed.

Lesson 4: A Standard Wireless Glucose Meter for All Users Might Not Be Feasible

Although blood glucose values were a necessary requirement because HF patients could have type-2 diabetes as comorbidity, the cost of the meter and test strips supply were significant. Accuracy and reliability of the meter were also a concern. Furthermore, blood glucose values did not contribute to any of the alerts that detected deterioration.

Lesson 5: Information Sharing Tools and Periodic Meetings Are Desired

Patients found that group meetings helped them learn from others' experiences and receive additional technical support. One patient suggested adding an online bulletin board to share information related to HF experiences, post announcements regarding upcoming meetings, and to discuss technical issues with the system.

Limitations

One of the main limitations was the small sample size. However, 3-5 participants are usually considered a sufficient sample size for usability studies [17]. Furthermore, refinements to the design were not made during the study period, as this was a preliminary phase that had a restricted scope, time, and budget. Improvements will be incorporated and tested in a future study. Another limitation was, as a field study, there was a lack of control over other variables such as changes in diet and medications. As a result, the accuracy of results, such as the improvement in quality of life, could be questionable. To mitigate this limitation, we encouraged patients to discuss any negative experiences and lifestyle changes along with positive experiences.

Comparison With Related Work

Our design complements existing research addressing the design and usability of mHealth systems. Similar to the weight and activity with blood pressure system (WANDA) in [10], we provided patients with wireless health technologies to measure and automatically send their weight, blood pressure, and blood glucose value. In terms of design, our approach confirms what has been found in [18] that an iterative approach which includes users has been shown to result in successful adoption HF telemonitoring. We also found that nurses and patients were able to spot and manage worsening cases that is consistent with [19], which found that alerts generated from transmitted blood pressure, weight, and symptoms values are effective in identifying deteriorating cases. The themes that emerged from users' experiences, such as reassurance, confirm the benefits of using home monitoring as articulated in [11]. The lesson learned about the importance of individualized care especially for patients with comorbidities in this study supports [20] which highlighted the need to acknowledge, routinely profile, identify personal goals, support individualized case management, and include the patients' perspective and overall outcomes in evaluation [20]. Refining a system design to be personal has also been demonstrated by Triantafyllidis et al [18].

Conclusions

Advances in eHealth trends such as the Internet of Things are driving interest in the development and use of feasible mHealth systems. Although devices that measure health data are available to consumers, systems that allow these devices to communicate and share information with providers are needed because home monitoring could alleviate the burden of HF management on patients and providers. Features to monitor changes in weight, heart rate, and report shortness of breath could be useful for identifying deteriorating HF cases. The intelligent dashboard with automated risk classification and alerts sent to caregivers can also help to lower the burden of patient management in which typically few nurses or caregivers handle large number of cases.

We have shown that continuous monitoring infrastructure in the home can lead to better and higher quality information, which can lead to improved health outcomes as well as reduced hospital readmissions and cost savings. However, we saw the need to tailor the messages to individual preferences as important. We also saw that home logistic support is critical for widespread deployment of such technologies. We found from exit interviews that patients often are socially isolated and hence including a form of social networking technology in the app can bring them together and provide peer support. Overall, future designs should include patients' needs such as personalized apps and messages, two-way communication with providers, enhanced visualization features, social support, and high levels of technical support. Features for providers are also needed, such as custom rules for each patient, solutions to address gaps in data, incorporation of changing standards, advanced charts, and limited alerts. Although this study did not incorporate and test these needs and is no longer used at the hospital, changes are planned for a future design.

Acknowledgments

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Conflicts of Interest

Dr Samir Chatterjee was a Co-PI in this research project which took place from March 2014 to June 2015. After the completion of this project, he founded a startup company DCL Health that is commercializing some of these technologies.

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Abbreviations

DSR: design science research
HF: heart failure
ICD: Implantable Cardioverter Defibrillator
IRB: Institutional Review Board
LLUMC: Loma Linda University Medical Center
MLHFQ: Minnesota Living with Heart Failure Questionnaire
NYHA: New York Heart Association
PT and INR: Prothrombin Time and International Normalized Ratio Monitor
SUS: System Usability Scale
WANDA: weight and activity with blood pressure system

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Original Paper

Designing eHealth Applications to Reduce Cognitive Effort for Persons With Severe Mental Illness: Page Complexity, Navigation Simplicity, and Comprehensibility

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Abstract

Background: eHealth technologies offer great potential for improving the use and effectiveness of treatments for those with severe mental illness (SMI), including schizophrenia and schizoaffective disorder. This potential can be muted by poor design. There is limited research on designing eHealth technologies for those with SMI, others with cognitive impairments, and those who are not technology savvy. We previously tested a design model, the Flat Explicit Design Model (FEDM), to create eHealth interventions for individuals with SMI. Subsequently, we developed the design concept *page complexity*, defined via the design variables we created of distinct *topic areas*, distinct *navigation areas*, and number of columns used to organize contents and the variables of text reading level, text reading ease (a newly added variable to the FEDM), and the number of hyperlinks and number of words on a page.

Objective: The objective of our study was to report the influence that the 19 variables of the FEDM have on the ability of individuals with SMI to use a website, ratings of a website's ease of use, and performance on a novel usability task we created termed as *content disclosure* (a measure of the influence of a homepage's design on the understanding user's gain of a website). Finally, we assessed the performance of 3 groups or dimensions we developed that organize the 19 variables of the FEDM, termed as page complexity, navigational simplicity, and comprehensibility.

Methods: We measured 4 website usability outcomes: ability to find information, time to find information, ease of use, and a user's ability to accurately judge a website's contents. A total of 38 persons with SMI (chart diagnosis of schizophrenia or schizoaffective disorder) and 5 mental health websites were used to evaluate the importance of the new design concepts, as well as the other variables in the FEDM.

Results: We found that 11 of the FEDM's 19 variables were significantly associated with all 4 usability outcomes. Most other variables were significantly related to 2 or 3 of these usability outcomes. With the 5 tested websites, 7 of the 19 variables of the FEDM overlapped with other variables, resulting in 12 distinct variable groups. The 3 design dimensions had acceptable coefficient

alphas. Both navigational simplicity and comprehensibility were significantly related to correctly identifying whether information was available on a website. Page complexity and navigational simplicity were significantly associated with the ability and time to find information and ease-of-use ratings.

Conclusions: The 19 variables and 3 dimensions (page complexity, navigational simplicity, and comprehensibility) of the FEDM offer evidence-based design guidance intended to reduce the cognitive effort required to effectively use eHealth applications, particularly for persons with SMI, and potentially others, including those with cognitive impairments and limited skills or experience with technology. The new variables we examined (topic areas, navigational areas, columns) offer additional and very simple ways to improve simplicity.

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KEYWORDS

Internet technology; mobile application; cognitive impairment; eHealth; eHealth design; e-mental health; schizophrenia; severe mental illness; usability; website design

Introduction

The closing of long-term hospitals and the increasingly abbreviated stays in acute care facilities leave persons with severe mental illness (SMI) more dependent on outpatient services and self-care to support their community well-being. Prevailing in-person mental health service delivery models have resulted in a situation where many treatments, proven efficacious over the past 30 years, are not readily available [1-4]; available services rarely meet the established standards for care [5-8]; only 40%-50% receive specialty mental health care in a given year [6-8]; and only 4%-15% receive even minimally adequate mental health treatment—far short of evidence-based standards [7,9,10]. Consequently, the majority of persons with SMI live in communities where they and their families receive few services, and those services fall substantially short of the established standards for care [11,12]. Clearly there is a need for cost-effective ways to increase receipt of care and successfully disseminate evidence-based interventions to communities [11].

eHealth technologies are being used increasingly in general medical care [13-16] and to a lesser, though growing, extent in mental health treatment [17-20] as a way to improve service receipt and reduce illness burden. In this study, eHealth refers to the use of consumer-facing information and communication technologies to support health [21,22], with a focus on Web-based and mobile phone apps. As eHealth technologies become more prominent, the dearth of models to effectively design them for persons with SMI [21,22], and others with cognitive impairments, will result in significant obstacles to obtaining services for these individuals and exacerbate already inadequate receipt of services [6]. Several investigators have identified the difficulty that those with SMI have in using websites designed for the general public [22-24]. In response, research has been conducted to develop designs appropriate for those with SMI [25-28].

As part of our prior work, we developed an empirically supported design model to create eHealth technologies that persons with SMI, with little or no prior technology experience, could use effectively [23]. The resulting nascent model, termed the Flat Explicit Design Model (FEDM), proved to be quite effective. Using this model, we created a Web-based intervention, termed Schizophrenia Online Access to Resources (SOAR), to provide in-home multifamily psychoeducational treatment to persons with schizophrenia and their family members [23]. The intervention website was highly valued, frequently used, and had significant effects on important outcomes (eg, reducing positive symptoms) [29,30]. Its design proved to be quite effective. In tests comparing this website to public websites for persons with SMI, those with SMI took less time to find contents, had greater success finding contents, and rated it easier and less frustrating to use [24].

This study evaluated several additions to the design model (FEDM, Textbox 1) used to create SOAR. Observations during previous usability studies suggested that some individuals with SMI had difficulty scanning a page effectively for content and creating a mental model of the layout and organization of a screen's contents [23,28]. Generally, these are important requirements to effectively navigate standard eHealth apps. Others have found that individuals with schizophrenia are not able to use websites that are well designed, but intended for the general public [22]. These observations, coupled with previous findings, and knowledge of the cognitive deficits associated with SMI led us to develop the novel concept of *page complexity* as potentially important to the cognitive effort required to comprehend and effectively use an eHealth app. In elaborating a model of page complexity, we developed the new design constructs of distinct *topic areas* and *navigation areas*. Additionally, our experience led us to speculate that the number of columns used to organize contents, number of words and hyperlinks on a page, and the text's reading level and simplicity (ie, reading ease) would also influence the cognitive effort required for comprehension and navigation and thus, an app's usability. We hypothesized that these constructs and variables would have an effect on the ability of persons with SMI to navigate eHealth technologies. This study was designed to test: these new constructs; the initial validity of our concept of page complexity; a set of variables to define page complexity; the addition of a new variable, reading ease, to the FEDM; and three functional dimensions we developed to organize the 19 variables of the FEDM. These dimensions were designed to have practical implications for creating effective designs. The study had persons with schizophrenia perform tasks on 5 public mental health websites during which data were collected on the ability to find contents, time to find contents, subjective evaluation of

the websites, and influence of the homepage designs on a user's understanding of a website.

Textbox 1. Dimensions and variables of the Flat Explicit Design Model (FEDM): page complexity, navigation simplicity, and comprehensibility.

Dimension 1: page complexity

- Number of navigation areas: A minimal number of navigation areas per screen preferably in 1 location and prominent on the screen.
- Number of topic areas: A minimal number of independent topic areas on a screen.
- Number of columns: A minimal numbers of columns on a screen that present page contents.
- Depth of hierarchy: A minimal number of screens or pages that need to be navigated in order to find desired contents.
- Number of themes: A limited number of disparate themes or topics on any 1 screen.
- Display distractions: A plain presentation that minimizes distracting and superfluous content (eg, decorative displays or images).
- Reading ease: Text should use words that are understandable and simple sentence structures.
- Number of hyperlinks: Use of hyperlinks in navigation areas in order to decrease the number of navigation areas on a page. In the use of these, the need for minimal depth of pages also must be considered.
- Use of low-level hyperlink categories to navigate to contents: The organization of the hyperlinks to an app's contents should be accomplished by using low-level categories, that is, less abstract categories, closer conceptually, as well as closer in the navigational hierarchy, to final destination contents, and thus there should be relatively more hyperlink categories on navigation screens, particularly the home screen.

Dimension 2: navigation simplicity

- Toolbar: A single constant navigational tool bar is used to improve comprehension and navigation.
- Explicit hyperlink labels: Navigational elements should not need inference or interpretation to understand. Hyperlinks, icons, headings, and labels should be explicit.
- Hyperlink location: Navigational elements should be placed in a minimum of different locations and preferably in the upper left of a page, where users begin searching.
- Introductory content location: Minimize introductory text before the hyperlinks that lead to an app's contents.

Dimension 3: comprehensibility

- Number of words: Minimal words should be used, but they must convey concepts without the need to interpret meaning.
- Page Length: Emphasis should be placed on scrolling down a page for additional content versus navigating to another page. A longer page is more complex than a shorter page, but that is better than making the page shorter by having users navigate to another page.
- Memory aids: Memory aids should be used, for example, pop-up menus, to facilitate navigation.
- Reading Level: A low reading level should be used.
- Inference: There should be minimal need to infer meaning or think abstractly in order to understand the written content presented.
- Use of Dialect: Words used should employ target groups' vernacular and vocabulary.

Methods

Participant Recruitment and Selection Criteria

Participants were recruited from 6 community psychiatric rehabilitation outpatient centers, which provided day treatment programs. To receive services, one had to have an SMI diagnosis and appropriate insurance (eg, Medicare). Staff identified individuals with proper diagnoses and discussed the study with them. Those who were interested were told when study staff would be there (ie, to conduct usability testing). Enrollment criteria were as follows: age ≥18 years; a chart diagnosis of schizophrenia or schizoaffective disorder; physical ability to read the screen of a computer and use a mouse; and ability to read at a 5th grade level. There were no requirements for prior computer, Internet, or website use. The research protocol was approved by the University of Pittsburgh's institutional review board.

Participant Background Information

The Global Assessment Scale (GAS) [31] was used by study staff who conducted the usability testing to rate each participant's level of functioning. All staff were formally trained and experienced at rating persons with schizophrenia using the GAS. Sociodemographic and computer experience information were also collected (Table 1) —one participant did not answer the computer access question.

Choice of Websites for Evaluation

Five websites that included information on schizophrenia were chosen for the study. The website SOAR [30] was developed to deliver family psychoeducational treatment using the FEDM. Its address was not provided because it is currently under study. The other 4 were identified using Google to search for the word schizophrenia and by searching the Google directory. The websites were chosen to represent variation on important design variables:Schizophrenia.com (started in 1995), one of the first websites listed in the search results, provides support groups,

science-based information, and discussion forums for individuals and families; the website of the National Alliance on Mental Illness (started in 1979), designed to provide education, advocacy, help, and public awareness to individuals and family members; Chovil.com (started in 1997), was created by an individual with schizophrenia and, thus, may contain design insights not commonly found in other sites; and the National Mental Health Association-Mental Health America (founded in 1909) has a website that focuses on individuals with mental illness and provides resources to promote mental health wellness. All websites were downloaded and cached locally to ensure that their contents remained static throughout the study.

Training of Testers

All testers were mental health professionals and had experience working with individuals with SMI. They also all had experience in providing training to individuals with schizophrenia on how to use computers and navigate websites from previous research projects. Two of the authors (AR and SE) provided training to testers and supervised them as they conducted the testing procedures on each other and other staff. Additional supervision was provided during the data collection for this study.

Participant Training and Testing

To ensure the basic knowledge needed to navigate the websites, each participant was taken through a brief tutorial using 3 preselected public websites (different from the 5 tested) to teach the basic elements that would be needed to navigate the 5 websites being tested. The topics covered included using a mouse, hyperlink text, navigation buttons, pop-up menus, and scroll bar to scroll up and down a page. The longest training took 22 minutes. This was based on tutorials we had used previously [29,32]. All who met eligibility criteria were able to master the use of these basic elements. Training was provided before the testing occurred by the research staff conducting the usability testing.

Characterizing Each Website's Homepage Complexity

Each website's homepage was characterized in terms of 19 variables (Table 2). Reading level (in terms of school year), reading ease (for which higher values represent easier reading ease), and total number of words were determined using the grammar (which utilized the Flesch and Kincaid formulas) [33] and word count functions in Microsoft Word. The number of hyperlinks and columns of contents on the homepage were counted manually. If a homepage had sections with different numbers of columns, a weighted average was calculated by summing the number of columns in each section multiplied by a section's proportion to the total length of the page. A *topic area* was defined as being a distinct area of a screen or page that was devoted to a given topic or purpose, and it could contain both nonhyperlink and hyperlink text. A *navigation area* was a distinct area of a screen or page that contained 1 or more hyperlinks grouped together by proximity and typically related to one another via a common topic. Many topic areas were composed of text (ie, nonhyperlink text), which introduced the topic of the area, and included 1 or more hyperlinks associated with the topic. If a set of hyperlinks occupied a separate area of the page, was not associated with any text, and represented a distinct topic from other areas in proximity, it was classified as a topic area, and it was also classified as a navigation area.

Website Evaluation Procedures

The usability testing occurred in private rooms at the psychiatric rehabilitation outpatient centers. Testing was done on our computers. During the testing, to control for learning effects, the order of testing of the 5 websites was varied across participants using a 5×5 Latin square design. Likewise, the order of presentation of tasks within each of the 3 different types of tasks participants performed were varied across individual websites.

Website usability testing was conducted using software, Ergobrowser, (Ergosoft) for recording and timing website navigation. Participants were timed by pressing a special keyboard button, which started and stopped the timing for each subtask. It also recorded which subtask participants were performing.

Tasks to Evaluate Website Usability Performance

Task 1: Homepage Content Disclosure Performance

To assess the effectiveness with which a homepage's design conveys information about a website's contents (what we term homepage *content disclosure*), participants were asked to study a homepage for 60 seconds. They could scroll down the page but not use the mouse to open pull-down or pop-up menus. Then, while still being able to look at the page, they decided (using the options of yes or no) whether they thought a website contained information on 7 topics: how schizophrenia is treated, how to find a good psychiatrist, the side effects of medications, the causes of schizophrenia, how to find volunteer work, how to know whether a person has schizophrenia, and how many people have schizophrenia. The 7 topics were chosen so that information was present on 5 of the 7 topics on each website. For analyses the participants were put into one of 2 groups based on the number they got correct: one group was those who got ≤5 correct, the other group was those who got >5 correct. One subject did not complete this task.

Task 2: Find Specific Information—Ability and Time

To assess the ability to accurately navigate each website, participants were asked to find content on 3 topics: (1) treatments for schizophrenia, (2) side effects of medications used to treat schizophrenia, and (3) the causes of schizophrenia. Participants were given a maximum of 5 minutes to find the information on each topic. Once a search was over, participants were returned to the homepage to begin the next search. For analysis, we used 2 measures: whether for all 5 tasks the subjects found the correct information and, for the tasks solved correctly, the mean number of seconds needed to correctly find the information. This time was missing for 5 participants.

Task 3: Reactions to a Website

Following testing on a website, participants were asked to rate their impressions of the ease of use of a website using a 5-point scale ranging from 1 ("Not at all") to 5 ("Extremely").

Data Analyses

The values obtained for the number of a website's navigation and topic areas, links, columns and words on the home page, and home page length are included in Table 2. Each variable was dichotomized; that is, the values of each variable were coded into 2 levels: "less complex" versus "more complex" (Table 3). For the 5 websites used in this study, several of the 19 variables overlapped in their variation with other variables, yielding 12 distinct variable groups (Table 3).

We organized the 19 variables of the FEDM into 3 dimensions or *factors*. To make an initial assessment of the validity of these 3 dimensions, coefficient alphas were computed to assess the internal consistency of the variables within the 3 dimensions. A summary score was created for each of the 3 dimensions by adding the dichotomized values of the variables within each dimension. Analyses of the relationships of the usability outcomes to the 19 variables, as well as to the 3 dimensions' summary scores, were performed using mixed model regressions that accounted for the repeated measures within subjects and across websites. Logistic regressions were used for ability to find all 3 pieces of information versus not finding all 3, and the content disclosure task, which consisted of the number of times each participant correctly identified whether 7 topics were addressed by a website, after only examining the homepage. Performance for the content disclosure task was grouped into ≤5 or >5. Linear regressions were used for mean time to find information, and ease of use. Initially univariate regressions were done followed by multivariable models that included all 12 nonoverlapping FEDM variable groups. Analyses of the summary dimension scores were also completed with mixed effect regressions.

Demographic information, reports of computer experience, and overall function measured by the GAS were summarized with means for continuous variables and frequencies for categorical variables.

Results

Principal Findings

The mean age of participants was 47.2 (SD=6.62); 50% (19/38) were females, and 40% (15/38) were African American/Black (Table 1). Twenty participants (53%) reported prior computer use, of which 27% (10/38) had home access, 27% had only nonhome access, and 50% (19/38) had used websites previously.

Characteristics of the Websites' Design Complexity

Table 2 presents each of the 5 websites characterized according to the 19 variables of the FEDM. In terms of dimension 1, page complexity, Chovil and SOAR have the lowest design complexity, followed by Schizophrenia.com, with the National Alliance on Mental Illness (NAMI) and the National Mental Health Association (NMHA) having the most complex designs. For example, Chovil has the fewest columns, highest reading ease, and fewest hyperlinks. SOAR is designed using the fewest navigation areas, and both have the fewest topic areas for presenting contents. For dimension 2, navigation simplicity, SOAR and SZ.com have the simplest designs. The other 3 websites are relatively complex on this dimension. With dimension 3, comprehensibility, all websites have some good design characteristics. SOAR has the most, and is the only one to employ the target audience's dialect and require relatively less inference to understand contents. Chovil has the lowest reading level, followed by Schizophrenia.com, NMHA, and then SOAR, with NAMI having the highest.

Ability and Time to Find Information, Subjective Ease of Use Ratings, and Content Disclosure Task

Univariate analyses showed that the following 11 variables were predictors of the 4 usability outcomes (content disclosure, ability and time to find contents, ease of website use): few navigation areas,topic areas, columns, shallow depth of hierarchy, few themes, few display distractions, easy to moderate reading ease, constant navigational toolbar, moderate reading level, and explicit hyperlink labels (Table 3). In addition to the aforementioned 11 variables, the ability of a homepage to convey information about a website's contents to users (ie, content disclosure) was also associated with fewer hyperlinks. The ability to find the 3 pieces of information and the time to find the information were also significantly associated with the following variables: the use of low-level hyperlink categories, having hyperlinks in the upper left of the page, having fewer words on a homepage, shorter homepage length, use of dialect, and minimal inference required. In addition to the aforementioned 11 variables, ease of use ratings were also associated with fewer hyperlinks, use of low-level hyperlink categories, having hyperlinks in the upper left of the page, having the introductory text located after the hyperlinks to contents, having fewer words on a homepage, shorter homepage length, use of dialect,and minimal inference required.

The multivariable analyses indicated that the ability to navigate a website and find the information were significantly related to shallow depth, few themes presented, few display distractions, easy to moderate reading ease (odds ratio, OR=24.5, $P<.001$) and fewer hyperlinks (OR=–0.08, $P<.001$). For the mean time to find the information, shallow depth, moderate reading level (68 vs 47 seconds, $P<.001$) and fewer hyperlinks (68 vs 81 seconds, $P<.01$) remained significant. Users' ease of website use ratings were significantly related to having fewer navigational areas, topic areas, and columns (3.3 vs 2.9, $P=.06$), shallow depth, few themes presented, few display distractions, easy to moderate reading ease (3.6 vs 2.9, $P<.001$) and fewer hyperlinks (2.8 vs 1.6, $P<.001$). For the content disclosure task, the ability of users to correctly identify the contents of a website after only viewing the homepage was significantly and positively influenced by shallow depth, moderate reading level (OR=3.9, $P=.001$) and having fewer hyperlinks (OR=–3.4, $P<.001$).

Table 1. Participant characteristics (N=38).

Variable	n (%)
Sex	
Female	19 (50)
Age (years)	
31-40	6 (15.8)
41-50	23 (60.5)
51-59	9 (23.7)
Race	
White	22 (57.9)
African American, Black	15 (39.5)
Asian	1 (2.6)
Education	
<High school	6 (15.8)
High school	12 (31.6)
Some college or vocational school	14 (36.8)
College graduate	6 (15.8)
Overall level of functioning (Global Assessment Scale)	
<40	3 (7.9)
41-61	17 (44.7)
62-72	17 (44.7)
73-81	1 (2.6)
Computer access	
At home	10 (26.3)
Other than home	10 (29.0)
No access	17 (44.7)
Hours of computer use/week	
None	17 (44.7)
1-5	13 (34.2)
>5	8 (21.0)
Previously accessed websites	
Yes	19 (50.0)

Table 2. Measures of the Flat Explicit Design Model (FEDM) variables across 5 tested websites.[a]

The 19 design variables of the FEDM	Values for each website on the 19 design variables of the FEDM				
	SOAR[b]	SZ.com[c]	Chovil[d]	NAMI[e]	NMHA[f]
Dimension 1: page complexity					
Number of navigation areas	3	16[g]	4	20[g]	28[g]
Number of topic areas	4	17[g]	4	17[g]	29[g]
Number of columns	1.77	2.38[g]	1.58	3.65[g]	2.88[g]
Shallow depth of hierarchy	Yes	Yes	Yes	No[g]	No[g]
Few themes presented	Yes	Yes	Yes	No[g]	No[g]
Few display distractions	Yes	Yes	Yes	No[g]	No[g]
Reading ease[h]	43.8	43.3	52.3	37.7[g]	39.3[g]
Number of hyperlinks	97[g]	120[g]	45	132[g]	97[g]
Used low-level hyperlink categories	Yes	Yes	Yes	Yes	No[g]
Dimension 2: navigation simplicity					
Constant navigational toolbar	Yes	Yes	No[g]	No[g]	Yes
Explicit hyperlink labels	Yes	Yes	No[g]	No[g]	No[g]
Upper left hyperlink location	Yes	Some[g]	No[g]	Some[g]	Some[g]
Introductory content location after hyperlinks	Yes	Yes	No[g]	Yes	Yes
Dimension 3: comprehensibility					
Number of words	351	586[g]	609[g]	407	551[g]
Page length	13.7	25.0[g]	22.3[g]	15.9	24.7[g]
Memory aids used	Yes	No[g]	No[g]	Yes	Yes
Reading level (grade)[i]	10.9	10.2	9.4	12[g]	10.5
Minimal inference required	Yes	No[g]	No[g]	No[g]	No[g]
Use of dialect	Yes	No[g]	No[g]	No[g]	No[g]

[a]Each variable was split into 2 levels because there was adequate variability for each variable. One was defined as “less complex” and the other “more complex.” The demarcation for each variable was based on the relative complexity among the set of websites: the high end is “more complex” and the low end “less complex.”

[b]Schizophrenia Online Access to Resources.

[c]Schizophrenia.com.

[d]Chovil.com.

[e]National Alliance on Mental Illness.

[f]National Mental Health Association.

[g]Variable levels that were defined as more complex in this dichotomy.

[h]For reading ease, higher numbers represent better reading ease.

[i]For reading level, higher numbers represent more difficult reading level.

Table 3. Website performance for dichotomized[a] Flat Explicit Design Model variables in 12 variable groupings.

19 Flat Explicit Design Model variables[a] listed in their low-complexity form	Website complexity for each variable group[b]	N[c]	Content disclosure task: number of times ≥5 correct of 7[d]	Find contents: number of times all 3 tasks completed correctly[e]	Find contents: mean time (seconds) to correctly find contents[f]		Website ease of use rating[g]	
			n[e](%)	n[f](%)	Mean	Range	Mean	Median
Dimension 1: page complexity								
Few navigation areas Few topic Areas	High	113	30 (26[g])	62 (54.4[j])	60.2[i]	10.3-207.8	3.1[h]	3
Few columns	Low	75	13 (17)	54 (72.0)	50.1	12.4-169.3	3.4	4
Shallow depth of hierarchy	High	76	12 (16[g])	32 (42.1[j])	65.3[j]	10.3-207.8	2.9[j]	3
Few themes presented Few display distractions Easy to moderate reading ease	Low	112	31 (27)	84 (74.3)	50.6	12.4-169.3	3.5	4
Fewer hyperlinks	High	150	42 (28[h])	96 (63.6)	55.5	10.3-207.8	3.4[i]	3
	Low	38	1 (3)	20 (52.6)	58.0	21.1-169.3	2.7	3
Used low-level hyperlink categories	High	38	6 (16)	13 (34[h])	67.5i	22.4-150.3	2.8[i]	3
	Low	150	37 (25)	103 (68)	53.2	10.3-207.8	3.3	3.5
Dimension 2: navigation simplicity								
Used a constant navigational toolbar	High	76	7 (9[j])	39 (51.3[h])	60.3[h]	10.3-207.8	2.9[j]	3
Had moderate reading level	Low	112	36 (32)	77 (68.1)	53.5	12.4-150.3	3.5	4
Used explicit hyperlink labels	High	114	13 (11[j])	52 (45.6[j])	62.7[j]	10.3-207.8	2.8[j]	3
	Low	74	30 (40)	64 (85.3)	47.1	12.4-137.5	3.8	4
Hyperlinks were located in upper left of the page	High	151	31 (20)	82 (52.6[j])	59.6j	10.3-207.8	3.0[j]	3
	Low	37	12 (32)	34 (91.9)	42.8	12.4-112.1	4.0	4
Introductory content located after hyperlinks	High	38	1 (3[i])	20 (52.6)	58.0	21.1-169.3	2.7[i]	3
	Low	150	42 (28)	96 (63.6)	55.5	10.3-207.8	3.4	3
Dimension 3: comprehensibility								
Fewer words on homepage	High	75	18 (24)	53 (70.7[h])	51.8[g]	10.3-207.8	3.5[i]	4
Shorter homepage length	Low	113	25 (22)	63 (55.3)	58.7	15.7-169.3	3.1	3
Memory aids were available	High	75	19 (25)	50 (65.8)	54.6	15.7-169.3	3.2	3
	Low	113	24 (21)	66 (58.4)	57.1	10.3-207.8	3.3	3

19 Flat Explicit Design Model variables[a] listed in their low-complexity form	Website complexity for each variable group[b]	N[c]	Content disclosure task: number of times ≥5 correct of 7[d] n[e](%)	Find contents: number of times all 3 tasks completed correctly[e] n[f](%)	Find contents: mean time (seconds) to correctly find contents[f] Mean	Range	Website ease of use rating[g] Mean	Median
Use of dialect Minimal inference required	High	151	31 (20)	82 (54.0[j])	59.6[j]	10.3-207.8	3.0[j]	3
	Low	37	12 (32)	34 (91.9)	42.8	12.4-112.1	4.0	4
Reading level ≤11th grade	High	38	6 (16)	19 (50)	62.9	10.3-207.8	3.0	3
	Low	150	37 (25)	97 (64)	54.6	12.4-169.3[g]	3.3	3

[a,b]Variables that are collinear are grouped together. Each variable was dichotomized, or split, into two levels. One was defined as "low complexity" and the other "high complexity."

[c]The number of tasks performed on "high"- or "low"-complexity websites. N is the number of subjects times the number of websites summed across websites with low and high complexity level of the design variables, for example, if N=38 this would imply that 38 subjects viewed this level of complexity, and given there were 38 subjects total, this means that only 1 website met this criteria; if N=114 (ie, 38×3) this implies that 3 websites met this criteria.

[d]The number of times participants got >5 correct on a website. The data are separated in the table by whether the task was performed on websites with "high" or "low" complexity. Given there are 38 subjects the maximum correct is 38×5=190.

[e]The number of times participants correctly found all 3 pieces of information on a website. The data are separated in the table by whether the task was performed on websites with "high" or "low" complexity.

[f]This is based on the mean time to find information in the participants who correctly answered within the 5 minute time allotted.

[g]Significance $P>.05$

[h]Significance $P\leq.05$.

[i]Significance $P\leq.01$.

[j]Significance $P\leq.001$.

Assessment of the Theoretical Dimensions of the FEDM: Page Complexity, Comprehensibility, and Navigation Simplicity

The summed scores for the 3 proposed dimensions all had coefficient alphas=0.8 (page complexity alpha=0.95, Navigational Simplicity alpha=0.80, and comprehensibility alpha=0.84), indicating that the variables within each of these dimensions are internally consistent. For the usability outcomes of ability to find information, mean time to find information, and ease of website use scores, the dimensions page complexity and navigational simplicity were significantly related to more positive outcomes ($P<.01$ for all). For the fourth usability outcome of correctly identifying which information is present in a website after studying the homepage, the summary scores of Navigational Simplicity ($P<.001$) and comprehensibility ($P=.02$) were significant.

Discussion

Summary of Evidence

This study extends prior work with the FEDM for creating eHealth apps for individuals with SMI [23,24]. These findings indicate that the novel design variables of topic areas, navigation areas, and columns influenced the usability of websites for people with schizophrenia. The study provides support that the 19 variables in the FEDM capture important design constructs that influence usability. This evaluation provides initial support for the validity of the 3 new dimensions we created for organizing these 19 variables, that of page complexity, navigation simplicity, and comprehensibility. These dimensions focus on 3 characteristics of a design that are critical to the usability of technology, and likely the associated cognitive effort required by individuals for its use.

The written text of the tested websites was at a relatively high reading level. The calculated reading levels were potentially higher than their effective levels due to a number of words that increased the reading levels but that participants likely understood, such as "schizophrenia." In addition, the introductory text on the homepage of SOAR was at the bottom of the page, after the hyperlinks to contents, and thus its reading level likely had less of an effect on the complexity of the page for navigation, compared with websites where the text came prior to the hyperlinks or was interspersed among the hyperlinks.

For the variable "reading ease," low to intermediate levels were the best. Our common finding has been that, for most variables, less complexity is the best, but only within the context of certain trade-offs, as discussed later. This finding may indicate that text that is too simple may be written using more words, which makes it less efficient and more difficult to understand. Text at a slightly more advanced level may be more efficient and consequently easier for many to understand, including people with schizophrenia. Additionally, the amount of text was associated with the ability to find information, time to find information, and ease of use ratings. The lowest quantity of text

was the best. Our prior research indicates that more words should be used when necessary to ensure comprehension and make meanings explicit (eg, for hyperlinks) [24]. Taken together, this group of findings is consistent with the conclusion that text efficiency is the critical variable, as long as understanding is not compromised by using wording that is too brief, at too high of a reading level, or too abstract and, consequently, not explicit.

The number of columns used to organize the information on a screen may not capture the full impact of this variable on usability. Some websites varied the number of columns used as one proceeded down a screen, whereas others were consistent throughout the screen. It is likely that information displays that change over a single screen or page require more cognitive effort to understand and navigate than those that are consistent. In prior work we found that some persons with SMI did not understand the convention that columns separate contents across rows in a table[23]. Thus, the use of columns, and other geometric conventions, can pose usability obstacles.

When designing an app, several trade-offs must be made between the dimensions of the FEDM. For example, there is a trade-off between information density and a page's complexity. A standard approach to design is to minimize the content on a given screen, by having short, one- or two-word-long hyperlinks, relatively few hyperlinks on a screen, minimal text on navigation pages (vs final destination pages), and no more information than can fit on a single screen (ie, scrolling is not used). This approach emphasizes "paging," going to a new page to find additional information or hyperlinks, where again the contents are minimal. This minimizes information density and a page's layout complexity. These are 2 strengths of this design, but there are also potential shortcomings with this approach, particularly for those with SMI: (1) it requires relatively more navigation; thus, the difficulty of searching through an individual page is reduced at the cost of needing to navigate and search through more pages and a more complex hierarchy; (2) the short hyperlink labels may be enigmatic, particularly for those with SMI; and (3) the reduced information on a page may actually make it harder to understand the information being provided due to the limited context, whereas more information, to an extent, may improve users' understanding of the contents. More information can have some advantages, but is not independent of quantity or its organization as our results indicate. Providing more information can also necessitate longer pages, which may require scrolling. Scrolling has negative consequences associated with it. Achieving this without scrolling is the ideal solution, but it may be far better to make users with SMI scroll than to navigate to a new page and through a more complex hierarchy [22].

Given the novelty of several of the complexity concepts (eg, navigation areas, topic areas), we assessed variations in ways to measure them to explore whether a particular metric might prove superior for predicting usability. All variations performed similarly using this dataset.

Limitations

The influence on a website's usability of users' abilities to understand the text was potentially only grossly measured by assessing a page's reading level and ease. It might also be that the hyperlink, versus nonhyperlink text, was far more understandable on some sites than others, and that this subcomponent of the text had a greater influence on usability.

The tasks did not assess the ability to understand content but rather the ability to find contents. This has implications for interpreting these findings. For example, pictures and diagrams may inhibit navigational efficiency; however, in the correct context, they may aid in content understanding. We examined the usability of navigational pages, not the effectiveness of content pages.

Given the number of variables to websites, it is important to acknowledge that the results might not be the same with a different set of websites. Also, the conclusions must be tempered because of the collinearity among several variables. Having said this, we have had findings consistent with these in studies that used far more websites [28].

We have conducted similar evaluations to what are presented here on websites that we designed from scratch. The work reported here was intended to evaluate these design principles on actual websites available to the public. The use of real websites means that the range of designs is more limited than if the websites were constructed solely to evaluate design principles. However, this provides evaluation of these design principles on real-world apps, which is important for understanding the significance of design to the usage of actual websites. In this context, it must be pointed out that the FEDM does not necessarily apply to apps where navigation routes are predefined by design, such as in software installation "wizards," or similar apps where the user does not self-navigate but simply answers questions and the navigation path is preprogrammed based on responses to questions by the designer [25], and thus, in such apps, the hierarchy can be quite deep with many branching points, and still not be complex from a user's perspective. We only tested the websites on persons who had an SMI. Consequently, we do not know the extent to which these findings are relevant to other individuals.

The participants in this study did not include younger individuals in their teens and twenties. It is possible that these findings will not be as applicable to those who are earlier in their illness, or are more familiar with technology. Preliminary analyses of our data, yet to be published, indicate that age is not as important as expertise with technology in determining which designs are more or less usable.

Conclusions

Websites may contain vast resources; some have millions of pages [34]. Research to make such apps usable by persons with SMI, and others with cognitive impairments, who may also have limited technology experience, is still in its early stages[20,22,23,30]. A recent systematic review found only 10 studies, in addition to 3 we have conducted, which assessed barriers (and potential responses) to website use by individuals with mental illness (broadly defined) [35]. They found 42 barriers and 59 potential responses. Although some specific design responses to identified barriers do exist, and the number of evidence-based responses is growing, for many barriers, only

very general guidance can be offered at present. The evidence-based guidance that has been published offers a foundation for creating more usable designs.

Given the growing use of technology-delivered health care services, a major public health challenge is to create design models for those with special cognitive needs and low technology expertise, such as persons with SMI. Our findings, coupled with the findings of others who have shown that eHealth apps designed using standard models are not usable by many with schizophrenia [22], imply that apps designed specifically to accommodate the cognitive needs of persons with SMI are needed. When this is done, these designs can be more usable, and their use is more effective and efficient than those designed using standard models. This study further highlights these conclusions. The FEDM provides a model that can be used to aid the design of eHealth apps. It has been created based on empirical findings from usability studies and developed to provide specific recommendations for creating accessible designs. The FEDM's 3 dimensions provide practical constructs and guidance. At the simplest level, the 3 dimensions of navigational simplicity, reduced page complexity, and comprehensibility offer help in designing sites that support key tasks that users must accomplish during successful eHealth apps usage. Beyond these simple goals, the research shows the variables that contribute in each dimension allowing designers to estimate the impact of such things as the number of hyperlinks or images on a given page and how they relate to page complexity. Although some research has been conducted to identify design barriers to effective use of eHealth technologies, including our own, there is a clear need for additional research on both barriers and solutions that use rigorous experimental designs to enhance validity.

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Conflicts of Interest

None declared.

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Abbreviations

FEDM: Flat Explicit Design Model
GAS: Global Assessment Scale
SMI: severe mental illness
SOAR: Schizophrenia Online Access to Resources website

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Original Paper

Perceived and Performed eHealth Literacy: Survey and Simulated Performance Test

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Abstract

Background: Electronic health (eHealth) literacy of consumers is essential in order to improve information and communication technology (ICT) use for health purposes by ordinary citizens. However, performed eHealth literacy is seldom studied. Therefore, the present study assessed perceived and performed eHealth literacy using the recent conceptualization of health literacy skills.

Objective: The aim of this paper was to examine the association between perceived and performed eHealth literacies.

Methods: In total, 82 Israeli adults participated in the study, all 50 years and older, with a mean age of 67 (SD 11). Of the participants, 60% (49/82) were women and 72% (59/82) had a post-secondary education. The participants were first surveyed and then tested in a computer simulation of health-related Internet tasks. Performed, perceived (eHealth Literacy Scale, eHEALS), and evaluated eHealth literacy were assessed, and performed eHealth literacy was also recorded and re-evaluated later. Performance was scored for successful completion of tasks, and was also assessed by two researchers for motivation, confidence, and amount of help provided.

Results: The skills of accessing, understanding, appraising, applying, and generating new information had decreasing successful completion rates. Generating new information was least correlated with other skills. Perceived and performed eHealth literacies were moderately correlated (r=.34, *P*=.01) while facets of performance (ie, digital literacy and eHealth literacy) were highly correlated (r=.82, *P*<.001). Participants low and high in performed eHealth literacy were significantly different: low performers were older and had used the Internet for less time, required more assistance, and were less confident in their conduct than high performers.

Conclusions: The moderate association between perceived and performed eHealth literacy indicates that the latter should be assessed separately. In as much, the assessment of performed eHealth literacy in clinical settings should entail the structuring of tasks as well as shortening and automatizing the assessment.

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KEYWORDS

eHealth; literacy; performance

Introduction

Electronic health (eHealth) services have been rapidly expanding in many directions [1] yet connecting end-users to newly developed information and communication technologies (ICTs) and channeling patients to new products require an assessment of compatibility. End-user's assessment is conveyed in the concept of eHealth literacy, defined as "the ability to seek, find, understand and appraise health information from electronic resources and apply such knowledge to addressing or solving a health problem" [2].

eHealth literacy includes the concept of health literacy [3,4] as well as traditional literacy and numeracy, information, media, computer, and scientific literacies, as presented in the Lily model [5]. Assessing users' eHealth literacy has the potential to both align ICT technologies to consumers' abilities to use them and empower the latter to fully participate in health-related, knowledge-based, decision-making [5]. However, eHealth literacy has been mostly assessed with the self-report eHealth Literacy Scale (eHEALS) measure developed by Norman and Skinner (2006). The eHEALS taps perceive skills [6-10] using a questionnaire, rather than the actual performance examination of eHealth literacy levels, mostly due to time and expense considerations [11]. While eHealth literacy was assessed mainly through self-reports, health literacy was assessed and found to be associated by both self-reports and performance tests (for reviews see [12-14]). Considering the advantage of employing a short measure for the assessment of eHealth literacy, information on the association between perceived and performed eHealth literacy is warranted. A related interesting question is whether eHealth literacy differs from digital literacy only in terms of content. Thus, a distinction between digital literacy and eHealth literacy skills should be examined.

Though the association between perceived and performed digital literacy has been extensively examined in several studies (for a review see [15]), few studies delved into the issue in the health context [10,11]. The most comprehensive set of studies on digital and eHealth literacy skills was carried out in the Netherlands [11,16-18]. These studies employed a taxonomy of health-related Internet skills, based on the authors' digital taxonomy, consisting of medium-related skills (eg, operating a browser and navigating the Internet) and content-related skills (locating information and making use of it). The findings were consistent in locating deficiencies in skills, mostly in accessing information and making use of it, thus limiting users' taking full advantage of the resources the Internet avails. The only study comparing perceived (eHEALS) and performed health-related Internet skills [10] found that the correlations between eHEALS and successfully completed tasks on an Internet skills performance test were weak and non-significant. These findings are somewhat surprising, considering the assumption that subjective and objective skills are theoretically related concepts different in their measurement tools; indeed, subjective and objective numeracy are highly correlated (about r=.60; [19]). As consumers gain more experience in Internet use for health purposes [20], it is possible that perceptions of skills and actual performance become more aligned, if they are measured accurately.

The current study aimed at examining the association between the eHEALS as a perceived measure of eHealth literacy and eHealth literacy performance on both digital skills and content-related health Internet skills. Health Internet skills were conceived in terms of the following recent conceptualization on health literacy [14]: (1) accessing, defined as "the ability to seek, find, and obtain health information" (similar to "locating" in van Deursen and van Dijk's typology [17]); (2) understanding, defined as "the ability to comprehend the health information that is accessed;" (3) appraising, defined as "the ability to interpret, filter, judge and evaluate;" and (4) applying, defined as "the ability to communicate and use the information to make a decision to maintain and improve health." The appraise and apply skills are similar to "making use" in van Deursen and van Dijk's typology [17]. All these components relate Web 1.0 tasks. The Web 2.0 skill of generating new information was added to the performance test [21]. Furthermore, besides examining the successful accomplishment rate on the simulated tasks, the study also explored the process of accomplishing these tasks (eg, the confidence and motivation of participants), as perceived by the researchers and the amount of assistance required to complete the simulated tasks.

The following research questions were examined in this study: (1) Is successful completion rates of a task higher for relatively simple skills such as accessing and understanding health information and lower for appraising and applying? Is generating new materials the least successful task? (2) Is there an association between perceived and performed eHealth literacy, both at the overall skill level and between the components of the skills? (3) Is there a negative association between assistance provided in the performance tasks and skill level, both perceived and performed? (4) What are the associations between performed eHealth literacy and background characteristics (eg, age, gender, education, income, perceived health, and experience with the Internet)?

Methods

A telephone survey and a face-to-face computer simulation (performance test) were conducted. The following sections describe participant recruitment, data collection, the tasks participants were asked to perform, and data analysis.

Participants

Participants were recruited by a nationally representative random-digital-dial telephone household survey of Israeli adults aged 50 years and older. Calls were placed to 1206 residential households of whom 603 agreed to be interviewed, representing a 50.00% response rate and a sampling error of 2.04%. As there were only 206 participants (34.2%, 206/603) who used the Internet for health purposes in the representative sample, the sample was augmented by an additional 236 individuals (50 years or older who used the Internet for health purposes), resulting in 442 Internet users. Interviews were conducted in Hebrew, Arabic, and Russian by professional interviewers who went through a special training session to familiarize themselves with the questionnaire's terminology. The interviewers conducted the telephone survey using computer-assisted telephone interviewing software. At the end of the survey, participants who used the Internet for health purposes were asked whether they would be willing to participate in a second phase of the study. Those who agreed (22.9%, 101/442) were asked to provide contact information.

All 101 survey participants who agreed to participate in the second stage of the study were contacted and 28 (27.7%, 28/101) agreed to take part in the simulation and its recording. An additional 54 participants were recruited in a snowball fashion, using a selective quota to reach a sample as close as possible to the representative survey sample regarding gender, age,

education, chronic medical conditions, and income, resulting in a total 82 participants who completed both the survey and the performance simulation (Table 1).

Table 1. Participant demographics in the simulation (n=82) and the representative samples (n=223).

Variable	Simulation	Representative sample
Age (years), mean (SD)	66.95 (11.62)	60.96 (8.54)
Gender (women), n (%)	49 (60%)	138 (61.9%)
Ethnicity (Jewish), n (%)	68 (83%)	201 (90.5%)
Chronic conditions, n (%)	35 (43%)	87 (39.0%)
SRH[a], mean (SD)	3.08 (0.75)	3.30 (0.76)
Education, n (%)		
Elementary to high school	21 (26%)	59 (26.5%)
Post high school	59 (72%)	162 (72.6%)
Average income and above, n (%)	36 (53%)	118 (52.9%)
Internet experience (years), mean (SD)	12.16 (6.04)	10.17 (6.41)
Perceived eHealth[b] literacy[c], mean (SD)	3.17 (0.93)	3.12 (0.82)

[a]SRH: self-rated health.

[b]eHealth: electronic health.

[c]Perceived eHealth literacy measured on a scale from 1 to 5.

Procedure

The survey took place first. Respondents to the telephone survey who agreed to be later contacted for the second phase of the study were tested in their homes. Participants who were recruited via snowball were also first contacted by telephone, followed by the survey administration and then the home test. The survey took about 30 minutes to complete whereas the performance simulation took approximately 1.5 hours to complete. The simulation was carried out on a portable computer connected to a cellular modem and was recorded by a TechSmith Morae Recorder, version 2.2. This approach controlled for quality of the hardware, software, and Internet connection, and ensured that the setting was similar for all participants. The advantage of conducting the simulation at the participant's home is that they were in a familiar location; however, the shortcoming is that they were required to use a computer that was configured differently from the device they ordinarily used, which may have affected their performance.

The telephone survey was conducted between December 2013 and March 2014. The computer simulations were carried out at the participants' homes between May 2014 and April 2015 and all participants signed an informed consent form and indicated their preferred language in the simulation. The participants who were recruited through the snowball technique responded to the telephone survey a couple of days prior to performing the face-to-face computer simulation. Participants were given a sequence of 15 assignments one at a time. Although there was a time frame allocated for each assignment, participants were not aware of it. When they hesitated or had difficulties completing tasks, the researcher helped them to complete the task and move on to the next. The researcher documented every instance that assistance was provided.

Measurements

Perceived Electronic Health Literacy

Perceived eHealth literacy was measured by the eHEALS tool [5]. The scale is comprised of 8 items on a 5-point Likert scale from 1 (strongly disagree) to 5 (strongly agree). The scale was previously translated to Hebrew [9] and in a recent confirmatory factor analysis was found to be comprised of two factors: accessing and appraising [22].

Performed Digital and Electronic Health Literacy

Performed digital and eHealth literacy were measured through the completion of 15 computerized simulation tasks. The tasks were adapted from previous work [10,16-18,23,24] to the local context by conducting qualitative interviews and observations (eg, once a task was developed, it was run on 10 participants to assess acceptability, comprehension of instruction, and completion time). The tasks assessed digital skills and the health literacy skills used in Sorensen's [14] typology of health literacy including accessing, understanding, appraising, applying, and generating information (see Multimedia Appendix 1 for the specific tasks and Multimedia Appendix 2 for the coding scheme of the tasks by skill type, specifying digital skills and eHealth literacy skills [11,25]). Only one task was allotted to the generating skills, as few people in this age group reported engaging in Web 2.0 activities in our focus groups, in the current survey, and in other surveys conducted at the time adjacent to the planning of the simulation [26]. A time frame was allocated to each task (Multimedia Appendix 1). Tasks were registered as "completed independently" or "not completed" by the researcher during their administration and upon reviewing the recorded performance. A second evaluation of recorded performance was conducted by a different researcher, and in cases of disagreement, a third researcher overruled. The time

needed to perform the tasks was registered both by the researcher and by the recording software.

Researcher's Observations

A researcher performed a detailed and an overall observational judgment on each participant's performance. The observational judgments pertained to the participants' motivation to carry out the tasks, confidence, and proficiency level. All observational evaluations ranged from 1 (poor) to 5 (good). The observational evaluations were carried out both immediately after the completion of the tasks and later on the recorded performance. Two such observational evaluations were carried out on each performance, and in cases of disagreement a third observational evaluation took place.

Assistance Evaluation

Once the time limit for task completion elapsed or a participant said she/he was about to give up on the task, participants were offered assistance. The researchers evaluated the amount of assistance given to participants and the assistance was summed across digital aspects (ie, medium-related, van Deursen and van Dijk's typology, range 0 to 29), and health aspects (ie, content-related in terms of van Deursen and van Dijk's taxonomy, range 0 to 16).

Background Variables

Demographic and background variables related to health and Internet use (eg, age, gender, education, income, perceived health, and experience with the Internet) were documented as part of the survey.

Data Analysis

First, the data for basic descriptive statistics for the key variables of background information, perceived and performed eHealth literacy was analyzed. Second, a series of bivariate tests were conducted to assess the association between the key variables of perceived and performed eHealth literacy and also with assistance provided. The participants were then divided into two groups, based on their performed eHealth literacy, and their scores on perceived eHealth literacy, amount of assistance provided, evaluated performance, and background characteristics compared using the analysis of variance (ANOVA) procedure. All analyses were carried out using SPSS Statistics, version 23.0 [27].

Results

Characteristics of Participants

Characteristics of the simulation sample and the survey representative sample are presented in Table 1. The simulation sample was 60% (49/82) women, with a mean age of 66.95 (SD 11.62), and 83% (68/82) Jewish. About half of the participants reported chronic medical conditions, 72% (59/82) had post secondary education, and 53% (36/82) described their income as average and above. Participants' average length of time using the Internet was 12.2 years and they perceived their eHealth literacy level as moderate with mean of 3.17 (SD 0.93) on a 1 to 5 scale. Table 1 also presents the data on the characteristics of Internet users for health purposes from the representative sample. It can be seen that the simulation participants were older, less of Jewish ethnicity, reported similar income, and had more years of experience using the Internet, the latter possibly reflecting self-selection of participants more experienced and skilled in using the Internet.

Performed Electronic Health Literacy and Its Association With Demographic Attributes

Performance in the 15 tasks comprising the simulation was grouped according to skill type (digital literacy, accessing, understanding, evaluating, applying, and generating eHealth information). The descriptive statistics on performance and success rate in completing each skill type and the descriptive statistics for perceived eHealth literacy are shown in Table 2. It can be seen that the simpler the skill type, the higher the successful completion rate was. For example, 83% (10/12) of tasks involving accessing were completed successfully, as opposed to only 58% (2.3/4) of the tasks involving applying information. In addition, success rates in digital literacy are similar to success rates in the eHealth skills of accessing and understanding but higher than the other skills.

In order to examine the concurrent validity of performed eHealth literacy, participants were assigned to two groups based on their mean score obtained on the performed eHealth literacy scale, similar to an analysis carried out by van der Vaart et al [10]. We used the median score of the scale in this sample (median 28 on a range of 0 to 35) to create two groups: those with a high mean performed eHealth literacy score (median 29 or greater); and those with a low mean performed eHealth literacy score (median less than 29). The demographic comparison between the two groups is presented in Table 3. Individuals in the low performance group had a mean age of 71.68 (SD 11.84), significantly older than in the high performing group, who had a mean age of 61.69 (SD 8.89) ($F_{1,74}$=16.96, P<.001, eta square=0.186). In addition, they also had significantly fewer years of experience using the Internet with mean values of 10.54 (SD 5.81) and 14.13 (SD 6.14), respectively ($F_{1,74}$=7.23, P=.009, eta square=0.085). They reported marginally significantly less education ($F_{1,80}$ = 3.29, P=.074, eta square=0.039) and perceived themselves as marginally significantly less healthy than the high eHealth performing group with mean values of 2.95 (SD 0.93) and 3.36 (SD 0.89), respectively ($F_{1,74}$=2.99, P=.088, eta square=0.036). There were no significant differences between the high and low eHealth literacy performance groups in perceived income ($F_{1,66}$=1.25, P=.268, eta square=0.019) and the number of chronic medical conditions ($F_{1,66}$ = 0.22, P=.642, eta square=0.003), nor were there differences in the gender distribution between the groups, for example 43% (17/40) men and 58% (23/40) women in the high performing group (χ^2_1=0.2, P=.684).

Table 2. Descriptive statistics of tasks by skill type (n=82).

	Range	Mean (SD)	Success rate[a], %
Performed digital skills	0-35	29.70 (6.43)	71
Performed eHealth[b] literacy			
Access	0-12	9.98 (2.69)	83
Understand	0-10	7.34 (3.12)	73
Appraise	0-8	5.05 (2.54)	63
Apply	0-4	2.28 (1.51)	57
Generate	0-1	0.46 (0.50)	46
Overall	0-35	25.11 (9.58)	71
Perceived eHealth literacy			
Access	1-5	3.36 (0.95)	N/A
Appraise	1-5	2.83 (0.94)	N/A
Overall	1-5	3.03 (0.85)	N/A

[a]Success rate determined using the mean value.

[b]eHealth: electronic health.

Table 3. Scores for the low (n=40) and high performed (n=42) eHealth literacy groups in background attributes, perceived electronic health literacy, assistance, and evaluations by observers.

Variable	Low, mean (SD)	High, mean (SD)	F/χ^2_1	*P* value	Eta square
Background attributes					
Age	71.68 (11.84)	61.69 (8.89)	16.96	<.001	0.186
Gender, n (%) women	26 (62)	23 (58)	0.17	.684	0.002
Education[a]	3.93 (1.64)	4.50 (1.16)	3.29	.074	0.039
Income[b]	2.55 (1.18)	2.89 (1.33)	1.25	.268	0.019
Perceived health[c]	3.00 (0.91)	3.35 (0.92)	2.99	.088	0.036
Chronic conditions, n	1.57 (0.70)	1.50 (0.68)	0.22	.642	0.003
Internet use, years	10.54 (5.81)	14.13 (6.14)	7.23	.009	0.085
eHealth[d] literacy					
Perceived eHealth literacy	2.67 (0.70)	3.39 (0.85)	16.59	<.001	0.174
Assistance in digital skills[e]	8.84 (6.21)	3. 98 (4.90)	15.41	<.001	0.161
Assist health content[f]	3.79 (3.16)	3.55 (4.35)	0.08	.779	0.001
Evaluations[g]					
Skill	2.24 (0.79)	3.48 (1.01)	38.23	<.001	0.323
Confidence	2.62 (0.96)	3.40 (0.98)	13.24	<.001	0.142
Motivation	3.07 (0.89)	3.45 (1.01)	3.23	.076	0.039

[a]Education scored on a scale from 1 to 6.

[b]Income scored on a scale from 1 to 5.

[c]Perceived health scored on a scale from 1 to 5.

[d]eHealth: electronic health.

[e]Assistance in digital skills scored on a scale from 0 to 29.

[f]Assistance in health content scored on a scale from 0 to 16.

[g]Evaluations scored on a scale from 1 to 5.

Performed, Perceived, and Evaluated Electronic Health Literacy

Pearson correlations between overall perceived and overall performed eHealth literacy was computed, as well as correlations between the perceived eHEALS factors of accessing and appraise in both modalities (Table 4). The correlation between overall perceived and performed eHealth literacy was r=.34 (P<.01), and a similar association was found between performed digital literacy and perceived eHealth literacy (r=.31, P=.002). The correlation between the perceived access factor was significant with performed skills of accessing, understanding, appraising, and applying (r ranged from .32 to .49, P values <.05) and the least with performed skill of generating (r=.22, P=.023). The correlation between the perceived appraise factor was significant with all performed skills (r ranged from .21 to .25, P values <.05) except generating (r=.17, P=.060). Generating information also correlated the least with all other performed skills and overall performance.

Table 4. Inter-class correlations between performed and perceived tasks (n=82).

Digital skills	Inter-class correlations								
	1	2	3	4	5	6	7	8	9
Performed eHealth[a] literacy									
Access	.89[b]								
Understand	.80[b]	.88[b]							
Appraise	.69[b]	.79[b]	.93[b]						
Apply	.64[b]	.74[b]	.81[b]	.80[b]					
Generate	.49[b]	.53[b]	.58[b]	.58[b]	.68[b]				
Overall	.82[b]	.92[b]	.98[b]	.94[b]	.88[b]	.65[b]			
Perceived eHealth literacy									
Access	.34[b]	.32[b]	.39[b]	.49[b]	.36[b]	.22	.41[b]		
Appraise	.24[c]	.21[c]	.21[c]	.24[c]	.25[c]	0.17	.24[c]	.61[b]	
Overall	.31[b]	.28[c]	.31[b]	.37[b]	.33[b]	0.21	.34[b]	.84[b]	.94[b]

[a]eHealth: electronic health.

[b]Significant at .01.

[c]Significant at .05.

Participants in the low and high performed eHealth literacy groups were compared in terms of their perceived eHealth literacy score, the amount of help they received (digital and content), and the researchers' judgment on motivation, skill, and confidence (Table 3). Participants low in performed eHealth literacy were significantly lower in perceived eHealth literacy, with a mean value of 2.67 (SD 0.70) than participants in the high performed eHealth literacy group whose mean value was 3.39 (SD 0.85) ($F_{1,79}$ = 16.59, P<.001, eta square=0.174). Participants in the low performed eHealth literacy group were also granted more assistance, but only in the digital aspect of the tasks ($F_{1,79}$ = 15.41, P<.001, eta square=0.161) and not on the health content aspect ($F_{1,79}$ = 0.08, P=.779, η^2=0.001) of the tasks. Participants in the low performed eHealth literacy group were consistently evaluated as significantly lower in skill ($F_{1,79}$ = 38.23, P<.001, eta square=0.323), confidence ($F_{1,79}$ = 15.41, P<.001, eta square=0.161), and marginally significant in motivation ($F_{1,79}$ = 3.23, P=.039, eta square=0.089) by the researchers, compared with the high performing eHealth literacy group.

Provision of Assistance and Skill Level

Pearson correlations between assistance provided for digital and eHealth content tasks and perceived and performed eHealth literacy were computed. There was a positive association (r=.67, P<.001) between the two kinds of assistance, so that the more assistance one was given on digital tasks the more assistance they were also given on the eHealth content tasks. Assistance on digital aspects was negatively associated with both perceived (r=-.41, P<.001) and performed score (r=-.34, P<.001) assessments suggesting that the more one was given assistance on digital aspects of tasks the lower the performed score and the lower the perceived skill. However, assistance on eHealth content was negatively associated with perceived eHealth literacy (r=-.25, P=.023) while not significantly associated with performed eHealth literacy (r=.07, P=.529).

Discussion

Principal Findings

The current study is unique in that it examines facets of eHealth literacy using different assessments (perceived, performed, and evaluated). Perceived eHealth literacy was assed using the eHEALS tool, whereas the performed eHealth literacy

assessment was built on methodology and materials developed previously [10,21], while using the conceptualization of skills developed recently in the realm of health literacy. Evaluated eHealth literacy was carried out by two trained researchers, both during the simulation and subsequently, the latter using participants' recorded performance (recording available through the software). Finally, the study also recorded and analyzed the amount of assistance provided to participants.

The study has several important findings. First, the more complex the skill (eg, applying information as opposed to accessing information), the lower the successful completion of tasks. Successful completion rates thus created a gradient made of accessing, understanding, appraising, applying, and generating information. The skill of generating information (eg, writing in a health forum) is of special interest since the success rates in this task were very low; however, it is unclear whether the task is more cognitively taxing or merely an unfamiliar activity for people in this age group.

The second and main finding of this study is that perceived and performed eHealth literacy is significantly associated with each other, though to a moderate degree. The finding suggests that people make a reasonable, though not accurate, evaluation of their skill level. The significant association is in line with findings on perceived and performed numeracy [19], though the size of the correlation is smaller in the case of eHealth literacy and could result from murkier standards on the skill. The only other identical examination in the literature is in a study by van der Vaart et al [10], where the associations were also positive yet lower, ranging from non-significant to marginally significant. Though the tasks employed in this study were modeled after the previous works of van der Vaart et al [10,21], with necessary adjustments to the health literacy typology [14] and to the Israeli context, the association between the same construct in two assessment modes was higher in the current study. This could be attributed to several differences in context between the studies. The current study had a more restricted sample age; the higher correlation between performed and perceived eHealth literacy may be partially attributed to older adults' relatively accurate judgments of their performance level. Indeed, van Deursen [11] has found that compared to younger participants, older participants select more relevant and more reliable resources, suggesting that in our study older users' eHealth literacy judgments were more reliable. In addition, participants in our current study were not rewarded for their time and effort financially, as opposed to van der Vaart et al's study [10], and our study was conducted in the participants' homes (rather than in a higher education institution) allowing for more comfort. Finally, assistance was provided to participants who experienced difficulties in completing various tasks. These differences in context could have affected the results in unforeseen ways.

A third finding is that participants who performed low and high in performed eHealth literacy were different from each other in other aspects reported in this study (ie, assistance, motivation, confidence, perceived skills, and background characteristics), re-iterating previous findings on the digital divide in the health domain [9,11]. Interestingly, the difference between the high and low performing groups in evaluated motivation was only marginally significant and its effect size was the lowest among the evaluations of skill and confidence, suggesting that it could be possible for individuals to upgrade their skills. Indeed, Norman and Skinner [5] viewed eHealth literacy as a malleable process that evolves all the time and not as a static attribute.

Strengths and Limitations

The study possessed several strengths. First, it assessed eHealth literacy through actual performance, not relying on self-perceived assessment. It thus joins few works [10,11,21] in the field of health, possibly due to the arduous endeavor in terms of time and expenses [11]. Second, its sample is relatively big, considering the focus on performance. Third, the study augmented the perceived and performed assessment by a researcher's evaluation. These evaluations went beyond performance to address confidence and motivation, hitherto not included in previous such work. The evaluations were carried out both immediately after the performance by one researcher and on the recorded performance by a second researcher, and in cases of disagreement, by a third researcher.

The study has also several limitations. First, the sample is age-skewed to older adults, from 50 years and older. Results could be somewhat different, especially in terms of successful completion rates of task, among a heterogeneously aged sample. Second, the fact that participants were recruited on a voluntary basis implies that they might already have been more interested in using the Internet and searching for information, which could have influenced the results. In addition, the snowball recruitment of some of the participants may have contributed to the relative homogeneity of the sample (eg, overrepresentation of older participants in the simulation, compared to the survey). Third, the skill of generating was assessed with only one task and future studies will probably enlarge the assessment of this skill in view of the increased prevalence of social media, the different interactive competencies called for [21], and as emerged from the data, the gap in skill level between generating and all other skills. Indeed, generating appears to be a unique skill, even during the age of social media; the other skills measured (ie, accessing, understanding, appraising, and applying information) apply to social media just as they apply to other sources in the Internet and offline inter-personal interactions. Fourth, all the tasks in the simulation were in the participants' primary language in accordance with their preference (Hebrew, Arabic, and Russian); hence, participants were not challenged with content in a non-native language. Future studies, especially those conducted in locations with limited Internet content in a native language, could include performance section where participants are confronted with content not in their primary language. Fifth, the digital device used throughout the simulation was a laptop computer. As many people nowadays access the Internet via their mobile phones [28], where the operational skills needed are different (eg, using buttons, curser, clicking), future studies could add mobile health skills as well.

Future Advances

Performed eHealth literacy was assessed laboriously in this study: the simulation took about 1.5 hours and a similar amount of time was required to code and evaluate the performance of a single person. This duration is clearly impractical in clinical

settings. This calls for the development of a computerized, tailored test for performed eHealth literacy. The results of the present work indicate what this future tool could look like. Specifically, the moderate association between perceived and performed eHealth literacy, the high completion rates of accessing tasks concurrent with low variance, and the low completion rates in the generating task point to several attributes. First, the test needs to be short so that it can be applied in clinical settings. Hence, it could be adaptive so that performance determines the next task which saves time in measuring items an individual is likely to succeed in. Second, the test could contain a few perceived eHealth literacy items; perceptions take little time to measure and in this case are indicative of performance, at least in Web 1.0-related tasks [29]. Third, the envisioned tool could test less the skill of accessing (where the variance is low) and test more the advanced skills. Fourth, tasks will need to be more structured to allow for automatic scoring that does not rely on complex evaluation.

Conclusions

A better understanding and assessment of eHealth literacy is essential in order to improve ICT use for health purposes by ordinary citizens. Improved understanding and assessment are prerequisites for enhancing eHealth literacy, thereby empowering patients in self-management of their health. This is even more important to those needing this most, such as long-term patients and the elderly. The present study demonstrated that performed eHealth literacy could be validly and reliably measured, that it is related to both human observations of skill, motivation, confidence, provision of help, and background characteristics, on the one hand, and to self-perceived eHealth literacy, on the other hand. The next stage of developing computerized adaptive short testing tools for eHealth literacy is advocated.

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Conflicts of Interest

None declared.

Multimedia Appendix 1

Specific tasks.

[PDF File (Adobe PDF File), 1MB - humanfactors_v4i1e2_app1.pdf]

Multimedia Appendix 2

Coding scheme of performance by skill type for digital and electronic health literacy skills.

[PDF File (Adobe PDF File), 214KB - humanfactors_v4i1e2_app2.pdf]

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Abbreviations

eHEALS: eHealth Literacy Scale
eHealth: electronic health
ICT: information and communication technology

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Review

Considerations for an Access-Centered Design of the Fever Thermometer in Low-Resource Settings: A Literature Review

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Abstract

Background: The lack of adequate information about fever in low-resource settings, its unreliable self-assessment, and poor diagnostic practices may result in delayed care and under-or-overdiagnosis of diseases such as malaria. The mismatches of existing fever thermometers in the context of use imply that the diagnostic tools and connected services need to be studied further to address the challenges of fever-related illnesses and their diagnostics.

Objective: This study aims to inform a product-service system approach to design a reliable and accessible fever thermometer and connected services, as well as contribute to the identification of innovative opportunities to improve health care in low-resource settings.

Methods: To determine what factors impede febrile people seeking health care to access adequate fever diagnostics, a literature search was conducted in Google Scholar and PubMed with relevant keywords. Next, these factors were combined with a patient journey model to design a new product-service system for fever diagnostics in low-resource settings.

Results: In total, 37 articles were reviewed. The five *A*s framework was used to categorize the identified barriers. The results indicate that there is a poor distribution of reliable fever diagnostic practices among remote communities. This paper speaks to the global public health and design communities. Three complementary considerations are discussed that support the idea of a more holistic approach to the design of fever diagnostics: (1) understanding of the fever diagnostics patient journey, (2) identifying user groups of the thermometers in a specific health care system, and (3) assessing different needs and interests of the different users.

Conclusions: Access to basic, primary health care may be enhanced with better information and technology design made through the involvement of system users.

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KEYWORDS

fever diagnostics; sub-Saharan Africa; thermometer; low-resource settings; design; patient journey; product-service system

Introduction

In low-resource settings, fever-related illnesses and their diagnostics represent a particular challenge. Despite the improvements achieved through the Millennium Development Goals, more than 40% of the population of Africa, especially sub-Saharan Africa, lives in extreme poverty and suffers from high health care disparities [1]. While the disease burden of malaria, for example, is well quantified, the burden of other diseases is underappreciated. Existing literature refers to common misdiagnosis associated with a narrow vision of diseases; similarity of clinical profiles of illnesses; and lack of treatment guidelines, laboratory resources, and of adequate and complementary diagnostic tools [2-4]. Despite the successful adoption of rapid diagnostic tests, there are yet untapped opportunities to develop support tools to facilitate the distinction of often-neglected fever-related illnesses.

The fever thermometer is one of the simplest medical devices that are widely and commonly used to support almost all kinds of everyday health care in hospitals, health care centers, physicians' offices, ambulances, and laboratories worldwide [5]. The threshold of fever differs significantly between different individuals [6]. This subjective nature is related to the fact that different variables influence the assessment of body temperature, such as age, gender, ethnicity, physical exercise, ambient temperature, body site of measurement, and operator techniques [7-29]. Common temperature assessment sites are oral, axillary, ear, and rectal and it is inappropriate to compare temperature readings measured at different body sites. The monitoring of fever enables caregivers to follow the course of an illness and evaluate the ability of the immune system to fight it. In addition, for hyperthermia and a group of high-risk illnesses (eg, heart problems and diabetes), fever can indicate a severe condition for which delayed treatment is not acceptable [30]. However, in low-resource settings, thermometers are not used nor understood by everyone [31,32]. For the majority of mothers and other caregivers of young children, tactile measurements of body temperature (eg, with a hand against the forehead) is often the only resource to assess fever [33-35]. Palpation performed by mothers is seen as a useful and accurate first step in deciding if and when a child of less than 5 years of age needs to be referred to health care services [36,37]. On the other hand, there is some divergence in the literature regarding the reliability and specificity of fever self-assessment and, consequently, the value of fever thermometers for the lower level of caregivers (ie, village health teams, including parents and community health workers). In fact, self-assessment has been shown to be inaccurate and unreliable when compared with the objective standard of rectal measurement of body temperature with a thermometer [31,38-40]. Introduction of a chemical thermometer (ie, forehead temperature strips), designed to be disposable after one-time use, made temperature recording easy and safe as an alternative method for assessment of fever in low-resource settings [41]. However, the sensitivity of the chemical thermometer is inaccurate and inconsistent and produces frequent false-positive results compared to the mercury thermometer [42]. Therefore, it is not recommended for use by health care providers [24,43]. This might indicate that the fever thermometer, as it is designed, may not entirely fulfill its purpose given its existing mismatch with the context and the end users of health care systems (ie, in sub-Saharan Africa). Poor diagnostics may lead patients to be overdiagnosed or diagnosed with the wrong disease, resulting in a waste of medical resources and contributing to resistance to medication. In addition, overlooked diagnosis may lead to inadequate and unnecessary self-treatment or neglected or delayed treatment of patients, which in turn brings related risks for the patient and their communities [4,44]. Thus, the mismatches of the existing medical devices in the context of use imply that the diagnostic tools and additional health care services need to be studied further in order to address the challenges of fever-related illnesses and their diagnostics and to fulfill users' needs.

The objectives of this study are to inform a systemic (ie, design) approach to develop a reliable and accessible fever thermometer and connected services, as well as to contribute to the identification of innovative opportunities to improve health care in low-resource settings [45-47]. To address the challenge of fever diagnostics, it is of importance to comprehend the health care system and user contexts. This is achieved through a literature review to determine the factors preventing people from accessing and receiving adequate fever diagnostics and follow-up in low-resource settings. Next, these factors are looked upon from a systemic (ie, design) approach to propose complementary considerations for a product-service system approach for fever diagnostics. This could conclusively lead to maximizing the value in existing health care programs and health infrastructures and to improvements in the quality of health care services.

Methods

Search Strategy for the Literature Review

A literature review was conducted to identify the barriers to assessing body temperature in low-resource settings. In order to clarify and quantify the relationship between fever diagnostics and a health care system, Uganda was selected as a representative country of the sub-Saharan African region. Publications were retrieved from Google Scholar and PubMed using the following keywords: *fever* and *Uganda*, *barrier* and *febrile treatment*, *thermometer* and *diagnosis*, *drug shop*, *rural Uganda*, *healthcare*, *measuring body temperature*, and *misdiagnosis*. An additional keyword, *perception*, was used after retrieving the publications from the first search. Simultaneously, related articles were searched based on data extracted from citation indices. Articles were selected if they included qualitative and/or quantitative studies that identified barriers to assess the body temperature in resource-constrained environments, especially in Uganda. Articles were excluded if they only focused on specific countries in low-to-middle-income economies excluding Uganda.

Study of Barrier Categorization

The five *A*s of access to care by Penchansky and Thomas [48,49] were used to categorize the barriers identified in the searched literature. Characteristics and expectations of both health care providers and their clients were grouped into the five *A*s: accessibility, availability, acceptability, affordability, and

accommodation. This framework was selected among others for this study given its extensive use in the field of health care [48,50-53], its degree of detail, and its comprehensiveness regarding the different health care service *users*. Although the aim of this study was not to compare existing frameworks, the following description highlights the most relevant considerations for the authors' choice.

In the five *A*s framework, accessibility refers to the geographic distribution of health care facilities. Availability relates the existing quantity of resources (ie, personnel and technology) with the ones required to meet the demands of the people. In the framework of Peters et al [50], for example, these two dimensions are merged and are therefore less adequate in circumstances where incomplete or unsuitable health care facilities are located nearby health care seekers. Affordability relates the direct and indirect charges related to health care services to the ability and willingness of health care seekers to pay them. Acceptability refers to the inherent characteristics of the system in place regarding genre, ethnicity, and social class, for example, and is often susceptible to mutual social and cultural appraisals. Finally, accommodation is determined by the extent to which the offered services are adjusted to match the client's access capacity (eg, hours of operation and people's ability to receive treatment without prior appointments) [48]. This aspect, in particular, points toward an interesting service design component and the consideration that systems can purposefully be designed to adjust to the lifestyle of health care seekers that other frameworks do not include.

The two latter aspects are often merged into one dimension. In Prahalad's innovations in the bottom of the pyramid [53], these two aspects combined are renamed *awareness* of providers. In Peters et al [50], acceptability is only described from health provider's perspective. The 4 *As* framework of the World Health Organization [5] is focused on medical equipment. Accommodation and acceptability are described as technical *appropriateness* to context. In McIntyre et al [51] and in Grimes [52], access barriers to health care in low- and middle-income countries are categorized into only three dimensions: acceptability, affordability, and availability [51]. Accessibility and availability are merged and defined as "being at the right place, at the right time." Accommodation and acceptability are seen as a corresponding dimension between a participant's expectations and the services provided.

Results

Overview

A total of 37 articles were included and reviewed. These include 25 studies that relate to treatment of febrile illnesses, of which seven address fever diagnostics and three address health care services in Uganda. Also included in the literature were four studies that looked at medical devices in low-resource settings and two studies that addressed more generally the barriers to accessing health care in low-resource settings. We identified 11 main barriers to accessing and receiving adequate fever diagnostics that were divided into the five categories (see Table 1) [3,4,31,33,40,44,54-63]. They will be discussed in detail in the following sections.

Accessibility of Health Care Services in Uganda

The difficulty and delay in accessing treatment of febrile illnesses is attributed to a large extent to the physical distance between health care providers and health care seekers. The physical distance to health care providers influences people's choices of health care providers when seeking care for febrile illnesses. This mostly affects people living in rural areas in Uganda, where the majority of the population (84.4%) lives [54]. According to the definition from the Ugandan government, the health care sector can be divided into the public sector and private sector [56] (see Textboxes 1 and 2).

Table 1. Barriers to access of diagnostics of fever-related illness.

Category	Barrier	Reference
Accessibility	Distribution of, and distance to, health care providers	[4,44,54-56]
Availability	Incomplete medical infrastructure	[3,40,56-60]
	Failure to utilize medical equipment	[59,60]
	Lack of health care professionals	[61]
	Lack of training for health care professionals	[3,55,60,62]
	Poor supervision by local authorities	[54,56]
Acceptability	Cultural beliefs and influence from community members	[58]
Accommodation	Mismatch between available information and awareness, knowledge, and education needs	[57,63]
	Lack of relevant and complete diagnostic information	[31,33]
Affordability	Cost of treatment	[54-57]
	Cost of transport to health care provider	[56,57]

Textbox 1. Types of public health care providers in Uganda [56].

Public health care providers:

- National referral hospital (ie, advanced tertiary care)
- Regional referral hospital (ie, specialists services)
- General hospital (ie, general hospital care, secondary services, laboratory, and x-ray)
- Health center IV (ie, outpatients, wards, theater, laboratory, and blood transfusion)
- Health center III (ie, outpatient services, maternity, general ward, and laboratory)
- Health center II (ie, outpatient services only)
- Health center I (ie, outpost for outreach services)

Textbox 2. Types of private health care providers in Uganda [56].

Private nonprofit health care providers:

- Nongovernmental facilities

Private for-profit health care providers:

- Medical clinics
- Dental clinics
- Drug shops
- Maternity homes

Private informal health care providers:

- General merchandise shops
- Traditional healers
- Mobile health care providers
- Unqualified persons

The private health sector is categorized into private for-profit, private nonprofit, and informal providers. Drug shops categorized into private for-profit account for the largest proportion of all facilities in the private health sector in all districts except Kampala, where more clinics than drug shops can be found [56]. Public facilities, which include hospitals and health centers (II, III, and IV), make up 54.8% of the total Ugandan health care facilities, while 28.5% are private for-profit and 16.7% are private nonprofit [64] (see Figure 1). However, the distribution of health care facilities in rural areas is significantly different from the distribution of health care facilities in Uganda as a whole. While more than half of all health care providers in Uganda are from the public sector, the public sector accounts for only 18.6% in rural districts where the majority of health care providers are private for-profit (74.5%) (see Figure 1).

Regarding the distribution of care sought by people with febrile symptoms, 31.1% of people sought care from a health care provider. Among health providers, excluding traditional healers, the main providers visited by people with febrile symptoms were private for-profit providers (51.8%), followed by public sector (39.8%) and private nonprofit providers (8%) (see Figure 2). Despite other treatment options being available in the community, the majority of people suffering from febrile symptoms treated their febrile illnesses by themselves at home (43.5%) or took no action (22.4%) [56]. The main reason given for visiting private providers instead of public health care providers is the convenience of location (ie, proximity) (see Figure 3). This may be explained by the fact that the great majority of health care facilities are private for-profit (74.5%) in rural Ugandan districts (see Figure 1). The distance to health care facilities also impacts the timing of care. Delay of treatment for fever occurred less among the people who perceived the distance between their home and the health care provider to be less than 1 km compared to those who perceived it to be more than 1 km [44].

Figure 1. Share of health care facilities in all of Uganda (total) and in rural Uganda [56].

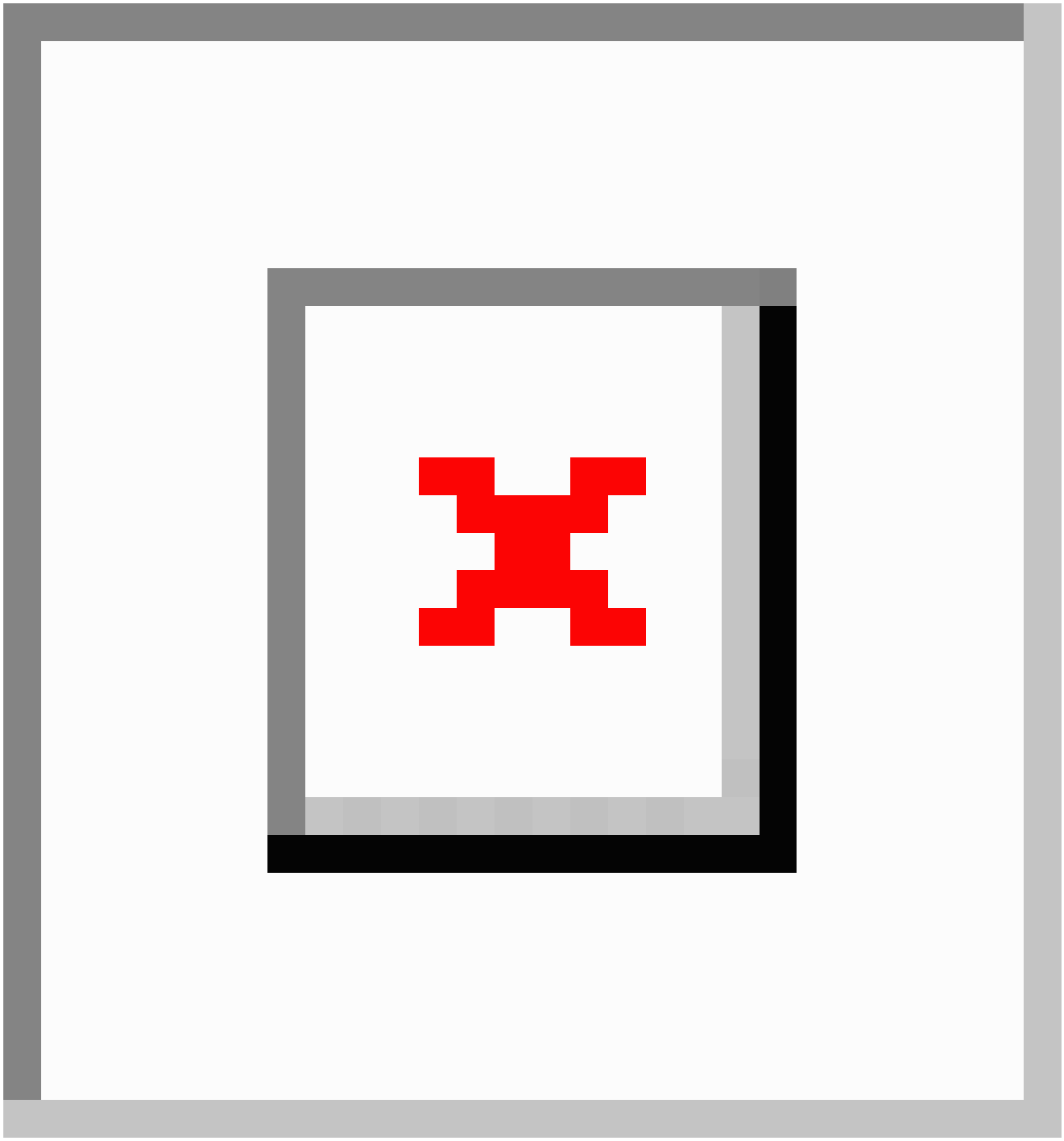


Figure 2. Distribution of health care received by people with febrile symptoms [56].

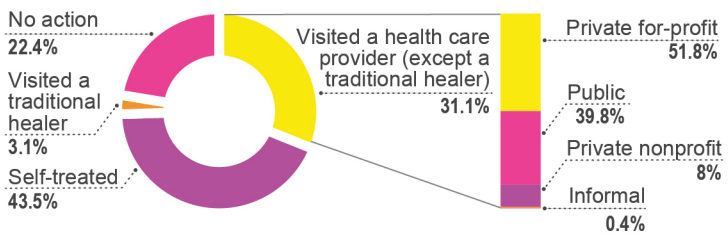
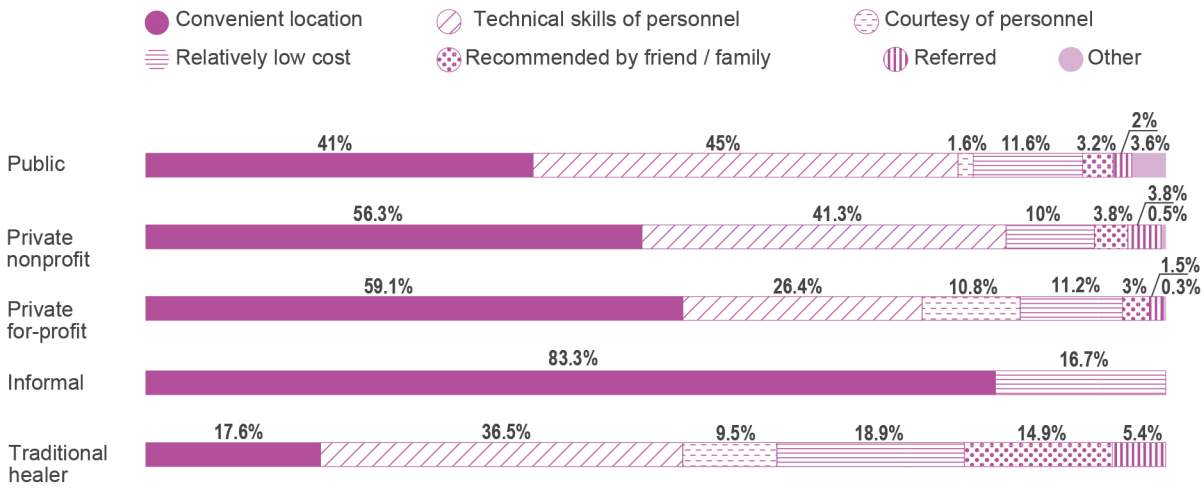


Figure 3. Reasons why caretakers chose specific health care providers for fever treatment [56].



Availability of Professional and Well-Resourced Services

Among the health care facilities, public facilities are perceived as having qualified and experienced health care providers by people seeking care for fever [55]. However, the government health sector is underresourced and understaffed and primary diagnostic equipment is frequently missing (see Figure 4). Compared to the private sector, where more than half of the private for-profit and nonprofit facilities are equipped with thermometers, public facilities were the worse equipped with thermometers among the formal health care facilities [56]. Furthermore, even though thermometers are available, a chronic understaffing problem in the public sector leads clinicians to routinely and inadequately assess patients' body temperature by placing a hand on their foreheads, versus utilizing thermometers, when it is peak time in the waiting room [57].

Regarding staff qualification, the private sector is invariably inferior to the public sector [3]. However, even though health care providers in the public sector were perceived as experienced, only 3 in 10 public health care professionals were able to diagnose 4 out of 5 very common illnesses (ie, malaria with anemia, acute diarrhea with severe dehydration, pneumonia, pulmonary tuberculosis, and diabetes mellitus). Among the most common, malaria with anemia was the least likely to be diagnosed correctly and only 9% of the cases were recommended the appropriate treatment [3]. Fever is more likely to be assessed by tactile measurement (ie, placing the palm or back of the hand on the forehead) than with a fever thermometer and the changes of fever over time are observed by patients or parents of child patients [31]. The absence of a fever thermometer at home hampers and delays the treatment of fever. Clinicians and nurses claim that people should have thermometers ready at home to quickly and objectively assess body temperature and be able to deduce how serious an illness may be [57]. Due to medical resource constrains in the public sector, the private for-profit facilities perform a key role in the supply of medicine. The main providers (83%), where febrile patients purchase medicine, are the private for-profit facilities and the second-major provider (10%) is the informal sector (see Figure 5) [56]. Informal providers are numerous, nearby, and more consumer oriented [65]. However, the private sector's knowledge and quality of treatment at drug shops are recognizably limited [4]. While personnel with good technical skills was the main reason given for choosing public providers (45%), 26.4% of people perceived that the private for-profit providers had personnel with good technical skills (see Figure 3). In addition, even though 85% of the public health care facilities were inspected by local authorities monthly or quarterly, only half of the private for-profit facilities (54%) were inspected monthly or quarterly and 36% were never inspected at all [56].

Figure 4. Availability of thermometers at different health care provider facilities [56].

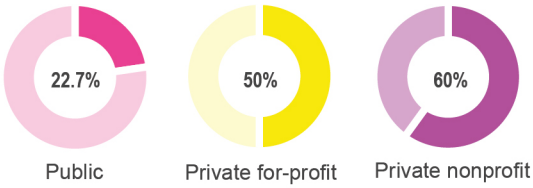
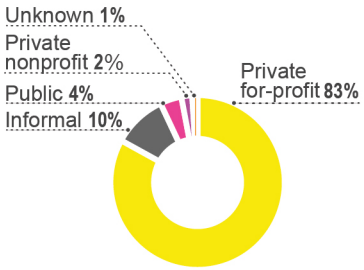


Figure 5. The distribution of health care facilities where medicine was purchased [56].



Acceptability of Existing Health Care Services

Besides the associated cultural beliefs regarding the subjectivity of fever itself, there are relevant acceptability aspects about how and when fever is measured among community social networks. Social networks and common practices in the communities play an important role in fever-related health care decisions. Nsungwa-Sabiiti et al [66] describe how mothers are often reluctant to seek professional health care for their ill children at an early stage [58]. Feeling unwell with any kind of fever symptom is perceived as the most important disease in their community and is believed to be caused by something you ate or drank, environmental conditions, mosquitoes, and being a symptom of other diseases. There was consensus among the members of the community that care for febrile symptoms is to be sought from the informal sector before visiting the formal sector. The health care facilities are visited as a definitive way to care for febrile people after treatment with herbs and medicine purchased from the shops [67].

Accommodation of Technologies and Services to Existing Needs

Technologies and services do not accommodate the needs, expectations, or habits of health care seekers in several ways. First, the reading of the thermometer, as it is designed, is often not understood. This may be due to the multiplicity of different meanings people associate with fever or a febrile condition. In a setting where there is little or poor information available about the required follow-up of fever with regard to required dosages of medication and risks associated with diseases, the diagnostic information provided by the thermometer does not match the semantics associated with fever [57,66]. Second, this is not limited to households. The lack of knowledge in health care services to manage nonmalaria febrile illnesses results in health workers treating patients that have a negative malaria test result with antimalarial medicines [63]. As the patients expect to receive care for their symptoms, it is essential to provide appropriate management and information of febrile symptoms to those people who do not have a malaria infection. Finally, another limitation related to the diagnostic information provided by most fever thermometers is related to fever kinetics. The reporting of patients' fever kinetics (ie, the progress of fever over time versus a punctual measurement) is essential for an adequate and accurate diagnosis. Since people often seek health care with delay, it is important for health care providers to know if the progress of fever based on memory is reliable [31]. Despite the accuracy of digital fever thermometers, since normal body temperature has individual variations, patients and parents need to know the patients' baseline morning temperature to be able to judge an increased temperature as fever [7].

Affordability

While the cost of treatment was a relatively minor determinant among a range of barriers to assess primary fever diagnosis compared to accessibility, the financial challenge is still one of the critical barriers and a concern for people seeking treatment for fever. The socioeconomic status of households has an effect on the timing of care seeking. Figure 6 shows the percentage of febrile children in Uganda that effectively sought timely care in different socioeconomic quintiles. Children with the lowest socioeconomic status were more likely to receive delayed care [44]. Although public health care services in Uganda are meant to be free, most patients have to pay for the treatment they receive and for the costs implied in transportation. Konde-Lule et al [56] demonstrated that in the public sector, half of the clients were charged for health services and paid an average of UGX 5381 (about €1.4). As expected, the majority of clients seeking care in private for-profit (86.5%) and nonprofit (84%) facilities were charged. The lowest average amount for health services is in private for-profit facilities where they cost UGX 4626 (about €1.2); the highest average amount for health services is in private nonprofit facilities where they cost UGX 7647 (about €2). The average monthly income of employees in 2013 was UGX 491,000 (about €128). Figure 7 illustrates the share of household expenditure by item group; health care expenditure accounts for 5% of total household expenditures [64].

Figure 6. Percentage of febrile children taken outside of their home for care within 24 hours (not delayed) versus after 24 hours (delayed) in different socioeconomic quintiles [44].

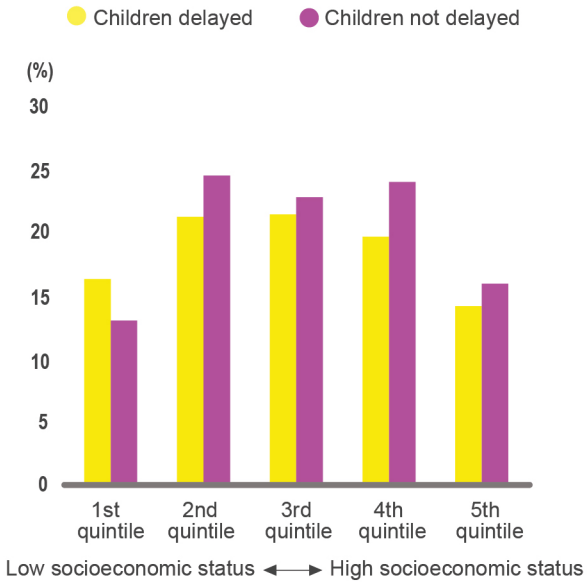
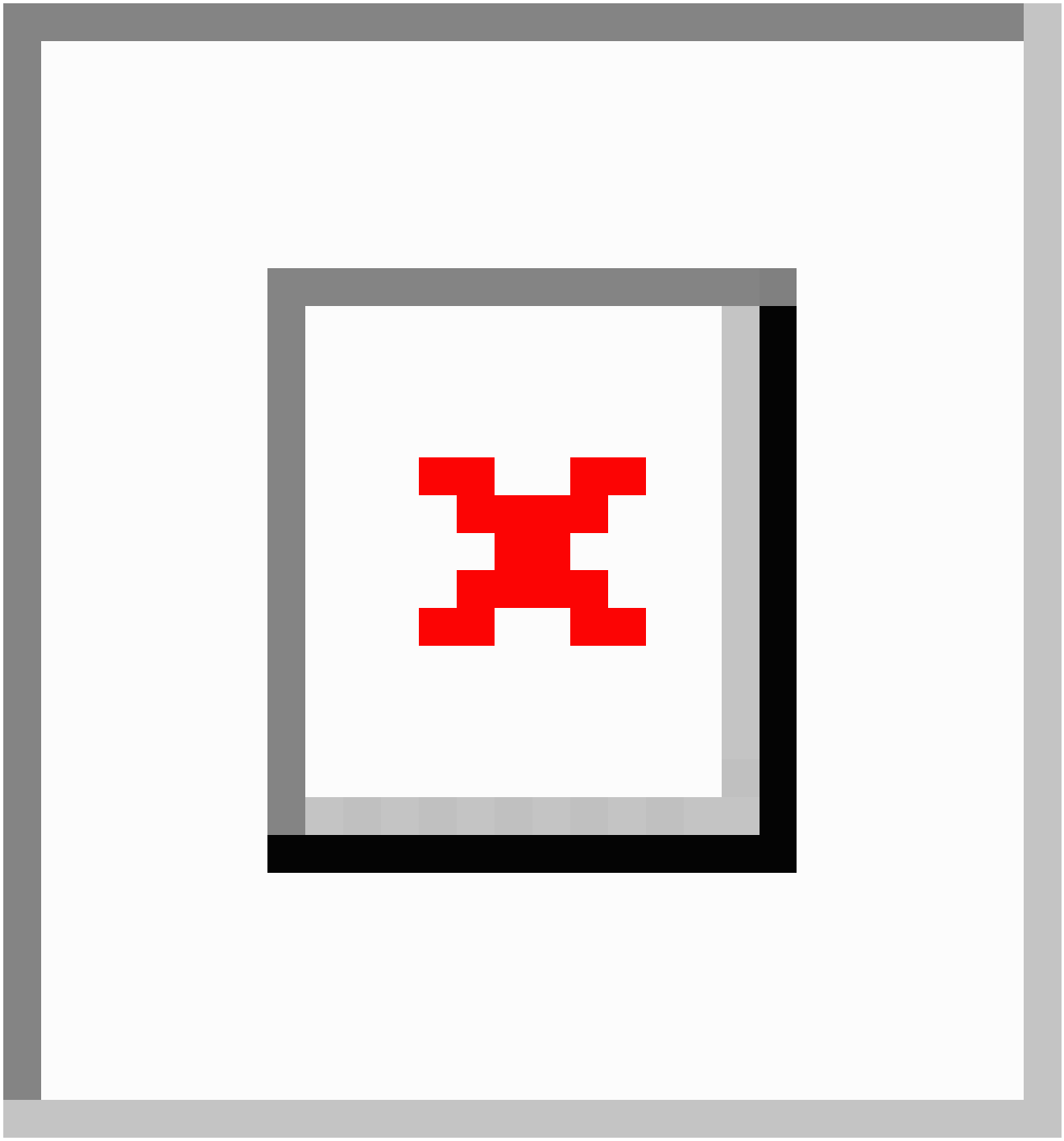


Figure 7. Share of household expenditure by item group (% of total expenditure) [64].



Discussion

Considerations for a Fever Diagnostics Product-Service System Design

Overview

This study is aimed at obtaining a comprehensive picture of the context surrounding patients and people seeking fever diagnostics in low-resource settings in order to inform a product-service system design approach and biomedical engineering approaches to fever diagnostics [68]. The field of medical devices and diagnostics design for low-resource settings is recent but broad. Literature about the field comes from contributing disciplines such as management science, technology transfer, industrial design, user-centered design, ergonomics, and biomedical engineering. Literature frequently refers to the current misfit of medical devices in the context of use [69-74] and models or frameworks for improved design processes [75-77]. In this paper, the authors argue that a systemic (design) approach may be more suitable to address fever diagnostics in low-resource settings by creating meaning and value to end users through not only new technologies, but also new services or processes. A user-centered design perspective, where user tasks are closely observed, runs the potential risk of placing a single aspect of use and interaction in isolation [78,79] because most people within a health care system are involved with two or more primary participants: consumers, patients, clinicians, and technicians. Health care is a very large social system and

involves many participants and roles in addressing the recovery of individual and social health. Therefore, a product-service system approach [80,81] to fever diagnostics could contribute to the enhancement of the quality of health services. This is true because it considers the physical and sociocultural environments; the financial, organizational, and scientific concerns of the health care systems; resource availability; users' level of knowledge; and the industrial and economic realm of medical devices [60,82,83].

The authors propose three complementary considerations for product-service systems design of fever diagnostics: (1) the fever diagnostic patient journey to clarify the situations in which health seekers encounter barriers, (2) the different users of a fever thermometer across that journey, and (3) the different capabilities and needs of the users.

In the next sections, we will discuss these considerations in connection to the barriers to fever diagnostics as identified in the literature review.

Understanding the Fever Diagnostics Journey

A patient's (and health professional's) journey helps to identify and understand the context in which interactions between thermometers and users occur and to identify when patients experience difficulties in accessing fever diagnostics in the health care system. Since body temperatures can be taken in different situations (eg, health clinic, hospital, and household), it is important to obtain a contextual picture of users and their user tasks. In addition, it widens the scope of analysis of fever diagnostics and contributes to the identification of innovation opportunities not only by means of products (ie, fever thermometer), but also services and programs. The authors categorized the barriers into a fever diagnostics journey model (see Table 2). The model was created by combining Table 1 (barriers to access) with the patient journey model proposed by Manchaiah and Stephens [84], focusing on the three phases related to access, namely *awareness*, *movement*, and *diagnostics*. Table 2 relates the barriers identified in the literature with a set of steps in fever diagnostics. In the table, some barriers are associated with awareness, others with movement or decision-making, and others with the diagnostic itself. Awareness barriers are related to the perceptions and habits regarding fever as well as the lack of appropriate information about the symptoms, why fever should be measured, what should be measured, and how and when to measure fever. In regard to the decision of whether to look for treatment, barriers include the difficulty of access to health care services and their associated costs. Finally, diagnostic barriers are related to the infrastructure available in terms of technology and human resources. This division of barriers provides a clear picture of how fever diagnostics can be addressed in a holistic way to identify opportunities for innovation that focus beyond the fever thermometer. This includes the design of meaningful displays and information, easy algorithms for decision-making, and connected services.

Table 2. Barriers for assessing body temperature throughout the fever diagnostics journey.

Category	Phases and their associated barriers		
	Awareness	Movement	Diagnostics
Acceptability	Cultural beliefs and influence from community members	N/A[a]	N/A
Accessibility	Mismatch between available information and awareness, knowledge, and education needs	Distribution of, and distance to, health care providers	N/A
Availability	N/A	N/A	Incomplete medical infrastructure Failure to utilize medical equipment Lack of health care professionals Lack of training of health care professionals Poor supervision of health care facilities by local authorities
Accommodation	N/A	Lack of relevant and complete diagnostic information	N/A
Affordability	N/A	Cost of treatment Cost of transport	Cost of treatment

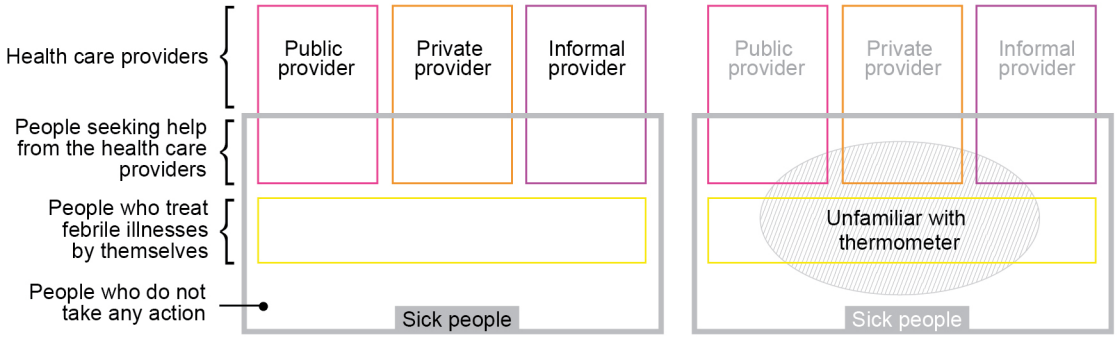
[a]N/A: not applicable.

User Groups of Fever Thermometers

Figure 8 provides a map of thermometer user groups involved in fever diagnostics in Uganda. In the diagram, there are two general types of roles: health care providers and sick people with fever symptoms. Three different types of health care providers are identified: public, private, and informal facilities. There are three types of sick people: those who seek help from the health care providers, those who are aware of the necessity to enhance their health condition and treat febrile illnesses by themselves, and people who do not take any action. In addition, it could be assumed that there are two types of febrile patients: those who are familiar with using thermometers and those who are unfamiliar. The analysis in this study reveals that each group of users deals with different barriers regarding access to temperature assessment. This is attributed to the fact that there are various levels of knowledge, awareness, experience in diagnosis, socioeconomic status, geographic restrictions, and

equipment available. This suggests that there is not "one-thermometer-fits-all" solution to the challenges faced in the health care context of low-resource settings like those in Uganda.

Figure 8. User groups of thermometers (left) and people who are unfamiliar with thermometers (right). Image is not proportional.



The Different Purposes of a Thermometer

Fever diagnostics plays an important role in monitoring fever-related illnesses as well as in reverse diagnostics (ie, to confirm or discard the suspicion of disease). The availability of diagnostic confirmation at home may increase willingness to receive treatment for fever from formal health care providers and reduce the morbidity and mortality rate caused by the delay of care. The first decision of treatment at home or in the community is especially important within the context of a restrictive community where people feel pressure from others in their social network when seeking care for febrile symptoms. As such, a thermometer that is designed for the purpose of reverse diagnostics or confirmation of fever in a household should have different properties than a thermometer designed for a clinical environment. For instance, the common digital fever thermometer may be expected to be easy to use, but in fact it requires literacy and a technological mental model to be used. In a clinical setting, hygiene, complementarity with other medical devices, size, and power lifetime are very important requirements [85-87]. However, whereas the focus given to accuracy and speed might make sense in a clinical environment, it does not make sense in a household environment since, in this case, the outcome-related decision is not clinical but, simply put, is represented by the question "Should I consult professional health care?" In the latter case, an easy interface design can help users distinguish severe from nonsevere illnesses by providing the states of body temperature with variations of visual interaction (eg, color and symbolic value) and auditory feedback rather than reporting a numeric value. This can be of importance since 43.5% of people who suffer from febrile symptoms treat their febrile illnesses by themselves at home. It is not desirable for all of these people to go to the doctor at the health centers and hospitals, since the workload at the health facilities is already too high [61]. In low-resource settings, costs are always crucial. As such, purchasing a thermometer instead of performing palpation, which is free, might be a barrier. However, a reliable fever indication by a thermometer could prevent overuse of medicines and unnecessary treatments and consequently reduce health care costs for the national health care system as well as for the patients themselves.

Conclusions

This study presents an outline of the barriers of access to fever diagnostics in low-resource settings. This study also discusses an approach that may lead to an improved fever thermometer and help to reveal opportunities for innovative, complementary, and holistic initiatives to improve diagnostics of fever-related illnesses. On basis of the reviewed literature focused on sub-Saharan Africa, three complementary considerations were proposed that potentially have an impact in how fever diagnostics are designed and implemented in low-resource health care systems. Firstly, the fever diagnostics journey shows the involvement of people in the different phases of diagnostics, from awareness to monitoring and follow-up. Secondly, within the same health care system, there are different users of a fever thermometer for whom the conditions of access to fever diagnostics also differ. And thirdly, these different users have different needs regarding the information that is offered. The health care system in Uganda, as in other sub-Saharan countries, is greatly divided between public and private providers, and it is clear that the choices available for communities in low-resource settings are limited. In order to improve the overall access to fever diagnostics in these settings it is important to look into the specific and potential roles and needs that the different *users* may have. Needs related to fever diagnostics may include access to information about fever, information about its meaning and that of other illnesses, and clinical guidelines for handling and follow-up through appropriate channels. They may also include the need for appropriate thermometers and decision-making support. The involvement of health care professionals at all levels, community health workers, patients, and drug shop owners in a product-service system design approach may contribute to a more inclusive and holistic tackling of fever diagnostics.

The outcomes of this research are currently being used as direct input for the development of a new context-based product-service system for fever diagnostics in East Africa.

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Conflicts of Interest

None declared.

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Abbreviations

N/A: not applicable

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