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Original Papers

<u>Original Paper</u>

Enhancing the Usability of an Optical Reader System to Support Point-of-Care Rapid Diagnostic Testing: An Iterative Design Approach

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Abstract

Background: In today's health care environment, increasing costs and inadequate medical resources have created a worldwide need for more affordable diagnostic tools that are also portable, fast, and easy to use. To address this issue, numerous research and commercial efforts have focused on developing rapid diagnostic technologies; however, the efficacy of existing systems has been hindered by usability problems or high production costs, making them infeasible for deployment in at-home, point-of-care (POC), or resource-limited settings.

Objective: The aim of this study was to create a low-cost optical reader system that integrates with any smart device and accepts any type of rapid diagnostic test strip to provide fast and accurate data collection, sample analysis, and diagnostic result reporting.

Methods: An iterative design methodology was employed by a multidisciplinary research team to engineer three versions of a portable diagnostic testing device that were evaluated for usability and overall user receptivity.

Results: Repeated design critiques and usability studies identified a number of system requirements and considerations (eg, software compatibility, biomatter contamination, and physical footprint) that we worked to incrementally incorporate into successive system variants. Our final design phase culminated in the development of Tidbit, a reader that is compatible with any Wi-Fi-enabled device and test strip format. The Tidbit includes various features that support intuitive operation, including a straightforward test strip insertion point, external indicator lights, concealed electronic components, and an asymmetric shape, which inherently signals correct device orientation. Usability testing of the Tidbit indicates high usability for potential user communities.

Conclusions: This study presents the design process, specification, and user reception of the Tidbit, an inexpensive, easy-to-use, portable optical reader for fast, accurate quantification of rapid diagnostic test results. Usability testing suggests that the reader is usable among and can benefit a wide group of potential users, including in POC contexts. Generally, the methodology of this study demonstrates the importance of testing these types of systems with potential users and exemplifies how iterative design processes can be employed by multidisciplinary research teams to produce compelling technological solutions.

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Introduction

Rising medical costs and physician shortages are increasingly straining health care systems worldwide. Additionally, many resource-limited areas lack access to the laboratory equipment, facilities, and other infrastructure necessary for diagnosing, monitoring, and treating various conditions and diseases. Rapid diagnostic tests (RDTs) delivered at the point-of-care (POC) promise to help address this growing global need for portable, inexpensive assessment techniques that can be performed in nonclinical settings.

The lateral flow assay (LFA) is a widely used RDT that uses a paper-based strip to collect biological samples (eg, blood, saliva, urine, or other fluids) and measure biomarkers of interest (eg, antibodies, pathogens, and proteins). To produce a quantitative test result, the strip must be analyzed using some type of reader, which a number of commercial and research endeavors have focused on creating. However, existing solutions tend to be bulky, expensive to manufacture, or require specialized knowledge to use, making them infeasible for deployment in many POC settings. This presents a need for a reader that is portable, affordable, and highly usable.

In addition, today's ubiquity of smart devices (eg, mobile phones and tablet computers) along with their processing power and data capture capabilities presents a broad opportunity to enhance POC medical diagnostics. The field of mobile health (mHealth) focuses on realizing this potential—for example, by developing novel systems that enable remotely located doctors or even patients themselves to use smart devices to perform clinical tests and view the results in real time. When such a test requires a sample of blood or other body fluids, a typical mHealth approach would utilize additional sensor hardware (eg, an aforementioned reader) that could analyze the sample as well as pair with a smart device to deliver the results through its interface.

The research presented in this paper focuses on the development of such hardware, presenting a novel system for biomarker-based health assessment developed by a multidisciplinary team of nutritional scientists, mechanical engineers, and human-computer interaction researchers through an iterative, usability-focused design process.

We call the final version of our device Tidbit, a stand-alone reader that can be wirelessly controlled by a smartphone or any other Wi-Fi-enabled computing system. This ability to pair with smart devices facilitates the regular installation of software updates and, in turn, more robust performance. Tidbit's integration with smart devices also boosts processing power and employs familiar interfaces that afford intuitive interactions for end users even without significant training. The system can be deployed in various contexts, including traditional clinical settings, POC diagnostics in resource-limited locations, or as part of at-home health self-monitoring.

Lateral Flow Assay Technology

As mentioned above, an LFA is essentially an instrument used for detecting the presence, absence, or specific level of some biological substance of interest, often referred to as an analyte or biomarker. Most LFAs do not require any external reagent, and a biological sample is simply applied to a testing medium (eg, a porous membrane that can transport fluid) to initiate and complete the test. An example of a well-recognized LFA is the home pregnancy test, which detects the presence of a hormone produced during pregnancy and displays a binary result. More broadly, the LFA has a wide range of applications, including micronutrient monitoring [1], as well as detection of diseases, internal organ failure [2], toxins [3], or illegal drugs [4]. The LFA's compact and portable form, low production cost, near-immediate output of results, and overall ease of use make it a popular rapid diagnostic test (RDT).

LFA technology continues to advance, for example, to provide quantitative output (ie, to measure the level of a biomarker of interest in a sample rather than a binary test result of whether or not the analyte is present). This quantification of the LFA signal is necessary for early-stage, high-sensitivity, and precise diagnostics. Traditionally, quantification has been performed in a clinic or research laboratory using benchtop research-grade instruments such as microwell plate readers [5-7]. Such instruments offer very high performance, but their large size and expensive cost make them infeasible for use in more modestly resourced application areas. Development of robust, portable, and low-cost LFA reader systems is therefore imperative to support diagnostics in POC, personal, and resource-limited settings.

The specific contributions of this study are presented in Textbox 1.

Textbox 1. Specific contributions of this study.

Specific contributions

- A series of functionality requirements and design considerations were identified as important to consider when developing mobile health (mHealth) technologies that support rapid diagnostic testing at the point of care

- A novel, fully functional device known as the Tidbit created via an iterative design process aimed at satisfying these specifications

- Findings and insights from multiple trials with users, including a better understanding of potential contexts of use, as well as compelling directions for future research

- A demonstration of how to go about employing iterative design methodology when creating novel mHealth hardware solutions, along with a discussion of the value of engaging in such processes

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Table 1. Most common customer-requested features for a lateral flow assay reader and corresponding features of the new Tidbit.

User-requested features	Corresponding design goals
Ease and convenience of operation	User can use their own smart device; automatic analysis at optimal time; results displayed in easy-to-read visual; can be powered by internal rechargeable battery or alternating current adapter
Quantitative read out	High accuracy imaging algorithm; result output in numbers with units or qualitatively
Automatic electronic documentation of results	Saves data on user's smart device; results can be sent to physician
Higher sensitivity	Highly optimized sensor; ability to incorporate fluorescence and other detection labels
Objective interpretation of results	Raw image data stored
Use of reader in quality control for strip manufacturing	Rapid test time allows high throughput; stand-alone portable reader; automatic checks for test strip validity
Handheld format and mobility	Small format reader; portable
Operational robustness	Repeatable testing process; protected data; automatic checks for result validity; data assigned a time, date, and patient ID
Physical robustness	Can be used in any lighting conditions
Audio or visual display of results	Visual display of progress and results
Connectivity to data management system	Wireless connectivity to any Wi-Fi-enabled device
Hard copy of test results	Stored results can be shared and printed
Compatibility with clinical workflow and systems	Easy incorporation into clinical systems
Stand-alone reader	Rechargeable battery power; works with any smart device
Batch/calibration data management system	Automatically builds secure database of results on smart device being used
Low price	Integrated flexibility—any cassette format can be used and any detection label can be read
Appealing design	Convenient shape and feel; trendy and professional design
Fast read out	Imaging and analysis takes only a few seconds
Wireless data transfer	Standard feature
Compatibility with unique cassette format	Standard feature
Compatibility with unique label	Ability to incorporate fluorescence and other detection labels
Available professional software	Standard feature
Compatibility with different tests and formats	Standard feature
Multiplexing	Can analyze multiplex signals

Designing Lateral Flow Assay Reader Devices

Several research and commercial endeavors have investigated smartphone-based reader systems that take advantage of the universal familiarity and ubiquity of smartphone technology. These systems typically include an accessory that attaches to a smartphone and often rely on the phone for imaging and quantifying results. Some technologies, such as the HRDR-300, feature an optomechanical smartphone attachment that reads fluorometric LFA [8], whereas others feature an optomechanical smartphone attachment that reads colorimetric LFA [1,9]. The Gene-Z [10] performs genetic analysis through a large iPod attachment and a custom microfluidic chip. Others use electrochemical sensing smartphone attachments integrated with custom microfluidic chips [11], whereas another employs an optomechanical attachment to turn the smartphone camera into a microscope for sample imaging [12]. Despite the promise of these technologies, each has limited functionality and potential applications. The systems discussed have been developed to perform with specific test formats and are only compatible with specific smartphones, resulting in limited potential applications and markets. Additionally, even with an eventual goal of being a consumer product, none of the discussed technologies have addressed the principles of universal design or usability.

Beyond accurate performance, a number of features that users consider important and should be included in an LFA reader have been identified in the literature, as shown in Table 1 [13]. Unfortunately, our review of the aforementioned systems finds that current readers do not fulfill many of these requirements, particularly those regarding simple operation, mobility, speed, and low cost.

Methods

This study addresses the above motivations and goals through an iterative design methodology. Specifically, the research consists of three stages and accompanying system variants: (1) a design critique and in-lab study with 26 participants of our

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germinal prototype NutriPhone; (2) ideation, prototyping, and in-lab evaluations with 6 participants of the second version of our system that adopted a stand-alone reader; and (3) development and in-lab evaluations with 6 participants of our refined reader system Tidbit.

Version 1: The NutriPhone System

System Specification

Our initial ideas were rooted in the design space of prior mHealth diagnostic systems, leading us to first focus on developing reader hardware that could attach directly to a smartphone. We called our first version NutriPhone, which, as shown in Figure 1, consists of a small plastic reader accessory that clips over a smartphone's camera, a custom LFA in a plastic cassette, and a smartphone app that guides the user through the testing process and delivers the diagnostic result.

To use the system, a user starts the app on an Apple iPhone or iPad and is presented with step-by-step instructions for testing the analyte of interest. This process involves a finger prick to collect a single blood droplet on the test strip, which is then inserted into the clip-on attachment. The software takes a picture of the test strip using the phone or tablet computer's camera, performs the appropriate analysis, and displays the result to the user. The entire process, including the blood draw, takes approximately 10 to 15 min.

Team Design Critique

Our first step in evaluating the design of the NutriPhone prototype was an in-house critique informed by the LFA and usability literature. We identified several areas for improvement related to software compatibility, physical specifications, and contamination.
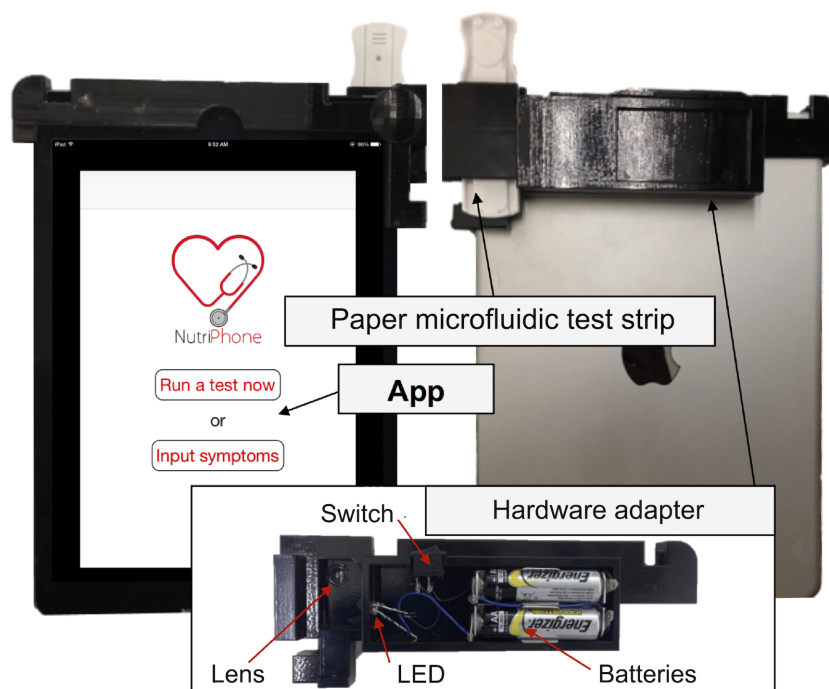
First, similar to a number of existing reader systems, our Version 1 (V1) NutriPhone is only compatible with iOS devices. However, Android is currently dominating the smartphone market with a worldwide smartphone market share of 87.6% [14], resulting in a very limited market for NutriPhone among global smartphone users. Furthermore, considering that a key POC application area is resource-limited settings where many people do not own a smartphone [15], we see a need to move toward a platform-agnostic reader.

In addition—and again similar to many existing readers—our V1 prototype will not fit over a case or cover that may be on the user's smartphone or tablet computer. A different design is therefore necessary to accommodate the various physical constraints of today's smart devices. Relatedly, the physical specifications of readers such as NutriPhone typically fit only one particular test strip cassette size and shape, requiring a multitude of apparatus to read test strips of different types from diverse manufacturers. Finally, we recognized that contamination could be a major problem with current readers, including NutriPhone, as the user is required to place body fluids directly adjacent to a smart device.

In-Lab User Studies

We next held institutional review board (IRB)-approved (Protocol ID# 1410005065) in-lab human trials with 26 participants to assess basic usability and receptivity toward NutriPhone. Participants included 20 females who were drawn from an on-campus recruiting system and were aged between 18 and 27 years. Participants had varying levels of education, ranging from high school to graduate degrees. None had previously used our device.

Figure 1. The Version 1 system consists of a plastic accessory that clips around an Apple iPhone or iPad, a disposable lateral flow assay test strip, and an app that processes images and displays results.

Each participant was given information about the function of the test strips and the general purpose of the reader. They were not given any technical background on how the reader works or how to use it, as we wanted to observe each participant figuring out the process on their own. For this study, we paired the reader with an Apple iPad 2 and had the app open and ready to use. Without instructions, each participant ran through the steps of the app and eventually placed a prerun test strip into the reader, which generated a predetermined result. The participants were informed beforehand that this result was randomly generated and did not reflect their own personal medical data. We collected observational notes, encouraged participants to think aloud, and conducted interviews where we asked questions about the device and use process. The entire process took less than 30 min. Although the size of our study sample was limited, we were able to identify a number of features and use cases that we would need to support in future design iterations.

To begin, all participants had some level of difficulty finding the power switch and test strip insertion point, causing them to flip or rotate the Apple iPad and attached device in an attempt to locate these components, suggesting that the design was unintuitive. Additionally, 6 participants expressed hesitation about inserting the test strip into the device, and we observed their uncertainty about which orientation to use to insert the strip as well as their failure to insert the strip all the way. Similarly, several participants honed in during interviews on the "confusing" nature of inserting the strip.

Our qualitative thematic analysis of the interview data surfaced more encouraging themes as well, particularly regarding the "very easy" usability of the app. One of the participants stated that s/he:

> ...liked how the text was really big and the instructions were fairly clear; it came with images. [Participant 9]

Another participant said:

> ...there are visual instructions, so for [inexperienced] people or for the elderly, it's easy to maneuver. [Participant 10]

Altogether, our internal critique and user study motivated us to preserve the positively received components of NutriPhone's app interface and focus our next design iteration on addressing the identified limitations and problems of the V1 hardware, such as compatibility, contamination, and overall usability.

Version 2: A Stand-Alone Reader

In accordance with the increasing focus on usability in product development and case studies reporting on its practical implementation [16], we undertook iterative design methods to create an updated system aimed at addressing the shortcomings of the initial version as well as the current state-of-the-art LFA reader technology.

Design Ideation

On the basis of identified problems with the current readers, user-requested features, and participant feedback from our V1

prototype, we settled on a number of crucial characteristics for the next version of our reader. These specifications allowed us to immediately make several decisions regarding the format and components of the new design.

Paramount was simple operation, which was not observed with the V1 prototype, along with mobility and low cost, which are particularly important for POC diagnostics in resource-limited settings. To allow total mobility, we wanted to create a reader that was battery-powered, and to support universal compatibility, we opted for a stand-alone reader that would not require physical attachment to the smart device controlling it. To keep the cost low, we aimed for a design with minimal materials and parts, which resulted in an approximate cost of US $60 for our prototype. Assuming that mass production could bring the cost down even further, this makes our device much less expensive than currently used lab equipment such as microplate readers, which cost thousands of dollars, and other POC readers, which are typically priced in the hundreds of dollars [10].

To increase portability and usability, we also found it important to make the new reader compatible with any smart device and incorporate the ability to read test strip cassettes of any size and LFA format (eg, multiplex and different detection labels). We also considered the eventual incorporation of different filters into the reader, which will be necessary to read different detection labels. Additionally, a static external camera was employed to overcome the technical limitations and inconsistency involved in using a smartphone camera for imaging.

Lastly, we emphasized the creation of a unique and appealing design that evokes positive affect to promote adherence and individuals' overall desire to continue long-term use of the device in an at-home health monitoring setting. To increase the reader's ease of use, we decided to make the internal components entirely enclosed so that the user's only concern would be to place a test strip into the reader without becoming distracted or overwhelmed. We therefore incorporated a pull-out tray for insertion of test strips. We also placed indicator light-emitting diodes (LEDs) on the outside of the reader to let the user know that the system was functioning correctly.

Prototyping

On the basis of these criteria and the requisite dimensions, we imagined various design forms, the first of which was an hourglass shape as shown at the top left of Figure 2. However, although the design received positive reception from our research team and other colleagues during informal feedback sessions, we soon abandoned the hourglass reader upon realizing its impracticality with regard to housing the necessary internal components. Other ideas, also shown in Figure 2, included a simple rectangular prism, a rectangular prism with a slanted front face, and a cylinder. Both rectangular prism designs offered simplicity, with the slanted face variant's asymmetry reducing the risk of users attempting to place the reader upside down. Inspired by recent devices such as the Amazon Echo [17], Mac Pro [18], and Google OnHub [19], the cylinder design added visual interest with a compact physical footprint.

Figure 2. Clockwise from top left: rendering of hourglass design, computer-aided drawing of rectangular prism, cylinder, and rectangular prism with sloped face designs. All incorporate a pull-out tray for insertion of test strips, external indicator light-emitting diodes, and a charging port.
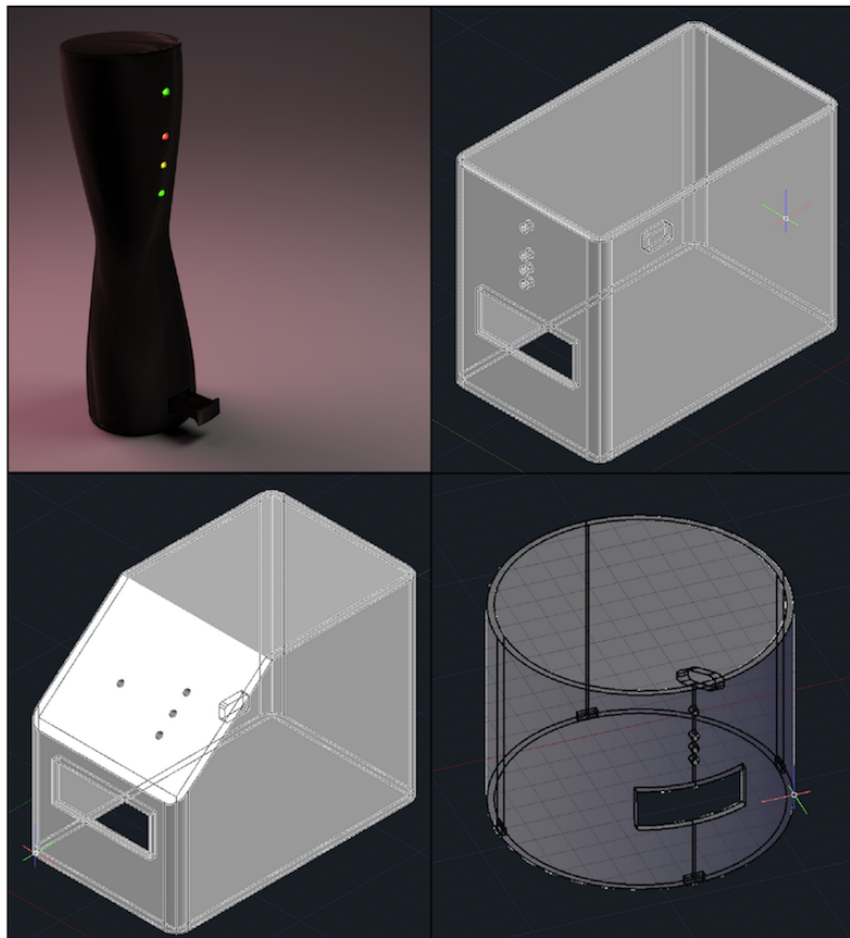

Figure 3. Rendering of the Version 2 design with Apple iPhone for size reference.

Three-dimensional printed prototypes of the designs were printed in white acrylonitrile butadiene styrene plastic and painted black. Weighing a number of trade-offs related to fabrication complexity, aesthetic appeal, and physical footprint, we ultimately settled on moving forward with the cylindrical design as rendered in Figure 3.

Figure 4 shows the high fidelity, assembled Version 2 (V2) prototype. To support testing consistency and repeatability, the case is made of opaque plastic, which isolates the internal components and LFA from variable external light. This also allows the device to be used in any lighting conditions, from bright sunlight to total darkness, without any loss of image quality. The pull-out tray also supports consistency and repeatable imaging, as the tray's design accommodates various test cassettes from diverse manufacturers, and the edges of the tray are sloped so that variably sized cassettes are held securely in the center.

For diagnostic testing, a user first powers on the reader, running it on either alternating current (AC) power or the battery. The reader then broadcasts a preconfigured encrypted wireless network, allowing direct wireless transfer of commands and image data to a smartphone, tablet computer, computer, or other Wi-Fi-enabled device. This approach also allows for additional security, as the reader can only be accessed by a device that is in close proximity and has the necessary credentials.

After the reader and device are connected, the user can begin a diagnostic test by launching the system app. Because the reader works with various types of LFA, the app first asks a user to select the desired test from a list of options. This selection loads the corresponding procedure, which varies between test type in terms of time required between steps, the region of interest for image analysis, and the calibration curve used to quantify analyte concentration. The app then shows a series of steps and pictures that instruct the user in performing the appropriate sample collection and strip cassette insertion for the chosen test. The usability of these instructions was verified in the V1 in-lab study.

Figure 4. Version 2 prototype with a large format C-reactive protein test strip cassette inserted in the pull-out tray.
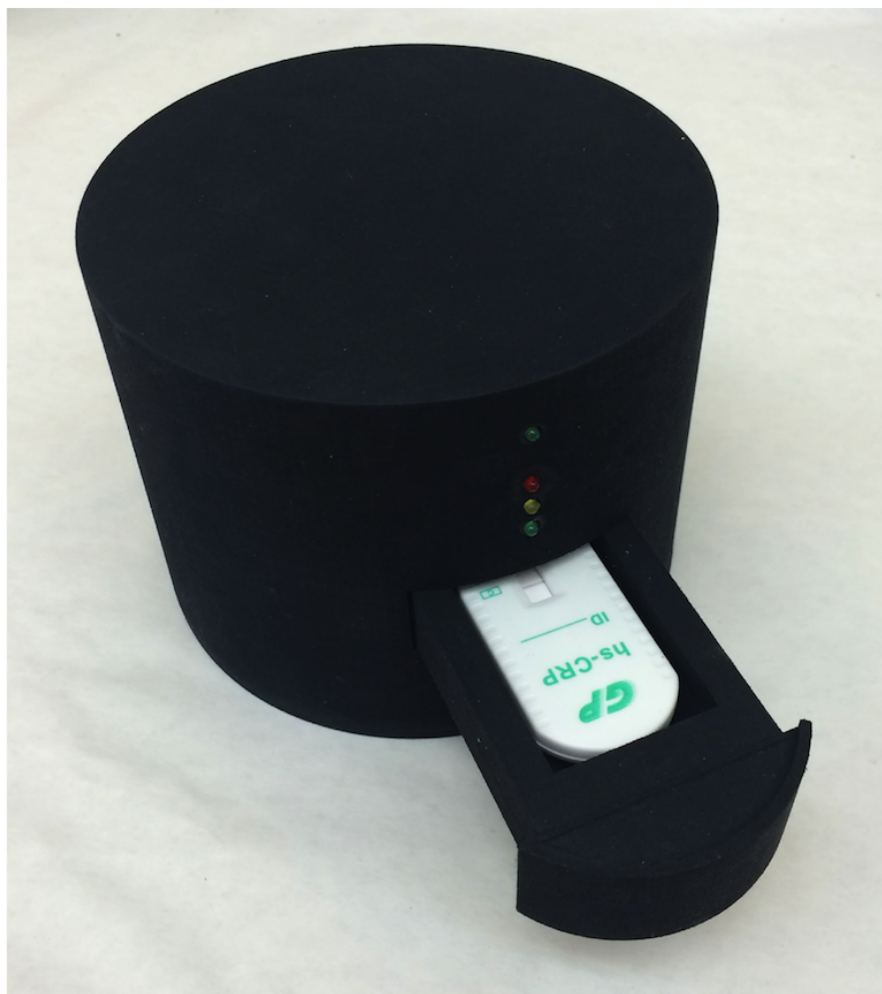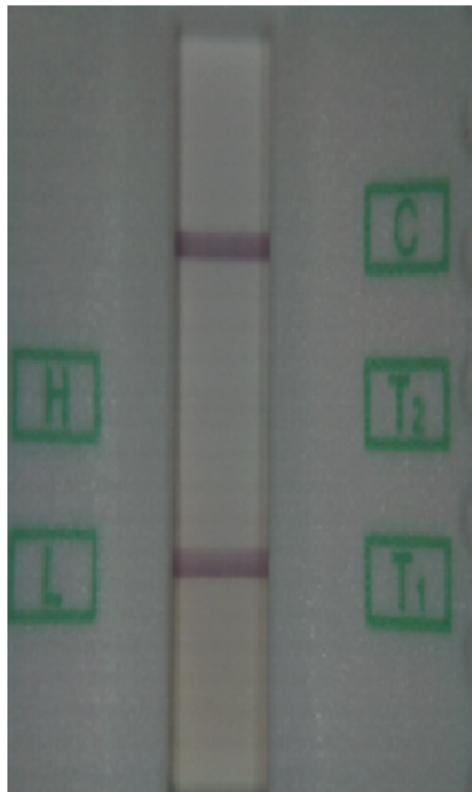
Figure 5. An image of test and control lines on a lateral flow assay taken by our Version 2 reader shows consistent, flat illumination.

Once a test cassette is inserted into the reader, indicator LEDs on the outside of the reader show development and analysis progress in the form of a stoplight-style red-yellow-green lighting system. When the test strip has completely developed, the internal lighting and camera are activated to capture an image of the strip (Figure 5), which is then sent to the smart device. The software then performs the necessary image analysis and compares the result to a predetermined calibration curve to obtain a quantitative result, which is displayed to the user and stored in the app. No results are stored on the reader itself, meaning it does not contain any sensitive patient data and can be used asynchronously by multiple users without risking the disclosure of individual results.

In-Lab Usability Testing

To assess usability and potential use cases and to gather general feedback and insights, we ran an IRB-approved (Protocol ID# 1602006140) small-scale usability study with 6 participants (3 females, 3 males, aged 22-72 years) recruited by word of mouth. All participants were native English speakers residing in the northeastern United States, and they had varying levels of education, ranging from some high school to graduate degrees. None had previously used our device.

Each participant was first given information about the function of the test strips and the general purpose of the reader. They were not given any technical background on how the reader works or how to use it, as we wanted to observe each participant figuring out the process on their own. For this study, we paired the reader with a laptop computer and had the app open and ready to use. Without instructions, each participant ran through

the steps of the app and eventually placed a prerun test strip into the reader, which generated a predetermined result. That is, no blood was drawn, given that our goal was focused more on exploring how participants feel about and handle interacting with the system. The participants were informed beforehand that this result was randomly generated and did not reflect their own personal medical data. After receiving the result, each participant was asked to complete a System Usability Scale test, and the study then concluded with an interview session to gather open-ended feedback about the V2 system and the testing process. The entire process took less than 30 min.

The resulting mean system usability (SU) score was 87.1 (σ=9.8), which is above the 90th percentile when compared with prior scores of other systems [20]. Although the sample size was small (n=6) and additional research would be necessary to confirm whether these results generalize to wider populations, they do provide a solid preliminary indication that different age groups and education levels found our V2 design to be highly usable.

The feedback given in the debrief interviews and our observations during participants' interactions with the system were also encouraging. One of the most noteworthy findings was that the older participants (n=3, aged 65-72 years) generally expressed much more excitement about the new reader and the process of using it than the younger participants (n=3, aged 22-26 years), reinforcing the need for a universal design. Multiple participants (n=3) also highly appreciated the battery power and wireless aspects of the reader, and most (n=4) either explicitly commented on the helpfulness of or could be observed reacting positively to the external indicator LEDs. In addition,

all participants were able to intuitively handle simultaneous use of the app in conjunction with the reader, affirming our assumption that incorporating a familiar device would aid the usability of a new system.

However, most participants (n=5) expressed confusion, either verbally or through facial expressions, about which way the test strip should be inserted into the reader. In fact, the process of placing the test strip into the reader universally caused the most hesitation among all participants. One participant thoroughly examined the reader and wondered where the test strip should be inserted before realizing that there was a pull-out tray. Without prompting from us, the participant went on to explain the confusion by saying:

> [It]'s hard to see with all the black. Maybe you should write "PULL" on it.

Version 3: The Tidbit

Design and Development

On the basis of insights gained in the evaluation of V2, we further refined the design of our reader, which we called Tidbit. The internal components, cost, and functionality of Tidbit are the same as the V2 design, as our focus in this iteration was on enhancing user interaction.

As seen in Figure 6, the new reader features a novel egg shape, which elicited positive reactions from potential users during informal feedback sessions. This design is also no longer symmetrical, reducing the chance of a user inadvertently placing the Tidbit upside down. Tidbit is also smaller than the V2 design, making it more portable and less expensive to produce. Additionally, the pull-out tray has been eliminated, and the test strip cassette is now inserted directly into the reader. This feature was aimed at eliminating the confusion we observed regarding where the strip should be inserted. To combat any additional confusion, we also added more detailed pictures in the app instructions that explicitly illustrate which way the test strip should be inserted. Finally, Tidbit features two colors that could be changed to suit the end user's needs or tastes.

In-Lab Usability Testing

Undertaking a round of evaluations on our Version 3 (V3) system, we again conducted a small-scale IRB-approved (Protocol ID# 1602006140) study to assess usability and gain feedback from potential users. By word of mouth, we recruited 6 participants (3 male, 3 female, aged 24-54 years) who all reside in the northeastern United States and have varying levels of education, ranging from high school to graduate degrees. None had previously used our device. The study's procedure was identical to that of the V2 usability trial, except the Tidbit was wirelessly paired with a tablet computer (Apple iPad 2), rather than a laptop computer.

Figure 6. Tidbit, our Version 3 design and new test strip cassettes. The confusing pull-out tray has been eliminated, and the asymmetry of the device prevents users from inadvertently placing it upside down.

Results

Overall, the study indicated that the Tidbit's design changes made the device more intuitive and straightforward to use. We saw a bump in mean SU score to 89.6 (σ=7.3), which, as mentioned with the V2 system, is above the 90th percentile when compared with scores of other systems [20]. In addition, all participants were able to intuitively handle simultaneous use of the Apple iPad app in conjunction with the V3 Tidbit reader, which, together with our similar findings from the V2 study with a laptop computer, suggests Tidbit's ease of use across a range of platforms.

Though minimal, participants did express a few suggestions for even further improvement that are worth noting as design considerations for future study in this and related areas. The first issue surfaced because Tidbit was placed on a table or desk below participants' direct eye level, and so the device's curved face seemed to make the test strip insertion point difficult to see for some. A few participants (n=2) experienced momentary trouble in finding the slot and used their hands to physically search for and moved their heads downwards to look at the device head on and find the slot. One participant summarized this concern:

> The hole was hard for me to see immediately. Maybe it could be moved up.

The other main insight we noted as highly worthwhile to pursue going forward relates to delivering visual or other forms of feedback "that [the device] is working throughout," as one participant put it. For a device such as Tidbit, this may be accomplished by adjusting the timing of the indicator LEDs on the reader or by integrating additional feedback about the connection status and test strip development progress into the app interface.

Discussion

Principal Findings

"In analytical fields that pride themselves on scientific basis and experimental rigor, the hidden danger is to neglect areas that are not easily addressed in the framework of science and engineering" [21]. It is now well recognized that engineers can easily forget that they are not the typical users of the technologies they build, leading them to make development decisions that are not well suited to their target populations or contexts. This is an understandable challenge, given that experts' extensive specialized knowledge of a system makes it difficult to have empathy for and fully understand the needs of an end user; however, it is quite problematic in practice, as such a user-detached approach is likely to hamper adoption, adherence, and ultimately, impact. In this study, we have demonstrated the process and illustrated the value of utilizing iterative techniques and focusing on usability, providing an example of how multidisciplinary teams can successfully implement these design methodologies. The iterative design process and focus on usability detailed in this study informed a significant shift in design specifications for our system and revealed design considerations that could extend to the development of other mHealth technologies.

Design Consideration 1: Design Features for mHealth Technologies Should Adhere to the Principles of Universal Design and Accessibility

In developing systems with a breadth of possible use settings including clinical, POC, and resource-limited, it is essential to balance the needs of diverse users and create a design that is easily accessible for potential user communities. Through qualitative analysis of participants' comments, researchers' observations, and participants' interviews, we were able to improve the accessibility of our designs and hone in on elements that were helpful to users.

Specifically, in terms of software user interfaces for mHealth apps, we found that a large, black font on a white background was viewed as a vital element for accessibility among a diverse population. Similarly, large navigation buttons and straightforward, simple language seemed to aid users in progressing through the app instructions. We also observed the enormous benefits of visual aids, including diagrams, photos, and video, in addition to the textual instructions, as many users commented on their helpfulness in guiding them through the procedure. Although participants in our usability trials were native English speakers, such visual aids could also be beneficial for users who are less familiar with written English.

With regard to hardware for POC health technologies, we recommend designing platform-agnostic systems whenever possible. In addition to allowing universal compatibility in diverse settings, not relying on a particular smart device allows designers to take advantage of users' familiarity with their own personal device. We also propose that POC technologies are developed to be low cost, wireless, and battery-powered, as users noted the importance of these features, and economical pricing and portability are particularly important for adoption in resource-limited settings where budget and reliable infrastructure (eg, electricity and transportation) can be problematic.

Design Consideration 2: Simple Operation and an Appealing Design Could Help in System Adoption and Adherence

In designing mHealth systems for long-term adoption, encouraging continued use is essential. This goal inherently implies the importance of a simple, intuitive design and a rewarding experience—essentially, users need to enjoy using it. With our V1 prototype, we observed that this was not the case, as users struggled with various aspects of the hardware, and we addressed the observed issues, along with any new ones that arose, in our subsequent design iterations. The resulting Tidbit design is asymmetrical with external lights indicating that the reader is correctly functioning, which have been shown to enhance the overall usability of the system. Through both qualitative and quantitative analyses, we verified that our final Tidbit design is both well liked and easy to use. Although long-term adherence needs to be verified in future field trials, we hope that our attention to simplicity and aesthetics in our design will aid in continued use.

Design Consideration 3: Remain Flexible During the Design Process

The incorporation of universal design principles through an iterative design process implies that designers will likely need to rethink their ideas and make alterations whenever necessary. After considering user needs (Table 1), our findings from the user trials with the V1 prototype, and the goal of adhering to universal design principles, we realized that a complete overhaul of our original ideas was necessary. Being flexible in our design process allowed us to abandon the conventional smartphone attachment design that has been used in the previously discussed reader technology [1,8-12] and imagine a novel stand-alone reader. A stand-alone reader solves many issues inherent to smartphone-attaching readers, including variability in image quality and processing power with different smartphones, compatibility with various smartphone types and sizes, and placing biomatter near a user's personal smartphone.

Limitations and Future Work

In addition to potential future work we mentioned previously (eg, rethinking positioning of the test strip slot and delivery of more visual feedback), a key next step is conducting field trials of Tidbit in naturalistic at-home, remote clinical, or other POC contexts to ensure that it remains an effective and usable tool in realistic settings and over extended periods of usage. One particular concern is that participants in lab-based studies such as ours can display demand characteristics [22] wherein they try exceptionally hard to perform well at the given task, so results could be different in the wild.

Another limitation of our in-lab evaluations was their small sample sizes, although 5 participants are typically considered sufficient for usability studies [23]. Additionally, restrictions on our time and budget did not allow us to test our designs with more diverse samples, such as resource-limited populations. It would therefore be desirable to involve larger and more diverse groups of participants in studies such as ours, going forward.

Additionally, the goal of our usability studies was to examine how participants used the new hardware design, so participants did not go through the process of pairing the Tidbit with the computing device. This would essentially involve powering on the Tidbit and connecting a smart device (eg, laptop computer, smartphone, etc) to the Tidbit wireless network, so, in theory, anyone who has connected a device to a wireless network should be able to complete this step. However, future usability studies should investigate how easy it is for participants to do this, as it will be very important if the system is going to be marketed as an in-home product.

Conclusions

This study presents the design process undertaken to develop the Tidbit, an inexpensive, easy-to-use, portable optical reader for LFA signal quantification. Potential applications for our system include in-home personal health monitoring; use in a clinic, doctor's office, or pharmacy; and diagnostics in resource-limited settings. Our iterative design methodology enabled us to derive a novel, robust technological solution grounded in the preferences and identified requirements of potential users, with usability testing confirming the reader's ease of use and overall positive reception. As researchers continue to develop portable personalized medical systems, it is important to incorporate the needs of and test with potential users throughout the design process. We hope that our study will encourage other researchers to incorporate similar approaches to create innovative systems that support the principles of universal design.

Conflicts of Interest

DO and DE have an equity interest in VitaScan (formerly VitaMe Technologies Inc), which is commercializing micronutrient diagnostic technology that may use the technology described herein.

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Abbreviations

AC: alternating current
LFA: lateral flow assay
LED: light-emitting diode
mHealth: mobile health
POC: point-of-care
RDT: rapid diagnostic test
SU: system usability
V1: Version 1
V2: Version 2
V3: Version 3

Original Paper

Challenges During Implementation of a Patient-Facing Mobile App for Surgical Rehabilitation: Feasibility Study

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Abstract

Background: Translating research into practice, especially the implementation of digital health technologies in routine care, is increasingly important. Yet, there are few studies examining the challenges of implementing patient-facing digital technologies in health care settings.

Objective: The aim of this study was to report challenges experienced when implementing mobile apps for patients to support their postsurgical rehabilitation in an orthopedic setting.

Methods: A mobile app was tailored to the needs of patients undergoing rotator cuff repair. A 30-min usability session and a 12-week feasibility study were conducted with patients to evaluate the app in routine care. Implementation records (observation reports, issues log, and email correspondence) explored factors that hindered or facilitated patient acceptance. Interviews with clinicians explored factors that influenced app integration in routine care.

Results: Participant completion was low (47%, 9/19). Factors that affected patient acceptance included digital literacy, health status, information technology (IT) infrastructure at home, privacy concerns, time limitations, the role of a caregiver, inconsistencies in instruction received from clinicians and the app, and app advice not reflective of patient progress over time. Factors that negatively influenced app integration in routine care included competing demands among clinicians, IT infrastructure in health care settings, identifying the right time to introduce the app to patients, user interface complexity for older patients, lack of coordination among multidisciplinary clinicians, and technical issues with app installation.

Conclusions: Three insights were identified for mobile app implementation in routine care: (1) apps for patients need to reflect their journey over time and in particular, postoperative apps ought to be introduced as part of preoperative care with opportunities for patients to learn and adopt the app during their postoperative journey; (2) strategies to address digital literacy issues among patients and clinicians are essential; and (3) impact of the app on patient outcomes and clinician workflow needs to be communicated, monitored, and reviewed. Lastly, digital health interventions should supplement but not replace patient interaction with clinicians.

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Introduction

Background

The use of health and wellness applications have grown rapidly over the past years [1], including the implementation of digital health technologies in routine care. Such technology has the potential to provide ongoing personalized care for patients. However, the elements that contribute to an effective app, as well as the best ways to integrate *patient-facing* apps in routine care, are relatively unexplored. In parallel, the lack of evidence for apps' efficacy and effectiveness continues to be a key barrier to mainstream adoption of mobile apps in routine care [1,2].

To date, the majority of literature focuses on implementing clinician-facing digital technologies in health care settings [3,4], with few studies examining the challenges of implementing patient-facing digital technologies in routine care [2]. This study reports on the challenges experienced when implementing mobile apps for patients in routine care, focusing on supporting patients undergoing rotator cuff repair in an orthopedic setting.

Rotator Cuff Repair

The shoulder joint is a ball-and-socket joint between the scapula (socket) and the humerus (ball). The rotator cuff is a group of four tendons that connect the muscles attached to the scapula to the humerus. The function of the rotator cuff is to rotate the ball in the socket and therefore, move the arm.

Tears of the rotator cuff are a common cause of shoulder pain and upper limb weakness [5]. The tears of the rotator cuff commonly occur with upper limb injury or with age-related degeneration [6]. Often, this injury can be treated nonsurgically; however, depending on the patient, the tear, and severity of the injury, surgical repair may be required [5].

To achieve the best results from surgery, patients should adhere to a strict postoperative rehabilitation protocol to prevent retearing of the tendon and regain maximum shoulder function (Multimedia Appendix 1). This protocol is a local guideline developed by consensus between surgeons at Macquarie University Hospital (MUH) participating in this study. It includes wearing a sling, completing daily exercises, limiting shoulder use, and attending physical therapy. A recent study has identified a positive relationship between poor patient adherence to the rehabilitation protocol and an increased rate of rotator cuff retear during the first 12 postoperative weeks [7]. One of the reasons for poor adherence with the rehabilitation protocol is the tendency for patients to diminish the importance of the protocol over time, as visits to their surgeon become less frequent and their level of pain decreases.

Study Focus

To improve patient adherence with the rehabilitation protocol, a mobile app using the Healthy.me platform was developed for patient use. Full details of the Healthy.me platform are described elsewhere [8-13]. The rationale for using an app is the convenience of having rehabilitation information (including exercise videos and contact information) easily accessible via a mobile phone and the ability of the app to encourage adherence to the rehabilitation protocol outside of visits with health care professionals.

The aim of this feasibility study is to examine factors that facilitate or hinder the implementation of a patient-facing app in routine clinical care following rotator cuff surgery.

Methods

Study Design

A 30-min usability session and a 12-week study were conducted with patients undergoing rotator cuff repair surgery to evaluate the usability, feasibility, and acceptance of the app to support the patient's postoperative rehabilitation. A mixed-methods approach was used to incorporate the collection of quantitative app usage data, qualitative data through feedback from patients and clinicians, as well as implementation records taken by researchers during the study.

This evaluation was performed on patients attending for surgical treatment at MUH, Sydney, New South Wales (Australia), which is a private teaching and tertiary referral hospital. Personnel involved in the study included orthopedic surgeons, practice and ward nurses, health informaticians, software engineers, and research and administrative staff. Ethics approval was obtained from the Macquarie University Human Research Ethics Committee.

Patients booked for rotator cuff repair at MUH were eligible to participate in this study if they were in the age range of 40 to 65 years, English-speaking, in possession of an Internet-enabled iPhone or Android mobile phone, and intended to undergo surgical treatment for rotator cuff repair.

All participants received standard postoperative care. Participants were required to complete a 10- to 15-min questionnaire at their first preoperative visit and at their routine visits 2 weeks, 6 weeks, and 12 weeks postoperatively. Participants could comment further on a voluntary basis via email or telephone during the 12-week study period.

Patient Recruitment

Eligible patients suitable for the study were initially recruited by the surgeon, practice nurse, or a research team member during the patients' preoperative consultation at the orthopedic clinic. Patients could also be recruited by the ward nurse during their recovery in the ward after surgery.

Patients suitable for the study were initially recruited by the surgeon, practice nurse, or a research team member during the patients' preoperative consultation at the orthopedic clinic. Patients could also be recruited by the ward nurse during their recovery in the ward after surgery.

Participants provided written informed consent. They were advised that they could cease app use at any time and return to standard care involving regular outpatient clinic visits. They were also given an email address and a mobile phone number to a research team member for queries, issues, or comments during the 12-week period.

App Development and Features

A steering group with 5 representatives from orthopedics, consumer informatics, and software development was formed and met over 3 months for 2 hours every fortnight to codesign the app, formulate the study design, and compose educational content for patients. An internal usability study with 10 individuals was conducted with all major usability issues addressed before patient recruitment. Three meetings were also held with all clinicians involved to refine ways to introduce the app to patients before study commencement.

A mobile app was developed that contains information on the postoperative rehabilitation program. It contains (1) postoperative rehabilitation exercise videos; (2) important information and restrictions at different stages of the recovery; (3) contact information of the surgeon, practice nurse, and the research team; and (4) a *pillbox* for patients to record their medications and dosage. Figure 1 shows a screenshot of the home page of the app. Full details of the app development process are outlined in Multimedia Appendix 2.

To improve adherence with the rehabilitation protocol, patients were encouraged to complete a 3-min questionnaire daily within the app (Multimedia Appendix 3). The questionnaire was designed to address common issues relevant to the participant's stage of postoperative recovery (Multimedia Appendix 1). Participants were sent a weekly SMS text message (short message service, SMS) reminder to complete the questionnaire (Multimedia Appendix 1).

Whereas the app is not available for public use, the app was installed on the mobile phones of participants in this feasibility study using the TestFlight platform on iPhone operating system (iOS, Apple Inc) devices. Participants with an Android device were provided with an URL, where participants could download the app directly from Google Play Store, following email validation by the research team.

Data Collection and Analysis

App Usage Data

Patient app usage was assessed using a system log that recorded time of app access, app features used, and the duration and frequency of use for each app feature. Descriptive statistics were computed for the usage data.
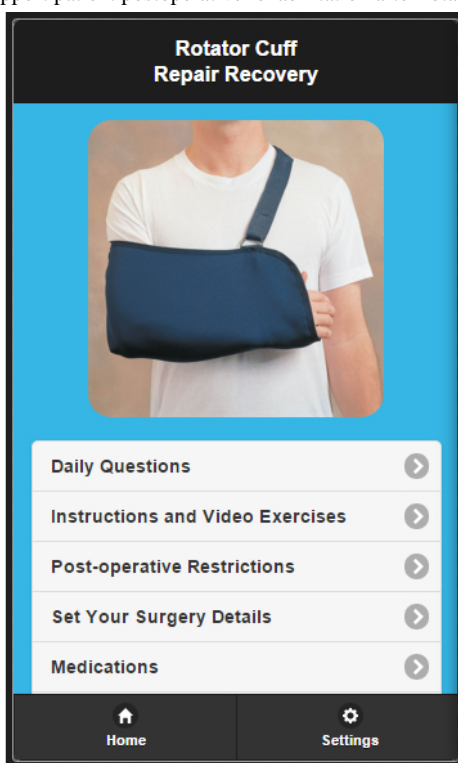
Questionnaire Data

The Western Ontario Rotator Cuff Index is a standardized and validated questionnaire that quantifies pain, analgesic usage, and quality of life specific to rotator cuff disease [14,15]. The questionnaire was completed by the participants preoperatively and at their routine 2-week, 6-week, and 12-week postoperative visits. Clinical outcomes of these data are not reported here.

Implementation Records

Implementation records (ie, field notes recorded by researchers that detail the implementation process of the app) were collected during the study. These include participant observation reports, issues log, and email correspondence with participants. For participants recruited by the research team, observation reports were made in accordance to a predefined template (Multimedia Appendix 1) during the usability session. These reports contained details of the usability session, researcher observations of the participant (eg, body language and who else was there), and issues that had facilitated or hindered participants' use of the app. An *issues log* (eg, technical problems with the app or telephone conversations with participants) was also maintained by the research team during the study.

Figure 1. Home page of the app developed to support patient postoperative rehabilitation after rotator cuff repair.

Semistructured Interviews

At the completion of the 12-week study, a member independent of the app development team conducted a semistructured interview with the clinicians involved to explore key issues that emerged from the implementation records. An interview schedule was developed in consultation with the research team (Multimedia Appendix 1). Responses from early interviews were used to refine the schedule for later interviews [16]. No patients were available for poststudy interview because of lack of availability or interest.

Mapping of Patient Workflow

Before clinician interviews, a series of cross-functional flowcharts showing a workflow were drawn for patients requiring rotator cuff repair at MUH, representing the interactions between four main settings: the patient's home, general practitioner (GP), orthopedic clinic, and hospital (including ward nurse and physiotherapist). Standard flowchart symbols were used [17] (Multimedia Appendix 1). The initial flowcharts were drafted by the research team based on their observations, and interviews with clinicians served to verify the patient workflow steps.

Qualitative Data Analysis

For the qualitative data analysis, audiotapes were transcribed verbatim. Two members (AL and VL) read through all interview transcripts and implementation records independently, following the constant comparative method and thematic analysis [18,19]. An initial thematic framework was developed from a sample of transcript and record data, with VL coding the remaining data according to the framework, with no new themes or revisions. AL then reexamined the themes and supporting quotes, and results were discussed with all the authors. Any disagreement was resolved via group discussion and consensus. Rigor was addressed by coding according to a comprehensive framework; an iterative process of constant comparison between framework and data; and discussion of themes with all the authors [20]. Quotes are reported with no alterations.

Results

Patient Characteristics

Participant completion rate was low (47%, 9/19). Participants were in the age range of 42 to 67 years (mean=55.4 years, standard deviation [SD]=8.6 years). One participant (aged 67 years) was above the age eligibility criteria but was included in the feasibility study because of his enthusiasm to participate in the study. Patient demographic data are shown in Multimedia Appendix 1. (Note: participants are included in the study if they have provided consent, and completed most of the questionnaires or installed the app).

App Usage Statistics

Eight out of 9 participants installed the mobile app. System log showed that the mean duration of app usage was 46.9 days (SD=24.5 days, median=42.5 days, interquartile range [IQR]=29 days). A total of seven app features were monitored, namely, home page, daily questionnaire, exercise videos, rehabilitation information, surgery details, contact information, and pillbox. Access frequencies for each feature are outlined in Multimedia Appendix 1. For those who have installed the app (n=8), most (6/8) have used all features of the app but at different levels of frequency (Multimedia Appendix 1). Across participants, apart from accessing the home page (mean of 121 times per participant during the 12 weeks, SD=49, median=134.5, IQR=55), completion of daily questionnaires on rehabilitation adherence (mean=45, SD=24, median=40, IQR=26.5) was the primary activity. The journeys that contained exercise videos (mean=10, SD=5, median=11, IQR=4.5) and rehabilitation information (mean=10, SD=7, median=8, IQR=5) were the next most accessed features.

Workflow of Patients Requiring Rotator Cuff Surgery

Figures 1-4 detail the main steps of patient workflow required for a rotator cuff repair and the subsequent rehabilitation procedures at MUH. These flowcharts describe a set of chronological stages for patients undertaking rotator cuff repair. Legends for flowchart symbols are listed in Multimedia Appendix 1. Figures 2-5 describe each of these stages.

Figure 2. Patient workflow for a general practitioner (GP) referral to an orthopedic surgeon.
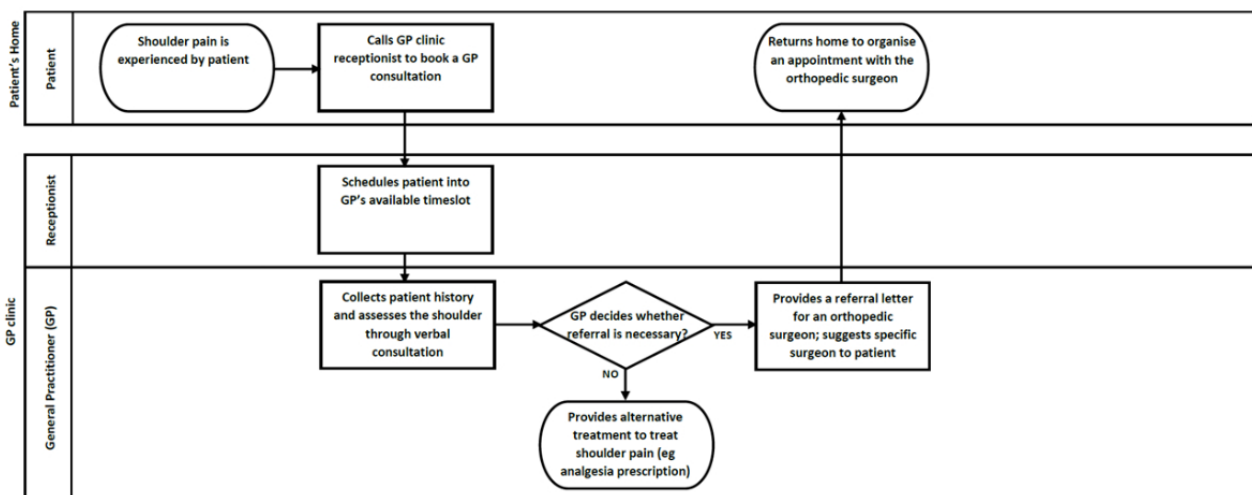
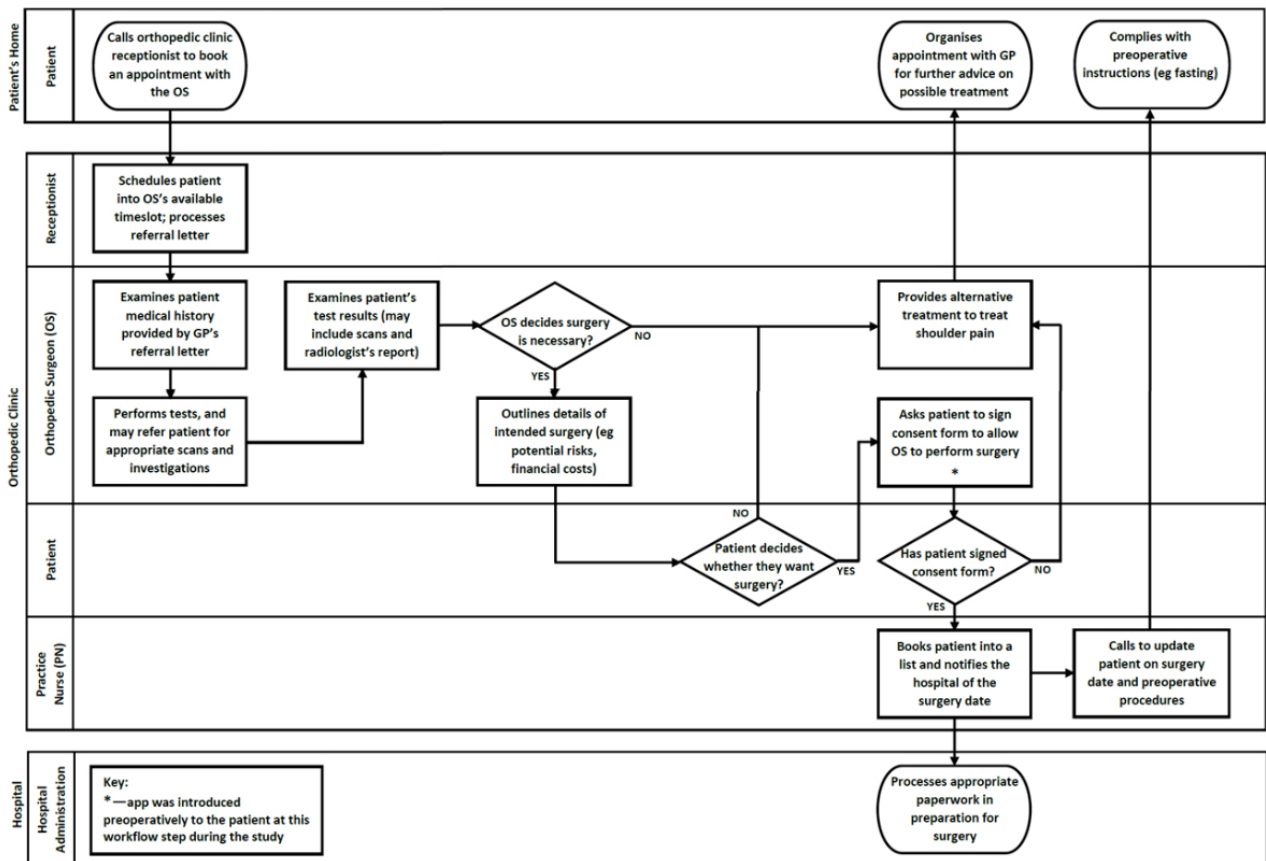**Figure 3.** Patient workflow for the preoperative procedures required before surgery.

Figure 4. Patient workflow during a rotator cuff repair surgical procedure.
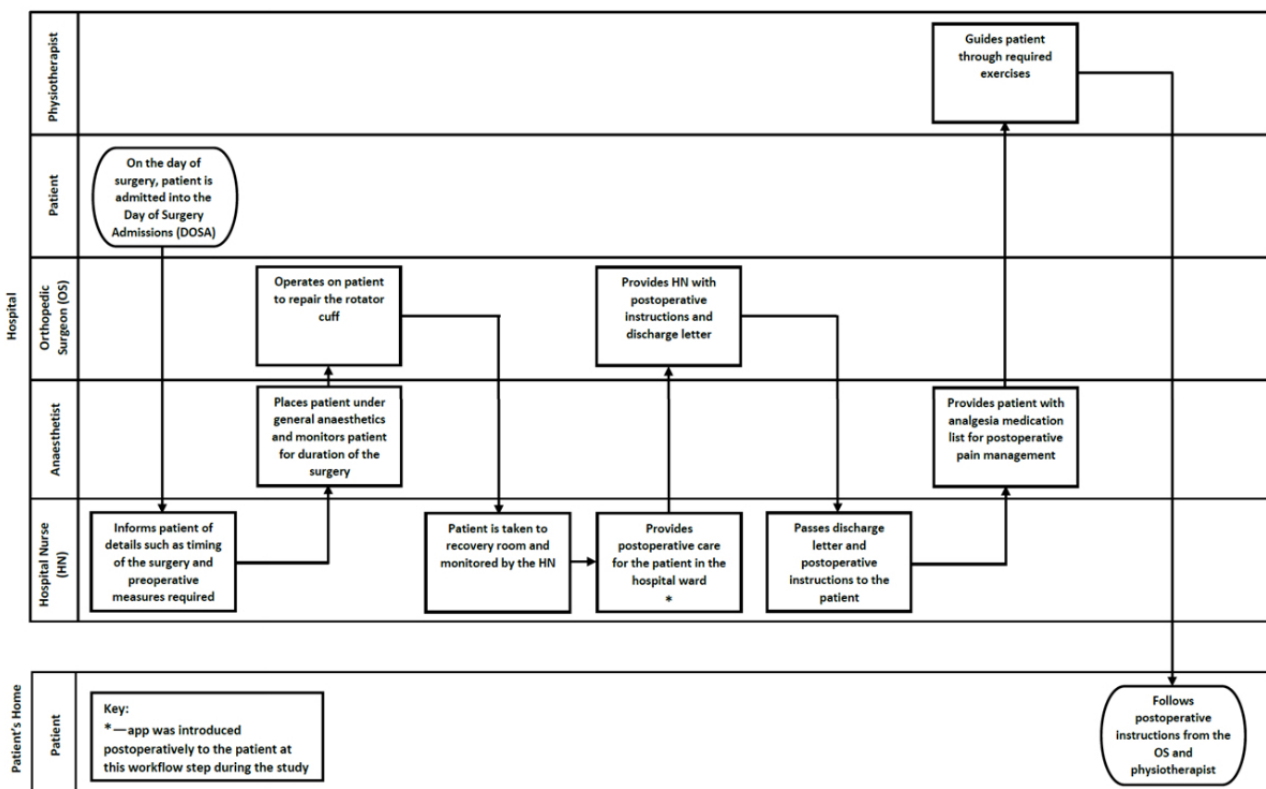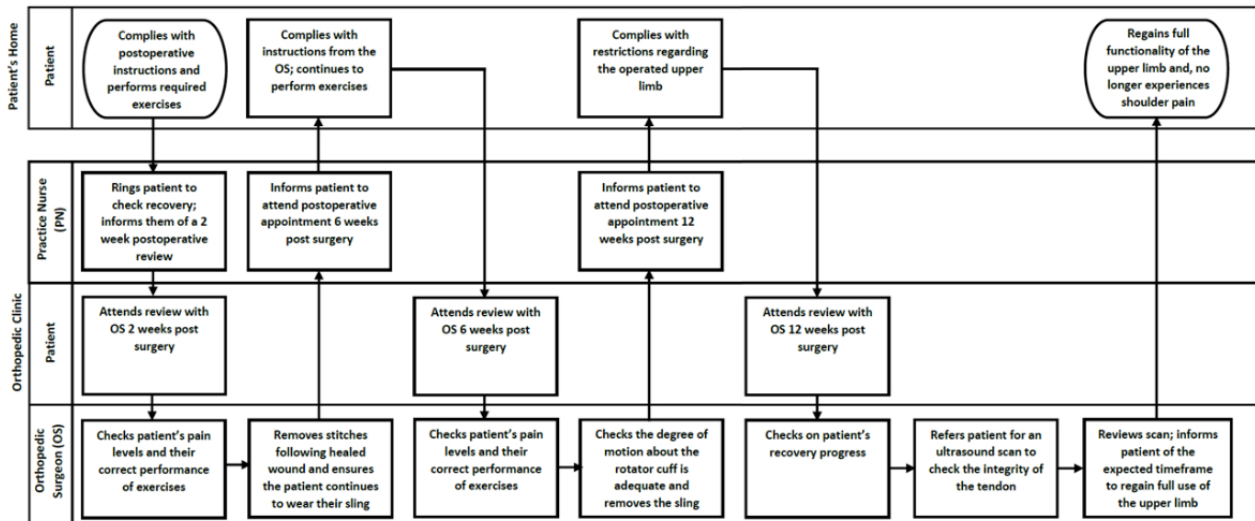
Figure 5. Patient workflow for postoperative reviews with an orthopaedic surgeon.

Patient Perceptions

Patient feedback was obtained from three sources: observation reports at the preoperative meeting, issues log, and email correspondence collected during the study. Issues reported by patients or recorded by researchers are detailed in Textbox 1.

Patient perspectives on the role of the app in their postoperative rehabilitation are illustrated below.

Questionnaires regarding rotator cuff recovery need to more accurately reflect the patient's journey:

> *I felt that if the questions changed to reflect the recovery milestones I had reached, then the app would be more relevant.* [Participant ID 3, Age 42, Female]
>
> *I thought the questions were quite good for the first six weeks but needed to be changed for the second six weeks as they are less relevant and this affects the frequency of filling out the questions.* [Participant ID 1, Age 67, Male]

The inability of the app's questionnaires to relate to more specific scenarios:

> *I think there is a fundamental question missing from this questionnaire, namely, is the operated arm dominant arm? This would greatly affect the answers to many of these questions.* [Participant ID 1, Age 67, Male]
>
> *The questions about pain might be more useful if they included a question about pain when exercising. I have very little pain when undertaking normal activities but during and after exercises I have a much higher level of pain.* [Participant ID 1, Age 67, Male]
>
> *Sleeping has also contributed some level of pain and stiffness as I have reverted from sleeping propped up on my back to sleeping on my non operated side (I use to always sleep on my operated side).* [Participant ID 1, Age 67, Male]

Clinician Perceptions

Clinician feedback was obtained from two sources: implementation records during the study and semistructured interview at poststudy. Issues reported by clinicians or recorded by researchers are reported in Textbox 2.

Clinicians' perspectives on factors that affected patient acceptance and app integration in routine care are outlined below. Some clinicians have also provided suggestions on remedies:

Lack of coordination among multidisciplinary clinicians about new changes from the app:

> *The rehab program we brought in for the app was an agreed standard program that I'm happy with but most physios elsewhere have got my old rehab schedule not the new rehab schedules. So it's a matter of actively changing across the board places where they're going to go and formalising the fact that we've changed our rehab program so I think it's just a communication issue.* [Clinician ID 4]

Deficient digital literacy experienced among patients:

> *If it's the elderly, it's negative [responses] because half of them don't even know how to use the phone. The smartphone.* [Clinician ID 2]
>
> *Firstly, the demographic, 40-65 has a higher proportion of "tech-ludites" There are people who use a smartphone but don't use apps...Secondly, there are people who think they are good with apps and they were daunted...And there were a number of people who...once were shown the app, go...too many steps. If you come back and do the study in 20 years' time, everyone will be okay with it.* [Clinician ID 4]

Time investment involved through daily consultation with the app:

> *Some said that they were too busy, that they didn't want to. That was probably the main [reason].* [Clinician ID 5]

Textbox 1. Patient issues regarding the mobile app.

1. Population variation in digital health literacy

- Patients not remembering iPhone operating system (iOS) passwords when installing app.

- Patients forgetting app password when attempting to log in.

- Patients unfamiliar with Wi-Fi setup at home and expressed concern on how to access the app at home.

- Patients with high digital health literacy did not express any difficulties with the app.

- One patient expressed preference to install the app on their iPad, which was not on their person, resulted in a verbal account of instructions. That patient could complete installation successfully at home.

- One patient expressed unfamiliarity with the app download process, which raised questions on whether the use of mobile apps for such patients is appropriate.

2. Patient state and their health status (eg, pain, fatigue, comorbidities, and their concerns)

- Patients were disengaged during the usability study, possibly because of pain (confirmed by some patients verbally and observed through body language) or low digital health literacy, leading to unfamiliarity with app.

- Patients' preexisting orthopedic conditions or multiple injuries excluded their eligibility to use the app as the exercises were designed only for people with rotator cuff repair.

- Patients were unaware of the extent of postoperative restrictions until informed by the app.

- Patients seemed engaged throughout the session but started becoming impatient with the number of questionnaires.

- One patient expressed concern regarding how his ability to work will be affected (as he operates machinery at work).

3. App needs to more accurately reflect patient recovery journey

Patients expressed that the app needs to be more reflective of patient recovery journey, such as questions changed to reflect recovery milestones, provision of advice for specific scenarios, and that some restrictions need to be relaxed in certain circumstances as patients progress over time.

4. Privacy concerns over data collection

Patients express concerns over privacy and sharing of information with institutions, such as insurance and workers' compensation (eg, WorkCover).

5. Role of caregivers

- Patients with low mobile phone literacy depend on caregivers to install the app. In one scenario, caregiver also did not display adequate digital literacy to comfortably install the app (eg, forgetting Apple ID and iOS password).

- Patient reliance on caregiver leads to participant withdrawal from study as caregiver becomes unavailable to look after patient.

6. Time limitations

- In-person meetings were carried out immediately after patients attended their first meeting with their surgeon, and some patients did not have the time to stay for an additional 20 to 30 min to meet with researchers about the study.

- One recruited patient pulled out because of time investment required being too much at the usability study.

7. Credibility of app content

- Patients asked if exercise information was approved by surgeons.

Textbox 2. Clinician issues regarding the mobile app.

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1. Lack of coordination among multidisciplinary clinicians

- Surgeons have their own rehabilitation protocol. Designing this app was also a way to consolidate differences in approaches and attitudes among surgeons in standardizing a postoperative rehabilitation protocol.

- However, some physiotherapists were not aware of the new rehabilitation protocol and thus, provided instructions to patients that were not consistent with those embedded in the app.

- Similarly, one patient reported discrepancies between the app and clinician instructions at hospital discharge.

2. Deficient digital literacy skills among clinicians

- Some clinicians noted that a self-perceived lack of confidence and skills in using new technologies may have hindered their willingness to introduce the app to patients.

3. Demanding workload and competing demands

- Clinicians are often too busy (or have forgotten) to introduce the app to patients.

Introducing the app during the preoperative stages of a rotator cuff surgical patient:

> *I think the big issue would be adequate pre-op engagement and instruction.* [Clinician ID 4]

> *Pre-operatively, because you need all that information pre-operatively. You need them to remember their pain levels and all that sort of thing and their discomfort. So it definitely would have to be started pre-operatively.* [Clinician ID 5]

New app features to closely reflect patient recovery journey:

> *The trouble is that it runs for six weeks and the patients are doing the same exercises for six weeks and after two weeks, they know what they're doing. Maybe we could look at… they get prompted every day for the first week or two but then for the next four weeks, maybe they get contacted less.* [Clinician ID 3]

> *What I really think would be good is to have some sort of generated referral [reminder] when it's time to have the scans done, I think that would be*

good...And maybe a booking system online with the app so then they're given a date and they can choose the time that suits them so that it's an automated [process]. [Clinician ID 5]

Suggestions on ways to educate patients on how to use the app:

> *One thing that probably we didn't think about in the app is a practice app. Something that says let's pretend you've had something, let's pretend you're [at] day 5, these are the questions that you'll be asked so that they get to play with it without it being recorded as part of their management but purely as their education.* [Clinician ID 4]

> *When you download the app, download an instructional video that whenever in doubt, it can say this is what you got to do...* [Clinician ID 4]

Other Issues

Other issues emerged regarding the organizational setting are reported in Textbox 3. Technological issues with the app are outlined in Textbox 4.

Textbox 3. Organizational issues regarding the mobile app.

---

1. Information technology infrastructure

- Failure to connect to the local Wi-Fi at outpatient clinic or in hospital.

2. Timing of introducing the app to patients

- Determining the optimum timing, persons of contact, and patient recruitment logistics across multiple health care settings is not simple.

- The need to constantly remind clinicians to offer patients to partake in the study.

- (For inpatients recruited postoperatively) Without knowing the app's existence before surgery, patients may have the propensity to decline automatically to participate, impeding patient recruitment rate.

3. Training clinicians on digital literacy and informing on impact is important

- Strategies to improve digital literacy and inform frontline clinicians on ways to integrate the app into routine care (and the subsequent impact on workflow and workload) are important.

Textbox 4. Technical issues regarding the mobile app.

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1. Problems with app installation

- Installation process for iPhone operating system (iOS) TestFlight has many steps that can be confusing for patients, possibly dissuading further involvement.

- App installation depends on receiving an email, with patients not necessarily linking their email account to their device. (In addition, there is the inability to customize TestFlight emails or the email address they are sent from. These emails could be categorized as spam and may cause confusion as they originate from a name and email address unknown to the user).

2. Problems with app distribution

- Issues with TestFlight hindering app distribution. For example, app expires on TestFlight after 60 days, where users must update the app. Users receive a notification detailing app expiration, which may have misled them to think that the study has ended.

- Distribution issues may reflect poorly on app developers, despite this issue being unable to be resolved from the app developer team.

3. Pre- and postimplementation support

- Troubleshooting of issues is more difficult to occur without an onsite technician.

- Some recruited patients did not respond to initial emails or secondary follow-up emails.

- Time spent providing technical support to and liaising with participants is significant, and appropriate resources should be allocated for this.

Discussion

Principal Findings

This feasibility study offers insights into the implementation of a mobile app for patients in an orthopedic setting. Our mixed-methods approach has identified factors that affected patient acceptance of the app ranging from patient-related factors (such as digital literacy and health status), contextual factors (eg, IT infrastructure at home, time limitations, and the role of their caregiver), personal concerns (eg, privacy over information sharing), to other factors (such as inconsistencies in instruction received from clinicians and the app, and app advice not reflective of patient progress over time). In parallel, factors that negatively influenced app integration in routine care include clinician-related factors (eg, competing demands, heavy workload, digital literacy, and lack of coordination among multidisciplinary team), organizational factors (eg, IT infrastructure in health care settings and optimal timing of introducing the app to patients), and issues related to the app (eg, user interface complexity for older patients and technical issues with app installation).

Whereas this study focused on rotator cuff repair, barriers experienced from patients, clinicians, and health care organizations (Textboxes 1-4) are highly likely applicable to other health care settings when implementing patient-facing apps in routine care.

Comparison With Prior Work

The use of mobile health technology as an intervention to provide patient care is becoming increasingly common [18,19]. They have been used to support chronic disease management such as diabetes, cardiovascular, chronic lung diseases (ie, chronic obstructive pulmonary disease and asthma), mental health, and osteoarthritis [21]. Whereas these technologies involve a wide range of functionality to support patient self-management (such as to inform, instruct, record, display, guide, remind or alert, and communicate) [21], its application in the surgical setting remains limited.

At the time of writing, we are only aware of the mobile app developed by Semple et al to monitor patient recovery at home after surgery [22-24]. Semple et al demonstrated successful acceptance of the app in a feasibility study, with all 65 participants who were undergoing either breast reconstruction or orthopedic surgery completing the study. However, the examined cohort of Semple et al was of a relatively young age, and their associated familiarity with technology could be a contributing factor to their willingness to use mobile apps.

Our study, however, only targeted patients from an older age bracket of 40 to 65 years and experienced a lower study completion rate (47%). It has been acknowledged that a reduced usage of technology by the older population can be attributed to a variety of reasons, including but not limited to a deficient understanding of the benefits of mobile apps to provide care, reluctance to gain digital literacy skills, and physical impairments leading to a lacking confidence in navigating through app features [25]. By addressing these issues, app uptake by the older age group could potentially be improved in future studies.

Implications for Implementing Patient-Facing Apps in Routine Care

We identified three key challenges that impeded app uptake and integration during routine care and proposed suggestions to address them. These challenges may also be factors that contributed to the low participation or completion rate in this study.

Implementation Ought to Be Patient-Centric at All Times

Our findings indicated that advice from the app was not relevant to patients' recovery journey on some occasions. Apps should provide advice that relates to specific patient scenarios, recovery milestones, and individual progress, intelligently adapting to the patient's changing condition over time. They should also be designed and implemented with the patient in mind,

considering that patients could be experiencing pain, fatigue, comorbidities, and concerns that could affect their decision to use (or not use) the app at any time point during their treatment journey.

Our study also found that identifying an optimal time to introduce the app to patients in routine care is not straightforward. Patients may not have been ready to participate when the study was first introduced at the preoperative stage. The lead up to surgery is often a challenging time for patients, as they are anxious regarding the surgery and often are making significant adjustments to their regular work and home routines to accommodate the time off required for the surgery. However, patients should still have an opportunity to learn about the app during the postoperative stage, even when they have declined the opportunity to use the app earlier in their treatment journey.

To encourage uptake, apps designed for postoperative recovery ought to be introduced as part of preoperative care, where there are opportunities for patients to learn and adopt the app during their postoperative journey. Starting the recruitment process earlier in the patient journey, as well as having multiple points for patients to learn (or remind them) about the app postoperatively, could potentially improve participant uptake.

Implementation Should Be Digitally Inclusive for Patients and Clinicians

Our findings revealed that some patients may not have the digital health literacy necessary to use the app as a form of postoperative care, although there were some exceptions. Digital literacy concerns among *patients* should be addressed appropriately and accordingly, with adequate resources and support. Ownership of a mobile phone device is not a sufficient eligibility criteria, as participants may not be able to use the device to the full extent. There was a wide range of digital literacy competencies among participants in this study, ranging from those who only use a mobile phone for answering calls, texting, and have never used an app, to those who regularly use complex apps and felt that the app used in this study was too simple and did not address all their needs. The question of how to balance the high expectations of users with high digital literacy, and those struggling with low digital literacy, is an important issue in app design.

Our study also found that digital literacy concerns among clinicians need to be addressed. There were occasions when clinicians did not feel confident enough to introduce the app to patients because of their self-perceived lack of familiarity with apps. For example, some clinicians felt uneasy helping patients set up the app or addressing any technical concerns during app installation. Strategies to improve digital literacy among frontline clinicians, to help them tackle common problems expressed by patients during app installation and usage, and ways to incorporate the app into their work routine are of utmost importance.

Overall, the level of time and resources required in providing digital literacy support to patients and clinicians can be intensive. A *practice app* may assist those with low digital literacy become familiar with the app. To achieve implementation success of digital health technology in routine care, a sufficient budget to support patients and clinicians with their digital literacy concerns is necessary.

Implementation Needs to Be Communicated, Monitored, and Reviewed

Our study indicated that not all clinicians involved in patient care were aware of the app, resulting in inconsistencies in patient instructions received from some clinicians and the app. Communication with all clinicians involved is paramount. All parties need to be informed on how the app will impact on their clinic workflow, responsibilities, and patient communication. The overall impact of the app on patient outcomes and the flow-on effects on staff workload needs to be communicated, monitored, and reviewed. Ultimately, digital technologies should supplement and not replace patient interaction with clinicians.

Our study also found that clinicians were often too busy (or have forgotten) to introduce the app to patients because of their heavy workload and competing demands. The rotator cuff patient workflow is more complex than was originally anticipated (as indicated in Figures 2-5). There are many unanswered questions regarding the effects of introducing *patient-facing* technology into this complex workflow and how these technologies may affect clinician workload, patient-clinician interaction, and patient expectations. For example, what role should these technologies have in routine care? How, when, and where should they be introduced to patients? How do they affect clinician workload and workflow? Do they introduce any unintended consequences? Whereas the literature for implementing *clinician-facing* technologies is increasing, more empirical and theoretical guidance is required for implementing *patient-facing* technologies in routine care and personal settings.

Limitations

Several limitations need to be noted:

- Participant completion rate (47%) was low, which limited study generalizability. However, we have identified a range of factors that hindered the implementation of patient-facing apps in routine care, which is the major focus of this report.
- Participants were only recruited from MUH (an academic private hospital), where socioeconomic status of patients is likely higher than the general community. It has been previously reported that individuals with a higher socioeconomic status also have higher digital literacy rates [26]. However, we experienced a range of digital literacy competencies among our participants. Challenges regarding digital literacy could be significantly larger for studies conducted in public hospitals primarily treating patients with lower socioeconomic status.
- Using alternative platforms to distribute the app (such as TestFlight) may have hindered uptake rates, as most participants were not familiar with this app download process. When working with participants who may have digital literacy concerns, using traditional platforms for app distribution rather than alternative platforms may improve uptake rates.
- Although an analysis of the app usage system log revealed quantitative evidence of the most frequently used app

features, this may not be reflective of the patients' app experience. Unfortunately, no patient participants in this study were available for follow-up interviews. The app may not meet patients' changing needs and expectations during their recovery, which may be factors contributing to the low uptake. Future studies could consider using a theoretical framework to guide study implementation. These frameworks include (but are not limited to) the Exploration, Preparation, Implementation, and Sustainment (EPIS) framework [27]; Consolidated Framework for Implementation Research (CFIR) [28]; Promoting Action on Research Implementation in Health Services (PARiHS) framework [29]; and the Reach, Effectiveness, Adoption, Implementation, and Maintenance (RE-AIM) framework [30]. Studies should also measure patients' adherence to the app with strategies in place to improve participant follow-up.

- The rehabilitation protocol that the app was designed upon was specific to patients with rotator cuff tears undergoing surgery, which may have limited the intake of participants, as well as the generalizability of the app to other conditions. A wider range of exercise protocols could be implemented in the app so that it complements a larger pool of patients recovering from different injuries and surgical procedures. Future studies could also consider recording patient adherence to in-person rehabilitation programs and examine whether it is a contributing factor to app adherence.

- In addition, we did not recruit family members or caregivers to be participants of the study. As indicated in our study, caregivers have an important role to play in surgical patients' postoperative recovery; future studies could consider recruiting patients' caregivers as study participants to elicit their views.

Conclusions

The potential of mobile apps to support patient care is increasingly recognized, but they are still not routinely recommended by clinicians or integrated as part of standard care [19]. In this feasibility study, many challenges were identified, and we have emphasized three insights when implementing *patient-facing* technologies in routine care:

1. the importance for implementation to remain *patient-centric* at all times
2. to be inclusive of patients and clinicians of varying levels of digital literacy
3. the impact of the technology on patients and clinician workflow needs to be communicated, monitored, and reviewed.

Ultimately, digital health technology should supplement and not replace patient interaction with clinicians. Consumer, clinician, and service provider involvement are vital if mobile health is to fulfill its potential.

The science of implementing *patient-facing* technologies remains underexplored. Yet, the challenges in implementation are often not reported nor perceived important in academic literature [31]. With the emergence of next generation personal health technologies (eg, wearables, sensors, and medical devices) and their increasing popularity in the general population, further research is required to guide the implementation of *patient-facing* technologies across health care and personal settings to maximize their potential and prevent harm.

Authors' Contributions

AYSL, DB, KP, and EC were involved in the study conceptualization. AYSL, KP, DB, and PM were involved in study design. KP, PM, and AYSL were involved in journey design. AYSL, KP, DB, and PM were involved in all design and development. PM and VSLL were responsible for data collection. AYSL and VSLL were responsible for data analysis. AYSL and VSLL were responsible for the first draft, and AYSL, EC, KP, DB, VSLL, and PM were responsible for the subsequent drafts.

Conflicts of Interest

The university, EC, and AYSL involved in this project could benefit from any commercialization of Healthy.me or its technologies.

Multimedia Appendix 1

Supplementary tables.

[PDF File (Adobe PDF File), 165KB - humanfactors_v4i4e31_app1.pdf]

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Multimedia Appendix 2

App development and features.

[PDF File (Adobe PDF File), 9KB - humanfactors_v4i4e31_app2.pdf]

Multimedia Appendix 3

Daily patient questionnaire.

[PDF File (Adobe PDF File), 19KB - humanfactors_v4i4e31_app3.pdf]

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Abbreviations

CFIR: Consolidated Framework for Implementation Research
EPIS: Exploration, Preparation, Implementation, and Sustainment framework
GP: general practitioner
IQR: interquartile range
IT: information technology
MUH: Macquarie University Hospital
PARiHS: Promoting Action on Research Implementation in Health Services framework
RE-AIM: Reach, Effectiveness, Adoption, Implementation, and Maintenance framework
SD: standard deviation

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Original Paper

Defining Information Quality Into Health Websites: A Conceptual Framework of Health Website Information Quality for Educated Young Adults

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Abstract

Background: Today's health care environment encourages health care consumers to take an active role in managing their health. As digital natives, young educated adults do much of their health information management through the Internet and consider it a valid source of health advice. However, the quality of information on health websites is highly variable and dynamic. Little is known about the understandings and perceptions that young educated adults have garnered on the quality of information on health websites used for health care–related purposes.

Objective: To fill this gap, the aim of this study was to develop a conceptual framework of health website information quality with quality dimensions (ie, criteria) and associated quality drivers (ie, attributes) specified in the context of young educated adults' use of health websites for health care–related purposes. This aim was achieved by (1) identifying information quality dimensions of health websites from the perspective of young educated adults; (2) identifying the importance ratings of these quality dimensions; and (3) constructing a framework of health website information quality with quality dimensions and associated drivers specified in the context of young educated adults' use of health websites for health care–related purposes.

Methods: The study employed both qualitative and quantitative methods. Methods included semistructured group interviews and an individual quality assessment exercise grounded in visiting various websites and responding to Likert scale questions regarding the importance ratings of information quality dimensions and open-ended questions with specifying website quality drivers. Study participants included junior and senior undergraduate and graduate students in business, allied health, and public health majors. Qualitative, open-coding procedures were used to develop the conceptual framework reflecting the participants' means of assessing information quality on health websites.

Results: Five dimensions of information quality for health websites were identified: Completeness of information, Understandability of information, Relevance of information, Depth of information, and Accuracy of information. Completeness of information and Understandability of information were rated as the two most important quality dimensions by the study participants. Results indicated that these five information quality dimensions for health websites were supported by the following main driver themes: Content, Design, Links, Consumer resources, Search functionality, Supporting references, User focus, Content FAQ, Open access, Policy statements, and Site performance.

Conclusions: This study contributes to the literature by developing a health website information quality conceptual framework with quality dimensions and associated drivers specified for a young educated adult population. The detailed quality drivers supporting the corresponding quality dimensions provide a rich picture of young educated adults' perceptions on health website

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information quality. This framework can be used to guide the development of health websites, as well as the foundation for a means to evaluate health information from existing health websites with young educated adults as the target audience.

KEYWORDS

Introduction

Background

Today's health care environment encourages health care consumers (patients and caregivers) to take an active role in participating in their health care–related decision making and managing their own health [1]. Literature indicates that most consumers prefer to receive information about their illnesses and treatment options from multiple sources, including health care providers, other patients, and the Internet [2,3]. Health information on the Web increasingly plays an important role for consumers making a health care decision [4-6]. A 2013 Pew Project revealed [2] that 59% of the adults in the United States have looked on the Web for health information, with 6.75 million health care–related searches being performed per day [7] and 35% of people use the Web-based health information to make diagnoses but only half of them check with medical professionals [2]. Erroneous and misleading health information on the Web increases the risks of wrong self-diagnosis, damaging treatment attempts, and delaying or canceling doctor visits [2]. Given the magnitude of the amount and use of health information on the Web and its significant impact on consumers' health care decisions, as well as their overall approach to maintaining health, it is imperative that health websites provide consumer-perceived quality health information used for health care consumers making informed health care decisions and other health care–related purposes.

The study of health information quality is somewhat complicated because of various perspectives of defining and measuring information quality [8-14]. Past systematic reviews on the quality of health information for consumers on the Web [10,11,13] acknowledged the complexity of this concept because of the existence of the large number of criteria and different ways to categorize them. Reviews also recognized the lack of conceptual clarity regarding the consensus on what constitutes information quality and what the major dimensions and attributes are. Among the studies that have explored information quality from a health care consumer's perspective [7,9,15-17], few have made efforts to extensively define and specify the quality dimensions and the underlying attributes, which results in a lack of clarity regarding consumers' perceptions on information quality. In this regard, construct development is needed to decompose and better understand the construct of information quality from the perspective of those likely to use technology for health care–related purposes.

The concept of information quality is also complex in the eyes of health care consumers [10,12] and goes well beyond an assessment of information accuracy [8-10]. Although the involvement of health experts will enhance the accuracy of health information, reliance on the perspective of health experts can be problematic. Health care consumers seek and appraise information differently from experts [15] in specifying the different quality dimensions and associated attributes that define information quality. Moreover, health care consumers' perceptions of information quality impact the perceived usefulness and ease of use of a health information system, which further impacts their use and continued use of the system [18-23]. To design and develop a health website that better meets the expectations of health care consumers, further research is needed to conceptualize information quality from health care consumers' perspectives. A more complete understanding of this perspective may provide guidance for user-centered websites that can help consumers seek and evaluate health information, and thus, assist with their self-care and other health care–related purposes.

We focus this study of health information quality on college-educated young adults to reflect the demographics of health website users as among the most likely to seek and depend on health information on the Web [2,24,25]. As digital natives, young adults can exploit high levels of interactivity and personalization features available in the health websites that allow them to take advantage of using health information on the Web for health care–related purposes [26]. It is conceivable that this target group would be Internet savvy for discerning health information quality on a website. However, studies to date have not specified the quality of health information for websites for this consumer group.

The goal of this study was to develop a health website information quality conceptual framework with quality dimensions (ie, criteria) and associated quality drivers (ie, attributes) specified in the context of young educated adults' use of health websites for health care–related purposes. We use general model structures of system and service quality found in the information system and marketing literature as a starting point to explore the dimensions of information quality, as well as the attributes that drive each of the information quality dimensions. The process we take to attend to this goal involves (1) identifying information quality dimensions of health websites from the perspective of young educated adults, portrayed to be among the most active technology health care consumers; (2) establishing the importance ratings of the identified health website information quality dimensions; and (3) constructing a health website information quality framework with quality dimensions and associated drivers deemed relevant by young educated adults.

Young Educated Adults as Health Care Consumers

Young adults (in the age range of 18-26 years) are seen as generally healthy. Yet, they face challenges to keep healthy while reducing the risk of developing chronic conditions. Mental health, substance abuse, homicides, suicides, and motor vehicle accidents are all areas of concerns that impact the overall health and life of a young adult. These issues and challenges make young adults search for health-related information via the Internet to cope with health-related concerns and stresses [27-29]. Young adults search health information for various purposes, such as learning about health conditions, seeking online support, looking for treatment options, and prevention and screening information [2,30,31], or see the Internet as an acceptable resource that offers *anonymized* information or support for sensitive conditions or symptoms [32].

As reported by the 2015 Pew Research Center Report, "for some groups, especially young adults, those with high levels of education, and those in more affluent households, internet penetration is at full saturation levels" [24]. The study found that 93% of young adults (in the age range of 18-29 years) have remained the most likely to go on the Web, even as the Internet population has grown and even with documented larger increases in certain age cohorts (eg, adults aged 65 years and older) [33]. Research indicates that young adults trust the information on the Web and consider the Internet as a valid source of health advice [30,34], which calls for the necessity of not only ensuring the accuracy of health information on the Web but also providing content and design that allows users to cognitively and perceptually discern information quality.
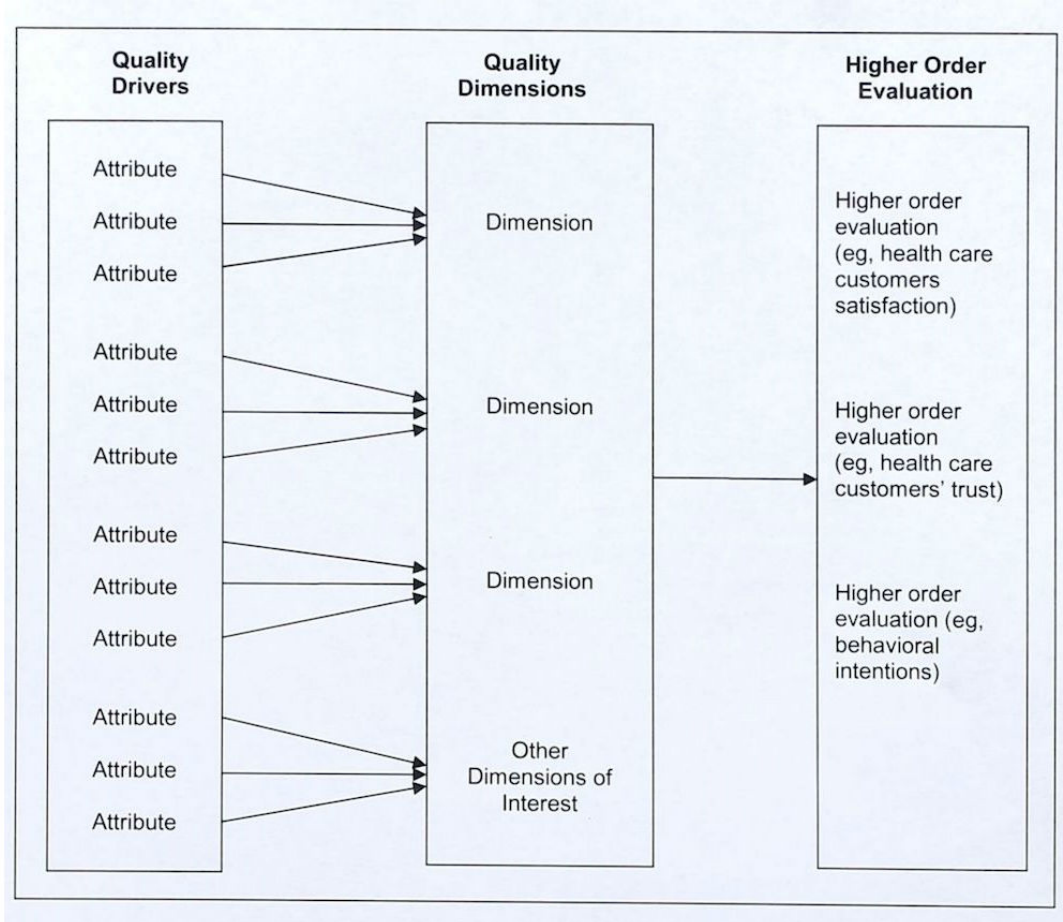
Studies found that younger adults do much of their health information management through the Internet and that those groups most likely to have done so are between the ages of 18 to 29 years, women, and college graduates [2,24,25]. Previous studies examining the use of the Internet for health information have focused on populations of interests, including healthy volunteers [7,9], clinicians [8,35], caregivers [16], and adult patients [17], with age ranging from 19 to over 65 years. Yet, few studies have focused on the young adult population [36,37]. How young adults group perceives the quality of health information from health websites remains unclear.

Information Quality

Information quality has been defined as *fitness to use* [38]. The DeLone and McLean Information System Success Model [39] demonstrated that information quality is an antecedent to system use and user satisfaction that lead to system benefits. As the most frequently tested model in the information system literature, the Technology Acceptance Model (TAM) indicates that perceived usefulness is important regarding the attitude toward technology and the ultimate behavioral intention [19], and perceived information quality is partial perceived usefulness. Empirical studies have examined the relationship between information quality dimensions and higher level evaluations. For example, several studies applied the System Success Model, TAM, and Web service quality models to successfully demonstrate the connections between perceived information quality, perceived usefulness, and intention to use or actual use [16,18-23,39-43]. A study investigating the trust factor in consumers' decisions regarding whether to use Web-based health advice indicated that credibility of information and personalization of content predicted *selection* (trust) of advice sites [24]. Fewer studies have focused on the linkage of quality drivers to dimensions.

Indeed, both information system and marketing literature provide conceptual models that exhibit the general structure of linking objective or perceived quality attributes (ie, drivers) to perceived quality dimensions and subsequently to other higher level evaluations of technology success [19,39,40]. Figure 1 summarizes this general structure and draws attention graphically to the distinctions and relationships between the concept of drivers and dimensions [19,39,40]. This distinction helps to clarify the health information quality construct and proposes potential causal relationships. As indicated, the leftmost box of Figure 1 contains quality attributes (ie, drivers), which may be objective or perceptual. The middle box represents the model of system quality dimensions (ie, criteria). Finally, the rightmost box contains elements such as overall customer satisfaction, customer trust, and behavioral intentions (eg, intent to use the system). We use this general model structure as a starting place and adapt it to the context of health care where young educated adults search for health information from health websites for health care–related purposes.

Figure 1. General model structure on three levels of website evaluation and their relationships.

Health Information Quality Dimensions Recognized in the Literature

Information quality is recognized as a multidimensional concept [44]. Terms such as *quality dimensions* [9,45] and *criteria* [10,11] have been used to reference the multidimensional nature of website quality. We define quality dimensions for purposes of this study as "abstract rules by which the quality of information is judged," which aligns with the definition used in a recent systematic review on health information quality criteria [13,46]. For this study, information quality dimensions are quality characteristics manifested in health information.

Health information quality evaluation by consumers, as part of health website quality evaluation, has received considerable research attention and resulted in notable literature reviews. Kim et al [11] identified content, design and aesthetics, disclosure, and currency as information quality dimensions. Eysenbach [10] and Seidman [12] found that the most frequently used dimensions to evaluate health information quality included accuracy, completeness, readability, design, and a series of technical criteria (eg, disclosure, reference provided, and internal search engine present). Neither of these reviews identified dimensions specific to particular consumer groups. Zhang et al [20] presented 11 dimensions grouped in three categories: (1) Substance criteria included accuracy and completeness; (2) formality criteria included currency, credibility, and readability; and (3) design criteria included accessibility, aesthetics, navigability, interactivity, privacy and data protection, and

cultural sensitivity. In addition to the dimensions summarized in the above three reviews, quality criteria, such as accuracy [8-10,13], comprehensiveness [8-10,13,41], credibility [10,13,41,47], authority [13,48-50], understandability [10,15,51], relevance [15,51], and currency [11,13,15] have been used to evaluate health website information quality in many empirical studies. Summatively, research has produced differences as well as commonalities in quality dimensions and various ways to categorize these dimensions; this reflects the complexity of the concept and the lack of consensus on defining information quality [13]. There are a number of potential reasons for these variances, including the method of constructing the list, prospectively identifying a limited number of potentially relevant dimensions to study, and efforts to overgeneralize and aggregate studies targeting different user groups. Furthermore, none of these quality dimensions were designated to the young educated adult population.

The ability to achieve ideal levels of information quality may be limited by resources (time and money), which makes understanding the rating of information quality dimensions to be useful in feature and content trade-off situations. Furthermore, rating relevant dimensions provides research insight into the evaluation process that consumers exercise in assessing information quality. Only a few studies investigated the priority of quality dimensions, and these studies indicate that not all quality dimensions are equally weighted in the health care consumers' evaluation process. Stvilia et al found that health care consumers rated information quality dimensions in

the following order based on a 5-point Likert scale: (1) accuracy, (2) completeness, (3) authority (reputation), (4) usefulness, and (5) accessibility [9]. In contrast, Stanford and colleagues found currency of the information is valued most by general health care consumers [52]. The conflict in findings of the health care consumer's rating among studies may, in part, be attributed to the limitations in the scope of information quality dimensions used in individual studies, which supports the importance of developing a broad list of relevant information quality dimensions to obtain a more complete picture.

Health Information Quality Drivers Recognized in the Literature

Information quality dimensions offer some insight but not sufficient guidance to the content and design features that trigger user assessments of information quality. We define information quality drivers as the observable attributes that consumers expect or look for when they evaluate health website information quality [13]. Association of these drivers with the information quality dimensions they support helps to relate concrete features of the abstract quality dimensions. Studies that aligned with the definition of drivers used in this study indicate that consumers determine health information quality by looking for quality drivers such as owners of the website, source of the content, author's credentials, additional source of support (eg, links), disclosure information, quality seal and third-party endorsement, including government agencies or professional associations, and so on [6,9,10,13,16,35]. These quality drivers serve as clues to whether heath information contained on a health website meets a given quality dimension criterion. From this perspective, quality drivers (we use the term quality drivers henceforth) are akin to *quality indicators* [10,15,46], *quality markers* [9], and *surrogates* [53] identified in past studies, which have used both quantitative and qualitative methods to dig more deeply into the underlying meaning of quality dimensions. These quality drivers serve as signals to the visitor of the quality of information contained on health websites. Consumers evaluate information quality by looking for these signals [9].

Identifying and distinguishing information quality drivers for health websites from existing literature is somewhat challenging. The confusion of classifications of quality dimensions and drivers presented in the literature creates some difficulties in discerning the three levels of the evaluation (see Figure 1) for health information quality. For example, *disclosure* was classified as one quality criterion at the dimension level in some studies [11], whereas it was recognized as a quality driver when consumers judge the credibility of information in other studies [9,13,35]. Eysenbach et al summarized a list of drivers, indicating how information is presented on the website, but those drivers were classified as criteria at the dimension level in the study [10]. Similarly, Bernstam et al used 15 quality drivers to evaluate information quality from breast cancer websites but labeled them as technical quality criteria [35]. Moreover, we found that individual quality attributes were grouped together representing the same aspects of website design (eg, identity, purpose, content, design, user-feedback, and privacy), and these quality groups were named as criteria [14] or constructs [35], which mixed up the levels of quality dimensions and drivers.

These variations of the classifications and naming across previous studies challenge defining the information quality construct and identifying the associations of quality dimensions with concrete quality drivers perceived by health care consumers in the health website environment. It is difficult to discern whether individual drivers or classes of similar drivers (referred to as themes) contribute to multiple information quality dimensions. Some studies proposed [6] or tested the association between quality drivers and the corresponding quality dimensions but failed [35]. Similar to the value of rating dimensions, identifying drivers that contribute to multiple quality dimensions facilitates prioritization and can highlight key tangible factors in the user evaluation process.

Research Questions

It is not surprising that Zeithami et al [40] suggested that future research focus on investigating the importance of different dimensions and perceptual attributes or drivers essential to electronic service quality and that Bliemel and Hassanein called for more research on consumer perspectives regarding health information quality evaluation [54]. Research is needed to discern how health care consumers understand and perceive health website information quality dimensions and the underlying attributes of each relevant dimension [55].

In response to the aforementioned issues and research gaps, the overall goal of this mixed-method study was to conceptually develop dimensions of the information quality concept and the associated quality drivers of each dimension in the context of young educated adults searching for health information from health websites for health care–related purposes.

To attend to these study purposes, we propose to answer the following research questions:

1. What dimensions (from a health care consumer perspective) comprise appropriate criteria for the design and the evaluation of quality of information published on health websites?
2. How do health care consumers rate the importance of the quality dimensions identified for information quality of health websites?
3. What are information quality drivers for each individual dimensions of information quality from a health care consumer perspective?

We will address these questions using the general model structure of website evaluation and their relationships (see Figure 1) as a general guide to (1) identify dimensions of health website information quality from the perspective of health consumers, (2) assess the importance of each dimension, and (3) present a conceptual framework of health website information quality with quality dimensions and associated supporting drivers by grouping drivers with driver themes to facilitate a means to begin to discern commonalities across dimensions.

Methods

Data Collection

This study employs a mixed-method design that includes quantitative (survey) and qualitative methods (group interview and open-ended website assessment exercise) to address the research questions. Mirroring past studies that explore the dimensions and factors of quality [45,56], we tapped into the knowledge of current and potential users of health websites using a user-centered approach that facilitated a ground-up conceptualization of information quality from the user perspective. To emulate current and potential users of health websites, our study participants are in the age range of 20 and 41 years and college educated (to stabilize education level among participants). Participants were recruited via class announcements and flyers. We obtained the approval from the institutional review boards at the institutes where the participants studied.

This approach was used to provide a comprehensive and relevant conceptual framework of information quality dimensions that tightly reflected the health care consumers' perspective. The framework was constructed in two phases. Phase 1 involved developing a list of quality dimensions informed by a consumer perspective, and phase 2 involved an exercise to (1) validate and prioritize the quality dimensions identified in phase 1 and (2) discern quality drivers for each of these dimensions to specify the health website information quality framework.

Determining Dimensions

In phase 1, we determined health website information quality dimensions of interest (level 2 of our framework) through four semistructured group interviews with junior and senior undergraduates and graduate students. Group interview was chosen to allow building and inspiration from the comments of others in efforts to develop a comprehensive list of dimensions [57]. Most student participants were within health care domains (but not engaged in direct patient care), as well as business domains. Approximately 10 students participated in each interview. Participants confirmed that they had visited health websites before phase 1 participation. In addition, the interview protocol included the question "What health websites are you most familiar with?" to further ensure all participants had direct experience with health websites being explored, could ground their responses, and to inspire candidate websites to be seeded in phase 2 of data collection.

The remaining interview questions were inspired by the higher order constructs presented in Figure 1. The protocol included questions and probes that attempted to cover all relevant dimensions of the concept of health information quality. The participants responded to the primary questions, "What quality dimensions of a health website would lead to... (1. visitor satisfaction, 2. promoting desired behaviors by the website sponsors, 3. visitor website loyalty, and 4. visitor trust)?" Participants in the group interviews were asked to address these questions from their general knowledge based on personal experience, the experience of others, and other information sources. As the number of responses from the group diminished, a few probing questions asking the participants to consider

various perspectives (well, sick, chronically ill, and had an injury) were introduced (eg, "if I were a..." patient and well-person looking for information) to ensure the group had exhausted their thoughts and to promote a comprehensive response. Interviewees were then asked to comment on the relevance of potential dimensions found in the literature that were not included in their responses, as a last measure to exhaust perspectives (note this literature included generalized reference to site visitors [10,47] as well as more specific patient populations [58,59]). We introduced data found from existing literature to ensure no key attributes were overlooked. Closing prompts directed participants to review the list of dimensions discussed by the group and inquired "anything else" and "is there anything missing" until it was clear that the group was saturated. There was increasing overlap and redundancy with prior groups in the dimensions identified for each subsequent group interview.

All dimensions suggested as relevant by any interview group were included in the cumulative list of dimensions for phase 2 of data collection. The research team reconciled conceptually redundant terms within and across interview groups. Furthermore, the team performed a literature review to determine whether the dimensions identified could be traced to prior literature (alignment of conceptual meaning). In such cases, where the dimension identified aligned with the conceptual meaning of terms found in past literature, further refinement of the term was done to facilitate connections between this study and prior research. The final, collective dimension list was a cross section of the dimensions identified by all four groups (see Table 1, which identifies the dimensions and provides connections to existing studies).

Determining Quality Drivers

Drawing on the dimensions provided by the foundational analysis, phase 2 consisted of a quality assessment exercise developed to determine underlying quality drivers. Junior and senior undergraduate and graduate students in colleges of business, allied health, and public health at two universities completed the exercise (198 students in total—92 students from the health-related domain and 106 from the business domain). No participants were health care practitioners. One university was in the Midwest of the United States and the other in the Eastern region of the United States.

As their first task, participants rated the general importance of each information quality dimension for health websites identified in phase 1 using a Likert scale on low importance to high importance scale of 1 to 5, with 1 anchored as: "I do not consider this characteristic at all in my assessment of this type of website"; and 5 anchored as: "This characteristic is very important to my assessment of this type of website." The participants did not visit any websites as part of this assessment. We used basic statistics for importance ratings of information quality dimensions for health websites.

Task 2 required participants to identify quality drivers for each of the dimensions. To conceptually ground participants in the actual decision-making process of assessing information quality, participants visited two health websites (one seeded—Web MD and the second of their choice). Participant choices in their

second site selection varied widely. By design, the order of visiting the two websites varied to reduce bias. Participants were asked to rate the websites with a focus on website context and the website quality decision-making process. Participants rated the two websites according to the identified importance dimensions. This rating was only used to stimulate thought and not as part of data analysis.

After the rating exercise, to gain insight into what drives the importance ratings of each quality dimension for health care websites, participants responded to a qualitative question of primary interest of this study, "What would cause you to rate a health website with a high score of 5 for name of quality dimension?" For example, "What would cause you to rate a health website with a high score of 5 for understandability?" Participants responded to the same questions for each dimension for two health websites. This was done to test the *within-subject* consistency in response to the assessment criteria.

Data Analysis

We calculated descriptive statistics such as the mean and standard deviation of the responses to the general importance of information quality dimensions. To understand the total span of our data, we also calculated the minimum and maximum values.

Qualitative procedures were used to review the participants' written commentaries to the open-ended questions asking them to explain what would cause them to rate a high score associated with five quality dimensions. Two researchers with expertise of different domains (information science and health information management) independently performed open coding [60] by identifying meaningful text from the responses that disclosed specific website drivers that would support each quality dimension. There was no predefined coding schema. As team members discovered new drivers associated with each quality dimension that did not map to the drivers they previously identified, they created a new code, a child code to the quality dimension, to explain a finding. Each coder independently reviewed and refined their code list containing detail drivers for each dimension.

A code reconciling process based on consensus was conducted to reach a stable list of drivers by integrating the perspectives of the 2 initial coders and a third member of the research team [61-68] for similar consensus-building approaches using investigator triangulation [69].

The third coder (representing the health information systems domain) who did not conduct individual coding work participated in the reconciliation process with the 2 open coders. The third coder reviewed the open coding performed by the previous 2 coders. With a third coder acting as referee, the coders reviewed and compared their resulting code lists to reconcile conceptually redundant code labels, to ensure adequate support existing for a code, to refine the labeling of resulting themes, and to harmonize the granularity of the codes. In cases where one coder identified a code not identified by the second coder, the team of three examined all the supporting text, working toward a reconciled agreement on whether the code was properly supported and should be represented in the health information quality framework as a detailed driver of identified quality dimensions. Such cases were a result of coder differences in granularity, which is when one coder created a broader code conceptualization than the other coder. When the expanded schemas involving each of the quality dimensions supported by detailed drivers appeared to become stable and three members reached consensus, the initial phase of data analysis was complete.

The 3 coders then performed axial coding, which is the process of relating codes to each other via a combination of inductive and deductive thinking [59] to group the resulting codes into quality driver themes that could be discussed across quality dimensions. The agreed upon themes among the 3 coders were defined as the quality driver categories (referred to as driver themes in the Results section). The final construction of the comprehensive framework of health website information quality consisted of the identified quality dimensions (presented with first letter capitalized), the quality driver themes for each dimension (presented with italicized and first letter capitalized), and supporting quality drivers (eg, codes)(presented with italicized only). We provide the differences in presentation to assist the reader in identifying the referenced level of the framework for each concept presented.

Results

Information Quality Dimensions and Importance Ratings for Health Websites

Five dimensions of information quality in the context of health websites emerged: (1) Accuracy of information; (2) Completeness of information; (3) Depth of information; (4) Understandability of information; and (5) Relevance of information. The definition of each dimension and the corresponding example studies are presented in Table 1.

Table 2 lists the importance of these quality dimensions across all participants. Completeness of information and Understandability of information were the two top dimensions perceived by study participants. These dimensions may serve as the foundation for health website sponsors and designers to consider in their website design and evaluation.

Table 1. Health websites information quality dimensions and their definitions.

Quality dimension	Definition
Accuracy of information	The degree of concordance of the information provided with the best evidence or with generally accepted medical practice [8-10,20]
Completeness of information	The proportion of priori-defined elements covered by the website; breath of information [8-10,20,24]
Depth of information	Level of information details [18,24,38]
Understandability of information	Readability with information in plain language containing statistics of text, explanations of medical language and acronyms, choice of display formats for numerical or graphical information, and clarity of images [10,11,20,37]
Relevance of information	Applicability of each item of content to potential users' health situations, such as personalized health tools or age-specific information [11,37]

Table 2. Information quality dimension list and importance rating for health websites.

Dimension	N	Responses, n (%)					Median	Mean (SD[a])
		1	2	3	4	5		
Completeness of information	196	0 (0.0)	0 (0.0)	1 (0.5)	21 (10.1)	174 (88.8)	5	4.883 (0.3382)
Understandability of information	196	0 (0.0)	0 (0.0)	1 (0.5)	25 (12.8)	170 (86.7)	5	4.862 (0.3601)
Relevance of information	195	0 (0.0)	1 (0.5)	9 (4.6)	49 (25.1)	136 (69.7)	5	4.641 (0.5958)
Depth of information	196	0 (0.0)	1 (0.5)	12 (6.1)	57 (29.1)	126 (64.3)	5	4.571 (0.6325)
Accuracy of information	159	0 (0.0)	8 (4.0)	18 (11.3)	21 (13.2)	112 (70.4)	5	4.491 (0.8850)

[a]SD: standard deviation.

Drivers of Information Quality Dimensions for Health Websites

The answer to the qualitative question revealed the meaning of each information quality dimension from the study participant's perspective. We labeled the meaning of each quality dimension with quality drivers, which indicate the study participants' perceptions about quality dimensions and tangible website features and functions expected for a health website. Figures 2-6 illustrate the associated supporting drivers (see bullet points in each figure) for each of the five quality dimensions. Collectively, these figures provide a health information quality framework with quality dimensions and drivers targeted at educated young adults.

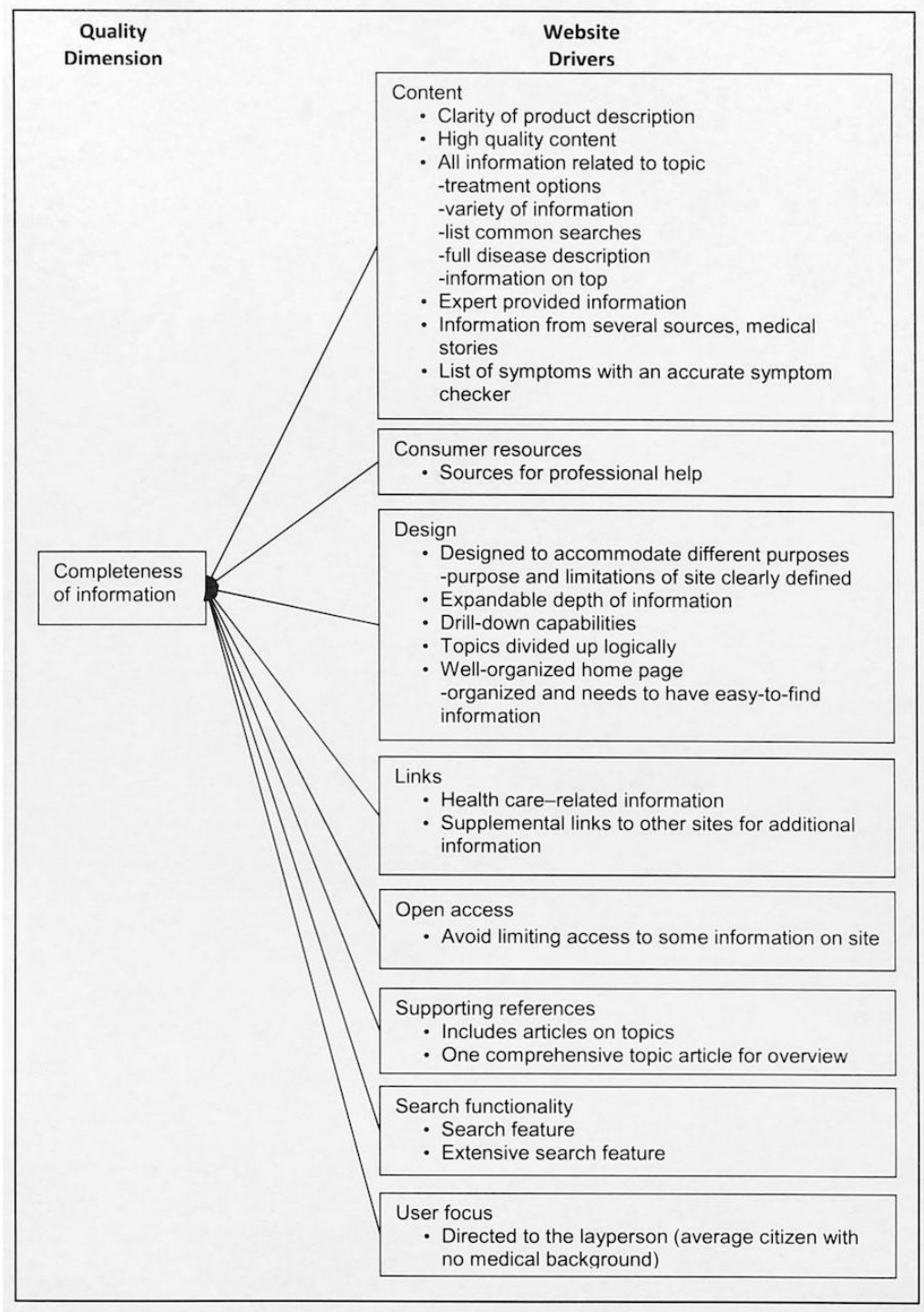**Figure 2.** Quality driver themes and detailed drivers for completeness of information on health websites.

Figure 3. Quality driver themes and detailed drivers for understandability of information on health websites.
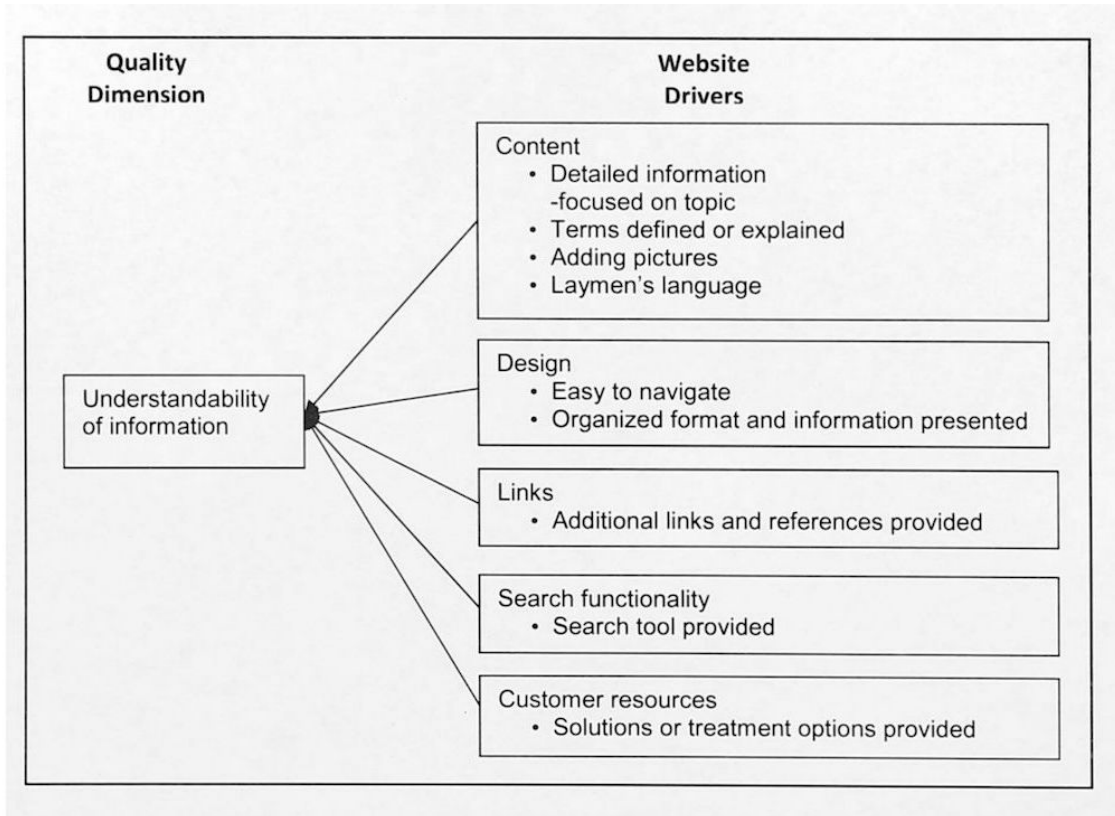
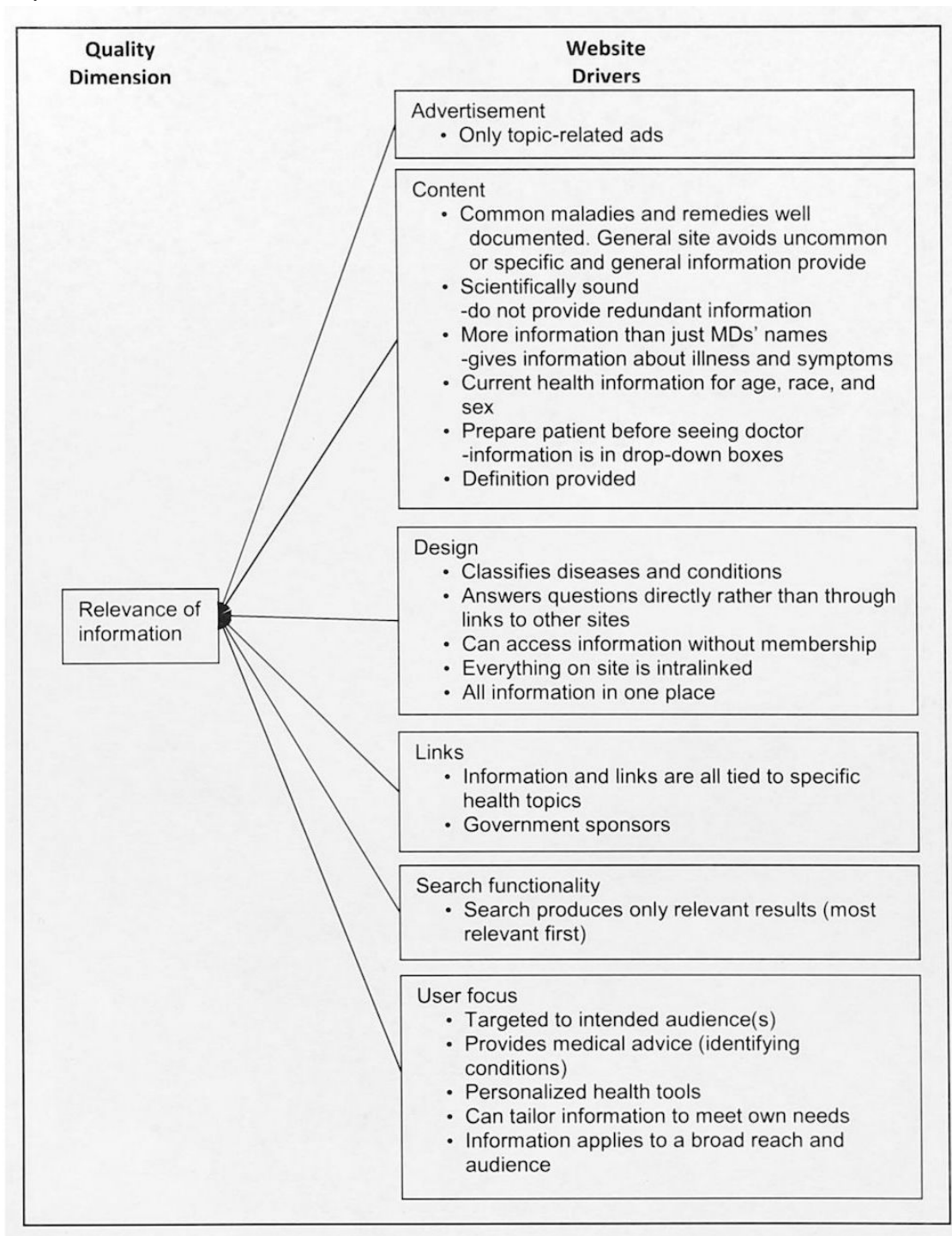**Figure 4.** Quality driver themes and detailed drivers for relevance of information on health websites.

Figure 5. Quality driver themes and detailed drivers for depth of information on health websites.
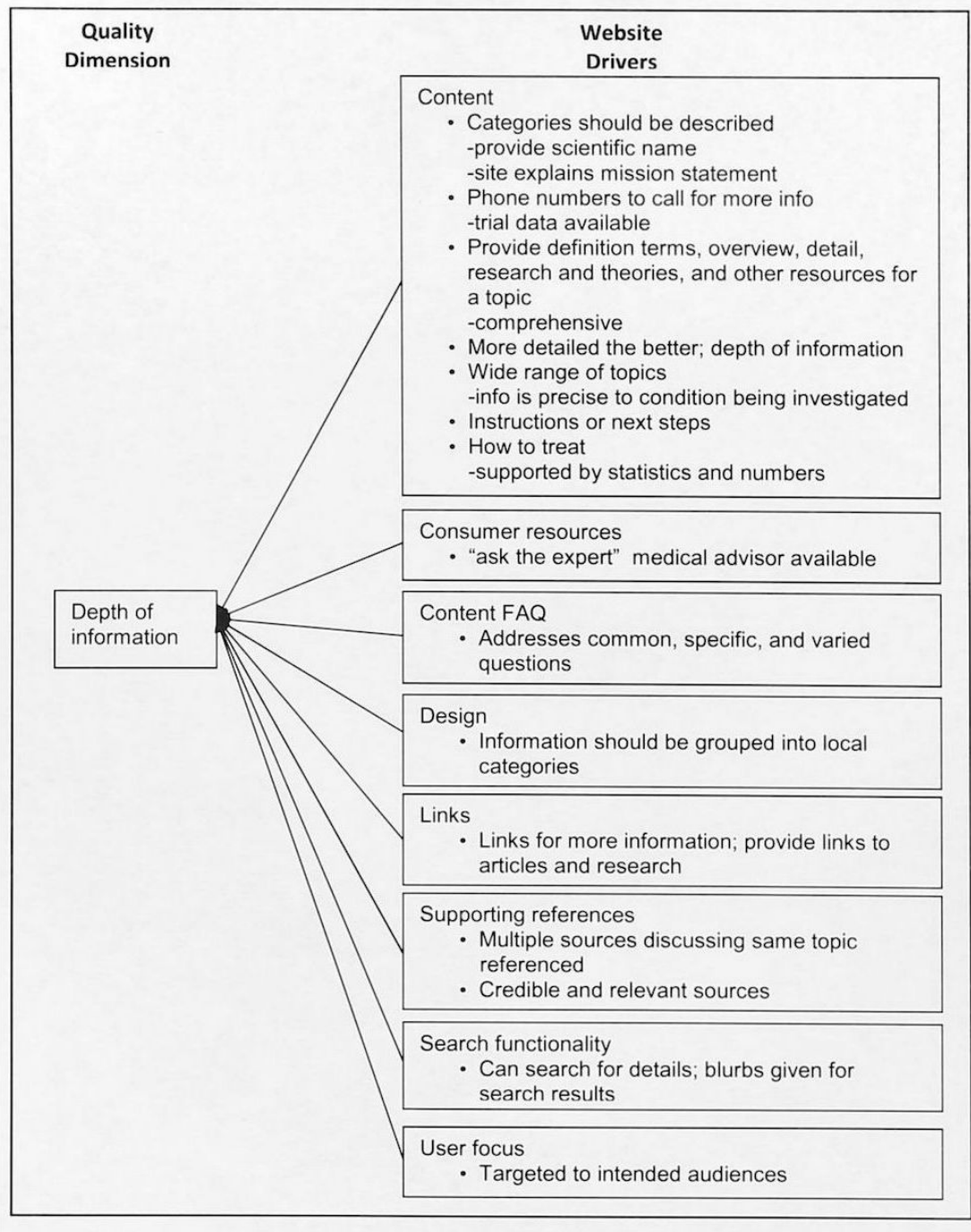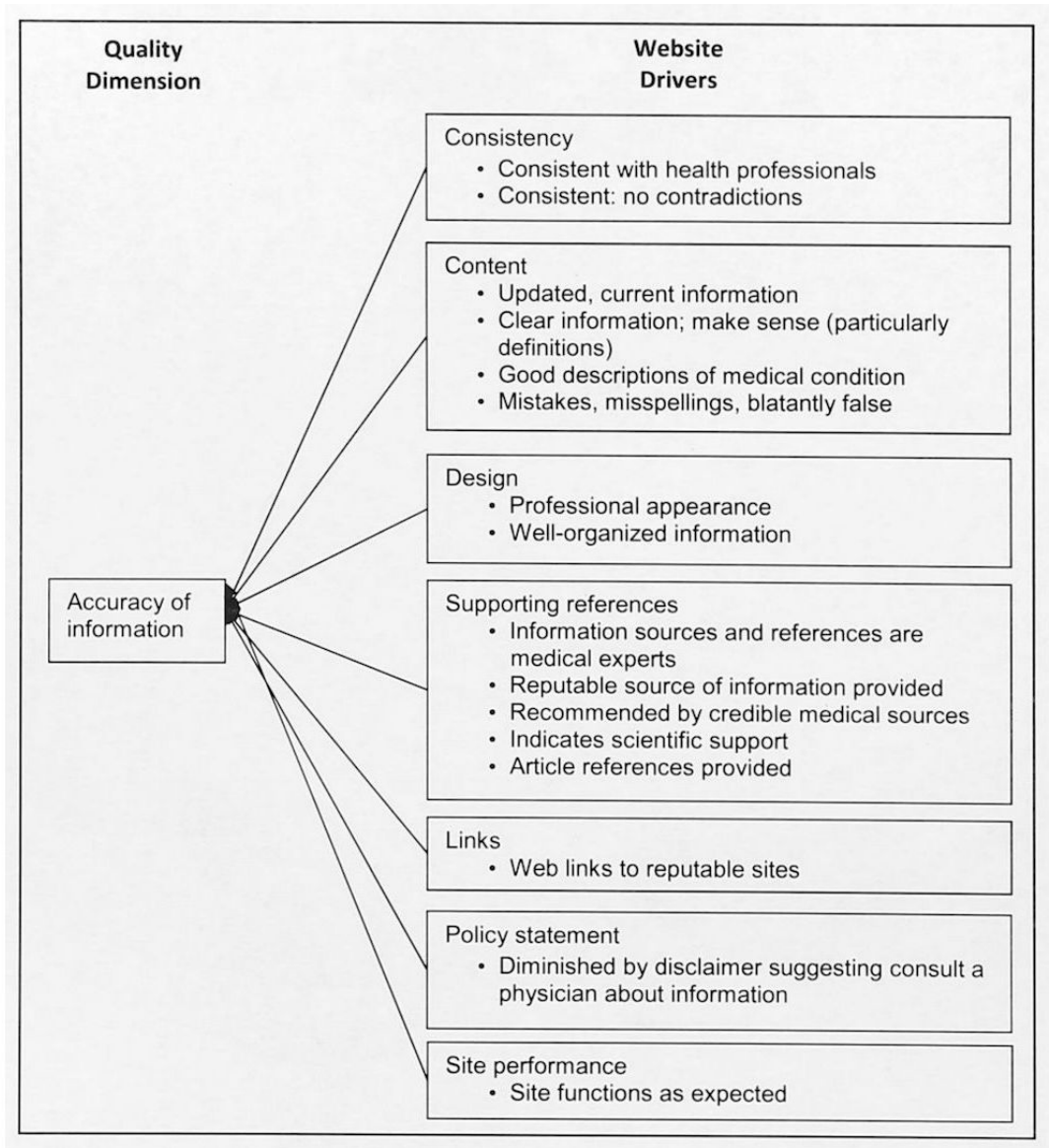
Figure 6. Quality driver themes and detailed drivers for accuracy of information on health websites.

Driver Themes Crossing Information Quality Dimensions for Health Websites

We found recurring drivers and grouped them into the driver themes. Figures 2-6 illustrate the associated driver themes with the supporting drivers (see bullet points in each figure) for each

of the five quality dimensions. These higher order driver themes (eg , *Content*, *Design*, and *Search functionality*) are supported and grounded with the detailed drivers. These driver themes provide a means to analyze across dimensions. Table 3 details distinct and common themes across dimensions.

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Table 3. Information quality driver themes across quality dimensions.

Quality driver theme	Completeness of information	Understandability of information	Relevance of information	Depth of information	Accuracy of information
Content	X	X	X	X	X
Consumer resources	X	X		X	
Design	X	X	X	X	X
Links	X	X	X	X	
Open access	X				
Supporting references	X			X	X
Search functionality	X	X	X	X	
User focus	X		X	X	
Advertisements			X		
Content FAQ				X	
Consistency					X
Policy statement					X
Site performance					X

We found that the drivers related to *Content* and *Design* are common drivers across all five dimensions. *Links*, *Search functionality*, *User focused* (targeted toward the health care consumer), *Consumer resources*, and *Supporting references* driver themes appear in three and more dimensions. Some driver themes are unique to a certain dimension, such as *Consistency* and *Policy statement* in Accuracy of information, *Open access* in Completeness of information, *Advertisements* in Relevance of information, and *Content FAQ* in Depth of information.

Discussion

The study findings lay out a multidimensional and conceptual framework of young educated adults' perceptions on health website information quality with five quality dimensions and the supporting drivers for each of individual dimensions. In general, few studies of health website information quality make any efforts to compare multiple dimensions of health information quality and *drill down* into the quality driver level [9,18]. We add to the novelty of this study by also identifying general driver themes and discovered recurring themes crossing dimensions.

Information Quality Dimensions for Health Websites

Although some aspects of the five dimensions of information quality are individually supported in past studies [8-11,20,24,37,38], the collective list has not been represented in any one study or collectively constructed from the ground up with users to our knowledge.

Ideally, all drivers associated with the identified dimensions would be strategically and systematically applied to the health website design to address health information quality dimensions. However, adding features and services to a website are associated with time and cost. Having some indication of priority can help developers make decisions when decisions regarding features, functions, and services must be made to align with time and dollar budgets. On the basis of the study findings, developers may want to pay extra attention to Completeness of information and Understandability of information drivers, given their rated importance by young educated adult consumers. *Consumer resources* drivers such as *provide sources for professional help, provide solution options, and "ask the experts" medical advisor available* may merit special attention, as they are associated with these two quality dimensions.

We acknowledge that Accuracy of information is an important quality dimension in the health care context, as health information could significantly impact consumers' decisions on treatments [2,6]. Although included in the resulting information quality framework, participants in this study did not rate Accuracy of information as high as the other information quality dimensions (see Table 2). This is an interesting finding, as information accuracy received the highest ratings among competing dimensions in other studies [9,41]. There are a few possible reasons for this finding. First, study participants may possess some underlying assumption that health care experts are the sources of content of health websites who validate the accuracy of information on health websites before being released to general consumers. Second, the study population of young educated adults is Internet savvy and usually has a relatively high eHealth literacy level [69]; therefore, this population may employ their Internet skills to perform cross-validation techniques to assess information accuracy by searching other sites. Third, understandability may at least, in part, serve as a proxy for assessing accuracy; medical terms and descriptions may confuse those not trained in a medical field. The educated young adult consumer group may interpret complete understandable information as possessing greater information quality over information that is complex and challenging to discern, even if accurate. Fourth, as we gave study participants a fairly wide varieties of contexts to answer interview questions and did not ask study participants' health status during data collection, relevance, depth, and accuracy of information may not be as important as Completeness and Understandability of

information depending on the incidents (eg, well or ill) they used at the time of data collection.

This study does not subordinate the need for accurate health websites but does provide indication that health care consumers use comprehension, logic, and easily discerned indicators of mistakes to assess accuracy. The following *Content*-related drivers provide some insight into the attributes that are considered in assessing the accuracy of information: *good description of medical conditions, no misspelling, definitions making sense, and updated or current information,* as well as *consistency, clean design, policy, supporting references* with credible sources *,* and *site performance* to construct perceptions of accuracy. Our findings support that accuracy alone does not result in young educated adults' perceptions of health information quality; additional quality dimensions are necessary to construct their perceptions of health information quality. The message for website sponsors and designers is two-fold: (1) aim for health care consumers to understand health information with accuracy and (2) engage with the website's target audience to assess the understandability and perceptions of accuracy.

Information Quality Drivers for Health Websites

Our study revealed quality drivers associated with the identified dimensions that are specific to the young educated adult consumer group. The drivers associated with Completeness of information and Understandability of information reveal that the young adult population expects that health websites *provide sources for professional help*, provide *solution options*, and make *"ask the experts" medical advisor available.* Our list of drivers also indicate that a certain level of customization is desired as indicated by drivers, such as information *tailored to meet their own need,* and *provide treatment options* and *personalized health tools.*

In contrast to previous studies [10,18,20], our findings did not reveal quality drivers related to the privacy issues. This finding may be attributed to the popularity of social media websites (eg, Facebook, blogs, and Twitter) among young educated adults [33]. Given the openness of social media, young adults may pay more attention to the speedy communication and seek online group support rather than the concerns of protecting their personal health information.

We identified abstract driver themes related to these drivers to provide a means to further analyze the drivers, particularly to determine relationships among dimensions. We found that several driver themes exist in more than one dimension. Different dimensions manifesting the same driver themes indicate some degree of overlap in the conception of dimensions on the websites. The most common driver themes (occurring in three or more of the information quality dimensions) include: *Content, Design, Links, User focus,* and *Search functionality.* We will address the drivers related to these recurring themes for cross-dimensional insights.

Concerning content, previous studies evaluating health information quality found content quality was mostly derived from domain-specific medical guidelines, textbooks, or literature [10,20]. In contrast to the previous studies, our study found that study participants seek more detailed and practical information,

such as *descriptions of medical conditions, list of symptoms with an accurate symptom checker, medical stories, terms defined and/or explained, adding pictures, trial data available,* and so on, as the young adults population expect to find actionable advice from the Internet rather than only gaining knowledge about certain health issues. With high education level, young adults have high expectations on the content of health information. For example, young educated adults expect the content to be specific and provide some depth as reflected by the following drivers: *provide research and theories for a topic, instructions or next steps,* and *how to treat supported by statistics and numbers.* Furthermore, young educated adults seem to have an appreciation for varied forms of content, including text, graphics, pictures, audio or videos, animations, and any other form of information presentation [5,18].

It is possible that repeated driver occurrence with the five various dimensions reveals particularly important attributes for designers to consider when prioritizing functionality. The recurring drivers related to the *Design* theme focus on the organization of content, and frequently reference categorization and grouping. The drivers related to *Links* reference connecting to outside websites (perhaps for more information or to validate website information). *User focus*–related drivers reveal the attributes of use a *lay language,* information *tailored to meet their own need, provide treatment options* and *medical advice,* as well as *symptom checker and personalized health tools,* such as providing tailored medical advice based on the information input by health care consumers. A comprehensive search function (across the website) seemed to be a recurring theme with *Search functionality*, which highlights young educated adults' expectations for the website interactivity features and the efficiency in seeking information.

Limitations and Future Studies

This study does have limitations in interpretation and generalization, which help to point the direction toward further research. First, although there are comprehensive quality criteria, guidelines, and voluntary codes of trust for both website developers to comply with and for consumers to judge the quality of a website [25,58], no *golden standard* criteria for assessing information quality in health websites from a health care consumer's perspective have been accepted [11]. The quality dimensions and drivers found in this study set a foundational attempt to provide tangible guidelines of website information quality features for website developers and health care consumers to reference. More studies should be conducted to perfect and validate information quality dimensions and drivers to achieve the model parsimony. A standard instrument that measures consumers' information quality perceptions needs to be developed with the validated quality drivers explored from this study as items to measure each of the five dimensions, to devise appropriate rating scales, and to test them out and be finally refined. This instrument should be designed to be able to measure perceived information quality in different contexts, such as populations with focused characteristics, purposes, and reasons for seeking health information on the Web, with appropriate changes in wording.

Second, the sample only included individuals with health care backgrounds and business professions and within a certain age span. Although the sample represents two large groups of health care consumers, not all types of potential health care consumers in varying backgrounds are represented. Future work may expand the populations of study and decompose the construct of health care consumers with different characteristics (eg, age, socioeconomic status, education level, and health status and conditions) to investigate the impact of consumers' perceptions on health website information quality evaluation. An example research question could be "What differences will be in the importance rating of health information quality dimensions by consumer groups with different health literacy levels?"

Third, as the general structure showed in Figure 1, a substantial number of empirical studies have examined the relationship between quality dimensions and higher level evaluations (eg, consumer satisfaction) but not the association of quality drivers (eg, attributes) with quality dimensions as done in this study. Information quality dimensions and drivers identified in this study can be adapted to those causal models to examine how objective quality drivers (ie, attributes) that drive information quality dimensions in health websites impact higher level evaluations. An example research question could be "How do the quality drivers in the *Design* driver theme impact completeness, understandability, relevance, depth, and accuracy of health information, which further impact the use of health websites?"

Conclusions

This study fills the gap in the consumer health informatics field by defining the quality of health information on health websites through a detailed, multilevel health information quality framework, with dimensions and drivers specified from the perspective of young educated adults. The multidimensional framework of health website information quality presented in this study unifies as well as extends the existing representations of website information quality in the literature. The quality dimensions and drivers found in this study (1) are a first attempt to provide a comprehensive framework specifying underlying meaning of individual quality dimensions, (2) extend existing frameworks by associating these drivers with corresponding quality dimensions, (3) provide a unique view of information quality that has not been specified to such a granular level, and (4) provide a solid foundation for developing an instrument or tool to guide the evaluation of health information from health websites.

Our health website information quality framework has implications for user-centered design and health information system evaluation for the young educated adult audience. It is clear from the findings that accuracy is a foundation, rather than a complete expression of information quality in designing health websites. The identified quality drivers provide indication of what website features young adults consider when they evaluate health website information quality and therefore can be used in research and practice as levers to guide development and assessment of information quality of health websites and to better understand the target group.

We encourage future efforts to validate the proposed framework in additional contexts and with additional user groups. We also encourage using study results as a start toward developing a standard health information quality assessment tool. In addition, we acknowledge that information quality is only one aspect of health website quality. Future research to conceptually decompose other aspects of health website quality, such as design quality, is needed.

Conflicts of Interest

None declared.

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Abbreviations

TAM: Technology Acceptance Model

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<u>Original Paper</u>

Formative Assessment: Design of a Web-Connected Sedentary Behavior Intervention for Females

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Abstract

Background: Sedentary behavior (SB) is a significant risk factor for heart disease, diabetes, obesity, and early mortality, particularly among women, and the health consequences associated with SB are independent of physical activity status. Interventions utilizing wearable technologies can improve SB, but their effectiveness is influenced by individual preferences, device engagement strategies, and technological features, which may affect user compliance. Gathering a priori insight from target populations on their preferences for program tools and strategies may assist researchers in identifying effective methods to improve the efficacy of SB interventions.

Objective: The objective of this study was to (1) explore the likeability (likes and dislikes) and usability (engagement intentions and navigation) of a wearable device (Movband) and its accompanying website (dashboard), (2) examine social incentive preferences (teammates), and (3) assess the feasibility (participants' experiences during an activity-monitoring period) of these tools for use in an intervention to reduce SB in girls and women.

Methods: A total of 9 girls (mean age: 8.9 years, standard deviation [SD] 1.1 years) and 11 college-aged women (mean age: 22.6 years, SD 3.2 years) participated in this study. Separate focus groups were held for girls and women, and all participants attended one before and the other following a 7-day activity-monitoring period. During the focus groups, participants were prompted with questions to address the study aims, and the nominal group technique was used to compile lists of group-specific preferences for the activity-monitoring system. The top three ranking likes and dislikes were reverse coded to determine likeability.

Results: The top-ranking responses for the girls and women were the following: visual display of movements and ease of navigation (dashboard like), boring to look at and no calorie-tracking function (dashboard dislike), backlight and long battery life (Movband like), and color and not waterproof (tied for girls) and vertical time display (Movband dislike). Additionally, participants identified several aesthetic preferences and functional limitations. At the second focus group visit, the majority of the participants self-reported less SB during the previous week. Objective data from the activity-monitoring period revealed that the average steps per day for girls and women were 12,373.4 (SD 2617.6) and 8515.8 (SD 3076.7), respectively.

Conclusions: These results suggest that the girls and women liked many features of the Movband and dashboard. However, several dislikes were mentioned, which may negatively influence compliance and the effectiveness of the activity-monitoring system and require improvements before using in an SB intervention.

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Introduction

A lifestyle characterized by significant periods of inactivity or sedentary behavior (SB) [1] represents a major risk factor for heart disease, diabetes, obesity, and early mortality, particularly among women [2-5]. Interventions to reduce sedentariness in girls and young women are not well established [6,7], but those exclusively targeting SB, as opposed to in combination with physical activity, appear to produce the greatest improvements [8]. More importantly, whereas a high prevalence of SB exists [9,10], particularly in those living in the southern region of the United States [11,12], the health consequences associated with SB are independent of physical activity status [13]. Thus, the need for effective intervention strategies to improve SB in this population is apparent.

Technology for Activity Promotion

Using technologies such as the Internet and wearable devices is efficacious in promoting activity-related behavior changes [14,15]. Electronic activity-monitoring systems, consisting of a wearable device and accompanying website and/or mobile app, collect objective measures of lifestyle activity and provide feedback beyond the display of basic activity count information from a device alone to facilitate self-monitoring [16]. Studies utilizing these activity-monitoring systems to increase physical activity in youth [17] and adults [16] have shown promise; however, less is known about their influence on SB [15,16,18]. Wearable technology in itself can improve sedentariness by increasing the user's awareness of the behavior [19], but the effectiveness of emerging technologies is highly influenced by individual preferences, device engagement strategies, and technological features [20,21], all of which can affect compliance to device use and the achievement of activity goals.

Appealing to the Target Population

Developing programs that appeal to target populations may improve the efficacy of interventions utilizing wearable technology by maximizing participants' engagement and compliance in the program. One concept that is particularly relevant to health promotion efforts targeting specific groups is the marketing mix, which involves the integration of four elements (ie, product, price, place, and promotion; the 4Ps), to satisfy consumer needs and wants with the goal of facilitating behavior changes [22]. Here, we focus only on the product, which has three forms: core (ie, the underlying benefit to the consumer), tangible (ie, the physical product), and augmented product (ie, additional features influencing long-term compliance) [22]. Related to improving sedentariness, the products are the reduced health risks associated with less SB (*core product*) and the strategic facilitators used to support these changes (ie, wearable devices and user engagement strategies; *tangible and augmented products*). An understanding of girls and young women's preferences for the tangible and augmented intervention components may enhance the efficacy of these tools to produce the desired behavior changes.

Social Incentives

Enhancing motivation for behavior change is commonly achieved through the use of incentives (*augmented products*), which can be monetary or social in nature. Although financial incentives can encourage individuals to make changes in behavior [23], they may also undermine the potential increases in enjoyment for positive health behavior changes [24]. In contrast, social incentives (eg, partners/teams, competition, and altruism) have been associated with enjoyment and improvements in activity patterns [25-28]. Partner-based programs, in particular, have been associated with motivation, social support, and accountability for physical activity–related changes [26-28], whereas the use of this strategy to improve SB is unknown.

Purpose

On the basis of the need to improve SB, studies supporting the efficacy of wearable technologies to improve activity patterns and the evidence demonstrating that preferences and social incentives may influence health behaviors, the aims of this study were to use formative assessments (1) to gain knowledge on the likeability and usability of an activity-monitoring system in girls and young women, (2) to examine social incentive preferences, and (3) to assess the feasibility of these tools for use in an intervention to reduce SB in this population.

Methods

Participants

Healthy girls (aged 8-11 years) and young women (aged 19-30 years) were recruited from Birmingham, Alabama, through flyers, print and Web-based ads, and through word of mouth. Prospective participants were screened via phone or email to ascertain eligibility. Specifically, prospective participants' eligibility was determined by their responses to the following questions:

1. *Do you (does your child) have any medical conditions that would prevent you (them) from participating in physical activities?*
2. *Have you used any physical activity–monitoring devices in the past 3 months?*
3. *Do you (does your child) have an allergy to latex?*
4. *What is your (your child's) current activity level?*

For the adults, the different activity parameters were classified by their response to the following statement: a daily profession where literally no exercise is done and most of the time is spent sitting in a chair (no exercise); some time in a day is spent moving from place to place, spending some time at a desk or in a chair (some exercise); most of the day is spent working as a skilled labor (moderate exercise); or most of the day is spent doing some physical work or involves daily exercise for most of the day (athletic). When screening parents or legal guardians (herein referred to as parents) of prospective minors, the content was adjusted to include terminology specific to children (eg, asking about physical activity habits, sports and recreation

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involvement). Those who self-reported no medical conditions that would prevent them from engaging in physical activity, had not worn a physical activity monitor in the past 3 months, had no allergies to latex, and indicated that they had a sedentary or moderately active lifestyle were included in the study. Age, height, weight, and race/ethnicity were also self-reported by the women and parents. The body mass index (BMI) was calculated for women (weight in kg/height in meters squared), whereas the BMI percentile and z-scores were determined for the girls [29]. Written informed consent from the women and parents, in addition to child assent, was obtained before their study involvement. The institutional review board at the University of Alabama at Birmingham approved this study (X150120004).

Design

Each participant attended two focus groups, one before and the other following a 7-day activity-monitoring period. Recognizing that the age-related preferences are likely to exist, separate focus groups were held for girls and women. These focus groups were structured to elicit information on the likeability and usability of an electronic activity–monitoring system that consisted of a wearable device (Movband, Model 2, DHS Group, Houston, TX, USA) and its accompanying website (hereafter referred to as the dashboard). Likeability was evaluated by participants' perception (ie, likes and dislikes) of the dashboard and activity monitor. Usability was evaluated by participants' engagement intentions, navigation of the system, and feature and functionality preferences. Social incentive preferences were explored by assessing participants' interest and age preferences for a teammate. Feasibility was evaluated by examining participants' experiences during the activity-monitoring period (ie, device failure, forgetting to put it back on after showering, etc). To accomplish these goals, the nominal group technique, a structured variation of a small group discussion that allows for full group participation and results in a set of prioritized responses, was employed as described elsewhere [30]. However, individual responses were verbalized to the entire group, as opposed to individually written [30], and subsequently recorded on a large easel pad by the facilitator. Thereafter, participants ranked their top three responses from the compiled list (see *Focus Groups* section).

Focus Groups

A summary of the dashboard and Movband features are displayed in Textbox 1. During the first focus group, participants sat around an oval table in groups of 2 or 3, sharing a computer that displayed the dashboard containing sample activity data from a user (OA). The dashboard is a three-part platform and, upon log-in, the default platform provided users with graphical displays of activity (ie, moves [a measure of physical activity], steps, and miles) that were viewable over a custom time frame

(ie, days, weeks, months, and custom). The dashboard display included preset activity goals (ie, 12,000 moves, 10,000 steps, or 4 miles) and an indicator of one's progress toward their daily goal (Figure 1). Participants were given a 5-min observation period to explore the dashboard features and, thereafter, were presented with a series of questions (Table 1). Where appropriate, as indicated in Table 1, participants were asked to individually rank their top three responses from the list of compiled responses and record them on the small piece of paper provided.

Participants were then given a 5-min observation period to explore a black Movband device (Figure 1). The Movband is a wrist-worn accelerometer that syncs with the dashboard via Universal Serial Bus (USB). On the device, users can view their daily moves and mileage; to view steps, users must access the dashboard. By design, the device resets the moves to zero each night at midnight, whereas the miles accumulate over time. Movband's proprietary algorithm takes into account pace, movement intensity, and stride length to calculate moves and miles. Stride length is determined by age, sex, and height. Although users may accumulate many moves in low-intensity activity, greater mileage is the result of fast-paced, high-intensity activities. Preliminary evidence suggests that the Movband is valid for children [31,32] and has been used for adults [33]. Following the Movband observation period, the participants were asked related questions and individually ranked their responses where appropriate (Table 1). Lastly, participants were asked about their willingness to have a teammate (Table 1) to explore their interest and age preferences for a partner.

Following the first focus group, participants were compensated US $10 and asked to wear the Movband at all times, with the exception of bathing and showering, until their second focus group visit 1 week later. This activity-monitoring period was used to obtain objective activity measures. During their second visit, participants synced their device with the dashboard, observed their activity from the previous week, and returned their Movband. Participants responded to questions, which included a subjective measure of SB and problems experienced and ranked their responses accordingly (Table 1). Following this visit, participants were compensated an additional US $10.

Analyses

Summary statistics were calculated for the participant characteristics. Where appropriate, rankings were tabulated for each item and the top three responses were reverse coded as follows: first, 3 points; second, 2 points; third, 1 point. Responses with tied rankings were also reported. All unique responses from the participants are displayed in the Multimedia Appendix 1. Quantitative data are presented as the mean (standard deviation; SD).

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Textbox 1. Features of the dashboard and Movband.

Dashboard

- Graphical displays of moves, miles, and steps that can be viewed over a custom time frame

- Personalized goal-setting capabilities and progress toward goal indicators

- Group-based dashboard

- Compatible with third party activity trackers and apps (eg, Fitbit, Garmin, Jawbone, and MapMyFitness)

- Front-end system for user interaction

- Admin Center for researchers to create groups and challenges, set goals, and communicate via email with group members

Mobile phone app available

Movband 2

- Wrist-worn accelerometer

- Wristband available in multiple colors

- Consumer purchase price of US $30

- Visual display of moves and miles on device

- Tracks moves (a measure of physical activity), miles, and steps

- Vertical time display

- Universal Serial Bus (USB) syncing

- Rechargeable battery

- 30-day battery life

Table 1. Focus group questions.

Questions	Focus group visit[a]	Ranked
Questions for Dashboard		
What do you like about this website?	1	Yes
How often would you log-in to the website to see your movements?	1	-
What is your least favorite feature on this website?	1, 2	Yes
What is your favorite feature on the website?	2	Yes
What problems did you experience while using the website?	2	-
Questions for Movband		
What do you like about the Movband?	1	Yes
What do you not like about the Movband?	1	Yes
After using the Movband for a week, what do you like about it now?	2	Yes
What do you not like about it now?	2	-
Do you feel like you were less sedentary in the past week? If so, what did you do differently?	2	Yes
Question for teams		
How do you feel about having a teammate who is younger (for the women) /older (for the girls) than you?	1, 2	-

[a]Each participant attended two focus groups, one before and the other following a 7-day activity-monitoring period. Numbers indicate visit during which the question was asked.

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Figure 1. Movband and Dashboard. The dashboard allows users to view graphical activity data (ie, moves, steps, and miles) over a custom time frame (ie, days, weeks, months, custom), daily activity goals, and one's progress toward reaching the daily goals.

(a)

(b)

Results

Participants

A total of 29 women and 12 girls were screened for eligibility (recruitment source: flyers [n=6], Web-based ads [n=29], and word of mouth [n=6]). Of this sample, 14 women and 10 girls were deemed eligible, and 11 women and 9 girls participated in this study. Participants' characteristics are provided in Table 2. Of the total participants 56% girls (5/9) and 72% women (8/11) in our sample were classified as overweight or (ie, average BMI ≥25 or ≥30 kg/m^2[women]; BMI percentile ≥85th or ≥95th [girls]). Furthermore, 67% girls (6/9) and 55% women (6/11) were ethnic minorities. Parents reported most of the girls (67%, 6/9) to be moderately active, whereas most of the women (82%) engaged in some activity (Table 2).

Likeability

Likeability was evaluated by participants' perception of the dashboard and Movband monitor. For the dashboard, the highest-ranking responses (of 23 unique responses; see Multimedia Appendix 1) for overall likeable features reported by girls were the visual display of movements (score of 15; visit 2) and the ability to recall activity from the past (score of 13; visit 1). The ability to store steps, moves, and miles (visit 1) and daily measurements and tracking over time (visit 1) were

tied in rankings with a score of 8 (Table 3). Goal attainment was another feature liked by the girls and cited during both focus group visits. For the women, the highest-ranking likeable dashboard features (of 24 unique responses) were its ease of navigation (score of 21; visit 1), goal attainment (score of 17; visit 2), and incentives and prizes (score of 13; visit 1). The women also cited the hour-by-hour breakdown and the dashboard interface as favored features. Regarding the dashboard dislikes, the highest-ranking response (of 13 unique responses) cited by the girls was boring to look at (score of 16; visit 1), followed by worries of forgetting their log-in password (score of 14; visit 1) and the color (score of 9; visit 2). In contrast, the highest-ranking dislike (of 21 unique responses) for the women was the inability to connect to a calorie tracker (score of 12; visit 2), followed by the inability to personalize goals (score of 11; visit 1) and the inability to track heart rate, which were tied in rankings (score of 11; visit 1).

The backlight feature of the Movband (score of 13; visit 2) was ranked the highest (of 20 unique responses) among the girls. Other favorable features included its ability to count steps (score of 9; visit 1), the ease of use (score of 8; visit 1), and mile accumulation feature (score of 8; visit 2). The women ranked the long battery life (score of 15; visit 1) the highest (of 28 unique responses), followed by price (score of 13; visit 1) and the time display (score of 12; visit 2). Top ranking dislikes cited

by the girls (of 28 unique responses) were the color (score of 11; visit 1), not waterproof (score of 11; visit 2), as well as not being pretty and the vertical time display (tied in rankings with a score of 10; visit 1,). Similarly, the women cited vertical time display (score of 13; visit 1) and not waterproof (score of 12; visit 1) and tied in rankings with a score of 11, the rectangular shape (visit 1) and lack of date feature (visit 2), as their top-ranking dislikes (of 29 unique responses).

Usability

Usability was evaluated by participants' engagement intentions, navigation of the system, and feature and functionality preferences. Regarding website engagement (ie, *How often would you log into the website?*—Table 1), the girls responded with a log-in duration (ie, *2 or 4 hours a day*) or mentioned frequency (ie, every day) (*at lunch, everyday*, *every single day*, *every day*, *every afternoon*, and *morning and night*). Other responses were weekends (*Saturday morning, afternoon, and evening*) or outside school time (*days I'm off from school*).

Women indicated that they would engage with the website daily (using an app), weekly, multiple times per week, or monthly. The range of system dislikes and functional limitations and preferences identified by our participants suggest that women were more thorough than the girls during the observation periods as some of their preferences (Table 4 and Multimedia Appendix 1) revealed that their navigation through the system went beyond that of the "default platform" displayed in Figure 1. Likewise, some preferred features described by our participants are readily available in the dashboard but went unnoticed (eg, personalized goal setting; Textbox 1). There were no website-related problems mentioned by the girls. However, two general issues were mentioned by the women: problems syncing their devices after the activity-monitoring period (because of a company upgrade that we were unaware of) and the presence of an error message despite "fixing" the error. One woman noted that she was not technologically savvy and may need a cheat sheet to navigate the website.

Table 2. Participant characteristics.

Characteristics	Girls (N=90)	Women (N=11)
Age in years, mean (SD[a])	8.9 (1.1)	22.6 (3.2)
Height in inches, mean (SD)	54.4 (4.0)	65.5 (2.9)
Weight in pounds, mean (SD)	76.7 (21.9)	167.1 (27.4)
BMI[b], kg/m^2, mean (SD)	-	27.4 (3.8)
BMI, z-score, mean (SD)	−0.05 (2.2)	-
BMI, percentile, mean (SD)	53.5 (43.9)	-
Weight status classification (n)		
Underweight	1	-
Normal weight	3	3
Overweight	2	6
Obese	3	2
Race/ethnicity (n)		
African American	4	5
Non-Hispanic white	3	5
Hispanic	1	0
Asian	1	1
Activity level		
None	-	1
Some	3	9
Moderate	6	1

[a]SD: standard deviation.

[b]BMI: body mass index.

Table 3. Summary of focus group responses for the dashboard and Movband for girls.

Responses for girls	Focus group visit	Score
Dashboard likes		
Ability to recall activity from the past	1	13
Ability to store steps, moves and miles[a]	1	8
Daily measurements[a]	1	8
Tracking activity over time[a]	1	8
Progression toward goal attainment	1	5
Visual display of movements	2	15
Ability to see goal attainment	2	8
Same as the previous week[b]	2	7
Display of total steps[b]	2	7
Dashboard dislikes		
Boring to look at	1	16
If you forget your password, you can't get in	1	14
Nothing	1	8
Boring to look at	2	16
Color of dashboard	2	9
Does not display entire total	2	8
Movband likes		
Ability to count steps	1	9
Ease of use	1	8
Comfortable	1	5
Ability of screen to light up	2	13
Miles do not reset every night	2	8
Tells the time	2	7
Movband dislikes		
Color	1	11
Not pretty[c]	1	10
Vertical time display[c]	1	10
Nothing[d]	1	7
Flat and uncomfortable on wrist[d]	1	7
Not waterproof	2	11
Uncomfortable in general and to sleep with	2	9
Sometimes uncomfortable	2	6

[a,b,c,d]Matching letters indicate responses with tied rankings by visit.

[e]Top three responses from a compiled response list were individually rank and reverse coded as follows: first, 3 points; second, 2 points; third, 1 point (range of possible scores: 1-33).

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Table 4. Summary of focus group responses for the dashboard and Movband for women.

Responses for women	Focus group visit	Score
Dashboard likes		
Ease of navigation	1	21
Incentives and prizes	1	13
No advertisements	1	8
Goal attainment	2	17
Hour-by-hour breakdown	2	12
The dashboard	2	10
Dashboard dislikes		
Inability to personalize daily goals[a]	1	11
Does not allow tracking of heart rate[a]	1	11
Cannot compare activity with weight loss	1	10
No Bluetooth capability	1	7
Not connected to calorie tracker app	2	12
Inability to set daily goals	2	9
Inability to track weight loss	2	6
Movband likes		
Long battery life	1	15
Price	1	13
Narrow wristband	1	7
Time display	2	12
No need to charge it	2	10
Good feedback on moves and steps	2	9
Movband dislikes		
Vertical time display	1	13
Not waterproof	1	12
Rectangular shape	1	11
Watch does not show the date	2	11
Unable to wear monitor other than on the wrist	2	9
Need for smaller wristband	2	5

[a]Matching letters indicate responses with tied rankings by visit.

[b]Top three responses from a compiled response list were individually rank and reverse coded as follows: first, 3 points; second, 2 points; third, 1 point (range of possible scores: 1-27).

Social Incentive Preferences

Social incentive preferences were explored through the assessment of participants' interest and age preferences for a teammate. At the first visit, the majority of the girls' responses were in support of having an older teammate, citing the opportunity to meet new people and having a friend with whom they could discuss their activity. Only two responses indicated that a teammate may not be preferred ("horrible" and "I don't like it but I just go with the flow"). At visit 2, all of the girls were in favor of having a teammate and mentioned their excitement and the benefits of the teammate, which included the potential teammates' maturity level, friendship, and knowledge. During both focus group visits, the women expressed their interest to have a younger teammate for the following reasons: competition, motivation, accountability, role model, and support. Two responses from the women also revealed that their teammates' current activity level was more important than their age. However, some concerns regarding the awkwardness with not knowing their teammate (visit 1) and a preference to not interact with a teammate and "just wear it [the Movband] and forget about it" (visit 2) were mentioned. Other responses indicated that teammate sex concordance (visit 1), having goals (visit 1), and the ability to set up a private chat between teammates would be ideal (visit 1).

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Feasibility

Feasibility was evaluated by examining participants' experiences during the activity-monitoring period. Activity data are displayed in Figure 2 and Table 5. One Movband did not function properly, which prevented us from collecting these data for one girl. The girls acquired an average of 12,373.4 (SD 2617.6) steps per day (Table 5). All of the girls revealed that they were less sedentary over the past week, and when asked what they did differently, the following responses were provided: *more activity, trying to get more steps*, *you have a goal to get 10k, 12k steps*, *sitting down less*, *slept less*, *be more active*, *move more*, *be different with your movements*, and *competitive*. Of total girls, 62.5% girls (5/8) with activity data achieved 11,000 to 12,000 steps per day, which has been associated with 60 min of moderate to vigorous physical activity [34] (Figure 2). The women acquired an average of 8515.8 (SD 3076.7) steps per day (Table 5). Approximately 50% of the women revealed they were less sedentary. The women expressing a reduction in SB stated that it was a result of monitoring their activity, making an effort to walk, being consciously aware of the Movband, and consciously trying to take the stairs:

...took the long way walking home and I would check and see where I was and then go for a walk or walk up and down the stairs.

Some responses demonstrated that the women were initially making an effort to move more but did not keep up with their activity:

...first day felt like I had to get up and do something—quickly went out the window and didn't do everything I wanted to do like go to the gym.

Those failing to self-report less SB sedentary in the previous week reported hectic schedules; however, other responses suggested that they may have been more aware of their activity levels:

No—it made me more aware to walk around more.

No—I wore it, I checked it. You did 4 miles today. Go me!

Of the total women, 45.5% women (5/11) met the recommendation of 10,000 steps per day [34], whereas all, with the exception of one, exceeded the step guidelines for sedentary behaviors (≤5000 steps per day [35]) (Figure 2).

Figure 2. Individual average steps per day for (A) girls and (B) women. Step-defined guidelines for being physically active (•••; ≥10,000 steps/day for women; 11,000-12,000 steps/day for girls) or sedentary (- - -, ≤5000 for women) are displayed. N=8 for girls due to unavailable data from one participant's activity monitor.
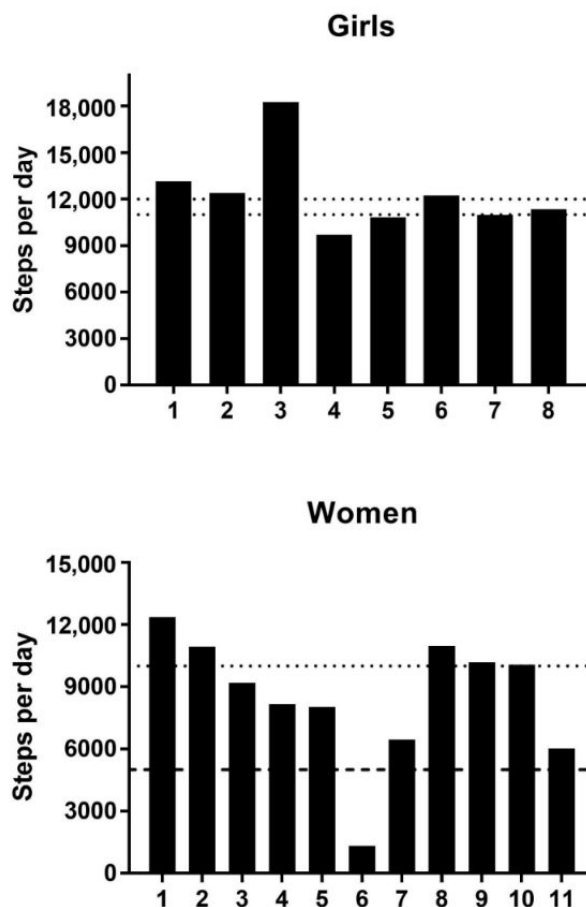
Table 5. Movband activity data during monitoring period.

Activity	Girls (N=8[a]) Mean (SD[b])		Women (N=11) Mean (SD)
Steps/day	12,373.4 (2617.6)		8,515.8 (3076.7)
Moves/day	14,917.6 (3153.8)		10,269.2 (3708.8)
Miles/day	5.2 (1.3)		4.0 (2.0)

[a]Because of unavailable data from one participant's activity monitor; low intensity activity results in the accumulation of more moves, whereas high intensity activities result in the accumulation of more miles.

[b]SD: standard deviation.

Discussion

Principal Findings

This study used formative assessments to (1) examine the likeability and usability of the Movband and its accompanying dashboard, (2) explore teammates as a social incentive to motivate behavior change, and (3) determine the feasibility of these tools for inclusion in an intervention to reduce SB in girls and young women. In this process, we employed a consumer-focused approach to better understand the preferences of our target population. Our findings suggest that the participants (1) liked many features of the Movband and dashboard and found the system to be user-friendly, however several dislikes and desired aspects were identified; (2) expressed an interest in favor of teammates but preferences for sex concordance and interaction strategies that allowed for private messaging were preferred; and (3) desired additional modifications related to aesthetics, functionality, and device comfort that need to be addressed before the use of this activity-monitoring system as an intervention tool to reduce SB.

Wearable technology has shown promise in improving activity patterns in youth and adults [16,17,36]. However, our understanding of the most effective intervention strategies to modify SB, as an exclusive intervention target, is insufficient, and this may be due to a lack of involvement and collaboration between populations of interest and researchers in the planning and development of behavioral programs [7,37]. Gathering a priori insight from these individuals on their preferences for program tools and strategies may assist researchers in identifying effective methods that can improve the efficacy of SB interventions. For these reasons, an understanding of the Movband and dashboard likeability and usability among our participants was a vital step in assessing their feasibility.

To our knowledge, this is the first study to use formative assessments to examine participant preferences for the Movband and dashboard in our planning and development of an SB intervention for girls and young women. Others studies have explored user preferences for Movband system in children [38] and college students [39] but not with the intent to develop an SB intervention. The study in children examined their perceptions of three commercially available activity-monitoring systems with the devices worn simultaneously and reported that the Movband system was the least "liked" among the participants [38]. The possibility that the comparisons between the commercially available systems may have prejudiced the

children's opinions of the Movband system cannot be ignored. To reduce the likelihood of this occurring in this study, participants were only eligible if they had not worn an activity monitor in the past 3 months to ensure that they were inexperienced in monitoring their activity with emerging technologies or to wash out any previous experiences with electronic self-monitoring tools. The study in adults incorporated Movband technology into a Web-based kinesiology course and received positive feedback related to its ability to encourage favorable physical activity habits among students; however, a newer model of the device (ie, model 3 as opposed to model 2) was used and the study aims were not focused on health behavior modification but rather enhancing the learning experience [39]. Taking a consumer-focused approach and segmenting our focus groups in this study allowed us to identify age-specific design and functional preferences that might influence the appeal, perceived value, and ability of this activity-monitoring system to influence SB. Although our participants found the activity-monitoring system to be user-friendly, they identified several unfavorable aesthetic features and functional limitations that may affect their engagement compliance if not addressed.

The popularity of emerging wearable technologies lies in their ability to influence health behaviors [20] through their intrinsic behavior change techniques [40]. A content analysis of the Movband activity-monitoring system demonstrated that it lacks key behavior change components, including a social support feature [38]. Social support is an important component for activity-related behavior changes [41,42], and the use of partners/team-based strategies has been associated with social support, motivation, and accountability [27,28]. In addition, studies in youth and young adults have indicated that friends can motivate activity-related behavior changes and may even improve device wear compliance [37,38]. As such, we explored the participants' receptiveness to having an older (for girls) or younger (for women) partner. Interest was high in favor of having a teammate, as participants identified friendship, support, motivation, competition, accountably, and role modeling as potential benefits. However, the women preferred sex concordance among teammates and interaction strategies that allowed for private messaging. At present, the dashboard does not possess the capabilities to allow users to communicate with one another through messaging or chat rooms, limiting the potential use of this platform [43].

Conducting focus groups before and after the activity-monitoring period allowed us to explore participants' experiences with the Movband activity-monitoring system in a free-living setting

and assess its feasibility to decrease SB. The majority of our participants self-reported a reduction in SB during the monitoring period. Studies utilizing electronic activity–monitoring systems have been effective in decreasing SB in young adults, but researchers have explicitly instructed participants to interact with the Web-based platform and aim to achieve their daily goals, which was enhanced by the intrinsic behavior change techniques of the system (eg, motivational emails after achieving goals) [44,45]. Our participants neither received explicit instructions to alter their activity patterns nor did they have access to the dashboard outside the focus groups. Their only instruction was to wear the Movband at all times, with the exception of bathing and showering. When asked about what they did differently, the many responses indicated that both girls and women made a conscious effort to move more, suggesting that the device increased our participants' awareness of their SB, which is supported by others [19]. The Movband data lend objective support self-reported changes in SB as all but one of the women exceeded step criteria indicative of a sedentary lifestyle (≤5000 steps/day) [35], despite less than half (45.5%) of the women achieving the recommendation of 10,000 steps/day [34]. A sedentary lifestyle step-based index has not been fully established for girls [35]; however, 62.5% of our participants achieved 11,000-12,000 steps per day, which has been associated with 60 min of moderate to vigorous physical activity [34]. The range of dashboard preferences identified by our participants during focus groups suggested that the women were more thorough during the observation period, as some of their preferences (Table 4 and Multimedia Appendix 1) indicated that their searches went beyond that of the "default platform" (Figure 1). Likewise, many of the preferred features described by our participants are readily available in the dashboard (Textbox 1) but went unnoticed indicating the need for a demonstration component to highlight the platform capabilities.

One of the unique features of this activity-monitoring system is that the dashboard was readily available for our use and is compatible with third party devices and apps (including the popular Fitbit; Textbox 1), which may be one strategy to overcome some of our participants' aesthetic and functional preferences. However, many features available on the compatible devices (eg, prompts/cues for periods of inactivity, automated sleep, heart rate, and food logging tracking) are not inherent to the Movband system and, in addition to the interpretation of activity data (eg, equivalence of Movband steps vs Fitbit steps), may present challenges from a research standpoint. Thus, although the platform compatibility is an appealing feature of this system, identifying ways to address potential challenges related to participant engagement and data interpretation will be necessary.

Limitations

This study is not without limitations, including the small sample size and hence the generalizability of preference findings to similar populations of girls and women. Our participants did not have access to the dashboard during the activity-monitoring period, which may have influenced their activity patterns and system preferences. In contrast, our sample was diverse in age, race, and ethnicity, with a larger proportion of minority participants than nonminority participants, which in turn is the strength of our study.

Conclusions

In summary, our findings revealed that the Movband and dashboard are user-friendly, yet several age-specific modifications related to aesthetics and functionality require improvements and subsequent formative assessments to increase the appeal, likeability, and potential use of this activity-monitoring system as an intervention tool. Considerations for the use of this system in an SB intervention include age-specific tailoring of the dashboard and implementing platform demonstration component to ensure that participants are aware of all functional capabilities. Using team-based designs to enhance motivation and social support may encourage participants' engagement and promote compliance in future behavioral interventions, but teams should be sex-matched and the platform should include message boards and team chat features. Interventionists who are interested in conducting efficacy studies to reduce SB in girls and young women by using wearable technologies should consider the preferences, opinions, and prior self-monitoring experiences of their target population to identify the feasibility of their intervention tools.

Acknowledgments

Conflicts of Interest

None declared.

Multimedia Appendix 1

Unique responses for girls and women by visit.

[PDF File (Adobe PDF File), 36KB - humanfactors_v4i4e28_app1.pdf]

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Abbreviations

BMI: body mass index

SB: sedentary behavior
SD: standard deviation
USB: Universal Serial Bus

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<u>Original Paper</u>

Workarounds Emerging From Electronic Health Record System Usage: Consequences for Patient Safety, Effectiveness of Care, and Efficiency of Care

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Abstract

Background: Health care providers resort to informal temporary practices known as workarounds for handling exceptions to normal workflow unintendedly imposed by electronic health record systems (EHRs). Although workarounds may seem favorable at first sight, they are generally suboptimal and may jeopardize patient safety, effectiveness of care, and efficiency of care.

Objective: Research into the scope and impact of EHR workarounds on patient care processes is scarce. This paper provides insight into the effects of EHR workarounds on organizational workflows and outcomes of care services by identifying EHR workarounds and determining their rationales, scope, and impact on health care providers' workflows, patient safety, effectiveness of care, and efficiency of care. Knowing the rationale of a workaround provides valuable clues about the source of origin of each workaround and how each workaround could most effectively be resolved. Knowing the scope and impact a workaround has on EHR-related safety, effectiveness, and efficiency provides insight into how to address related concerns.

Methods: Direct observations and follow-up semistructured interviews with 31 physicians, 13 nurses, and 3 clerks and qualitative bottom-up coding techniques was used to identify, analyze, and classify EHR workarounds. The research was conducted within 3 specialties and settings at a large university hospital. Rationales were associated with work system components (persons, technology and tools, tasks, organization, and physical environment) of the Systems Engineering Initiative for Patient Safety (SEIPS) framework to reveal their source of origin as well as to determine the scope and the impact of each EHR workaround from a structure-process-outcome perspective.

Results: A total of 15 rationales for EHR workarounds were identified of which 5 were associated with persons, 4 with technology and tools, 4 with the organization, and 2 with the tasks. Three of these 15 rationales for EHR workarounds have not been identified in prior research: data migration policy, enforced data entry, and task interference.

Conclusions: EHR workaround rationales associated with different SEIPS work system components demand a different approach to be resolved. Persons-related workarounds may most effectively be resolved through personal training, organization-related workarounds through reviewing organizational policy and regulations, tasks-related workarounds through process redesign, and technology- and tools-related workarounds through EHR redesign efforts. Furthermore, insights gained from knowing a workaround's degree of influence as well as impact on patient safety, effectiveness of care, and efficiency of care can inform design and redesign of EHRs to further align EHR design with work contexts, subsequently leading to better organization and (safe) provision of care. In doing so, a research team in collaboration with all stakeholders could use the SEIPS framework to reflect on the current and potential future configurations of the work system to prevent unfavorable workarounds from occurring and how a redesign of the EHR would impact interactions between the work system components.

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Introduction

Growing Adoption of Electronic Health Record Systems

Electronic health record systems (EHRs) can improve the way medical information is stored, communicated, and processed by those involved in delivering health care [1]. Adopting EHRs may result in favorable outcomes related to patient safety [2-4], quality of care [4-6], efficiency [4,7-10], and reduced costs [11,12]. In pursuit of these benefits and support provided by governmental stimuli programs [13], an increasing number of hospitals around the world have adopted EHRs [14-16].

Although adoption rates of EHRs are rising [17], realizing the promising benefits of adopting EHRs is far from evident. Many studies address unfavorable and often unanticipated outcomes of adopting EHRs. Examples include health care providers suffering from poor navigation [18,19], difficulties in finding the right information in the EHR [20], not all clinical work being supported by EHRs [21], never ending system demands [22], and significantly disrupted workflows due to modified timing, sequence of work practices, and revised professional responsibilities [23-26].

Workarounds to Electronic Health Record System Usage

Many causes of unfavorable outcomes of adopting EHRs can be traced back to discrepancies between the behavior and intentions of EHR users and the workflow as dictated by the EHR—often termed workflow mismatches [22,23,27-29]. Health care providers develop workarounds when they perceive EHR usage negatively affecting their practices as a consequence of workflow mismatches [21,30,31]. Workarounds are defined as "informal temporary practices for handling exceptions to normal workflow [32]" that "do not follow explicit or implicit rules, assumptions, workflow regulations, or intentions of systems designers [33]." Workarounds allow EHR users to proceed in accomplishing their tasks, in particular when under conditions of high time pressure [32]. Identified reasons for EHR workarounds include a perceived lack of efficiency, task complexity dictating workflow issues, no desired option being available in the system-dictated workflow, and a lack of trust in electronic versus paper-based communication [21,32,34-37].

Workarounds are double-edged swords. They may improve workflow efficiency [30,38], situationally increase patient safety by, for example, overriding alerts to get critical medication to a patient as soon as possible [27], or assist physicians when they purposefully order a wrong drug to trigger the alert system to suggest the right one [27]. However, workarounds frequently also lead to unstable, unavailable, or unreliable information or work protocols [32]. They may negatively influence the safety, effectiveness of care, and efficiency of care. For example, workarounds may bypass important security blocks (eg, working in a so-called emergency mode in nonemergency situations and thereby omitting security checks) [33] or lead to administering medication to the wrong patient or in incorrect doses [31,33]. Furthermore, they cloak deficiencies as devising workarounds rather than bringing problems to the attention of systems designers causes problems to remain hidden, which simultaneously inhibits optimization [39]. Finally, workarounds undermine standardization by using an alternative way to accomplish a task, thereby not conforming to a system-enforced way of working designed to safeguard patient safety or to eliminate variability [40,41]. Given their potentially adverse influence, research into workarounds has a prominent place in health care, and workarounds have been identified, analyzed, and described for various systems (eg, medication delivery systems, electronic medical records, and barcode medication administration systems), in various contexts (eg, academic vs nonacademic hospitals), and ways (eg, direct observations, expert panels, and surveys) [36,42-47].

Contribution

Existing literature primarily provides insight into types of EHR workarounds (paper and computer-based) [21,36], multiple reasons behind EHR workaround creation such as data confidentiality concerns, system instability, resistance to change, task complexity, knowledge gaps, and a perceived lack of efficiency [21,36,48-51], and describes several key features of EHR workarounds such as workarounds being avoidable or unavoidable, deliberately chosen or unplanned, and temporary or routinized [47]. However, research into the scope and impact of EHR workarounds on patient care processes is not as extensive. Knowledge of the scope and impact of EHR workarounds on organizational workflows and outcomes of care services is limited, and there are 2 areas of concern. First, concerning the scope of EHR workarounds, knowing whether a workaround solely affects the single EHR user who devised it or whether its effect extends beyond the EHR user to the work context of other health care providers is key to infer its impact on the overall patient care workflow. Second, knowing whether the impact of an EHR workaround is favorable or unfavorable, for example the influence it has on EHR-related safe and effective and efficient delivery of care, provides insight into how to address these concerns. This study addresses these issues and contributes to existing literature in 2 ways. On the basis of a large case study, we present an overview of 15 bottom-up identified rationales for EHR workarounds and give a definition for each rationale. In addition, for the most prominent workarounds identified per rationale, their scope and impact on patient safety, effectiveness of care, and efficiency of care are analyzed and discussed from a sociotechnical perspective using the Systems Engineering Initiative for Patient Safety (SEIPS) framework [52]. The research question central to this study was as follows: "What EHR workarounds are developed by health care professionals during their ordinary medical practice, and what are their rationales, scope, and impact on patient safety, effectiveness of care, and efficiency of care?"

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Methods

Study Design

To identify and analyze EHR workarounds, a case study was performed at one of the largest university hospitals in the Netherlands. The hospital adopted a hospital-wide EHR in 2015. Over 8000 hospital staff work with the EHR, and 100% of all orders (eg, medication, blood tests, lab results, and x-rays) are entered through the EHR. Enforced by strict hospital policies, paper-based orders are no longer accepted. The EHR, purchased from a large US EHR vendor, is an integrated suite of health care software. Its applications support functions related to patient care and management, registration and scheduling, clinical systems for health care providers, ancillary laboratory, pharmacy and radiology systems, and a billing system.

The research project involved 6 major chronological phases, as illustrated in Figure 1. The following subsections address the data collection phases (I and II) and data analysis phases (III,

IV, V, and VI) in greater detail. A summary of the data collection and analysis setup used for all 3 settings is provided in Table 1.

A more comprehensive description of the research approach taken for this study has been published as a study protocol [53].

Data Collection

We adopted a qualitative approach consisting of nonparticipant direct observation combined with semistructured follow-up interviews with physicians, nurses, and clerks using the EHR while performing their ordinary medical practice. The observations allowed us to observe workarounds while work practices and EHR use by health care professionals unfold in situ [54]. The semistructured follow-up interviews allowed us to gain greater insight into each observed workaround, more specifically their scope (ie, patient, professional, and organization) and impact (ie, consequences for patient safety, effectiveness of care, and efficiency of care).
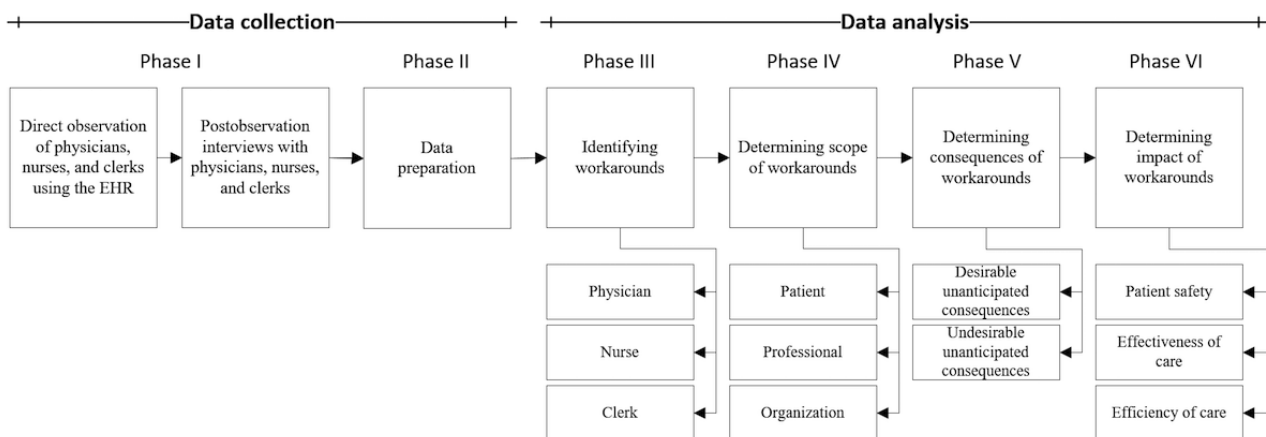
Figure 1. Illustration of the 6 research phases.

Table 1. Summary of research design by process studied.

Process	Preparing outpatient consultation	Providing outpatient consultation	Providing inpatient consultation
Sample	14 physicians and 5 nurses (same staff as in providing outpatient consultation process)	14 physicians, 5 nurses, and 3 clerks (same staff as in preparing outpatient consultation process)	17 physicians and 8 nurses (nurses perform clerical tasks)
Participant selection criteria	Must have completed the required training to use EHR	Must have completed the required training to use EHR	Must have completed the required training to use EHR
	Must have used EHR from the moment of its implementation	Must have used EHR from the moment of its implementation	Must have used EHR from the moment of its implementation
Setting	Private office	Examination room	Inpatient ward
Interaction	User-system	User-patient and user-system	User-patient and user-system
Procedure (per person)	Direct observation while preparing outpatient consultation, asking opportunistic questions while observing, and semistructured follow-up interviews	Direct observation while providing outpatient consultation and semistructured follow-up interviews	Direct observation during ward rounds and postward round EHR usage and semistructured follow-up interviews
Data analysis	Transcribing and subsequent bottom-up coding of audiovisual recordings in ATLAS.ti.	Transcribing and subsequent bottom-up coding of audiovisual recordings in ATLAS.ti.	Transcribing and subsequent bottom-up coding of audiovisual recordings in ATLAS.ti.

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A total of 31 physicians, 13 nurses, and 3 clerks were observed and interviewed (see Table 1). These numbers were not fixed beforehand: observations and interviews continued till the research team agreed that data saturation was achieved. Participants were recruited via the director of medical staff and director of operations, as well as participants suggesting other participants. Data were gathered within 3 clinical specialties: pediatrics, gynecology, and internal medicine. All these specialties use the same EHR of which the look and feel is identical, although additional specific functionalities tailored to each specialty are used. Within each specialty, providers were observed while using the EHR in 3 distinct processes: the preparation of outpatient consultation, providing outpatient consultation, and providing inpatient consultation. All direct observations and interviews were audiovisually captured by a small and unobtrusive camera positioned at a static location facing the monitor displaying the EHR. All physicians, nurses, clerks, and patients were asked for an informed consent before any recording took place. In total, around 200 hours of audiovisual material was captured.

The recordings were transcribed by VB in separate Microsoft Word documents and imported into a software application named ATLAS.ti. Within these imported documents, quotations were created for selected text sections or video frames possibly relating to an EHR workaround. After processing all transcriptions, VB reviewed each transcription, followed by KK and MJ validating the transcriptions and quotations to ensure (1) quotations indeed related to a workaround, (2) there was consistency among the quotations in terms of the range of the selected data, (3) minimal discrepancies existed between the audiovisual data and transcribed text, and (4) no relevant sections of data were overlooked.

Data Analysis

A bottom-up (ie, inductive) approach to coding was followed [55]. A provisional coding taxonomy containing multiple rationales for EHR workarounds was first created based on impressions and notes taken during each observation and interview. Before actual coding started, the coding team consisting of 2 independent coders (VB and an external [communications] researcher) was instructed on the EHR, the coding taxonomy, the meaning of each code, and the basics of coding in ATLAS.ti. To safeguard coding quality, the coding team coded the same copy of several random interview transcriptions using the provisional coding taxonomy. Copies of both coders were compared and discrepancies and ambiguities were discussed and resolved.

After the provisional coding taxonomy was finalized, the coding team began open coding. New codes or alternative code names could be proposed when data did not fit into the provisional taxonomy codes. Discrepancies in terms of codes assigned to the same quotation were resolved through discussion with the coders and MJ. The provisional coding taxonomy was adjusted when necessary. The tentative coding taxonomy developed itself over time into a final set of codes. The majority of the transcriptions was independently coded. Moreover, 25% of the transcriptions were coded by both coders. For these

transcriptions, inter-rater reliability was calculated to be 0.72 and inter-rater agreement was 0.93.

After coding all transcriptions, VB, KK, MW, and MJ analyzed each workaround in terms of its source of origin, scope, and impact. To facilitate this, we adapted one of the most widely used health care human factors systems frameworks, the SEIPS framework [52] (see [53] for more details). With the integrated and holistic perspective of the SEIPS framework, relationships between a health care work system (including workarounds), processes, and outcomes can be studied. The SEIPS framework has already proven valuable in studying workarounds in various health care contexts [33,56]. The adapted SEIPS framework is explained in greater detail in the Results section.

The first data analysis step after coding concerned determining the scope of each workaround by studying which stakeholders (ie, patient, professional, organization, or a combination thereof) were actually affected by the workaround. In the second step, the consequences of each workaround were determined, and each consequence was labeled as desirable or undesirable [27]. In the final step, the impact of each workaround consequence on the safe, effective, and efficient delivery of care was determined. The impact of each workaround was determined by analyzing the audiovisual fragments and related transcriptions of the direct observations and, in particular, the follow-up interviews conducted with the observed health care professionals using the workarounds. For most workarounds, their impact on patient safety, effectiveness of care, and efficiency of care was relatively clear: the impact was either directly visible or elaborated upon by the observed health care professionals at the moment of observing or clarified during the follow-up interviews. In case the impact could not be directly or accurately determined after the interviews, assistance from multiple other experts such as EHR developers, quality assurance staff, or hospital management was requested to provide additional insight. We define patient safety, effectiveness of care, and efficiency of care as follows:

- Patient safety is defined by the Institute of Medicine as "the prevention of harm to patients" [57]. In our context, we interpret this as any EHR-related incident resulting from a workaround which could possibly harm patients receiving care.
- The Institute of Medicine defines effective care as "providing services based on scientific knowledge to all who could benefit and refraining from providing services to those not likely to benefit, avoiding underuse and overuse, respectively" [58]. Workarounds may result in unstable, unavailable, or unreliable information on patient care (processes) or work protocols [32]. In our context, we interpret this as whether the workaround impacts the accuracy and completeness with which not just the single EHR user who created the workaround but the overall hospital staff in the case study hospital deliver care to patients (that is of proven value and has no significant tradeoff).
- The Institute of Medicine defines efficiency as "avoiding waste, including waste of equipment, supplies, ideas, and energy" [58]. We also interpret this as resources such as time or finances expended in relation to the accuracy and

completeness with which EHR users achieve goals [59]. Research has shown that the ratio between provider-EHR system and provider-patient interaction demands careful balancing [60-62] and that EHRs claim a significant portion of physicians' time and draw attention away from their direct interactions with patients and from their personal lives [63,64]. Workarounds may increase or decrease the efficiency through which EHR users achieve their goals.
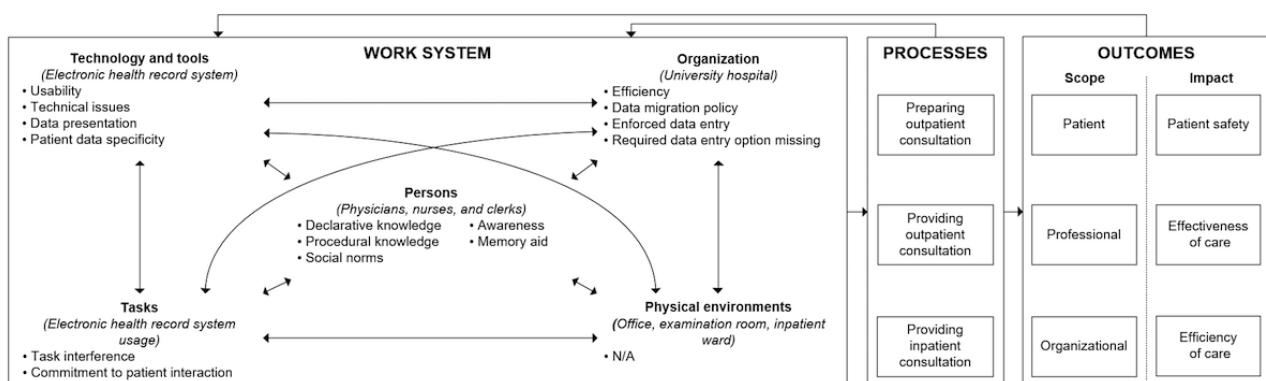
Results

Rationales for Electronic Health Record System Workarounds

A total of 15 rationales for EHR workarounds could be identified from the audiovisual data. Table 2 provides an overview of the EHR workaround rationales including definitions.

Table 2. Identified rationales for EHR workarounds and their definitions.

Rationale for EHR workaround	Definition
Declarative knowledge	Not knowing how to use (a part of) the EHR to accomplish a task
Procedural knowledge	Knowing how but not being proficient enough to use a part of the EHR to accomplish a task
Memory aid	Writing patient data down on paper (eg, keywords) or adding visual elements to parts of text in a progress note (eg, boldfacing, italicizing, or underlining) to remind oneself
Awareness	Storing patient data that are perceived important by the EHR user for other colleagues to be noticed in a data field other than the intended field in the EHR
Social norms	Informal understandings among health care professionals leading to the creation and dissemination of workarounds (eg, mimicking workarounds devised by colleagues to accomplish a task or working around the system as friendly requested or enforced by a fellow clinician)
Usability	High behavioral user cost in accomplishing a task
Technical issues	(A part of the) EHR halting, crashing, or slowing down, hindering the EHR user in accomplishing a task
Data presentation	Preferring a different data view (eg, visualization by means of charts or graphs rather than plain text)
Patient data specificity	Needing to enter or request patient data with greater or lesser specificity than offered or enforced by the EHR
Task interference	Inability to perform multiple tasks at once (eg, simultaneously treating a patient on a treatment table as well as entering patient data into the EHR)
Commitment to patient interaction	Valuing patient interaction over computer interaction (ie, writing things down on paper and afterwards entering this into the EHR)
Efficiency	Using an alternative way to accomplish a task that improves actual efficiency
Data migration policy	Not having (direct) access to required historical data due to data not having been imported from previously used systems to the current EHR
Enforced data entry	EHR enforcing user to enter patient data of which neither the user nor the patient has knowledge of
Required data entry option missing	EHR not offering the required data entry option (eg, 3.75 mg prednisone rather than the available options of 2.5 mg or 5 mg)

Figure 2. Conceptual framework used to study electronic health record system (HER) workarounds based on the Systems Engineering Initiative for Patient Safety (SEIPS) framework including an overview of the 15 identified rationales for EHR workarounds and the work system components they are associated with.

To analyze and determine the scope and impact of each EHR workaround, we used an adapted version of the SEIPS framework [52] tailored to our context (as discussed in Results). As illustrated in Figure 2, the framework consists of 3 main blocks that in turn consist of multiple components:

- The *work system* in which EHR workarounds are created, consisting of the observed and interviewed persons (physicians, nurses, and clerks), tools and technologies used (the EHR and other information systems), tasks performed (treating a patient on a treatment table or entering a patient's medical history, ordering medication, etc in the EHR), case study organization (the university hospital), and the physical environments in which the case study participants were observed and interviewed (private offices, examination rooms, and inpatient wards). The arrows between the components illustrate their interrelated nature. The components may act simultaneously and jointly exert influence over processes and resulting outcomes.
- The 3 *processes* in which case study participants were observed and interviewed and in which the EHR workarounds were revealed: the preparation of outpatient consultation, providing actual outpatient consultation, and providing actual inpatient consultation.
- The *outcomes* of EHR workarounds in terms of their scope (patient, professional, organizational, or a combination thereof) and impact (patient safety, effectiveness of care, and efficiency of care).

To reveal their source of origin, each of the 15 identified rationales for EHR workarounds was associated with 1 of the 5 work system components (as shown in Figure 2). The following section discusses each component of the work system and their associated workaround rationales in greater detail.

Electronic Health Record System Workarounds: Scope and Impact

The following subsections elaborate upon each component of the work system shown in Figure 2 and their associated workaround rationales. Per work system component, a table lists the associated rationales for EHR workarounds including several observed workarounds per rationale. For each workaround, its scope and potential impact on the safe, effective, and efficient delivery of care is listed.

The scope column indicates the degree of influence of a workaround, specifically which stakeholder(s) (may) experience (mostly unfavorable) consequences of the workaround. Within this column, P stands for patient, C for health care professional (clinician or clerk), O for the overall organization (eg, other specialties or hospital management), and a combination of these 3 letters for a combination of the foregoing stakeholders. Within the safety, effectiveness, and efficiency columns, ↑ denotes an increase, ↓ denotes a decrease, • denotes a negligible influence, and ? denotes undecided in case the impact of the workaround

on patient safety, effectiveness of care, or efficiency of care could not be accurately determined (eg, impact being highly situational).

The amount of observed EHR workarounds is too large for all to be listed and discussed. We therefore highlight the most prominent workarounds and their consequences per workaround rationale and discuss their scope and potential impact.

Persons

The Persons component refers to the observed and interviewed physicians, nurses, and clerks [52]. The 5 rationales for workarounds in this category primarily concern human-related factors: declarative knowledge, procedural knowledge, memory aid, awareness, and social norms. Table 3 provides an overview of prominent Persons-related workarounds and their scope and potential impact.

Declarative Knowledge

Declarative knowledge-related workarounds resulted from EHR users not knowing how to accomplish certain tasks at hand in the EHR. Whenever this occurred, users argued that they either had not (yet) taken part in necessary training to accomplish a given task or that they did take part in training but considered it too superficial and as a result still had no knowledge of how to use (a part of) the EHR. For example, a physician did not know how to use the functionality that automatically imports relevant patient data from the EHR into a letter to be sent out to, for example, a general practitioner or fellow clinician. Instead, the physician manually reentered patient data from the EHR into a letter. The physician managed to proceed with her workflow, albeit in a less efficient way and the reentering of patient data being prone to mistakes. Another physician did not know how to sign the patient treatment plans she created. Although the EHR allowed her to proceed with her workflow without signing any treatment plans, other clinicians may be led to believe these treatment plans are still pending to be reviewed and signed, and as a consequence, patients may not receive proper care.

Procedural Knowledge

Procedural knowledge-related workarounds resulted from EHR users considering themselves insufficiently proficient (despite having taken part in training) to safely and correctly use a part of the EHR to accomplish certain tasks at hand. For this reason, users devised other ways which they were more comfortable with—at least for the time being—to accomplish their task. For example, during a patient consultation session, a physician wanted to order an allergy test so the patient could immediately make an appointment at the reception desk after the consultation session. However, the physician was unsure whether her draft order was filled out correctly. She requested a colleague to review her draft order later that day, which improved patient safety, but she had to send the patient home with the request to call for making an appointment the following day.

Table 3. Prominent EHR workarounds concerning Persons and their scope and potential impact (↑ denotes an increase, ↓ denotes a decrease, • denotes a negligible influence, and ? denotes undecided. P stands for patient, C for health care professional [clinician or clerk], and O for the overall organization).

Rationale	Workaround	Scope	Safety	Effectiveness	Efficiency
Declarative knowledge	Manually reentering patient data from the EHR into a letter due to not knowing how to use the automatic letter generation tool	C	↓	•	↓
	Asking colleagues for assistance when not knowing the correct referral codes when referring patients to colleagues of another specialty	C	•	•	↓
	Not registering treatments due to not knowing what treatments are supposed to be registered and which ones should not	O	•	↓	↑
	Not signing treatment plans due to not knowing how to	PO	↓	↓	•
	Asking colleagues how to order antihemorrhagic drugs in *emergency situations* due to not knowing how to	PC	↓	↓	↓
Procedural knowledge	Requesting colleagues to review draft orders (eg, allergy tests) due to being uncertain whether the draft orders have been entered properly	PC	↑	•	↓
	Entering patient data via progress notes due to being unsure how to use certain EHR functionalities (eg, family history matrix)	PC	↓	↓	•
	Entering the same patient data in 2 near-identical data fields due to being unsure which data field entry will be forwarded to the right colleague	C	•	•	↓
	Rebooting the EHR due to not knowing how to efficiently navigate back to the main screen	C	•	•	↓
	Purposefully ordering too great a quantity of drugs (eg, 2 tubes instead of 1) due to being unsure of what quantity will eventually be delivered	P	↓	↓	↓
Memory aid	Temporarily boldfacing, italicizing, or underling parts of text in progress notes as a memory aid for questions to be asked or appointments made	CO	•	•	•
	Writing down keywords in a patient's progress note in advance of an outpatient consultation session as a reminder	C	•	•	•
	Writing patient data from other EHR tabs or external information systems down on paper as a memory aid to avoid excessive toggling between EHR tabs or windows while writing a progress note	C	↓	•	↑
Awareness	Purposefully entering patient data perceived important for other colleagues to see in data fields that are directly shown on the user's screen when opening a patient's health record, rather than in the intended field(s)	PCO	↓	↓	↑
	Bookmarking scheduled patient consultation sessions with specific colors, indicating these patients will be seen by clinicians not yet having a personal identity	CO	•	•	•
	Writing specific patient data down on paper next to entering this into the EHR as a heads-up for the following clinician seeing the patient afterwards	C	•	•	↓
Social norms	Copying a workaround after having heard of or seen a workaround being used by a colleague in practice (eg, entering patient data into a data field supposed to be exclusively used by another specialty)	C	?	?	↓
	Entering patient data (eg, allergies or vital signs) into an inappropriate data field as commanded by a superior, without entering these data into the appropriate data field(s)	PCO	↓	↓	?
	Entering patient data (eg, allergies or vital signs) into an inappropriate data field as requested by a fellow clinician, in addition to entering these data into the appropriate data field(s)	PCO	?	?	↓

Memory Aid

To remind oneself, EHR users would apply temporary mark-up to parts of text. Specifically, physicians and nurses were observed to temporarily boldface, italicize, or underline specific parts of text in progress notes as a reminder for them to, for instance, ask specific questions or plan a follow-up appointment. This information was supposed to be removed when finalizing the progress note. However, this was sometimes forgotten, causing fellow clinicians from both within and outside of the specialty of the EHR user to think an appointment still had to be planned or specific information asked when reviewing the progress note.

Awareness

EHR users would purposefully enter patient data they perceived important for other colleagues to see in data fields other than the intended data field(s). For example, physicians and nurses

entered important patient data in a data field that is strictly meant for listing patient discharge criteria. Data entered in this field are directly shown on the EHR user's screen when opening a patient's health record, making this an attractive field to store important data and draw attention. However, as soon as a patient is (re)admitted to the hospital and the important data stored into the patient discharge criteria field are replaced by actual discharge criteria by another clinician, these data are lost and no longer visible, thereby jeopardizing patient safety.

Social Norms

EHR users mimicked workaround behavior from their colleagues. This primarily occurred either after having heard of or seen a workaround being used by a colleague. For example, most physicians generated lists of patients with identical medical conditions (based on patient data present in the system). Within these lists, much to their frustration, physicians were unable to add additional free text alongside each patient entry in the top-level overview. Physicians argued this hampered them in efficiently searching through their patient lists, as they had to look into each patient entry one by one. A physician heard from a colleague that the neonatology group managed to add free text to each patient entry by looking into the property menu of each patient entry and selecting "NICU note" (neonatal intensive care unit)—a functionality developed by the EHR vendor as requested by the neonatology group. Free text could then be entered in a field that would be shown alongside each patient in the top-level overview. The physician managed to find this hidden functionality and shared her knowledge of this workaround with her colleagues working outside of the neonatology department. These colleagues in turn rapidly copied this workaround behavior, much to the annoyance of the neonatology staff who consider this abusive use of their data field polluting their own patient records.

Table 4. Prominent EHR workarounds concerning Technology and Tools and their scope and potential impact (↑ denotes an increase, ↓ denotes a decrease, • denotes a negligible influence, and ? denotes undecided. P stands for patient, C for health care professional [clinician or clerk], and O for the overall organization).

Rationale	Workaround	Scope	Safety	Effectiveness	Efficiency
Usability	Copy-pasting patient data from previous progress notes into a new progress note and subsequently modifying and supplementing these data due to usability issues with the standardized data entry template	PCO	↓	↓	•
	Manually planning (follow-up) appointments due to the automatic planning functionality providing bad visibility and oversight	C	•	↓	↓
	Postponing order entry in the EHR system during phone calls with patients as the EHR phone call interface does not accept orders	C	?	↓	↓
Technical issues	Writing down important information on paper and reentering this information into the EHR after the system crashes as booting backup takes too long	C	↓	↓	↓
	Registering batches of patient bleedings in a tailor-made standalone database as the EHR only accepts 1 bleeding registration per minute	PCO	↓	↓	•
	Either being informed by a colleague or regularly manually checking whether an expected patient had arrived in the waiting room as the arrival notification system is broken	PCO	•	•	↓
	Redrawing hemophilia family trees on paper due to failed data migration from the system used before the EHR and the current EHR	C	•	↓	↓
	Reentering orders into EHR after hardware-related printing issues, as orders are marked completed after print orders and cannot be printed again	PCO	↓	•	↓
	Repetitively adjusting predefined order sets because they contain known mistakes	PC	↓	↓	↓
Data presentation	Manually editing automatically generated letters because of, for example, undesirable font type, size, color, or order in which data are listed	CO	•	•	↓
	Drawing graphs on paper as the EHR was unable to generate the desired chart or graph (eg, line chart instead of pie chart)	PC	•	↓	↓
	Textually describing affected joints or connective tissues by rheumatology in a patient's progress note due to absence of a virtual body	C	•	↓	↓
	Drawing a body on paper and indicating affected joints or connective tissues by rheumatology and subsequently scanning and importing this into her	C	•	↓	↓
Patient data specificity	Further specifying patient data (eg, race, allergies, and social history) in progress notes because the standardized data entry template does not facilitate a sufficient specificity level	PC	↓	↓	•
	Skipping data fields in the standardized data entry template because they are considered inapplicable or irrelevant to the patient being seen (eg, smoking or drug use history when seeing a toddler)	C	•	•	↑

Technology and Tools

Four EHR workaround rationales primarily relate to the Technology and Tools component. That is, these workaround rationales resonate most closely with the EHR [52]. An overview of prominent Technology- and Tools-related workarounds and their scope and impact per workaround rationale related to this component is provided in Table 4.

Usability

Usability-related workarounds were devised when clinicians experienced user interface-related challenges while accomplishing a task in the EHR. For example, the EHR offers an extensive standardized data entry template for medical record keeping. However, whenever patient data had to be entered into the EHR during or after each patient visit, nearly all observed users preferred copy-pasting patient data from previous progress notes into a new progress note and subsequently modifying and supplementing this data. Only a selected portion of data was entered via the standardized data entry template (eg, vaccinations, medical diagnoses, current medication, and orders) as this is required as per the hospital policy. Reasons given for not using the standardized template include excessive up and down scrolling within the template due to the order of data fields presented to the user being misaligned with workflows in practice, inconsistent and confusing placement of user interface elements (eg, sign or agree buttons), and the template containing too much irrelevant screen clutter (eg, information or functionalities deemed entirely irrelevant). Although users preferred to enter data via progress notes over using the standardized template, clinicians argued this practice causes patient data to get lost in the system over time. As commented by a physician:

> For this patient, over 25 progress notes were created this week. […] We rarely copy-paste all information from an existing progress note into a newly created progress note. So, I am afraid important information simply gets lost in the EHR over time.

Technical Issues

Technical issues related to the EHR hindered users in accomplishing their tasks. For instance, multiple physicians occasionally experienced their EHR to crash whenever they loaded the growth analyzer functionality used to document, monitor, and analyze the growth and development of patients. Because booting the entire system backup again took minutes to complete, the physicians would write down important information on paper and reenter this information into the EHR either after the patient left the room or later that same day. Another example concerned the patient arrival notification system not automatically updating itself as it should have. As a result, clinicians had to either regularly manually check whether an expected patient had arrived in the waiting room or be informed by a colleague (eg, a clerk) that the patient had arrived.

Data Presentation

Data presentation workarounds relate to instances where either data in a patient's health record were not presented to the clinician in line with expectations or when the EHR was incapable of presenting the data in a way preferred by the clinician. In both cases, clinicians would (re)organize or (re)visualize the data themselves—often on paper. For example, an infectious disease physician wanted to show a patient's blood test results over a specific period of time by means of a graph. However, the EHR was unable to generate any charts or graphs, and as a result, the clinician herself had to draw graphs on paper.

Patient Data Specificity

Clinicians experienced the EHR to occasionally prevent them from being sufficiently specific when entering patient data. For instance, a physician had to specify a patient's race in the EHR. The EHR offers a range of possible races from which 1 option can be selected. Although the available and applicable option mixed race could be chosen, the physician argued that "mixed doesn't really tell us anything. I'd rather just write down that her father is Moroccan and that her mother is Dutch." The physician decided to further specify the patient's race in a newly created progress note. However, because the number of progress notes tends to increase quickly over time, these data may sooner or later be overlooked and thereby jeopardize patient safety.

Tasks

Task-related workarounds were driven by factors related to the tasks performed by physicians, nurses, or clerks while using the EHR. Among these factors are workload, time pressure, job content, cognitive load, and needs for attention [52]. Two workaround rationales are associated with this component: task interference and commitment to patient interaction (see Table 5).

Task Interference

While having to perform multiple tasks simultaneously, EHR users would write down patient data on paper to be entered in the EHR at another moment or temporarily enter patient data in an inappropriate single data field with the intention to reenter the data into the intended data fields afterwards. In the first case, a physician argued that due to the nature of her profession, she primarily examines her patients on a treatment table rather than providing consultation from behind a computer screen. Because she cannot examine patients and enter patient data into the EHR simultaneously, she wrote all necessary patient data down on paper during examinations as a memory aid, and reentered the data into the EHR as soon as patients left the examination room. She argued that this at least doubled her registration efforts, as before the EHR was implemented, filling out a paper form during the examinations sufficed. In addition, another physician was observed to knowingly enter all relevant patient data into a single inappropriate data field. Similar to the first case, she argued that she could not enter all patient data into the appropriate data fields while interacting with her patients. She would reenter all patient data from the single data field into the appropriate data fields after patients left the room.

Commitment to Patient Interaction

Multiple physicians and nurses argued that they have an unintentional inclination to spend relatively more time interacting with the EHR than making eye contact with patients during a patient's visit. A physician commented that from the perspective of a patient, seeing and having eye contact with a

doctor is an important psychological aspect of a patient's visit and well-being. As a result, clinicians decided to write down keywords during a patient's visit and enter these data into the EHR later on as they valued face-to-face interaction with patients over immediately entering patient data into the EHR. This same rationale applied to clinicians entering as much patient data or draft orders as possible into the EHR before seeing patients. Although both workarounds were perceived to be less efficient, clinicians argued this was offset by increased quality of care as they allowed them to spend more time interacting with their patients.

Table 5. Prominent EHR workarounds associated with Tasks and their scope and potential impact (↑ denotes an increase, ↓ denotes a decrease, • denotes a negligible influence, and ? denotes undecided. P stands for patient, C for health care professional [clinician or clerk], and O for the overall organization).

Rationale	Workaround	Scope	Safety	Effectiveness	Efficiency
Task interference	Writing patient data down on paper during examinations as a memory aid and reentering these data into the EHR after patients left the examination room, as some clinicians indicated that they cannot simultaneously examine patients and enter patient data	C	•	•	↓
	Writing patient data down on paper during telephone consultations as a memory aid and reentering these data into the EHR after the telephone conversation, as some clinicians indicated that they cannot simultaneously call and enter patient data	C	•	•	↓
	Entering all relevant patient data into a single inappropriate data field and reentering these data into the appropriate data fields after patients left the room	C	↓	•	↓
Commitment to patient interaction	Writing down keywords on paper during patient visits and entering these data into the EHR after patients left the room to spend more time interacting with patients	PC	•	↑	↓
	Entering patient data or draft orders into the EHR before seeing patients to spend more time interacting with patients	PC	•	↑	↓

Table 6. Prominent EHR workarounds concerning the Organization and their scope and potential impact (↑ denotes an increase, ↓ denotes a decrease, • denotes a negligible influence, and ? denotes undecided. P stands for patient, C for health care professional [clinician or clerk], and O for the overall organization).

Rationale	Workaround	Scope	Safety	Effectiveness	Efficiency
Efficiency	Not updating do not resuscitate orders as this has to be done every time a patient is readmitted to the hospital (sometimes every week)	PCO	↓	↓	↑
Data migration policy	Requesting lab results from longer than 5 years ago via an online form, as hospital management decided to not migrate lab results for more than 5 years ago to the her	PCO	↓	↓	↓
Enforced data entry	Entering patient data in progress notes rather than via the standard data entry template due to being forced to enter patient data of an unknown specificity level (eg, specific type of knee surgery a patient had 13 years ago)	PCO	↓	↓	↓
	Entering x in a mandatory data field to proceed when the supposed entry in the data field is not known or beyond one's expertise	CO	↓	↓	↑
Required data entry option missing	Creating blank orders as multiple desired orders (eg, multivitamin supplements) are not listed in the EHR despite being available	PCO	↓	↓	↑
	Entering (a part of) a patient's medication regimen in progress notes rather than the intended data entry fields in case the externally prescribed medication is not recognized by the EHR	PCO	↓	↓	↓
	Ordering a too low or too high drug dose enforced by technical limitations and entering a textual description in multiple data fields that the supposed dosage should be, for example, 3.75 mg per day instead of the ordered 2.5 mg per day	PCO	↓	↓	↓
	Entering a diagnosis that most closely resonates with the actual diagnosis as the desired data entry option is not offered	PCO	↓	↓	•
	Writing allergy-related patient information down in a progress note as the required allergy is not in the list of to-be-chosen allergies	PCO	↓	↓	•
	Leaving data field blank when the right option for "Reason for stopping medication" is not there in the drop-down list when stopping medication	PCO	↓	?	•

Organization

Workaround rationales associated with the Organization component of the work system stem from the organizational conditions in which EHR usage occurs [52]. Examples of organizational factors unintendedly driving the creation of workarounds are organizational and patient safety culture, supervisory and management style, and rules and regulations. Four EHR workaround rationales are associated with this component: efficiency, data migration policy, enforced data entry, and required data entry option missing (see Table 6).

Efficiency

Clinicians created workarounds to improve their actual efficiency of accomplishing tasks with the EHR. For example, clinicians knowingly did not reenter do not resuscitate (DNR) orders in the EHR. Although DNR orders are valid for up to 1 year, the EHR requires clinicians—as a result of the hospital policy—to reenter DNR orders every time a patient is readmitted to the hospital. In several cases, patients were readmitted every week on a routine basis. However, clinicians considered reentering DNR orders for such patients on a weekly basis a "waste of time" and therefore only entered a DNR order once. This order was only reentered upon request by the patient or after the order became invalid after a year. Although this practice made workflows of clinicians at hand more efficient, patient safety and effectiveness of care diminish as patients may change their mind about their DNR order after a week without explicitly communicating this to their clinician(s) (the latter being the main reason why this DNR reentry policy is enforced).

Data Migration Policy

Multiple clinicians felt enforced to request (essential) historical data because of data migration policy decisions taken by the hospital management team during the design and implementation phase of the EHR. For example, only lab results dating back to a maximum of 5 years were to be migrated to the new EHR. Multiple hematologists argued that "In order to determine the right dosage for our hemophilia patients, it is paramount that we know the antibody values of our patients against specific drug types, basically from their moment of birth till the present." To gain access to lab results entered into the system used before the current EHR for more than 5 years ago, clinicians have to fill out an online form that takes 5-10 minutes of their time. The processing of these forms is estimated to require additional 3 days. Not only does this negatively impact efficiency, but it also poses direct threats to patient safety in emergency situations where the right dosage of a drug cannot be accurately determined due to the absence of historical lab results data.

Enforced Data Entry

Clinicians occasionally experienced the EHR to force them to be overly specific when entering patient data. For instance, a patient told a physician to have had knee surgery back in 2003. When entering this information into the EHR, the physician was forced to specify the precise type of knee surgery from a multitude of possible options. Both the physician and patient were unsure of the exact type of knee surgery and the physician was unable to simply enter 'knee surgery'. This required specificity level of data entry did not stem from technical limitations, but was enforced by the hospital policy as the options for knee surgery from which the physician can choose are linked to the types of knee surgeries performed within the hospital. The physician decided to enter these data in a progress note rather than in the appropriate data field.

Required Data Entry Option Missing

The EHR occasionally did not offer data entry options desired by clinicians, particularly when ordering medication, altering a patient's current medication regimen, or entering symptoms into the patient's Problem List. For example, a physician wanted to order 3.75 mg of prednisone (1.5 tablets) per day for a patient. However, the EHR did not accept 3.75 mg and forced the physician to choose from either 2.5 mg (1 tablet) or 5 mg (2 tablets) per day. According to the physician, the EHR does not understand that the 2.5 mg tablets can be easily broken into half by patients. As the desired option of 3.75 mg was unavailable, the physician ordered 2.5 mg per day but entered a textual description in multiple data fields that the supposed dosage should be 3.75 mg per day. Although this workaround solved the workflow mismatch at the time, the physician commented to be "one hundred percent sure" that a medication error will occur to one of his patients sooner or later. "If one of my patients would be (re)admitted to hospital and the attending physician would only notice the EHR-enforced prescribed dosage of 2.5 mg of prednisone per day in the patient's medication overview rather than the prescribed dosage of 3.75 mg per day in the textual description, you can imagine what kinds of mistakes could be made." Upon closer inspection, it turned out that the root cause of this workaround did not result from the fact that the EHR could not process the physician's order. Instead, the drug ordering functionality of EHR is purposefully programmed this way as a result of the hospital policy as the list of all possible drugs to be ordered are derived from the inventory of the hospital pharmacy.

Physical Environment

The Physical Environment component of the work system refers to the environment and its conditions in which various tasks are carried out [52]. We observed and interviewed the case study participants in 3 distinct physical environments: private offices, examination rooms, and inpatient wards. However, no workaround rationales were associated with these physical environments or their conditions such as room layout, noise, lighting, temperature, or work station design.

Discussion

Contribution

Health care providers resort to informal work practices known as workarounds to handle exceptions to normal workflow unintendedly imposed by EHRs. Although workarounds may occasionally be favorable [27,30,38], they are generally suboptimal and may jeopardize patient safety, effectiveness of care, and efficiency of care [31-33,39-41]. Given their potentially adverse impact, understanding why and how workarounds occur is pivotal to develop user-friendly EHRs and achieve greater alignment between work contexts and EHRs.

Existing literature primarily provides insight into multiple reasons behind EHR workaround creation [21,36,48-51] and describes several key features of EHR workarounds [47]. However, research into the scope and impact of EHR workarounds on patient care processes is not as extensive. This narrows our understanding of the effects EHR workarounds have on the organizational workflows and outcomes of care services. This study contributes to the body of literature on EHR workarounds in 2 ways. First, we presented 15 bottom-up identified rationales for EHR workarounds. Our bottom-up approach meant looking at data in an open-minded way that led to the identification of 3 rationales that hitherto had not been identified by prior studies. Second, for each workaround rationale, we analyzed workarounds on their scope and impact from a sociotechnical perspective using SEIPS as a reference framework [52].

Identified Rationales for Electronic Health Record System Workarounds

After coding our data using a bottom-up approach, we compared our results with those in existing literature on EHR workaround rationales to look for commonalities as well as differences. Concerning similarities, multiple of our rationales have also been described with identical terms in prior studies which have identified workarounds related to memory aid [21,36,37,48,65], awareness [21,36,37,48], efficiency [21,36,37,48], patient data specificity [21,36,48], commitment to patient interaction (termed "sensorimotor preferences") [36,48], required data entry options missing (termed "no correct path") [21], technical issues [51], and social norms (termed "cultural factors") [51]. In addition, in prior studies, our EHR workaround rationales "declarative knowledge," "procedural knowledge," and "usability" have been separately categorized [51] as well as merged in a single rationale [21,36,37,48]: "knowledge/skill/ease of use." On the basis of our dataset, we found that "declarative knowledge," "procedural knowledge," and "usability" are rationales for workarounds that can be clearly distinguished and demand to be tackled in a different way.

Our workaround rationale taxonomy may be more refined compared with those in existing literature. Despite identical naming, existing examples of the rationale "efficiency" [21,36,37,48] may not be identical or applicable to our rationale "efficiency." For example, Flanagan ME et al [21] mention that their most frequently encountered example of computer-based efficiency workarounds concerned users "copying and pasting text from previous progress notes into a new progress note." Although our observed clinicians did the exact same thing, we found that the rationale for this workaround was actually "usability" because the clinicians favored entering and copy-pasting the majority of patient data in progress notes due to low perceived usability of the standardized data entry template. In our study, only workarounds to which no other underlying rationales were applicable but to purely accomplish a task with greater efficiency were labeled as "efficiency."

Our rationales "data migration policy," "enforced data entry," and "task interference" do not directly correspond with rationales identified in existing literature. In contrast, our dataset provided no evidence of workarounds that could be directly

related to task complexity [21,36,48,51], longitudinal data processes [21,36,48], trust [21,36], security [36,51], EHR vendor contract-related issues [51], or double or duplicate documentation due to hospitals using multiple incompatible EHRs [50]. However, not all workaround rationales identified in prior research apply to our hospital setting. For example, we did not identify the workaround rationales "trust" (defined as "greater trust in paper over electronic version") [21,36,37] or "security" (defined as "security associated with the EHR encourages paper use as an alternative") [36,51] because any paper-based orders are no longer and in no way accepted in the case study hospital. EHR users therefore have no other option but to create computer-based rather than paper-based workarounds to proceed with their workflow when placing orders. In addition, we found no workaround rationales that could be associated with the Physical Environment component of the SEIPS framework. This could be due to the nature of the EHR studied, contrary to, for example, studies investigating workarounds to barcode medication administration (BCMA) systems. For example, physical factors to BCMA workarounds such as unreadable medication barcodes (eg, crinkled, missing, and torn), unreadable or missing patient identification wristbands (eg, chewed, soaked, and self-removed), or loud ambient noise preventing nurses from hearing scanner alarms [33,66] were not applicable in any of the 3 physical environments in which we observed EHR usage.

Scope and Impact of EHR Workarounds

Three interesting observations can be made regarding the scope and potential impact of workarounds on patient safety, effectiveness of care, and efficiency of care. First, nearly all observed workarounds except for those related to the rationale "social norms" could have a positive or negative impact on at least one of these 3 dimensions. The potential impact of workarounds should therefore not be underestimated. Second, all workarounds related to the rationales "enforced data entry" and "required data entry option missing" could reduce patient safety. Likewise, all workarounds related to the rationales "enforced data entry," "required data entry option missing," "usability," and "data presentation" could reduce the effectiveness of care. All workarounds related to the rationales "task interference," "commitment to patient interaction," "technical issues," and "data presentation" could reduce the efficiency of care. Third, tradeoffs could also be seen between the 3 dimensions. For example, all workarounds related to the rationale "commitment to patient interaction" showed an increase in effectiveness of care at the expense of efficiency of care. Workarounds should therefore be assessed with care from multiple perspectives.

In summary, knowing the scope as well as impact of each workaround aids health care practitioners and other stakeholders such as EHR developers or management in prioritizing the handling of workarounds. For example, in our case study hospital, multidisciplinary teams consisting of among others physicians, nurses, quality assurance staff, and EHR developers work together to identify, analyze, and resolve workarounds. A well-defined workflow in a specific specialty such as medication ordering in the gynecology department is generally taken as a starting point for workaround identification and

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analysis. If the perceived potential improvements of resolving the workarounds are deemed satisfactory, the identified workarounds are studied more broadly in other specialties as well to see if hospital-wide improvements could be achieved. Workarounds that are found to affect patients or have the potential to negatively impact patient safety are resolved first as patient safety is concern number one. Likewise, workarounds that affect patients and have the potential to improve patient safety are sustained and, if possible, integrated in user-EHR workflows. It should be taken into account that our definitions of patient safety, effectiveness of care, and efficiency of care may not be directly applicable to other hospitals. Results should therefore be interpreted with care.

Added Value of the SEIPS Framework

Concerning the sociotechnical perspective, we used an adapted version of the SEIPS framework [52] tailored to our context to interpret, analyze, and determine the scope and impact of each EHR workaround. The integrative and holistic perspective of the SEIPS framework proved useful to study workarounds in relation to not just the health care work system in which they were created but also in relation to the care processes performed and resulting outcomes on patient safety, effectiveness of care, and efficiency of care. This was beneficial for 3 main reasons.

First, the SEIPS framework allowed us to indicate what workaround rationales are most closely associated with each of the 5 components of the work system. This aided us in more accurately determining how each workaround could be resolved. For example, workaround rationales associated with the Persons component include a person's declarative knowledge and procedural knowledge of using the EHR. Such workarounds may most effectively be resolved through personal training to assure optimal and proper EHR use. Likewise, workaround rationales associated with the Organization component may most effectively be resolved through reviewing organizational policy and regulations and subsequently EHR data entry policies, whereas Tasks-related workarounds may most effectively be resolved through task redesign. Workaround rationales associated with the Technologies and Tools component were primarily the result of clinicians bringing their own workflow in line with the EHR-dictated workflow, as the latter is relatively fixed. These workarounds may, therefore, most effectively be resolved through EHR redesign efforts. However, it should be taken into account that workarounds must be thoroughly assessed before they are classified under 1 of the 5 work systems components of the SEIPS framework. For example, "required data entry option missing" workarounds seemed to be related to Technology and Tools-related workarounds at first sight. Upon closer inspection, however, it turned out that the root cause of these workarounds did not result from the EHR not being able to, for example, process physicians' orders or list additional data entry options. Instead, the drug ordering functionality of the EHR is purposefully programmed this way as a result of the hospital policy as the list of all possible drugs to be ordered are derived from the inventory of the hospital pharmacy—making them Organization-related workarounds.

Second and related to the foregoing, the SEIPS framework is supportive in planning these redesign efforts of the work system.

Multidisciplinary teams of physicians, nurses, quality assurance staff, and EHR developers, as aforementioned, reflect on the current configuration of the work system to prevent unfavorable workarounds from occurring. Likewise, future work system configurations are discussed to, for example, explore how a redesign of the EHR would impact interactions between the work system's people, tasks, organization, other tools and technologies, and internal and external environmental factors.

Finally, the adapted SEIPS framework including the workaround rationales associated with each work system component in Figure 2 is a snapshot of the studied sociotechnical system based on approximately 14 months of observations and interviews. Because EHR workarounds are subject to gradual change caused by, for example, changes in one's knowledge of the EHR, personal preferences, regulations, policy, care directives, or financing structures of the hospital, workarounds are not set in stone and may change over time. Multiple snapshots are being taken over time and compared in search of interesting clues about the evolution of workarounds and implications hereof in practice.

Limitations of the Study

This study has several limitations. First, this study was performed at a large academic hospital. EHRs in academic hospitals tend to be more complex than their nonacademic counterparts, as they must cater to the needs of many diverse highly specialized patient care practices each with varying electronic functionalities [67]. Larger hospitals also tend to have access to more sophisticated and tailor-made EHRs including a large pool of technology-support personnel, contrary to smaller care practices generally relying on commercially available EHRs with less functionalities and limited information technology sources [47]. This means the results should be interpreted with care and may not be applicable to other health care contexts.

Second, the EHR studied had been in use for around half a year from the moment our first observations began. Although the case study participants indicated to be largely past the valley of despair [68], workaround rationales became increasingly or decreasingly prevalent as time progressed. For example, workarounds created due to a lack of declarative or procedural knowledge of using the EHR occurred far more frequently than the other types of workarounds within the first months of observation. These workarounds became less prevalent as case study participants steadily became more proficient in using the EHR while our observations continued for over a year. The greater the user proficiency with the EHR, the more other rationales for workarounds such as the need to enter patient data with greater or lesser specificity or preferring alternative ways of data presentation came to the fore.

Third, we may not have captured all workarounds used in practice. However, the observations and interviews continued till the research team (VB, KK, MW, and MJ) agreed that data saturation was achieved. This is confirmed by the large number and broad variety of workarounds we observed. This led to the development of a solid set of workaround rationales that can be used to analyze workarounds that we may not have seen during our observations or interviews.

Finally, to mitigate the Hawthorne effect during observations and audiovisual recordings, we clearly communicated to the participants what is in it for them. We explained how participating in the research project was an opportunity to improve the EHR and thereby reduce potentially negative impacts on patient safety, effectiveness of care, and efficiency of care. We also stressed that we were observing the EHR rather than the participant and clearly communicated that data gathered are made fully anonymous, cannot be traced back to them, and will not be shared with anyone else not belonging to the research team. This reassured the participants to use their EHR as they normally would without fear of potentially being reprimanded or rebuked after participation. Participants actually commented to be glad that research was being performed on EHR workarounds because they were aware of their potentially hazardous effects. Finally, the audiovisual camera was permanently and unobtrusively installed for the duration of the observations and interviews, and did not require frequent maintenance or recalibration. Observers were positioned at a safe distance from the clinician using the EHR (see [69]).

Future Research

Further research is currently being performed for the identification of key features of the identified EHR workarounds. Examples of such features include their cascadedness (ie, whether a workaround is stand-alone or initiates a series of additional workarounds), avoidability, anticipatedness, and repetitiveness. This knowledge may then be used to better understand the implications EHR workarounds may have on the safe, effective, and efficient delivery of care to patients, as well as aid in subsequently determining how they should be handled.

Two main recommendations for future research can be given. First, additional observational studies using a top-down approach (eg, [21,37,48] for top-down approaches) could be performed to see whether the coding taxonomy containing the 15 EHR workaround rationales could be refined or extended. Second, future research could also study how changes in work system component-related factors such as EHR user training, physical workspace layout, organizational policies, task content, or redesign efforts of the EHR could result in a more balanced and close fit between the various work system components.

Authors' Contributions

VB, KK, and MJ collected the data. VB, KK, MW, and MJ analyzed the data. VB wrote the manuscript. KK and MJ edited the manuscript. All authors read and approved the final manuscript.

Conflicts of Interest

None declared.

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Abbreviations

BCMA: barcode medication administration
DNR: do not resuscitate
EHR: electronic health record system
NICU: neonatal intensive care unit
SEIPS: Systems Engineering Initiative for Patient Safety

Original Paper

Healthy Beyond Pregnancy, a Web-Based Intervention to Improve Adherence to Postpartum Care: Randomized Controlled Feasibility Trial

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Abstract

Background: During the postpartum visit, health care providers address issues with short- and long-term implications for maternal and child health. Women with Medicaid insurance are less likely to return for a postpartum visit compared with women with private insurance. Behavioral economics acknowledges that people do not make exclusively rational choices, rather immediate gratification, cognitive and psychological biases, and social norms influence decision making. Drawing on insights from decision science, behavioral economists have examined how these biases can be modulated through carefully designed interventions. We have developed a Web-based tool, Healthy Beyond Pregnancy, that incorporates empirically derived concepts of behavioral economics to improve adherence rates to the postpartum visit.

Objectives: The primary objectives of this pilot study were to (1) refine and assess the usability of Healthy Beyond Pregnancy and (2) assess the feasibility of a randomized controlled trial (RCT) of the intervention.

Methods: We used a multistep process and multidisciplinary team of maternal-fetal medicine physicians, a behavioral economist, and researchers with expertise in behavioral interventions to design Healthy Beyond Pregnancy. We assessed the usability of the program with the Post-Study System Usability Questionnaire (PSSUQ), a validated 7-point scale, and semistructured interviews with postpartum women. We then conducted a feasibility trial to determine the proportion of eligible women who were willing to participate in an RCT of Healthy Beyond Pregnancy and the proportion of women willing to complete the Web-based program. Exploratory outcomes of the pilot trial included attendance at the postpartum visit, uptake of long-acting reversible contraception, and uptake of any contraception.

Results: The median PSSUQ score for Healthy Beyond Pregnancy was 6.5 (interquartile range: 6.1-7) demonstrating high usability. Semistructured interviews (n=10) provided in-depth comments about users' experience and further improved the program. A total of 34 postpartum women with Medicaid insurance were approached for the pilot trial, and 30 (88%) were consented and randomized. All women randomized to Healthy Beyond Pregnancy completed the Web-based program, had text-enabled cell phones, and were willing to receive text messages from the study team. Women in the Healthy Beyond Pregnancy arm were more likely to return for a postpartum visit compared with women in the control arm with 85% of women in Healthy Beyond Pregnancy returning versus 53% in the control arm (odds ratio in the Healthy Beyond Pregnancy group: 5.3; 95% CI 0.9-32.0; *P*=.06).

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Conclusions: We have developed a highly usable and acceptable Web-based program designed to increase attendance at the postpartum visit. Our pilot trial demonstrates that women are willing and able to participate in a randomized trial of a Web-based program and text messaging system.

Trial Registration: Clinicaltrials.gov NCT03296774; https://clinicaltrials.gov/ct2/show/NCT03296774 (Archived by WebCite at http://www.webcitation.org/6tpgXFzyk)

Introduction

During the postpartum visit, health care providers address a number of issues with both short- and long-term implications for maternal and child health. Clinicians counsel about contraceptive options, provide breastfeeding support, screen and refer for postpartum mood disorders, screen for cardiometabolic consequences of pregnancy complications, and discuss interconception care. They also connect women with primary care providers.

Attendance rates for the postpartum visit are markedly lower for women with limited economic resources [1]. In the United States, Medicaid provides health coverage to low-income adults, children, and pregnant women. Nationally, approximately, 50% to 60% of women with Medicaid insurance return for a postpartum visit, compared with over 80% of women with private insurance [2]. Medicaid programs serve pregnant women who are particularly vulnerable to poor health outcomes, and thus, this gap is critical.

The reasons for noncompliance with the postpartum visit are complex [1]. Women site a lack of transportation and childcare as contributing factors, as many clinics do not provide childcare during appointments. Women also indicate that they are unsure why the postpartum visit is important for their health [3-5]. This suggests that our care model does not engage all women to make good health care decisions postpartum and is disproportionately failing our most vulnerable mothers and infants. Innovative solutions that account for difficulty in making smart health decisions are imperative.

The field of behavioral economics acknowledges that people do not make exclusively rational choices. Immediate gratification, cognitive and psychological biases such as bounded rationality or status quo bias, and social norms profoundly influence decision making. Drawing on insights from psychology and decision science, the field of behavioral economics has examined how these biases can be modulated through carefully designed interventions [6]. Increasingly, these insights are influencing the health sciences as researchers seek more effective health interventions and health policy [7-14]. Given this, we developed an innovative Web-based tool, Healthy Beyond Pregnancy, with text messaging that incorporates empirically derived concepts of behavioral economics to improve adherence rates to the postpartum visit. We opted for a Web-based tool with text messaging, as low-income women between the age of 18 and 29 years use the Web-based application and send and receive text message more frequently

than any other demographics [15]. The primary objectives of this pilot study were to (1) refine and assess the usability of Healthy Beyond Pregnancy and (2) assess the feasibility of a randomized controlled trial (RCT) of the intervention.

Methods

Phase 1: Development and Assessment of the Usability of Healthy Beyond Pregnancy

Theoretical Grounding and Description of Intervention

We used a multistep process and multidisciplinary team of maternal-fetal medicine physicians, a behavioral economist, certified lactation consultant, and researchers with expertise in behavioral interventions to design Healthy Beyond Pregnancy. The broad conceptual steps that we used to develop and test Healthy Beyond Pregnancy are illustrated in Figure 1. The key behavioral economic concepts that informed Healthy Beyond Pregnancy and how they are implemented in the program include the following: (1) bounded rationality and information overload, (2) status quo bias or lack of self-control, (3) hovering or limited attention, and (4) framed incentives. These concepts are outlined below in detail.

First, bounded rationality and information overload indicates that patients' decision making is hampered by the overwhelming amount of information available and the difficulty in focusing on all of the information relevant to their care. Furthermore, the perception of personal relevance of the information presented will affect how the information resonates with the patient and how motivating it is toward healthy behavior. Given this, Healthy Beyond Pregnancy allows participants to define much of the content of their postpartum education and acknowledges that only 2 to 3 issues can be meaningfully addressed for most patients. The first step on the Healthy Beyond Pregnancy Web platform is a survey that assesses the participants' postpartum concerns from a scale of 1 to 5—with 1 representing not at all important to 5 representing very important. Women are presented with the following list of postpartum issues: (1) postpartum contraception, (2) breastfeeding support, (3) postpartum mood, (4) bowel and bladder function after delivery, (5) sexual activity after delivery, (6) optimizing interpregnancy health, and (7) follow-up after pregnancy complications such as gestational diabetes, hypertension, or spontaneous preterm delivery. Women's answers on the scale of 1 to 5 are entered into an automated algorithm, and they watch 2 to 4 videos that reflect their self-identified needs—women watch the videos that they scored as most important (4 or 5 on the scale). Women with a pregnancy complicated by gestational diabetes,

hypertension, or preterm birth will also view videos about the implications of these pregnancy complications. Given the health benefits of planned and timed pregnancies as well as breastfeeding, if a participant indicates that she is not interested in any of the postpartum domains, she will be shown videos on contraception and breastfeeding. Women are given the option to watch more videos if they want.
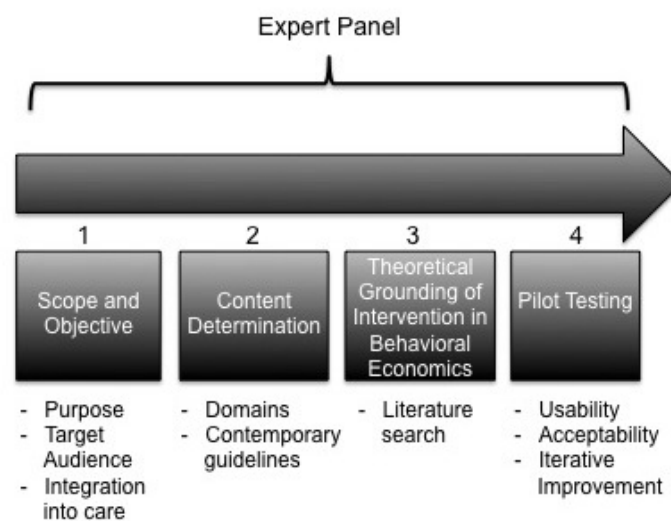
Second, status quo bias/or lack of self-control indicates that patients often make time-inconsistent choices—they may plan to go for a postpartum visit but put off making the appointment because the immediate costs (altering the status quo) loom larger than the delayed benefits of the visit [16]. Healthy Beyond Pregnancy makes scheduling and committing to a postpartum visit a default option. After defining their postpartum concerns and watching the educational videos, participants schedule a visit. This contrasts with our care model where women are asked to call and schedule their postpartum visit after they leave the hospital. After they schedule the visit, participants use a stylus to sign a commitment contract to attend this visit. Commitment devices restrict the choices of a future self and increase the probability of adhering to a future behavior [14].

Third, hovering or limited attention indicates that several tasks and choices compete for patients' attention. Patients need reminders to keep an action on the top of their mental stack [17]. Thus, Healthy Beyond Pregnancy participants receive

nudging text messages to keep the importance of their postpartum concerns in the forefront of their minds. Text messages were sent within 48 hours of their initial discharge from the hospital and within 72 hours for their scheduled postpartum visit. Examples of nudging text messages are included (see Multimedia Appendix 1). After participants schedule and commit to the postpartum visit, they are asked to share a short message service (SMS)–enabled phone number. We use this number to send motivational text messages, links to educational content, and relevant support services, as well as reminders about the date and time of their prescheduled and committed postpartum visit.

Fourth, the framed incentives emphasize on the fact that the uptake of behaviors can be influenced by salient incentives with proper framing [18]. Healthy Beyond Pregnancy rewards women who return for a postpartum visit with a cash incentive [19]. As part of the commitment contract, participants are informed that they will receive a US $40 cash incentive if they attend their postpartum visit. Cash incentives have been found to be more powerful than other incentives because they allow the recipient to apply it toward something that is personally important to them [19]. Thus, with framing the incentive as a positive reward instead of a deductible, they do not have to pay, which has the potential to increase behavior change without increasing the magnitude of the cost. The Web-based portion of the intervention is available at the URL at the end of the references.

Figure 1. Conceptual steps used to develop and test Healthy Beyond Pregnancy.

Usability Testing

Design and Participants

We recruited a convenience sample of 15 women from the postpartum floors of Magee-Womens Hospital. Participants were recruited in three groups of 5 with iterative improvements made to the website after each group of 5 completed their assessments. All participants used the website and completed a usability measure. A subset of women also participated in a semistructured interview. Women were interviewed until thematic saturation was reached, which occurred after interviewing 10 women.

Usability Assessment and Semistructured Interview

After viewing the Healthy Beyond Pregnancy program, participants completed a printed questionnaire to assess the website's usability. Usability is defined as the extent to which a product can be used to achieve its stated goals with effectiveness, efficiency, and the satisfaction of the user [20]. We administered the Post-Study System Usability Questionnaire (PSSUQ), a validated measure to assess user satisfaction with system usability [21]. The PSSUQ consists of 19 items that are rated on a 7-point scale, with low scores indicating strong disagreement with the statement. The questionnaire has three subscales that assess (1) system usefulness, (2) information

quality, and (3) interface quality. One question regarding error messages to fix problems was omitted, as it was not applicable.

After viewing the Healthy Beyond Pregnancy site, 10 participants also completed a semistructured interview. In the interviews, participants were asked about the strengths and weaknesses of the program, as well as recommendations for improvement. Interviews were audiotaped and transcribed for analysis. No field notes were taken, and transcripts were not returned to the participants. Interview questions are included (see Multimedia Appendix 2).

Analyses

Quantitative Analyses

For the PSSUQ, medians and interquartile ranges (IQRs) were calculated. A nonparametric test of trend (nptrend) was performed to compare scores across the three groups of 5. Analyses were completed using STATA 13 (StataCorp LLC).

Qualitative

To create the initial coding scheme, two investigators independently performed coding of two interviews to identify themes. The coding scheme was collaboratively modified after application of initial codes to two additional interviews. All interviews were then thematically recoded with the final coding scheme. We continued interviews until thematic saturation was reached (n=10). Qualitative coding was organized using ATLAS.ti 4.2.

Phase 2: Pilot Trial to Assess Feasibility of Randomized Controlled Trial of Healthy Beyond Pregnancy

Study Design

We conducted a pilot RCT to test the feasibility of randomizing postpartum women to Healthy Beyond Pregnancy or usual care. The trial was conducted at Magee-Womens Hospital, a large maternity hospital that provides care to women in Western Pennsylvania. The institutional review board of the University of Pittsburgh approved the trial (PRO16090292).

Inclusion criteria for the trial were (1) postpartum 6 to 72 hours from their delivery, (2) aged 18 to 50 years, (3) receipt of prenatal care through the Magee-Womens Hospital outpatient obstetrical clinic, and (4) "UPMC for You" Medicaid insurance. Women were excluded if they delivered in less than 24 weeks, experienced a fetal or neonatal death, did not speak English, or did not have a text-enabled phone. We recruited for the trial from November 2016 to February 2017.

Study investigators (KPH and FLF) who were part of the clinical team identified women eligible for the study. Participants were then approached for the study, consented, and randomized on the postpartum floor. We used computer-generated randomization to assign participants to Healthy Beyond Pregnancy or usual care in a 1:1 ratio. The Healthy Beyond Pregnancy program is described in detail in phase 1. It is not embedded in other parts of the hospital care and was administered by the members of the study team. The control arm received routine clinical care. This includes a reminder in their discharge paper work to call their clinic for a postpartum visit in 3 to 8 weeks.

Measures

Feasibility of Randomization

Our primary outcome included the proportion of eligible patients who consented to the study and the number of women randomized to Healthy Beyond Pregnancy who completed the Web-based program. We also assessed whether patients would recommend the program to a friend.

Exploratory outcomes included the proportion of women who attended a postpartum visit within 21 to 56 days after delivery and had an uptake of long-acting reversible contraception (LARC) and some form of contraception. The 21- to 56-day period is consistent with the Healthcare Effectiveness Data and Information Set (HEDIS) definition of a postpartum visit.

Demographic and Clinical Variables

Maternal and clinical data were abstracted from the medical records. These included maternal age, race, parity, gestational age at delivery, mode of delivery, opiate use during pregnancy, and number of prenatal visits.

Statistical Analysis

Outcomes were described using means or proportions. Demographic and clinical characteristics were compared between study arms using either independent sample t test or chi-square test. Differences in exploratory outcomes—attendance at the postpartum visit, receipt of LARC, or receipt of any birth control method other than condoms—between study arms were compared using univariate logistic regression. Importantly, this study was not powered to detect differences between groups in exploratory clinical outcomes such as adherence to the postpartum visit, and given the small sample size, multivariable modeling was not performed.

Results

Phase 1

A total of 15 women (three groups of 5 based on the timing of enrollment) participated in usability assessment of the Healthy Beyond Pregnancy website. Iterative improvements were made after each group of 5 completed their assessments. Participants were postpartum women aged between 22 and 38 years. Users spent between 9 to 15 min completing the program.

The median PSSUQ score was 6.5 (IQR: 6.1-7) demonstrating high usability. Each of the subscales also demonstrated high usability scores—median score on system quality was 6.6 (IQR: 6.25-7), median score on information quality was 6.6 (IQR: 5.8-7), and the median score on interface quality was 7 (IQR: 6-7). Although the median overall PSSUQ score improved over the course of the three usability testing groups—Group 1: 6.5 (6.5-7), Group 2: 6.7 (6.5-7), and Group 3: 6.8 (6.5-7)—this was not significant (P=.52).

The semistructured interviews (n=10) provided more in-depth comments about users' experience of using Healthy Beyond Pregnancy. The interview questions are provided in Multimedia Appendix 2).

The median interview time was 14 min (IQR: 10-15). Overall comments were positive with 90% (n=9) of women indicating that they would recommend the program to a friend who had just delivered. Important design improvements also emerged from these interviews. For example, we restructured our scheduling calendar to make available appointments easier to identify, changed the language in the tablet computer to make it more accessible (preterm birth became delivery in less than 37 weeks), and added a written summary of the personalized information provided by Healthy Beyond Pregnancy. Table 1 highlights themes identified by at least 40% of participants that emerged on the benefits of Healthy Beyond Pregnancy from the semistructured interviews.

Table 1. Participants' perspectives on utility of Healthy Beyond Pregnancy.

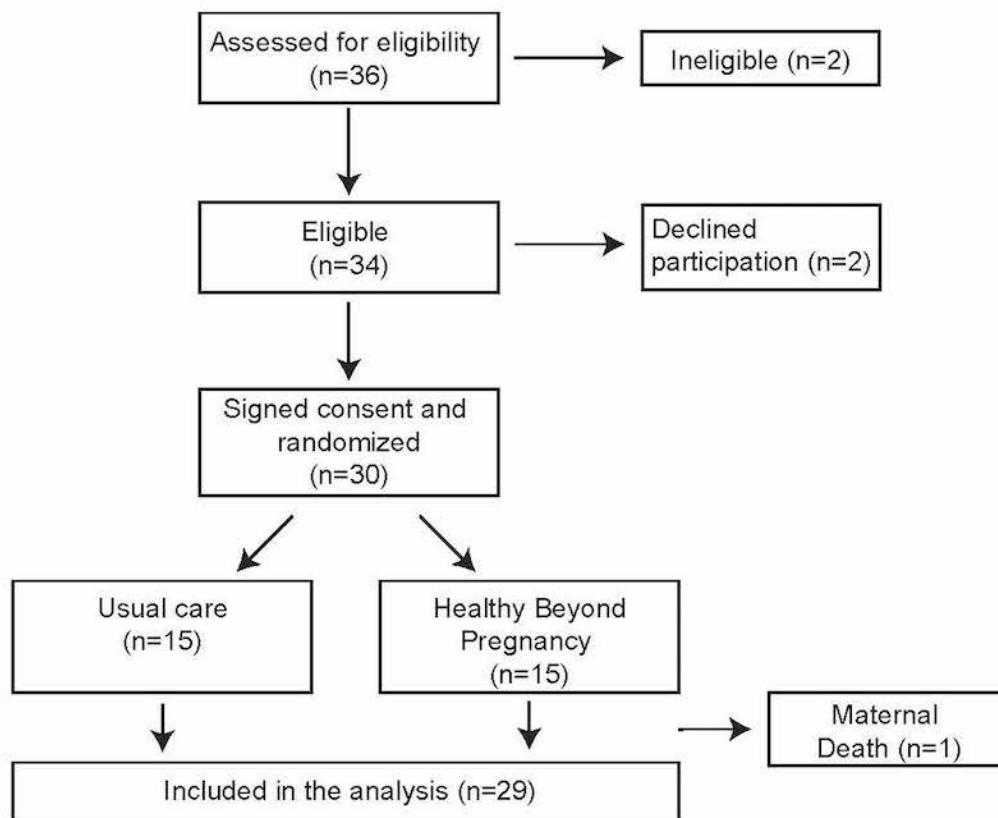| Theme	Participants identifying theme (n=10), n (%)	Examples
Help personalize postpartum care	4 (40)	"Provided enough information to help me focus my thoughts for postpartum visit." (ID: HBP7)
		"Helps me focus on the problems that are relevant to me." (ID: HBP9)
Decrease the stress of postpartum period	6 (60)	"It is really nice to schedule your appointment." (ID: HBP2)
		"Great to not have the stress of calling for an appointment." (ID: HBP4)
Program is easy to use	9 (90)	"I love that I can breastfeed while using the website." (ID: HBP3)
		"You don't have to struggle to get through the program." (ID: HBP6)
Highlights issues you are not focusing on	8 (80)	"There is so much on your mind...this reminds you about important issues." (ID: HBP1)
		"This reminded me not to forget about important issues for my health." (ID: HBP10)

Phase 2

Primary Outcomes

A total of 34 women were approached for the pilot trial, and 30 (88%) were consented and randomized (Figure 2). Importantly, all women randomized to Healthy Beyond Pregnancy were willing to complete the entire Web-based program, had text-enabled cell phones, and were willing to receive text messages from the study team. All participants randomized to Healthy Beyond Pregnancy indicated that they would recommend the program to a friend who had just delivered. The baseline demographics and clinical characteristics are outlined in Table 2.

Table 2. Demographic and clinical characteristics at randomization.

Variables	Usual care (n=15)	Healthy Beyond Pregnancy (n=15)	P value
Maternal age in years, mean (SD[a])	29.6 (4.3)	27.9 (5.0)	.31
Race, n (%)			
African American	6 (40)	10 (67)	.26
White	8 (53)	5 (33)	
Asian	1 (7)	0 (0)	
Nulliparous, n (%)	1 (7)	6 (40)	.03
Gestational age in weeks, mean (SD)	38.5 (0.4)	37.9 (0.5)	.30
Vaginal delivery, n (%)	7 (47)	11 (73)	.14
Number of prenatal visits, mean (SD)	8.5 (0.9)	10.4 (0.6)	.08
Opiate use, n (%)	7 (47)	2 (13)	.11

[a]SD: standard deviation.

Figure 2. Participant flow in Healthy Beyond Pregnancy feasibility study.

Exploratory Outcomes

All participants enrolled in the trial had UPMC Medicaid insurance, and thus, we were able to ascertain our clinical outcomes on all patients, as they must seek care through a UPMC facility, all of which use a common electronic medical record system. There was a trend toward more women in the Healthy Beyond Pregnancy arm returning for a postpartum visit compared with women in the control arm, that is, 85% of women in Healthy Beyond Pregnancy returning versus 53% in the control arm—odds ratio of 5.3 (95% CI 0.9-32.0; *P*=.06). Importantly these results were not significant. All exploratory outcomes are outlined in Table 3.

Table 3. Exploratory outcomes.

Outcomes	Usual care (n=15), n (%)	Healthy Beyond Pregnancy (n=14), n (%)	Odds ratio (95% CI)	*P* value
Attended postpartum visits	8 (53)	12 (85)	5.3 (0.9-32.0)	.06
LARC[a]	4 (26)	3 (21)	0.8 (0.2-4.2)	.74
Any contraception	11 (73)	11 (78)	1.3 (0.3-7.7)	.73

[a]LARC: Long-acting reversible contraception.

Discussion

Principal Findings

We have developed a highly usable and acceptable Web-based program designed to increase attendance at the postpartum visit. Our pilot trial demonstrates that women are willing and able to participate in a randomized trial of a Web-based program and text messaging system. Furthermore, we saw a trend toward increased compliance with the postpartum visit among women in the Healthy Beyond Pregnancy arm. These results were not significant.

Despite observing a trend toward increased postpartum visit compliance, we found similar rates in our two study arms in these contraception outcomes. There are several possible reasons for this. Some trial participants had postpartum tubal ligations before randomization—this included 26% (n=4) and 7% (n=1) of our control group and Healthy Beyond Pregnancy group, respectively. As there are benefits beyond contraception to the postpartum visit, we opted not to exclude these women from the trial. Furthermore, at our institution, some women with UPMC for You insurance qualify for an etonogestrel implant (a LARC method) before discharge. This, however, is not true for other Medicaid insurance products. Finally, women can also

opt to get a single medroxyprogesterone injection or a prescription for 3- to 6-month supply of combined oral contraceptive pills before discharge from the hospital. In addition, 20% (n=3) of women in our control arm fall into this category. Although there is documentation of contraception provision for these women, without establishing postpartum care, these women are at risk of not being able to establish a long-term contraception plan. Further investigation of our study tool with a larger sample size and a longer follow-up period is needed to help understand the impact of Healthy Beyond Pregnancy on contraception use after delivery.

The willingness of Medicaid recipients to participate in a trial designed to improve compliance with the postpartum visit is important because attendance rates for the postpartum visit are lower for women with limited resources, potentially contributing to health disparities. Minority women and women of lower socioeconomic status are at significantly increased risk of unintended pregnancies, short interpregnancy interval, and short duration of breastfeeding. The maternal and child health outcomes related to unintended pregnancies, short interpregnancy interval, and short duration of breastfeeding are well documented, and importantly, these measures can be impacted during the postpartum period [22-31]. Furthermore, Internet and mobile phone–based interventions may be particularly successful with our target population, as low-income and non-Hispanic black women aged between 18 and 29 years send and receive text messages more frequently than any other demographics [15].

An important component of our intervention is that it is designed to be both affordable and scalable. There are a number of other postnatal interventions, including patient education booklets, home visits, prescheduling visits, and cash incentives, that have been designed to improve postpartum care in the developed world [3,9,32-35]. Only two of these studies used an RCT study design, limiting conclusions about effectiveness. These data suggest home visits are effective in improving compliance with postpartum visits. Home visits, however, are expensive and difficult to scale. Patients can complete the Healthy Beyond Pregnancy program independently, and the text messaging system can be automated. Additionally, other investigators have used Internet-based and text messaging interventions in the postpartum period successfully [36-38]. Finally, incentives are

feasible, as many health plans already offer lower deductibles when preventative care milestones are met.

Limitations

It is important to emphasize that this was a usability study and pilot RCT to assess the feasibility of enrolling patients in a large study of Healthy Beyond Pregnancy. We enrolled patients immediately postpartum. This is a busy and potentially emotionally charged time for women. Furthermore, our intervention targets women from disadvantaged socioeconomic backgrounds who have additional stressors in the immediate postpartum period. Before pursuing a large RCT, we wanted to assess our ability to consent, randomize, and retain women in our study. Given the pilot nature of the project and small sample size, our findings regarding adherence to the postpartum visit must be viewed with caution. It is also important to note that our Healthy Beyond Pregnancy arm had significantly more nulliparous women than our control arm. Women with multiple children may be less likely to attend a postpartum visit. Thus, the greater proportion of nulliparous women in the Healthy Beyond Pregnancy arm may contribute to our increased adherence to the postpartum visit in this group. Nevertheless, the information garnered from this pilot trial will be important for a future efficacy trial. A larger trial will allow us to look definitively at attendance at the postpartum visit, as well as important health outcomes such as breastfeeding duration and provisions of LARC. These outcomes are critical to improve a number of short- and long-term maternal and child health outcomes.

Conclusions

We have developed a usable and acceptable Web-based program designed to increase attendance at the postpartum visit. Our pilot trial demonstrates that women are willing and able to participate in a randomized trial of a Web-based program and text messaging system. Importantly, although our trial was not powered to detect difference in attendance at the postpartum visit, we observed a trend toward increased compliance with the postpartum visit among women randomized to Healthy Beyond Pregnancy. A large RCT is needed to determine whether attendance can be increased robustly and whether this would translate into improved health outcomes.

Conflicts of Interest

None declared.

Multimedia Appendix 1

Sample nudging text messages.

[PDF File (Adobe PDF File), 28KB - humanfactors_v4i4e26_app1.pdf]

Multimedia Appendix 2

Semistructured interview questions.

[PDF File (Adobe PDF File), 18KB - humanfactors_v4i4e26_app2.pdf]

Multimedia Appendix 3

CONSORT-eHEALTH V1.6.

[PDF File (Adobe PDF File), 1MB - humanfactors_v4i4e26_app3.pdf]

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Abbreviations

IQR: interquartile range
LARC: long-acting reversible contraception
PSSUQ: Post-Study System Usability Questionnaire
RCT: randomized controlled trial

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<u>Original Paper</u>

An eHealth Application of Self-Reported Sports-Related Injuries and Illnesses in Paralympic Sport: Pilot Feasibility and Usability Study

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Abstract

Background: Sport participation is associated with a risk of sports-related injuries and illnesses, and Paralympic athletes' additional medical issues can be a challenge to health care providers and medical staff. However, few prospective studies have assessed sports-related injuries and illnesses in Paralympic sport (SRIIPS) over time. Advances in mobile phone technology and networking systems offer novel opportunities to develop innovative eHealth applications for collection of athletes' self-reports. Using eHealth applications for collection of self-reported SRIIPS is an unexplored area, and before initiation of full-scale research of SRIIPS, the feasibility and usability of such an approach needs to be ascertained.

Objective: The aim of this study was to perform a 4-week pilot study and (1) evaluate the monitoring feasibility and system usability of a novel eHealth application for self-reported SRIIPS and (2) report preliminary data on SRIIPS.

Methods: An eHealth application for routine collection of data from athletes was developed and adapted to Paralympic athletes. A 4-week pilot study was performed where Paralympic athletes (n=28) were asked to weekly self-report sport exposure, training load, general well-being, pain, sleep, anxiety, and possible SRIIPS. The data collection was followed by a poststudy use assessment survey. Quantitative data related to the system use (eg, completed self-reports, missing responses, and errors) were analyzed using descriptive statistics. The qualitative feasibility and usability data provided by the athletes were condensed and categorized using thematic analysis methods.

Results: The weekly response rate was 95%. The athletes were of the opinion that the eHealth application was usable and feasible but stated that it was not fully adapted to Paralympic athletes and their impairments. For example, it was difficult to understand how a new injury or illness should be identified when the impairment was involved. More survey items related to the impairments were requested, as the athletes perceived that injuries and illnesses often occurred because of the impairment. Options for description of multifactorial incidents including an injury, an illness, and the impairment were also insufficient. Few technical issues were encountered, but athletes with visual impairment reported usability difficulties with the speech synthesizer. An incidence rate of 1.8 injuries and 1.7 illnesses per 100 hours of athlete exposure were recorded. The weekly pain prevalence was 56% and the impairment contributed to 20% of the reported incidents.

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Conclusions: The novel eHealth-based application for self-reported SRIIPS developed and tested in this pilot study was generally feasible and usable. With some adaptation to accommodate Paralympic athletes' prerequisites and improved technical support for athletes with visual impairment, this application can be recommended for use in prospective studies of SRIIPS.

Trial Registration: ClinicalTrials.gov NCT02788500; https://clinicaltrials.gov/ct2/show/NCT02788500 (Archived by WebCite at http://www.webcitation.org/6v56OqTeP)

Introduction

Paralympic sport continues to grow and attracts athletes from all around the world. However, participation in Paralympic sport is, like all sport, associated with a risk of sports-related injuries and illnesses, and Paralympic athletes' additional medical issues are challenging to health care providers and medical staff [1].

Knowledge of sports-related injuries and illnesses in Paralympic sport (SRIIPS) is limited, and few prospective studies have assessed SRIIPS over time [2-4]. During the Paralympic Games in London 2012 and Sochi 2014, considerably higher injury incidences were recorded compared to the corresponding Olympic Games [5,6]. Paralympic athletes also have higher illness incidence rates compared to Olympic athletes [7]. To improve health and safety in Paralympic sport, there is a need for prospective longitudinal monitoring of SRIIPS over entire training seasons to determine distributions and etiological mechanisms [8,9]. To advance knowledge of the incidence and risk factors of SRIIPS, we have initiated a prospective longitudinal study using eHealth-based data collection of self-reports [10].

To allow data collection over longer periods of time and in heterogenous populations, athlete monitoring through self-reports is an established method of observing athletes' health, including both sports-related injuries and illnesses [11-13]. Self-reports enable collection of information on overall health based on simultaneous recording of injuries, physical and mental illnesses, sports exposure, training load, and risk factors, specifically adapted to the sports population of interest [8,14,15]. Moreover, self-reports provide more realistic data than reports by medical personnel who may underestimate the injury rates compared to athletes themselves [16].

By collecting data electronically, self-reports can be used with minimal memory bias and constitute real-time personalized data [17]. Advances in mobile phone technology and networking systems offer novel opportunities to develop innovative eHealth applications to collect data [18]. However, most studies have only included able-bodied athletes, and studies using eHealth applications in Paralympic athletes with various physical, intellectual, and visual impairments are lacking.

For successful implementation of an application, it is important to consider methodological and practical challenges [19,20]. Pilot studies allow the development and testing of the method and give advance warnings about where the forthcoming main research project could fail [21]. Potential sources of errors could be poor definitions, difficulties in interpreting questions and data, and failure to use the system. Establishing a user-friendly surveillance system that targets the population is therefore a key factor [8,22]. Thus, before initiation of full-scale research, a pilot study focusing on feasibility and usability issues is needed to ascertain the ability to use the new application for future data collection [23]. As Paralympic sport includes athletes with a wide range of impairments [1], the eHealth application must allow adaptation to users' specific needs and circumstances [24]. This is to ensure that they will be able to adopt the new monitoring system in daily procedures, regardless of their impairments, and that the output is experienced as useful for them [8,22].

The aim of this study was to perform a 4-week pilot study and (1) evaluate the monitoring feasibility and system usability of a novel eHealth application for longitudinal epidemiological research on self-reported SRIIPS and (2) report preliminary data on SRIIPS.

Methods

Development of the eHealth Application

The purpose of the eHealth monitoring is to enable Paralympic athletes to self-report SRIIPS, exposure to sport, and general health parameters in an e-diary. For the data collection, the Briteback survey tool was used. This tool is integrated with software built on team communication research. The tool allows researchers to construct specific surveys, which are sent automatically as Web links in emails and text messages. The surveys are adapted to computers, tablets, and mobile phones, and participants can choose how to enter their data. Automated system-generated statistics are provided immediately after reporting of data.

The prototype eHealth application was developed and adapted to Paralympic athletes based on a theoretical foundation of existing research within sports medicine [12,13,25], Paralympic athletes' own perceptions of experiences of sports-related injuries [26], our study protocol [10], and the Web Content Accessibility Guidelines 2.0 (WCAG 2.0) [27]. The main focus was to include features that are specific to Paralympic athletes. For example, pain, involvement of the impairment, and already existing medical issues may be present [26]. The research team, consisting of sports injury epidemiologists, physicians, physical therapists, and disability researchers together with computer scientists and athletes adapted and tested the system for Paralympic athletes.

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To evaluate a Web tool as feasible and usable for users with disabilities, the WCAG 2.0 guidelines require it to be perceivable, operable, understandable, and robust for all categories of users [27]. Therefore, a central requirement of the eHealth application was that athletes with a visual impairment, physical impairment, or intellectual impairment (Figure 1) could use it at the same conditions. To make the content usable to the athletes, the eHealth application was developed to meet the WCAG 2.0 accessibility guidelines. Principles related to user interface design, screen resolution, keyboard navigation, avoidance of seizure-causing content, and avoidance of content that causes mistakes were considered in the development. The application should also appear and operate in predictable ways, and the users should have enough time to read and use the content [27].

The final weekly e-diary consisted of 12 questions for athletes to respond to pertaining to the following topics:

- Participation in normal training
- Exposure to sport (sessions)
- Exposure to sport (hours)
- Exposure to competition
- Rate of perceived exertion
- Use of analgesics
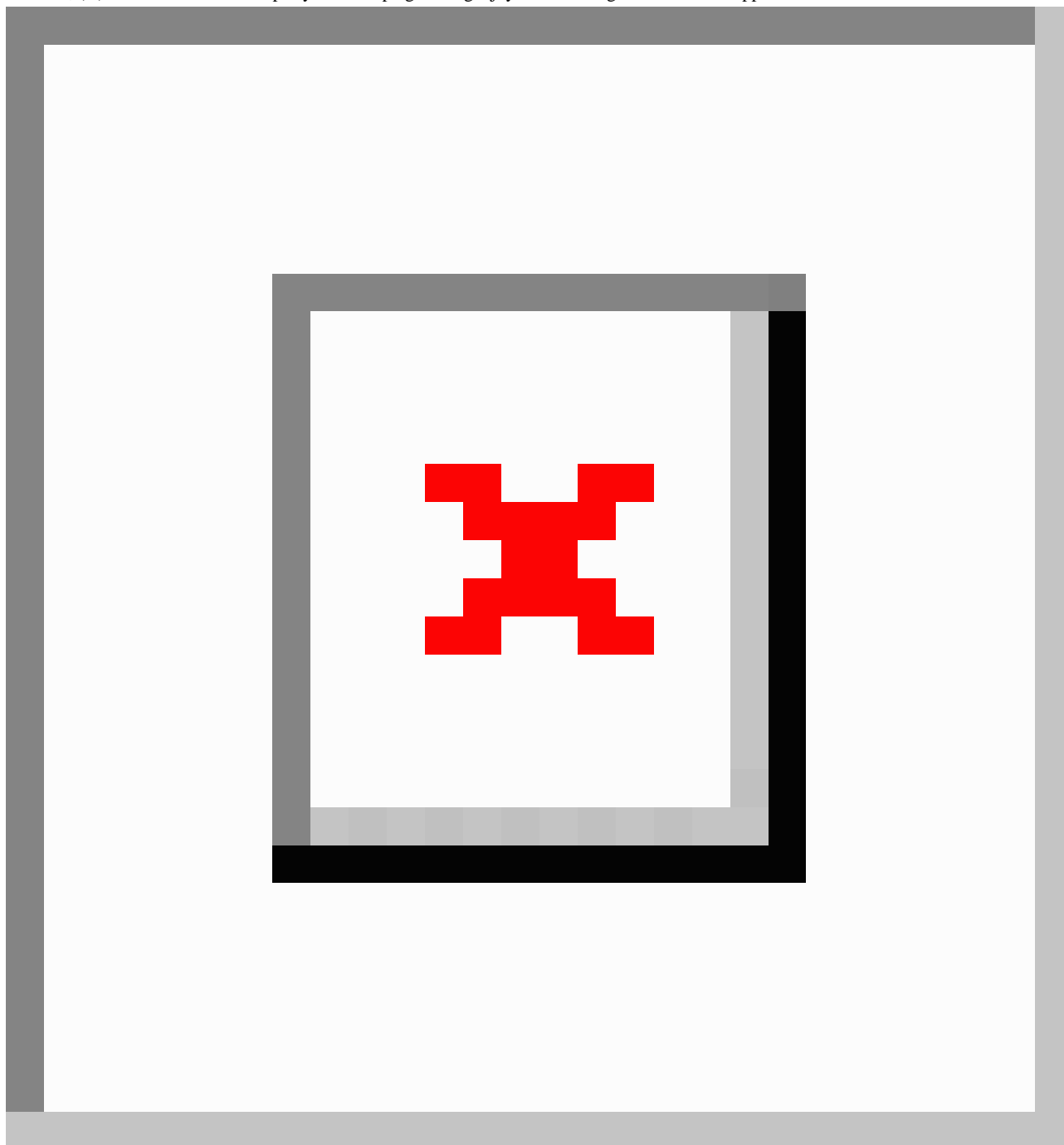- General well-being
- Sleep
- Anxiety
- Pain

- New injury
- New illness

Depending on responses, subquestions related to reported SRIIPS could also appear.

Study Population

A pilot study cohort stratified to represent the different impairments, genders, and sports was selected in June 2016 from the Swedish Paralympic Program. The following inclusion criteria, adopted from the study protocol [10], were used: age 18 to 55 years; being a registered athlete within the Swedish Paralympic Program; being classified as an eligible International Paralympic Committee athlete with visual impairment, physical impairment, or intellectual impairment; being able to communicate in Swedish; and having the opportunity to answer an e-diary weekly during 4 weeks. A total of 37 elite athletes were invited to participate, and 28, 9 women and 19 men (aged 20 to 51 years) with visual impairment (n=11), physical impairment (n=15), and intellectual impairment (n=2), accepted the invitation. The athletes were active in the following para-sports: shooting, canoeing, goalball, athletics, judo, swimming, boccia, cycling, table tennis, wheelchair rugby, cross-country skiing, wheelchair curling, and ice hockey. Four athletes, all with physical impairment, declined participation because of lack of time prior to the Paralympic Games 2016. Five athletes never responded, 3 with physical impairment and 2 with intellectual impairment.

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Figure 1. Survey design and technology formulated for use among able-bodied athletes need adaptations to Paralympic athletes with a broad range of impairments. (A) Visually impaired athlete using speech synthesizing technology adapted to the eHealth application, (B) Wheelchair basketball player with individual training behavior often without coach and medical staff, (C) Athlete often traveling using the eHealth application in her training environment, (D) Athlete with cerebral palsy and tetraplegia using a joystick to navigate the eHealth application.

Ethical Considerations

The study followed the ethical principles for medical research involving human subjects per the World Medical Association Declaration of Helsinki and the Strengthening the Reporting of Observational Studies in Epidemiology (STROBE) guidelines and is registered at ClinicalTrials.gov [NCT02788500]. The entire study was approved by the Regional Ethical Review Board in Lund, Sweden (Dnr 2016/169). Participation in the study was voluntary, and informed written consent was collected from all participants.

Feasibility and Usability: Theoretical Framework

Feasibility studies enable researchers to assess if a study design and preliminary results can be shaped into relevant findings and future interventions. It is necessary to pursue a feasibility study if (1) there are few previously published studies in the research area, (2) a specific intervention is used, and (3) the study population requires unique consideration of the method.

Feasibility can be referred to as the ability of users to adopt a new system in daily procedures with focus on the questions: Can it work? Does it work? and Will it work? Important aspects of feasibility in this study were acceptability (Is the application

suitable?), demand (Is the application likely to be used?), practicality (Can the application be used outside the intervention?), adaptation (Will the application work for this population?), integration (Can the application be integrated in an existing system?), expansion (Can the application be expanded?), and implementation (Can the application be successfully delivered to the participants?) [19].

Usability is a characteristic of quality in use, according to the International Organization for Standardization [28]. It denotes whether a system can be used technically by specified users to achieve goals with regard to (1) learnability (how easy users can learn the system), (2) efficiency (being able to complete a task), (3) effectiveness (the amount of effort required to complete a task), (4) satisfaction (the degree to which the user was happy with the experience while performing a task), and (5) error recovery (the users should make few errors, and errors should be easy to recover from) [28,29]. An important context of usability in this project was to ensure that an athlete with the expected ability due to their impairment can use the system and that the application is technically available to all potential users [30].

The Fit between Individuals, Task, and Technology (FITT) framework of information technology (IT) adoption was used to structure and present the data on feasibility and usability goals (Table 1). FITT suggests that IT adoption in health care is dependent on socio-organizational-technical factors including task-technology fit, individual-task fit, and individual-technology fit [31].

Table 1. Feasibility and usability goals structured according to the Fit between Individuals, Task, and Technology framework and the Post-Study System Usability Questionnaire.

Conceptual framework and measure	Data source
Feasibility	
Individual	
Demographics (gender, age, sport, impairment)	Athlete information
Fit to individual	PSSUQ[a]
	Data from the eHealth application (ie, missing answers, impairment related problems)
Task	
Fit into daily routines	PSSUQ
	Data from the eHealth application (ie, answer frequency)
Fit into Paralympic sport	PSSUQ
	Data from the eHealth application (ie, number of reported incidents, type of reported incidents). Interest from athletes and organization
Usability	
Technology	
Efficiency	PSSUQ
	Data from the eHealth application (ie, athlete workflow)
Effectiveness	PSSUQ
Learnability	PSSUQ
Satisfaction	PSSUQ
Error recovery	Reported and detected errors

[a]PSSUQ: Post-Study System Usability Questionnaire.

Textbox 1. Definitions of an injury and an illness.

Injury:

Any new musculoskeletal pain, feeling, or injury that causes changes in normal training or competition to the mode, duration, intensity, or frequency, regardless of whether or not time is lost from training or competition

Illness:

Any new illness or psychological complaint that causes changes in normal training or competition to the mode, duration, intensity, or frequency, regardless of whether or not time is lost from training or competition

For example, IT adoption in an athletic environment may depend on the fit between the attributes of the individual user (ie, motivation, experience, computer anxiety), attributes of the technology (ie, functionality, usability), and attributes of the task (ie, complexity, task, organization).

Data Collection

A 4-week SRIIPS pilot study was performed with an integrated poststudy feasibility and usability assessment [18,24]. The athletes were asked to weekly report sport exposure, training load, general well-being, pain, sleep, anxiety, and possible SRIIPS, according to the definitions in the SRIIPS study protocol (Textbox 1) [10]. The first author (KF) followed up on all data and any technical issues every week. After having completed the 4-week pilot study, the athletes were asked to assess the method using open questions related to the feasibility and usability (Table 1) [19,29] and a modified version of the Post-Study System Usability Questionnaire (PSSUQ) [32]. This is a questionnaire that was developed to assess user satisfaction after participation in scenario-based usability studies. With the PSSUQ, the researchers can understand which aspects of the computer system the users are particularly concerned with and which aspects they are satisfied with [32].

Data Analysis

Quantitative data related to demographics, system use, completed self-reports, number of reported incidents, missing answers, and system errors were analyzed using descriptive statistical methods.

The qualitative feasibility and usability data were condensed and categorized using a thematic analysis method. Thematic analysis is a flexible method for identifying, analyzing, and reporting patterns within various data sets (eg, texts, webpages, and interviews). The method provides rich and detailed information that is associated with the specific research question [33]. The focus here was on identifying opinions about the eHealth application, detecting methodological issues, and determining if the method matched the users' needs and behavior. Sentences containing aspects of relevance to feasibility and usability were transformed to themes, codes, and meaning units.

Data on SRIIPS collected during the 4-week period were analyzed using basic descriptive statistics. The incidence rates were calculated as the number of new incidents divided by total athlete exposure hours (per 1000 hours of sport participation) [10].

Results

Quantitative Poststudy Feasibility and Usability Evaluation

A total of 1643 self-reports, 1354 weekly e-diary reports, and 289 responses to follow-up questions were collected. The average weekly response rate was 95%. A total of 37 instances of missing data were noted in the weekly e-diary reports; 28 were observed among athletes with visual impairment, 7 from athletes with physical impairment, and 2 from athletes with intellectual impairment. Questions concerning pain, anxiety, and training load generally had a high response rate (96% to 100%). The questions with most missing answers (n=11) were about general well-being with horizontally displayed check boxes. The follow-up questions, for example, concerning SRIIPS symptoms, diagnosis, and injury severity, had on average 1 to 2 missing answers every week; 11 of these were from athletes with visual impairment and 2 from athletes with physical impairment. A total of 21 athletes, 8 with visual impairment, 12 with physical impairment, and 1 with intellectual impairment, provided complete postuse feasibility and usability data. Two technical errors related to the system and the speech synthesizer were reported by athletes with visual impairment. No system use errors occurred. Almost three-quarters (15/21, 71%) of the athletes reported that it was easy to complete the task. About three-quarters (16/21, 76%) of the athletes found it easy to define a new illness, and 52% (11/21) found it easy to define a new injury. About three-quarters (15/21, 76%) of the athletes reported that it was easy to use the closure form, and 62% (13/21) reported that the application was adapted to Paralympic sport. Most (18/21, 86%) of the athletes were satisfied with the experience of performing the task, and 90% (19/21) found it important to perform this study.

Qualitative Poststudy Feasibility and Usability Evaluation

A summary of the thematic analysis is presented in Table 2.

Health Monitoring in Paralympic Sport

The athletes' opinion was that some parts of the eHealth application were not fully adapted to Paralympic athletes. For example, the athletes found it difficult to know how to define and identify a new injury or illness, especially when their impairment was involved. In addition, more survey items related to an impairment were requested, as the perception was that some incidents occurred because of the impairments. The athletes also found it important to be able to report all new injuries and illnesses (ie, also injuries that had not been sustained during sports participation).

Table 2. Summary of the thematic analysis of the Paralympic athletes' feasibility and usability evaluation of the eHealth application.

Theme	Code	Meaning unit
Health monitoring in Paralympic sport	Feasibility to Paralympic athletes	The application is not specifically adapted to Paralympic sport
		It is difficult to define a new SRIIPS[a]
		Some injuries occur because of the impairment
Survey design	Complex incidents	It is difficult to report several injuries or illnesses
		Insufficient description of multifactorial incidents
		More free text alternatives and multiple check box alternatives would be good
Impairment diversity and usability	Usability to visually impaired athletes	It is not trouble-free to use a screen reader
		Horizontal questions do not work with VoiceOver
		It is easier to use free text alternatives
Longitudinal eHealth monitoring	Sustainability	It is easy to understand and follow the weekly e-diary
		The terminology used is intelligible
		It is important that this kind of study is conducted

[a]SRIIPS: sports-related injuries and illnesses in Paralympic sport.

Survey Design

Identified issues were also related to the survey design and were associated with the reporting of complex incidents using the survey design originally developed for able-bodied athletes. For example, if an athlete wanted to report 2 new injuries in the weekly report, they did not easily understand how to accomplish this task.

The perception was also that there were insufficient options for describing multifactorial incidents including an injury, an illness, and the impairment. To improve the design, the athletes asked for opportunities to better describe their incidents through free text or more multiple check box alternatives.

Impairment Diversity and Usability

Athletes with visual impairment had usability difficulties with tasks involving a visual analog scale and horizontal reply alternatives due to a technical problem with the connection between their speech synthesizer and the eHealth application. Some athletes with visual impairment chose instead to write free text at the end of the questionnaire or not leave a response at all. The questions using vertically displayed response alternatives worked well for the athletes with visual impairment. Athletes with physical impairment or intellectual impairment did not report any functionality problems.

Longitudinal eHealth Monitoring

The athletes stated that the use of the eHealth application was feasible and could be extended to longer periods of time. They perceived that it was easy to understand and use the application. Most of the athletes were of the opinion that the terminology was comprehensible and that it was easy to understand which dates and week they should report. A majority also stated that it is important that health monitoring is performed.

Data on Sports-Related Injuries and Illnesses in Paralympic Sport

One athlete dropped out during the study period; thus, 4-week data were available from 27 athletes. A total of 10 athletes (37%) reported anxiety, 15 (56%) reported pain, and 9 (33%) reported use of analgesics weekly. The median self-rated general well-being score was 4 (1-7). The average time spent on training each week was 7.6 hours. The median weekly rated perceived exertion was 6 (1-10). In total, 15 new injuries (reported by 12 athletes) and 14 new illnesses (reported by 12 athletes) were reported, giving an incidence rate of 1.8 injuries per 100 hours and 1.7 illnesses per 100 hours of athlete exposure, respectively. For 71% (5/7) of the injuries and 60% (6/10) of the illnesses, the athlete reported a higher mean training load than the week before. Tissue inflammation and pain (10/15, 67%) and upper respiratory tract infections (9/14, 64%) were the most common preliminary causes. A total of 80% (12/15) of the injuries were related to overuse, 66% (10/15) of the injuries were reported from athletes with visual impairment, and 57% (8/14) of illnesses were reported from wheelchair athletes. The typical injury severity was 1 to 3 days of time loss of training and 2.6 missed training sessions for illnesses. In 20% (3/15) of the injuries and 21% (3/14) of the illnesses, the impairment was perceived to be involved in the cause.

Discussion

Principal Findings

Advances in eHealth technology for athlete self-reporting and monitoring [34] have been rapid; however, the sport-specific functionality and usefulness of surveillance measures have rarely been established. Data with poor quality may thereby in the end cause problems with developing preventive measures [22]. Therefore, considering design quality and the meaning of data along with effective utilization of technology is crucial in the implementation of self-report measures [11]. Especially smaller feasibility studies with mixed methods have been shown to yield

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innovative results [19]. This led us to develop and test the eHealth application of self-reported SRIIPS specifically adapted to Paralympic athletes in this pilot study with particular focus on feasibility and usability. In summary, we found eHealth-based monitoring of self-reports of Paralympic athletes' health to be generally feasible and usable with regard to fitting into daily routines and using technology. However, the study revealed some critical factors, mostly related to the fit to Paralympic sport, which should be accommodated before this application can be used in full-scale research. It is also recommended that these critical factors be considered in existing and future injury and illness surveillance systems.

Feasibility and Usability

A critical conceptual issue related to feasibility and the fit between the individual, task, and technology was how to define and report new SRIIPS, especially when the impairment was involved. The athletes perceived that the eHealth application was not fully adapted, as some SRIIPS may occur because of the impairment. This observation corroborates the reports from a recent qualitative study where Paralympic athletes perceived that their impairments played an important role in the etiology of SRIIPS [26]. Moreover, a high prevalence of pain may complicate the process of defining and distinguishing a new sports injury from existing pain related to the impairment. This emphasizes the importance of adaptations of surveillance systems to the specific sport population, here Paralympic athletes' various and complex impairments. Thus, the use of questionnaires developed for able-bodied athletes cannot directly be transferred to Paralympic athletes without specific adaptations, such as, for example, visual impairments [35].

Regarding usability efficiency, the athletes described that there were not enough options for description of multifactorial incidents including injuries, illnesses, and impairments. The construction of questions and terminology has previously been reported to be a main issue identified by athletes, and athletes are more willing to complete surveillance systems if they can recognize themselves in the questions asked [20]. Accordingly, the survey design has been further developed following this pilot study. The definition of SRIIPS has been clarified, the survey items better adapted to Paralympic sport, additional alternatives related to the impairment have been added, the possibilities to report multifactorial incidents extended, and more examples and free text alternatives provided to improve athlete satisfaction and motivation. One of the most important objectives in self-report measures is to collect meaningful data in relation to the needs of the athletes [11]. Thus, it is crucial that data related to the impairment are routinely collected when SRIIPS are monitored in order to ensure study feasibility and usability.

Another usability design issue related to task completion was the human-computer error of the audible feedback system used by the athletes with visual impairment. Even though there have been developments of touch screen devices, many are still inaccessible to visually impaired users who often adopt error recovery compensatory strategies [36]. Electronic questionnaires that are too difficult to use may discourage responses and reduce data quality [37]. Some of the parameters (eg, the visual analog scale and horizontal Likert scales) will be slightly modified for athletes with visual impairment. The system worked well for athletes with physical impairment and athletes with intellectual impairment without any major learnability or error recovery issues. The relative lack of technical problems and barriers encountered is not surprising as the application met most of the accessibility criteria recommended in WCAG 2.0 and was adapted to Paralympic athletes' own perceptions of experiences of sports-related injuries [26,27].

Monitoring Sustainability

Possible explanations for the high response rate are the short study period and system usability adaptation for easy use on mobile phones and other platforms. A restriction in athlete monitoring using self-reports is the workload assigned to the athlete, implying that collection of as little and as relevant data as possible is important in long-term surveillance [11].

The athletes were of the opinion that the application was easy to understand and could be extended to longer periods of time. Thus, we considered the application to be feasible for Paralympic athletes and believe that it can be adopted in their daily procedures with regard to the ability of the users [38]. Finch et al [34] recently described that, along with the development of digital tools, data can favorably be collected in real time from athletes and not by the medical teams, which has also proven feasible in other studies [12,13].

Data on Sports-Related Injuries and Illnesses in Paralympic Sport

Only 2 similar studies within Paralympic sport have included athlete exposure based on time [39,40]. For effective implementation of prevention strategies, incidence based on athlete exposure is a key factor [41]. A limitation of these 2 studies [39,40] is that the inclusion of injuries only referred to trauma and medical attention. In our study, 80% of the reported injuries were related to overuse, which indicates the importance of using an injury definition in Paralympic sport that also includes these types of injuries. In addition, the observed high prevalence of pain and relatively high use of analgesics raises concerns about Paralympic athletes' health. Few studies have assessed the prevalence, causes, and behaviors associated with pain among Paralympic athletes, and further research on this topic is warranted.

Only a handful of studies have assessed the incidence of illnesses among Paralympic athletes. Studies at the Paralympics Games indicate that illness rates are similar to injury rates [25]. This was also found in our study as well. It is therefore important that illnesses are included in athlete monitoring, well in line with the recommendations of future research priorities [34].

Strengths and Limitations

A strength of this study is the detailed preparatory work undertaken to develop the eHealth application and specifically adapt it to Paralympic athletes with visual impairment, physical impairment, and intellectual impairment. Another strength is the subsequent evaluation and correction of feasibility and usability indicators of the monitoring system before the start of full-scale long-term studies. A limitation is that we only

evaluated poststudy reported feasibility and usability issues and that the qualitative analysis included only written answers and no interviews. Another limitation is that the pilot study period was relatively short, and it is therefore not possible to distinguish long-term results and response rates. A larger study sample including athletes from all Paralympic sports may also have provided further insights into the feasibility and usability of this novel eHealth application.

Conclusion

The novel eHealth-based application for self-reported SRIIPS developed and tested in this pilot study was generally feasible and usable. With some adaptation to accommodate Paralympic athletes' prerequisites and improved technical support for athletes with visual impairment, this application can be recommended for use in prospective studies of SRIIPS. This will advance our knowledge of the incidence and risk factors of SRIIPS and facilitate the development of evidence-based prevention measures adapted to Paralympic sport.

Authors' Contributions

KF and JL conceptualized the project. KF, JJ, ÖD, TT, and JL contributed to the design of the study, drafting of the manuscript, and review of the final manuscript. All authors read and approved the final manuscript.

Conflicts of Interest

None declared.

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Abbreviations

FITT: Fit between Individuals, Task, and Technology
IT: information technology
PSSUQ: Post-Study System Usability Questionnaire
SRIIPS: sports-related injuries and illnesses in Paralympic sport
STROBE: Strengthening the Reporting of Observational Studies in Epidemiology
WCAG: Web Content Accessibility Guidelines

Deciding How to Stay Independent at Home in Later Years: Development and Acceptability Testing of an Informative Web-Based Module

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Abstract

Background: Seniors with loss of autonomy may face decisions about whether they should stay at home or move elsewhere. Most seniors would prefer to stay home and be independent for as long as possible, but most are unaware of options that would make this possible.

Objective: The study aimed to develop and test the acceptability of an interactive website for seniors, their caregivers, and health professionals with short interlinked videos presenting information about options for staying independent at home.

Methods: The approach for design and data collection varied, involving a multipronged, user-centered design of the development process, qualitative interviews, and end-user feedback to determine content (ie, needs assessment) in phase I; module development (in English and French) in phase II; and survey to test usability and acceptability with end users in phase III. Phase I participants were a convenience sample of end users, that is, seniors, caregivers, and professionals with expertise in modifiable factors (eg, day centers, home redesign, equipment, community activities, and finances), enabling seniors to stay independent at home for longer in Quebec and Alberta, Canada. Phase II participants were bilingual actors; phase III participants included phase I participants and new participants recruited through snowballing. Qualitative interviews were thematically analyzed in phase II to determine relevant topics for the video-scripts, which were user-checked by interview participants. In phase III, the results of a usability questionnaire were analyzed using descriptive statistics.

Results: In phase I, interviews with 29 stakeholders, including 4 seniors, 3 caregivers, and 22 professionals, showed a need for a one-stop information resource about options for staying independent at home. They raised issues relating to 6 categories: cognitive autonomy, psychological or mental well-being, functional autonomy, social autonomy, financial autonomy, and people involved. A script was developed and evaluated by participants. In phase II, after 4 days in a studio with 15 bilingual actors, 30 videos were made of various experts (eg, family doctor, home care nurse, and social worker) presenting options and guidance for the decision-making process. These were integrated into an interactive website, which included a comments tool for visitors to add information. In phase III (n=21), 8 seniors (7 women, mean age 75 years), 7 caregivers, and 6 professionals evaluated the

acceptability of the module and suggested improvements. Clarity of the videos scored 3.6 out of 4, length was considered right by 17 (separate videos) and 13 participants (all videos together), and 18 participants considered the module acceptable. They suggested that information should be tailored more, and that seniors may need someone to help navigate it.

Conclusions: Our interactive website with interlinked videos presenting information about options for staying independent at home was deemed acceptable and potentially helpful by a diverse group of stakeholders.

Introduction

Most seniors want to live at home and remain independent for as long as possible, a goal reflected in many government policies [1,2]. Independent living encompasses a holistic concept of autonomy that includes the social, psychological, functional, and health care needs of seniors related to active aging [3]. In 2011, 92% of all Canadian seniors aged 65 years and older lived autonomously in private households [4], of whom the majority were house owners [5]. Most still drove their cars, which was their main means of transportation; fewer than 6% used public transport; and fewer than 3% walked or cycled [4]. Similar patterns are seen abroad [6,7]. However, because of age-related decline in health and autonomy, many seniors receive informal or formal care at home (30.1% aged 75-84 years, and 54% over 85 years) [8]. Moreover, most seniors and their caregivers will ultimately face a decision about whether they can continue living at home, and if so, how to maintain their independence [8,9].

Although there are multiple options for seniors to remain at home [10-12], many seniors and their caregivers are unaware of them [13,14]. Before deciding to move elsewhere, it is important that seniors know their options about aging safely in situ and weigh these options alongside the option to relocate [15]. Moreover, active involvement in decision making is key to helping people self-manage their health.

According to the Ottawa Decision Support Framework, people cannot make preference-based shared decisions without accurate knowledge of the options, an understanding of what is most important to them, and effective support from others [15]. In the decision to stay at home or relocate, different kinds of knowledge (eg, medical, social, financial, and familial) are needed and supplied by different stakeholders. A senior may prefer to stay at home, for example, whereas others may know it is unsafe or untenable for their caregiver. Although the final decision is preferably the senior's, it is important that all the stakeholders [16-18] are involved in informing and discussing the decision. A recent ongoing study on the implementation of a shared decision-making (SDM) guide for seniors and caregivers about whether to stay at home or move indicates that the SDM guide helps stakeholders be more involved in the decision [18]. However, the guide does not provide detailed information on seniors' options for remaining at home [19]. In addition, it is paper-based and so presentation of options is limited. Some European countries have developed Web-based tools for seniors that offer more flexibility [20,21]. We therefore developed a Web-based interactive decision support module

for seniors, caregivers, and health professionals in 2 Canadian provinces that would incorporate videos with discipline-specific information about diverse options for staying independent at home. As the module is interactive, people can watch only the videos relevant to their needs, and watch them again or watch others if their needs change.

Methods

Study Design and Context

We used a 3-phase, multiprong, user-centered design [22] involving a needs assessment with qualitative interviews (phase I), module development (including script, videos, and textual information; phase II), and acceptability and usability testing (phase III). The study was approved by the CSSS Alphonse-Desjardins (Lévis) Ethics Committee and University of Alberta Health Research Ethics Board (Pro00055678).

Because health care in Canada is delivered under provincial and territorial rather than federal health insurance plans, we focused on 2 Canadian provinces: Quebec, a largely French-speaking province in eastern Canada with over 8 million inhabitants including 1.5 million seniors, and Alberta, an English-speaking province in western Canada with over 4 million inhabitants and almost 500,000 seniors. English and French versions of the module were developed simultaneously.

We were guided by a multidisciplinary steering committee of experts in SDM (MG, FL), primary care (FL), rehabilitation (AJ), architecture (NR), intensive care (PA), and a caregiver (LB), who met during each phase of the research and were responsible for data collection and analysis, determining the content of the module, and designing it. Video development, structure, and content were informed by the Interprofessional Shared Decision Making (IP-SDM) model [23,24], one of the few SDM models to acknowledge the contribution of multiple stakeholders, including multidisciplinary health teams and caregivers, in informing individuals' health-related decisions [25-29]. It has already proven useful in multiple contexts, including in decisions about where frail seniors will reside [18,25,26,29-31]. We added architects and urban planners, who reflected on the importance of neighborly relations and familiarity with one's surroundings in decisions about keeping seniors independent in their communities [18,26,29,32-37] (personal communication from Roy et al, 2017).

Participants

We recruited convenience samples of potential end users of the module (seniors, caregivers, and health care professionals) from

Quebec and Alberta. Participants were identified using snowballing [38], based on our steering committees' social and professional networks.

Seniors were included if they were 65+ years and had struggled with how to remain independent at home. *Caregivers* (eg, son, daughter, or spouse) were included if they cared for a senior who had faced decisions about maintaining independence at home. Participants were excluded if they were cognitively impaired or not able or willing to sign informed consent. *Professionals* could be any professional with clinical experience in maintaining seniors at home, as well as built environment experts [39]. Teams caring for seniors could include caregiver representatives, home support workers, family doctors, home care nurses, nutritionists, social workers, pharmacists, physiotherapists, or occupational therapists.

Phase I: Needs Assessment

Data Collection

Inspired by other needs assessments [13], we conducted single, semistructured interviews to assess information needs for decision making about housing options (from lay and professional perspectives) among seniors, caregivers, and health professionals (see Textbox 1 for the interview guide). Interviews were conducted by 2 trained female research assistants with expertise in health care research. No prior relationship was established with participants other than a call or email contact to set a date for the interview. Field notes were taken. According to participants' preferences, interviews were conducted by phone or face-to-face in a place convenient for them. Interviews were conducted in French or English. Written informed consent was obtained. Participating seniors and caregivers received C$15 to cover expenses.

Data Analysis

Interviews were audio-recorded and transcribed verbatim. They were descriptively content coded by a researcher using a deductive approach (coding emerged from the data), and then checked by the research assistants who had conducted the interviews. We listed and then produced an overview of the most important information needs (factors most mentioned) for decision making about housing options, that is, options that could best support staying independent at home, barriers or facilitators, costs, and relevant sources of information. In collaboration with team members, these information needs were organized into 6 categories: cognitive autonomy, psychological or mental well-being, functional autonomy, social autonomy, financial autonomy, and people involved. The categories emerged from the data and were congruent with literature on stated reasons for institutionalization [40-47] and on the concept of *positive health* [48]. Most factors (codes) were mentioned by multiple respondents (saturation). No software was used, as we planned no analysis other than listing the needs (factors considered important for maintaining independent at home) to ensure that they were all present in the module.

Phase II: Development of the Module

Script

We linked information needs to solutions (options) and labeled them according to the IP-SDM model (focusing on identifying the decision and people involved, definition of their role, and providing information about options, including benefits, risks, and consequences) to ensure that they were addressed in the videos [49]. Video scripts were drafted and finalized by our steering committee. Participants from phase I were asked to provide feedback.

Videos

Interactive videos presented the options that best responded to the decision-making needs identified by end users. In the videos, the 15 stakeholders relate personal anecdotes, but include balanced, evidence-based information [50]. Videos can facilitate thinking and problem solving using verbal, nonverbal, and visual communication techniques [51,52] and can contribute to (shared) decision making [50]. They have proven appropriate for less literate populations [53] and people with vision or hearing disabilities. As the module is interactive, people can watch only the videos relevant to their needs, and watch them again or watch others if their needs change. Concrete (local) options as per province are further explained in a separate section of the website with links to more information sources. Users are invited to update and comment on this information using a comments tool. A webmaster approves all posts before publication and updates information.

Web-Based Decision Support

Although some evidence supports the use of the Internet by seniors [54-56], there are also concerns [57,58]. However, seniors will be increasingly computer literate as time passes [54-56], and the speed at which new options become available makes offline information provision (eg, paper brochures) inefficient. This Web-based module is accessible on computers, tablets, or mobile phones on demand (any time or place). It can easily be updated and host different media. Housing decisions need constant reevaluation as seniors' physical or mental health deteriorates [40], and Web-based decision support allows visitors to select the information relevant for their decisional stage, their personal or situational context, and their physical and mental functioning.

Phase III: Usability Testing

Participants

Participants were seniors, caregivers, and professionals who participated in phase I, and new participants recruited by snowballing and networking of team members. Participants were invited by personal email or by phone, and with an advertisement on the Arthritis Society of Canada website (Joint Health Express). The survey was also available on the interactive website itself (but not mandatory for visitors). A completed questionnaire was considered informed consent. No incentives were offered.

Data Collection

Participants were sent a Web-based questionnaire with instructions to view the interactive website at their own pace and convenience, and then answer 14 questions about its acceptability and usability (Textbox 2) [15].

Textbox 1. Interview guide.

Seniors/caregivers

Introduction

- What is your/your loved one's year of birth?

- What is your/your loved one's living situation?

- Do you/your loved one currently receive home care? (If so, which?)

- Which resources have you/your loved one added to your home to keep living there?

- Which community resources are available to you/your loved one and which do you/your loved one use?

- Can you tell me briefly what you think about your/your loved one's situation and whether you have ever thought about moving or trying to stay as long as possible at home, and how?

- (For caregivers only) What is your relationship with the senior?

- Can you tell me about the extent to which you are involved in the care of your loved one, and decision making about social and medical decisions?

Main

- As you/your loved one have grown older, what are the important factors to keep mobile (independent) in your/your loved one's home and your community? (ie, who/what helps you stay mobile/independent?)

- What do you think are the most important issues associated with staying independent at home (issues that should be addressed in our videos)?

- Do you know anything about your options, and the cost of each, in terms of staying at home or moving? Where did you/your loved one get information about these things?

- Did anybody ever bring up the question whether or not to stay at home or move with you/your loved one?

Professionals

Introduction

- What is your profession?

- Home or acute care?

- What is the percentage of older people in your clientele?

- How many years have you worked in this profession?

- Can you give me a short example of what the job is about (something you would tell a senior when they come to see you and do not know what you do)?

Main

- From your (professional) point of view, what factors or issues are important when considering mobility/independence in the home or community for older adults?

- What options are most often available for seniors for remaining mobile and independent at home, from your (professional) point of view?

- What do you think are the most important issues (issues that should be addressed in our videos)?

- Can you give an estimate of costs of the options that you mentioned?

- How do people get reimbursed for this?

Textbox 2. Usability test.

- Please rate each section of the module by circling one of the following to show what you think about the clarity of the information: 4—Everything clear, 3—Most things clear, 2—Some things unclear, and 1—Many things unclear.

- The length of each separate video was: Too short/Just right/Too long.

- The total time needed to watch all the videos was: Too short/Just right/Too long.

- The amount of information was: Too little /Just right /Too much.

- I found the presentation: Slanted toward staying at home/Balanced/Slanted toward moving elsewhere.

- Do you think the module would be helpful for people making this decision? Yes/No

- Do you think the module would be acceptable to use with people making this decision? Yes/No

- Did the full module (including the videos) meet your expectations?

- Would you like to use (or keep using) the module?

- What did you like about the module?

- What did you dislike about the module? (concerns)

- At what point would it be useful for seniors to see this module? When they are still able to function at home without help/When they are beginning to lose autonomy /When they can no longer function on their own at home/Other, please specify.

All questions were posted on the same page, and answers could be reviewed and changed until submission of the questionnaire. One reminder was sent after 4 weeks.

Data Analysis

We performed a descriptive analysis of the data, and calculated mean, median, and range when relevant. Summary statistics were performed using Microsoft Excel.

Results

Phase I: Needs Assessment

Study Population

Between March 20 and September 28, 2015, we interviewed 29 stakeholders: 15 in Alberta and 14 in Quebec. Participants included 4 seniors, 3 caregivers, and 22 health care and other professionals (see Table 1). None of those contacted refused to participate. One interview was conducted simultaneously with both members of a senior couple. The mean interview time was 31.45 min (range 11.42-69.47).

Important Factors Influencing Decision Making About Staying Independent at Home

Cognitive Autonomy

Respondents mentioned the need for seniors to think about future housing options before there is cognitive decline or an emergency (eg, a fall). Seniors also should be encouraged to consider their changing needs over time to avoid having to frequently reevaluate them. This way, when the time comes to relocate, they may avoid long waiting lists for assisted living facilities and adjust more easily to the new environment. At the same time, seniors may be well aware of risks, and what to do about them should be in their hands.

Psychological or Mental Well-Being

Depression among seniors was frequently mentioned. It may be associated with isolation, as well as with the general effects of aging and loss of autonomy. Depression medication is associated with reduced mobility and risk of falls, whereas social or exercise programs (eg, walking or gardening) may improve both mental and physical health. It was mentioned that all who are involved in decision making should encourage seniors to participate in activities that they enjoy. Participants also mentioned the importance of seniors being happy and feeling safe where they are, but that they must accept that their needs are changing before they decide to make adjustments (eg, use a walker). Having a positive attitude toward the options for staying at home and being involved in the decisions about them were considered important decisional needs. Attitudes often change once people have tried the equipment and seen the benefits for themselves.

Functional or Physical Autonomy

Functional autonomy encompasses physical ability (muscle mass, strength, and balance), the environment, and prevention and support. If seniors are less able to perform certain tasks or activities, instead of doing the task for them, it is important to teach them a new way to perform the task themselves. Autonomy also depends on their home environment. Environmental barriers indoors (furniture, carpets, clutter, and distance to the toilet in case of incontinence) and outdoors (curbs and stairs) should be assessed in terms of safety. In suggesting equipment such as walkers or grab bars, it is important to discuss with seniors what is important for them and what limits them from being active. Specialized architects and occupational therapists can suggest how to redesign the living environment, such as moving the bedroom and toilet downstairs. Urban planners, who are more concerned with the external environment, pay attention to curbs and other walkability features of cities and public spaces. However, it should be recognized that whatever adaptations one makes to the home and environment, choosing to stay independent at home may one day no longer be realistic, safe, or affordable.

Table 1. Sociodemographic characteristics of participants in phase I (N=29).

Characteristics	Quebec	Alberta	Total
Seniors	2	2	4
Age, range	87-88	82-84	82-88
Sex (female), n (%)	1 (50)	1 (50)	2 (50)
Marital status, n			
Married	2	1	2
Widowed	-	1	1
Living situation, n			
House or suburban or urban area	2	1	2
Apartment style condo or urban	-	1	1
Caregivers	1	2	3
Mean age, range	67 (N/A)[a]	69 (56-82)	68.3 (56-82)
Sex (female), n (%)	1 (100)	2 (100)	3 (100)
Relation with senior, n			
Spouse	-	1	1
Child	1	1	2
Living situation, n			
House with senior or urban	1	1	2
Bungalow with senior or urban	-	1	1
(Health) professionals	11	11	22
Type of professional, n			
Dietitian	1	1	2
Physiotherapist	2	2	4
Occupational therapist	2	1	3
Social worker	1	1	2
Family physician	1	-	1
Transition nurse in geriatrics	1	-	1
Geriatrician	1	1	2
Architect	1	1	2
Human resources consultant (community activities)	1	-	1
Pharmacist	-	1	1
Recreational therapist	-	1	1
Nurse or case manager in homecare	-	1	1
Coordinator at community organization that helps the elderly	-	1	1
Sex (female), n (%)	10 (91)	10 (91)	20 (91)
Years of experience, range	15.2 (5-33)	16 (5-31)	15.6 (5-33)
Percentage of elderly clients, range	82.3 (40-100)	77 (30-100)	79.5 (30-100)

[a]N/A: not applicable.

It is also important to assess people's mode of transportation to access services in the community. People who drive their own cars are often more active, but at some point, this may no longer be safe. Many special seniors' transport options exist such as buses for people with disabilities, taxis, as well as special seniors' services that offer drivers to accompany seniors to their medical appointments.

Social Autonomy

When people age, their contemporaries start to die, leaving some people feeling isolated. Being socially active was mentioned

several times. Although not everyone minds being alone, many benefit from having company and participating in activities with others. Social participation and having a social network are safer (somebody to call for help) and can be an information source about options. Many seniors are reluctant to ask for help, which means admitting to themselves and others that they are no longer autonomous. This reluctance can also make caring for them more difficult.

Financial Autonomy

To receive the help they need at home, seniors in many jurisdictions have to be willing and able to pay for services. Although some services are provided or reimbursed through government programs or tax credits, other services require direct payment from the senior. To be reimbursed, the senior must have the mental agility and patience to fill out difficult forms or have somebody to help him or her. With the Internet, it is increasingly possible to order and pay for things online and have them delivered (groceries, medication, or clothes) to the home, but many seniors are not able to do this, whether from lack of a computer, knowledge, or confidence.

People Involved

Seniors, caregivers, and health professionals need to understand each other's limits and communicate about their difficulties. As informal caregivers are often key to keeping seniors independent at home, they should be kept informed of everything regarding the senior's health care needs and options that help them stay at home. Without a single care coordinator, it is often the informal caregiver who manages the patient's *file*. Their needs should be taken into account too, as the burden can become too much for them and threaten their own health. Caregivers can be informed of caregiver associations and helped to gain access to services such as respite care.

Table 2 provides the quotes from participants, and Table 3 provides an overview of the factors.

Phase II: Development of the Module

The Script

On the basis of the factors identified in phase I, we developed scripts for 15 stakeholders in decisions about seniors' housing options: a decision coach, a senior, 3 types of caregivers (son, daughter, or spouse), a caregiver representative, a home support worker, a family doctor, a home care nurse, a nutritionist, a social worker, a pharmacist, a physiotherapist, an architect, and an occupational therapist. The decision coach explained how a decision should be made and introduced the rest of the videos,

and the architect added information about community, the built environment, and home adaptation. We kept the scripts as general as possible so that the information would not quickly become outdated and that it could be used in several contexts. Information that frequently changes, such as costs and resources, was presented on the resource page.

In total, 4 stakeholders commented on the script (caregiver, pharmacist, architect, and physiotherapist). Overall, they were positive about it. On the basis of their expert opinion, we made some editorial changes to the script and the list of resources, and a senior (female, 85 years old, living independently at home with her daughter) evaluated the final scripts. She was positive about them and the initiative as a whole, and she thought the information was complete and relevant.

The Final Module

The final product is an interactive website with video links and additional text-based resources for seniors, caregivers, and professionals, called *SupPortIng seNiors And Caregivers to stay mobile at Home* (SPINACH). It consists of 3 Web pages as discussed below.

Homepage

Visitors select English or French, and then choose whether to see the videos, consult the resources, or comment on or add to the resource page.

Video Page

A team of 15 members sitting around a table shows visitors the range of stakeholders involved in making decisions with seniors who wish to stay independent at home (Multimedia Appendix 1). A mouse scroll-over function presents a short description of what each team member will discuss in his or her 1- to 3.5-min video. After selecting a team member, a popup appears with the videos (Multimedia Appendix 2). The selected stakeholder talks about his or her decision-making experiences with staying at home or moving, provides information on decisions related to staying at home, and/or gives specific information on options or guidance in the decision-making process.

Resource Page

The resource page provides with background information on options for staying independent at home (eg, local resources, equipment, and links to informative websites). Visitors can add comments or additional information about local services. A webmaster evaluates them and controls publication.

Table 2. Quotes illustrating the main categories from phase I.

Theme	Quotes
Cognitive autonomy	*And if people want to live with a degree of risk, that's fine from my stand point. As long as they understand that [the risk and consequences]. I mean we can't wrap people up, you know in lots and lots of bubble wrap to totally protect them.* [A13, Geriatrician]
	Yes and it's, as I say, if you make the choice yourself it makes it easier for everybody. When you get to that point in life where you have to, and you don't have a choice and you have to go where you are sent, I think a lot of people have trouble adjusting. [A7 and A8, Seniors]
Psychological or mental well being	
Depression	*So what factors do you think are important to consider when trying to keep them mobile, I guess, in the community? [Interviewer]*
	Finding things they like to do. Like if they love animals, like walking the dog. If they like, you know, the river valley, take them to the river valley. Finding things to engage them so that they want to do it, not so they have to do it… [Participant]
	You know, for us we say as long as it's something active, it can be anything. You know, we can go for a walk and they love doing crossword puzzles, maybe we stop at a park, do some crossword puzzles. [A14, Coordinator in a home care company]
Attitude	*[…] when you go to a walker, you are giving up your dignity. […] You are no longer totally independent. Here I am, I am handicapped now, I cannot just stride off into the sunset. I need help. It's hard for people to understand the lack of enthusiasm for suddenly having to start using a cane and a walker.* [A5, Senior]
	Many seniors don't want to look like seniors. They don't want to look old. You know, even though it might improve their ability to be mobile. [A13, Geriatrician]
	I would say the bigger challenge is when someone is adamant that they will lose independence because of the walking aid and once they've tried it you can often convince people that actually when they use the walker, you can actually walk further because you can sit down when you are tired, you do not have to look for a bench to sit on. […] but it can be difficult to persuade people that they need to give it a try because a lot of people just cannot get past the stigma of seeing themselves as someone who is using a walker. [A2, Physiotherapist]
Functional or physical autonomy	
Physical functioning	*… if you don't use it you lose it! I get so tired of that phrase, but it's so true. And there is the social aspect [of exercise programs] as well, which is maybe almost as important as the mobility factor.* [A5, Senior]
Environment	*You want to age in your current location, you are attached to it, have memories but you have difficulties in moving around, using stairs, or you are anxious […]. My role is to see how we can modify this environment, do renovations, to make sure that you can be autonomous, that you feel safe and good in your home. It is possible that if there is nothing that can be done at the regulatory level, in terms of financial resources or support in your environment (family, neighbours) then the best option may be to move. But we know how hard it is to leave your house so we are here to help you.* [R5, Architect specialized in housing for the elderly]
Transport	*Can she (the senior) go out, take the bus, walking, what are the distances to walk in the suburbs to do the grocery shopping and bring back bags with groceries? Is there adapted transportation? And the time you have to wait before it comes to your house? Is there a taxi? Maybe it is less expensive to take a taxi than to move to a residence with services.* [R5, Architect specialized in housing for the elderly]
Social autonomy	*Like let's start doing this, you know, while you're healthy, while you're well, because then, you know once they've got that social network then that just opens up so many more doors.* [A11, Occupational therapist in home care]
	It's through social contacts really that you know about things. It's important that you know people, and they tell you about these things. [A5, Senior]
	A lot of it, you know like so many seniors, they say oh my kids are so busy, they can't do this, and they've got a very important job and all of that kind of stuff. But we need to actually kinda break it down, you know, the family members are the ones that...they certainly would do something if they knew what to do. Or if they knew that things would be a little better for their loved ones. [A11, Occupational therapist in home care]
People involved	*Some families are great and some are not but you need to be able to see that your supports are there and that they are functioning and healthy and that it is not taking its toll on one single person. But it often does.* [A6, Social worker]

Table 3. Overview of the categories and factors mentioned in the interviews (phase I).

Category, factor (code), and examples (subcodes)	Solutions	Barriers to implementation
Cognitive autonomy		
Good judgment regarding risks		
Estimate risks, being self-critical	Avoid risks	Attachment to belongings
Good judgment and decision making		
Incompetent	Power of attorney, personal directive	Needs to be put in place before cognitive decline
Competent: making decisions yourself makes adapting easier	Incorporate everyone's values and preferences	
Memory		
Remember to eat, take meds, and turn off oven	Caregiver, calendar, box for pills, and microwave instead of oven	Isolation, confusion
Thinking ahead		People do not know what their needs will be in 5-10 years
Psychological or mental well-being		
Happiness		
Happy at home	Stay at home	Functional incapacity, isolation
Feeling safe, fears		
Stays in because is afraid to walk outside	Motivation, support people	Attitude—not willing to use aids or ask for help
Depression		
Due to isolation, general effects of aging, loss of autonomy	Medication, exercise programs, and caregiver	Medication can affect mobility; lack of awareness about benefits of participation for mental and physical health
Functional autonomy		
Managing the basic needs		
Medication	Community and social care services, check with pharmacist	Medication interactions with comorbidity
Hygiene	Grab bars in bathroom, care services offered by public health care system	Adaptability of homes, attitude of seniors
Food preparation and access (quantity and quality)	Meal services, vitamin D supplements and calcium	Attitude—willingness or ability to cook
		Cost of meal services or ready cooked meals
The body		
Good muscle mass, cardiorespiratory	Exercise program, services at home	Lack of motivation, accessible programs, awareness, education, or confidence; fear of falling; focus on disability, pain versus on ability
Getting around (internal and external)		
Design of the environment	Remove architectural barriers (internal: furniture, carpets; external: sidewalks, stairs)	Attitude: do not want change, want to design own house
		Costs of home renovations
Transport	Bus or taxi for seniors or caregiver transport	Access to information, costs
Mobility	Walkers, canes	Attitude: "those are for old people," giving up dignity and independence

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Category, factor (code), and examples (subcodes)	Solutions	Barriers to implementation
Pay attention to environment	Height of curb, height and number of stairs, and rugs	Awareness of need to change habits (people already use the walls and counters for balance or support), muscles that have not been used for a long time, current habits not safe
Prevention		
Of falls, eating problems	Programs, equipment, awareness; learning new things that they can still do themselves instead of taking it out of their hands	
Social autonomy		
No isolation, well-being		
Hobbies, activities	Day centers, friends	People have habits and do not like to change. Try to find intrinsic motivation, but decision is up to them
Have people around you		
Friends, family, neighbors	Social worker or caregiver	Not everybody wants to meet other people and do things together
Ask for help (formal and informal)		
Emergency system, lifeline	Bracelet, call someone	Attitude: children are too busy
Financial autonomy		
Ability to pay and manage finances		
Pension, reimbursement, subsidies	Financial support, tax benefits, and health insurance	Income: not enough to pay for services
		Attitude: unwillingness to pay, inability to complete forms for reimbursement, mental capacity, online payments versus cash
People involved in caring for senior		
Good collaboration		
Caregiver and health care professionals understand each other's limits, communicate		Do not get on with social worker
Caregiver needs		
Decrease the burden	Respite care	Access to information, capacity to advocate, family member differences regarding how they view the senior
	Access to care when caregiver is not around	

Phase III: Acceptability of the Module

A total of 21 people completed the acceptability survey: 8 seniors, 7 caregivers, and 6 professionals. Respondents were mostly female (15/21). Mean age of seniors was 76 years (range 66-91), whereas the mean age of caregivers was 69 years (range 36-70; Table 4). Most seniors and caregivers had higher education (college or university; 12/15). Caregivers were mostly adult children of a senior parent. Seniors had either no caregivers (n=3), an adult child (n=2), a partner (n=2), or other (n=1). Professionals were a nurse, an urbanist, an architect, a social worker, and a community care worker. In addition, 3 other professionals gave feedback by email to the researcher.

Comprehensibility

With a mean overall rating of 3.6 out of 4, participants thought the videos were very clear (Table 4), although one senior suggested that content should better reflect differences across Canada.

Length and Amount of Information

Most participants were positive about the length of each video (17/21; 81%) and the amount of information (17/21; 81%), but fewer people liked the length of the videos altogether (13/21; 62%). Some thought the module was too long (n=7) or had too much information (n=2), whereas others wanted more information (n=2). Others indicated that the module could be better tailored to specific characteristics of the senior (n=4).

Table 4. Acceptability test results for seniors, caregivers, and professionals (N=21).

Acceptability test question	Seniors (n=8)	Caregivers (n=7)	Professionals (n=6)	Total group (N=21)
Comprehensibility of videos (mean rating out of 4) [a,b]				
Video: decision coach	3.7	3.8	3.5	3.7
Video: senior 1	3.9	4	3.7	3.8
Video: caregiver 1	3.4	3.8	3.7	3.6
Video: caregiver 2	3.5	3.8	3.7	3.6
Video: caregiver 3	3.9	3.8	3.7	3.7
Video: caregiver representative	3.3	3.7	3.7	3.5
Video: home support worker	3.6	3.8	3.7	3.7
Video: family physician	4	3.8	3.3	3.7
Video: nurse in homecare	3.7	3.8	3.3	3.6
Video: dietitian	3.8	4	3.7	3.8
Video: social worker	3.8	3.7	3.2	3.5
Video: pharmacist	3.7	4	3.7	3.7
Video: physiotherapist	3.9	4	3.7	3.8
Video: architect	3.6	4	2.8	3.4
Video: occupational therapist	3.6	4	3.2	3.6
Length of single videos, n (%)				
Too short	-	-	1 (17)	1 (5)
Just right	7 (78)	5 (83)	5 (83)	17 (81)
Too long	2 (22)	1[b] (17)	-	3 (14)
Time needed to watch all videos, n (%)				
Too short	-	-	1 (17)	1 (5)
Just right	4 (44)	5 (83)	4 (67)	13 (62)
Too long	5 (56)	1[2] (17)	1(17)	7 (33)
Amount of information, n (%)				
Not enough	1 (11)	-	1(17)	2 (9)
Just right	7 (78)	5 (83)	5 (83)	17 (81)
Too much	1 (11)	1[b] (17)	-	2 (9)
Presentation was balanced, yes	6 (67)	5 (83)	6 (100)	17 (81)
Helpful? yes	6 (67)	5 (83)	5 (83)	16 (77)
Acceptable to use for people in this situation? yes	8 (89)	5 (83)	5 (83)	18 (86)
Did module meet your expectations? yes	6 (67)	5 (83)	5 (83)	16 (77)
Would you like to use/keep using the module? yes	3 (34)	3 (50)	6 (100)	12 (58)
At what point would it be useful for seniors to see this module?, n (%)				
When they start losing their autonomy	3 (34)	2 (33)	3 (50)	8 (38)
When they are still able to function at home without help	6 (66)	4 (67)	3 (50)	13 (62)

[a]4—Everything clear; 3—most things clear; 2—some things unclear; 1—many things unclear.

[b]One caregiver did not watch any videos, and rated all as *Not applicable*.

Helpfulness

Most respondents thought the module was helpful (16/21; 77%). In total, 4 people did not agree because of navigation difficulties (1 senior), inadequate detail, 1 professional), lack of specificity or tailoring (1 senior), or design (1 caregiver). Of the participants, 1 senior was not prepared to accept her need to make any adaptations, so the information was of no interest to her.

Acceptability

Most respondents thought the module was acceptable (18/21; 86%), but 3 people did not because of a lack of information (1 professional), too idealistic presentation of options (1 caregiver), and navigation difficulties (1 caregiver). All professionals were eager to start using the module with their clients when finalized (6/6; 100%), as were most caregivers (3/7; 43%). Seniors were less willing to continue using the module (5/8; 66%) because of navigation difficulties or because it needed changes (n=2), or their preference for information face-to-face or in a brochure (n=2). A senior said she would return to the module when it becomes more relevant to her situation.

What People Liked About the Module

Participants liked the interprofessional character of the module, the diversity of information, the concrete and practical examples, and the information about available services. They also liked the positive tone (focus on what can be done instead of what cannot).

Concerns About the Module

The concern most often mentioned by seniors was its overall length. A senior and a caregiver mentioned that it did not portray the reality (eg, long wait times or services that are not available). A caregiver was negative about the whole module, saying he did not like watching videos. Some professionals wanted more details on the role of health professionals (eg, health evaluations by nurses). Others mentioned the challenge of using the module with people with dementia.

Discussion

Principal Findings

Using a 3-phase, user-centered design, we developed and tested the acceptability of an interactive Web-based module for seniors, their caregivers, and health professionals with videos presenting information about options for staying independent at home. A needs assessment (phase I) uncovered numerous decisional needs, including the need to start thinking about this decision early on, safety issues inside and outside the home, and the importance of social supports and psychological or mental well-being. In the production phase (phase II), we developed scripts that addressed these decisional needs, which were positively evaluated by end users and used to create 15 bilingual videos. These were integrated into an interactive Web-based module. In usability testing (phase III), this was found to be clear, comprehensible, and providing enough information, but users found that it took too long to watch all of the videos and that seniors might need assistance navigating the module. In total, 3 concluding reflections were derived from these findings.

First, research has shown that good levels of knowledge about services and support, as well as good housing, are associated with the likelihood of continuing to live in the community [59]. In accordance with our needs assessment, the content of the module focused primarily on the first steps in SDM models: identifying the decision and people involved and providing information about options, including benefits, risks, and consequences [13,27]. Decisions made in the absence of knowledge about available options are less likely to be accepted (phase I) and may result in feelings of uncertainty and conflict in the caregiver or conflict between the caregiver and the senior [9]. For a full SDM process, an interactive (face-to-face) discussion with all those involved in decision making is required to weigh all relevant information in light of personal and professional opinions and reach agreement about the best option [31,60]. As the Internet has been found to be one of the most commonly used and trusted information sources for health information among the elderly [56], this Web-based module can prepare people for this discussion. As decisional needs and Internet use vary with personal and sociodemographic characteristics [15,61], our videos present a variety of senior and caregiver profiles, and the viewer can select which ones to watch. However, acceptability test results led us to conclude that much shorter videos tailored to different characteristics could provide people with information even more closely matched to their needs, increase understanding, and decrease viewing time [20]. Future plans with this module are to tailor the information and videos to characteristics and situations, such as early symptoms of dementia, physical problems, and presence and type of caregiver. In line with concerns of participants who were uncertain about whether (other) seniors would be able to go through the module alone [58,62], we suggest that seniors go through the module with a caregiver. This would also facilitate personal dialogue between the senior and the caregiver and improve the process of SDM.

Second, staying active and being socially engaged were mentioned to be linked with staying healthy in both the needs assessment and the acceptability test. The concept of positive health refers to the capacity to live autonomously with physical, emotional, and social challenges [48]. This relates to the principles of self-management and *use it or lose it* mentioned by our participants (phase I), reflected in the videos (phase II), and positively evaluated in the acceptability test (phase III) [63]. This module helps seniors to self-manage and stay independent by helping them think about what they can and cannot do by themselves. Although seniors in our study showed less concern for social support, many professionals in our study mentioned its importance for well-being and autonomy, and other research supports this [64]. Social support may be a crucial and overlooked element of the inside and outside built environment and of community care options for seniors. The Internet may be another way to access social support [55].

Third, the module emphasizes the importance of involving seniors *and* caregivers *and* professionals in decision making, implying that they all need to know and understand the best available evidence regarding the risks and benefits of all options for staying independent at home [17,60,65]. This interdisciplinary aspect of our module, which was specifically

appreciated by participants and is considered key in IP-SDM [16-18], was possible because of the interdisciplinary and user-centered design used throughout the development of the module. Although future research should assess what types of end users should be involved in updating the module and to what extent, we will continue to involve end users in updating the module by inviting them to add regional information or propose adaptations using the comment function. This function will facilitate ongoing and sustainable patient and professional engagement in our process [66,67]. The Web-based and end user–adaptable nature of the module will also facilitate implementing and scaling up the intervention [68].

Limitations

Although people were initially enthusiastic about participating in several developmental rounds, the decreasing response per round indicated that more was needed to successfully create ownership and that participants were losing interest because of the lengthy process.

Data collection and identification of local resources took place in Quebec and Alberta only. Thus, although the videos are bilingual, generic, and in principle applicable to any context, local options are currently available only for Quebec and Alberta. Future studies could adapt the module to other Canadian

contexts. Finally, the modest number of participants in this project was adequate for a user-centered development process, but future phases of this project should use different study designs (eg, pre-post or randomized trial designs) and larger samples of participants to achieve generalizable results, for example, with regard to the effectiveness of the module or its implementation.

Conclusions

We adopted a user-centered design to develop a Web-based decision support module for seniors, caregivers, and health professionals that incorporates discipline-specific information about options for staying independent at home. The module was deemed acceptable and potentially helpful.

Seniors are often anxious and fearful when the first signs of loss of autonomy appear, and confused about what they can do about it. These are first steps toward providing them with the information they and their caregivers need to make decisions about how to stay independent at home. We plan to adapt the module to better target the most important user (the senior), and to continue its development and evaluation, as well as develop implementation strategies. In the meantime, the module is available on the Web as the information on the module is already of use for many seniors.

Conflicts of Interest

None declared.

Multimedia Appendix 1

Screenshot of stakeholders whose videos can be chosen using mouse scroll-over.

[PNG File, 166KB - humanfactors_v4i4e32_app1.png]

Multimedia Appendix 2

Screenshot of a stakeholder (architect).

[PNG File, 117KB - humanfactors_v4i4e32_app2.png]

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Abbreviations

IP-SDM: Interprofessional Shared Decision Making
SDM: shared decision making

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Original Paper

Characteristics of Adults Seeking Health Care Provider Support Facilitated by Mobile Technology: Secondary Data Analysis

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Abstract

Background: Mobile health technology is rapidly evolving with the potential to transform health care. Self-management of health facilitated by mobile technology can maximize long-term health trajectories of adults. Little is known about the characteristics of adults seeking Web-based support from health care providers facilitated by mobile technology.

Objective: This study aimed to examine the following: (1) the characteristics of adults who seek human support from health care providers for health concerns using mobile technology rather than from family members and friends or others with similar health conditions and (2) the use of mobile health technology among adults with chronic health conditions. Findings of this study were interpreted in the context of the Efficiency Model of Support.

Methods: We first described characteristics of adults seeking Web-based support from health care providers. Using chi-square tests for categorical variables and *t* test for the continuous variable of age, we compared adults seeking Web-based and conventional support by demographics. The primary aim was analyzed using multivariate logistic regression to examine whether chronic health conditions and demographic factors (eg, sex, income, employment status, race, ethnicity, education, and age) were associated with seeking Web-based support from health care providers.

Results: The sample included adults (N=1453), the majority of whom were female 57.60% (837/1453), white 75.02% (1090/1453), and non-Hispanic 89.13% (1295/1453). The age of the participants ranged from 18 to 92 years (mean 48.6, standard deviation [SD] 16.8). The majority 76.05% (1105/1453) of participants reported college or higher level of education. A disparity was found in access to health care providers via mobile technology based on socioeconomic status. Adults with annual income of US $30,000 to US $100,000 were 1.72 times more likely to use Web-based methods to contact a health care provider, and adults with an annual income above US $100,000 were 2.41 to 2.46 times more likely to access health care provider support on the Web, compared with those with an annual income below US $30,000. After adjusting for other demographic covariates and chronic conditions, age was not a significant factor in Web-based support seeking.

Conclusions: In this study, the likelihood of seeking Web-based support increased when adults had any or multiple chronic health conditions. A higher level of income and education than the general population was found to be related to the use of mobile health technology among adults in this survey. Future study is needed to better understand the disparity in Web-based support seeking for health issues and the clinicians' role in promoting access to and use of mobile health technology.

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Introduction

Mobile Health Technology

Mobile health technology is rapidly evolving with the potential to transform health care. Mobile devices, including mobile phones, tablet computers, and handheld devices with wireless Internet connectivity offer new opportunities to maximize health and wellness and improve long-term health trajectories for adults across the age continuum [1]. Mobile technology has been used to promote health behaviors, such as physical activity [2] and optimal nutrition [3], major determinants of health [4] that enhance physical and mental function [5] for healthy aging.

Self-management of health, defined as individuals assuming tasks to deal with medical management, role management, or emotional aspects of health conditions [6], is facilitated by mobile technology. Optimizing self-management of health is associated with an increase in average life years, a delay in the development of chronic health conditions, and lower Medicare costs [7]. Despite the advantages, the actual reach and availability of coordinated activities and programs on the Internet designed to promote self-management using mobile technology have been lower than expected, and attrition rates were high [8]. Individual engagement in positive health behaviors is necessary to achieve the desired outcomes [9]. Integrating health care provider support with this technology may be the key to improving this process.

Study Aim

The aim of this study was to assess the characteristics of adults across the lifespan, who seek health care support from providers facilitated by mobile technology. We selected an existing dataset to investigate Web-based human support seeking from providers rather than from family members and friends or others with similar health conditions. The impact of sociodemographic factors and other variables on Web-based support seeking for health issues from providers remains unclear. Understanding the characteristics of mobile technology users who do and do not seek Web-based support for health care issues from providers is needed for translation to clinical practice and to inform future health behavior research.

Background and Significance

The impact of mobile technology in the daily lives of people worldwide has increased markedly over the past decade and continues to expand. Mobile technology offers distinct advantages for optimizing health and wellness, with unlimited reach across economic and geographic boundaries, as well as continuous availability. Most Americans (95%) now own a mobile phone of some kind [10]. Furthermore, over half (62%) of mobile phone owners use their phone to search for health information [11]. Web-based searching for health information facilitated by mobile technology differs based on sociodemographic profile [12]. Mobile phone owners who were Latino or African American, aged between 18 and 49 years, and had a college degree were more likely to access Web-based health information [11]. Although the majority of mobile technology users report searching for Web-based health information, less is known about the human element in

Web-based communication and information sharing. The characteristics of individuals who use mobile technology to seek health care support from providers remain unclear. Greater understanding of Web-based health care support seeking from providers is needed to inform best practices for retaining individuals in positive health behaviors over time.

This investigation builds on existing data. A study using Pew Research Center survey data assessed the potential reach of mobile phones among adults and found that chronic health conditions affected mobile technology use. Slightly less than one quarter of the sample had diabetes, and these individuals were less likely to use mobile phones [13] compared with those without diabetes. Individuals with diabetes, with higher income, younger age, and Web-based health information searching were associated with higher mobile phone use [13]. These findings are consistent with other study results that found less affluent adults with chronic health conditions were largely disconnected from the world of technological tools and services, both physically and psychologically [14]. Thus, adults with chronic conditions were less likely to use mobile phones, and this appears to be because of older age and lower socioeconomic status, whereas adults with a higher level of education, younger age, nonwhite race, and high income were more likely to use mobile phones.

A previous study also indicated that two subgroups had a lower chance to be engaged users of health care resources facilitated by mobile technology, namely, males (odds ratio [OR] 2.24, 95% CI 1.23-4.08) and younger adults (OR 1.02, 95% CI 1.00-1.04), who were also less likely to return to health care resources on the Web for follow-up after 1 week [15]. Previous studies generally assessed mobile phone use rather than Web-based health care support seeking from providers. On the basis of these findings, we predicted that females, older and more affluent adults, and adults without chronic conditions would be most likely to use mobile technology to seek Web-based health care provider support.

The Efficiency Model of Support described by Schueller et al (2016) provides a framework for understanding the provision of human support in the context of behavioral interventions facilitated by technology. This model predicts that health care provider interaction in conjunction with mobile technology leads to more frequent and more effective use (eg, with greater individual engagement and lower attrition) [16]. Health may be enhanced when data generated by mobile devices are combined with assessment and intervention from health care providers. This model frames mobile technology as the facilitator rather than the driver of positive health behavior [17]. Integrating health care provider support for individual self-management of health facilitated by mobile technology is advantageous, and this model will guide future research and clinical translation.

Health Care Provider Perceptions of Mobile Health Technology

The health care provider perspective was not assessed in this survey; however, the perceptions of health care providers of mobile health technology use and the integration of human support must be considered to promote optimal use of the technology. A previous survey of health care professionals

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(n=500) found that the majority (86%) of respondents were accepting of mobile health resources and indicated that mobile technology will increase their knowledge of a patient's condition and improve their relationships with patients [18]. This survey found that only a small number (16%) of health care professionals currently recommend mobile health resources for patients, but just less than half (46%) plan to do so in the next 5 years [18]. In addition, a survey of nonclinician decision leaders in health care (n=900), representing medical technology companies, insurance, and other stakeholder groups, found more than half indicated that wireless, wearable health tracking devices, and other health technology advancements will help improve health care delivery [19]. This study investigated the sociodemographic profile and chronic health conditions of participants related to health care support seeking from a provider using mobile technology.

Methods

Design and Data Collection

The design of this study was a secondary analysis of cross-sectional survey data collected by random digit dialing by Princeton Survey Research Associates International for the Pew Research Center's Internet and American Life Project [20]. The data were collected from August to September 2012 with multiple attempts made to contact each sampled telephone number. Calls were staggered over times of day and days of the week to maximize the chance of making contact with potential respondents, and each phone number received at least one daytime call. A nationally representative sample of adults aged 18 years and older was recruited from all geographic census regions of the United States, including Northeast, Midwest, South, and West, as well as urban, suburban, and rural locations. Interviews were conducted in both English and Spanish. Telephone interviews were conducted by random digit dialing and included some individuals without a landline phone. According to Pew, within strata, phone numbers were drawn with equal probabilities [20]. Permission was obtained from the Pew Research Center to analyze the data, and the dataset was downloaded free of charge. The dataset did not contain any participant identifiers, and thus, was approved by the institutional review board at the authors' university for an "exempt" study before beginning analyses.

Measures

The sociodemographic profile of participants related to health care support seeking from a provider using mobile technology was investigated. Health care support seeking from a provider was defined as Web-based communication with a doctor or other health care provider (included Web-based or combination of Web-based and conventional support) the last time the respondent had a health issue. Response options also included Web-based health information seeking from friends and family members or others with a similar health condition. Covariates included chronic health conditions, defined as diagnosed conditions, such as diabetes, high blood pressure, lung conditions (asthma, bronchitis, or emphysema), heart disease (heart failure or heart attack), cancer, or any other chronic health condition.

Data Analysis

We first described the characteristics of adults seeking support from health care providers using Web-based or conventional methods. Using chi-square test for categorical variables and t test for the continuous variable of age, we compared adults seeking Web-based support by demographics. The primary aim was analyzed using multivariate logistic regression to examine whether chronic health conditions and demographic factors (eg, sex, income, employment status, race, ethnicity, education, and age) were associated with seeking Web-based support from health care providers for adults.

We performed three regression analyses. Model 1 included demographic variables. Model 2 added the variable of any chronic health condition into Model 1. Model 3 included three chronic condition groups (adults with one chronic condition, those with multiple chronic conditions, and those without any chronic condition) in addition to demographics. Wald χ^2 was reported to evaluate the fit for each regression model. All data were analyzed using the STATA version 14.0 (StataCorp, LP, College Station).

Results

Study Sample

The sample (Table 1) included adults (n=1453), the majority of whom were female 57.60% (837/1453), white 75.02% (1090/1453), and non-Hispanic 89.13% (1295/1453). The age of the participants ranged from 18 to 92 years (mean 48.6, SD 16.8). The majority 76.05% (1105/1453) of participants reported college or higher level of education. Of note, the category of less than or incomplete high school had few cases and was combined with the high school category. About half of the participants 50.72% (737/1453) reported any chronic health condition(s), with slightly more reporting one chronic condition than those reporting multiple chronic conditions 29.46% (428/1453) vs 21.27% (309/1453). Over half 54.16% (787/1453) of the respondents reported an income in the mid-range, and were employed 59.67% (867/1453) either part time or full time, or were self-employed. Less than one quarter 20.65% (300/1453) were retired.

Health Care Support Seeking

Most respondents reported seeking support for a health issue from a health care provider by visiting them in person or talking on landline phone 85.07% (1236/1453), compared with Web-based support seeking 14.93% (217/1453) through the Internet or email, or a combination of Web-based and conventional methods. According to bivariate analysis (Table 2) Web-based support seeking significantly differed by income, employment, race, education, and age ($P<.05$). Adults with income above US $30,000, being employed, having achieved college or higher education, and of white race sought support from a health care provider for a health issue on the Web, rather than by conventional means. Furthermore, adults seeking Web-based support were significantly younger (mean 46.1, SD 14.7) than those seeking conventional support (mean 49.1, SD=17.1).

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Table 1. A descriptive summary of study sample (n=1453).

Variable	Value
Health care provider support seeking, n (%)	
Yes, Web-based or both Web-based and conventional means	217 (14.93)
Conventional means only	1236 (85.07)
Chronic condition, n (%)	
No	716 (49.28)
Yes (any chronic condition), n (%)	737 (50.72)
One chronic health condition	428 (29.46)
Multiple chronic conditions	309 (21.27)
Sex, n (%)	
Male	616 (42.40)
Female	837 (57.60)
Income, n (%)	
<US $30,000	353 (24.29)
US $30,000-$100,000	787 (54.16)
>US $100,000	313 (21.54)
Employment, n (%)	
Employed (full-time, part-time, or self-employed)	867 (59.67)
Retired	300 (20.65)
Not employed for pay	286 (19.68)
Race, n (%)	
White	1090 (75.02)
Black or African-American	235 (16.17)
Asian or Pacific Islander	36 (2.48)
Other	92 (6.33)
Ethnicity, n (%)	
Hispanic	158 (10.87)
Not Hispanic	1295 (89.13)
Education, n (%)	
Less than or high School	348 (23.95)
College or higher	1105 (76.05)
Age, mean (SD)	48.63 (16.81)

Table 2. Comparison of Web-based and conventional support seeking (n=1453).

Variable	Web-based support (n=217) n (%)	Conventional support (n=1236) n (%)	Chi-square values (degrees of freedom)
Chronic condition			
No	101 (46.54)	615 (49.76)	
Yes (at least one chronic condition)	116 (53.46)	621 (50.24)	
Chronic condition			
No	101 (46.54)	615 (49.76)	
One chronic condition	70 (32.26)	358 (28.96)	
Multiple chronic conditions	46 (21.2)	263 (21.28)	
Sex			
Male	92 (42.4)	524 (42.39)	
Female	125 (57.6)	712 (57.61)	
Income			15.3^a (2)
<US $30,000	35 (16.13)	318 (25.73)	
US $30,000-100,000	117 (53.92)	670 (54.21)	
>US $100,000	65 (29.95)	248 (20.06)	
Employment			17.0^a (2)
Employed (full-time, part-time, or self-employed)	152 (70.05)	715 (57.85)	
Retired	23 (10.6)	277 (22.41)	
Not employed for pay	42 (19.35)	244 (19.74)	
Race			9.4^a (3)
White	148 (68.2)	942 (76.21)	
Black or African-American	39 (17.97)	196 (15.86)	
Asian or Pacific Islander	8 (3.69)	28 (2.27)	
Other	22 (10.14)	70 (5.66)	
Ethnicity			
Hispanic	23 (10.6)	135 (10.92)	
Not Hispanic	194 (89.4)	1101 (89.08)	
Education			6.6^a (1)
Less than or high school	37 (17.05)	311 (25.16)	
College or higher	180 (82.95)	925 (74.84)	
Age, mean (SD)	46.10 (14.71)	49.07 (17.12)	$2.4^{a,b}$

[a]$P<.05$.

[b]t statistic calculated from t test.

The multivariate logistic regression analysis of Web-based support from health care providers on chronic conditions and demographics is shown in Table 3. The odds of Web-based support seeking from a health care provider for a health condition were 1.62 times greater for adults with any chronic condition compared with adults without any chronic condition (Model 2). Furthermore, Model 3 showed that the odds of Web-based support seeking from a health care provider were 1.85 times greater when adults had multiple chronic conditions than those without multiple chronic conditions. Participants reporting other race were 2.15 times more likely to seek health support on the Web than whites. In Models 1 to 3, there were no significant differences in the odds of seeking support from a health care provider on the Web based on sex, age, or ethnicity, compared with those individuals who do not seek health information on the Web, after adjusting for covariates.

A disparity was found in access to health care providers via mobile technology based on socioeconomic status. Adults with annual income ranging from US $30,000 to US $100,000 were 1.72 times more likely to contact a health care provider on the Web, and adults with an annual income above US $100,000

were 2.41 to 2.46 times more likely to access a health care provider on the Web, compared with those with an annual income below US $30,000 (Models 2 and 3). In addition, the odds of seeking Web-based support were 1.51 to 1.53 times greater for adults with college or higher education than those with less than or high school education. In comparison with employed adults, retired adults were 57% to 58% less likely to contact a health care provider on the Web for support for a health issue, even after controlling for chronic conditions and other demographic differences, including age and income differences.

Table 3. Multivariate logistic regression of Web-based support from health care providers on chronic conditions and demographics (n=1453).

Web-based support	Model 1		Model 2		Model 3	
	OR[a] (95% CI)	P value	OR (95% CI)	P value	OR (95% CI)	P value
Chronic condition						
No (Ref.)						
Yes			1.62 (1.17-2.23)	.003		
Chronic condition						
No (Ref.)						
One chronic condition					1.52 (1.07-2.16)	.02
Multiple chronic conditions					1.85 (1.20-2.85)	.005
Income						
<US $30,000 (Ref.)						
US $30,000-100,000	1.65 (1.07-2.54)	.024	1.72 (1.11-2.65)	.015	1.72 (1.12-2.66)	.01
>US $100,000	2.27 (1.38-3.72)	.001	2.41 (1.47-3.97)	.001	2.46 (1.49-4.06)	<.001
Employment						
Employed (Ref.)						
Retired	0.50 (0.27-0.79)	.004	0.43 (0.25-0.74)	.002	0.42 (0.25-0.73)	.002
Not employed for pay	1.04 (0.70-1.54)	.86	0.97 (0.65-1.45)	.89	0.96 (0.64-1.44)	.85
Race						
White (Ref.)						
Black or African-American	1.42 (0.96-2.12)	.08	1.42 (0.95-2.11)	.08	1.40 (0.94-2.09)	.10
Asian or Pacific Islander	1.59 (0.70-3.62)	.27	1.66 (0.73-3.78)	.23	1.67 (0.73-3.80)	.22
Other	2.14 (1.23-3.74)	.007	2.15 (1.23-3.76)	.007	2.15 (1.23-3.77)	.007
Ethnicity						
Hispanic (Ref.)						
Not Hispanic	1.22 (0.73-2.04)	.46	1.16 (0.69-1.95)	.57	1.17 (0.70-1.96)	.56
Sex						
Male (Ref.)						
Female	1.05 (0.78-1.42)	.76	1.05 (0.77-1.41)	.77	1.05 (0.78-1.42)	.76
Age	1.00 (0.99-1.01)	.60	0.99 (0.98-1.00)	.18	0.99 (0.98-1.00)	.15
Education						
Less than or high school (Ref.)						
College or higher	1.45 (0.97-2.16)	.072	1.51 (1.01-2.67)	.045	1.53 (1.02-2.30)	.04
Full Model Wald χ^2	45.61	<.001	54.26	<.001	55.05	<.001

[a]OR: odds ratio.

Discussion

Principal Findings

The key findings of this study included the characteristics of the users of mobile health technology across the life span ranging from 18 to 92 years. In this study, the likelihood of seeking health care support on the Web increased when adults had any or multiple chronic health conditions. A higher level of income and education than the general population was found to be related to the use of mobile health technology among adults. This is consistent with previous survey research that found high annual income was positively associated with higher usage of Internet technology [21]. We found that annual income of less than US $30,000 negatively impacted the use of mobile health technology. Annual income of above US $30,000 was positively associated with the use of mobile technology to seek Web-based support from a health care provider. Notably, our bivariate analysis showed a significant difference in the use of Web-based support by age. However, when adjusting for other demographic covariates and chronic conditions, age was no longer a considerable factor.

The findings of this study indicate that factors other than age have a greater impact on health support seeking from a provider facilitated by mobile technology. A randomized trial that supported Web-based data sharing between individuals with diabetes and health care providers resulted in a greater decrease in HbA1c compared with usual care over 6 months [22] and 1 year [23]. Mobile technology facilitated this interaction longitudinally. Adults across the age continuum with chronic health conditions, who receive health care provider support on the Web, will benefit from self-management of health facilitated by the technology. Mobile technology moves health care into the context of the individual's daily life, filling gaps between episodic clinic visits.

A previous investigation found that many participants in the over 50-year age group reported a dislike of sharing health information on the Web through social media sites (eg, Facebook and Twitter) [24]. Middle-aged and older adults may perceive privacy as an issue in Web-based support seeking regarding their health. The survey used in this study did not address social media; however, these findings point to multiple considerations for promoting mobile health technology, which is still used less frequently than traditional offline support seeking for health issues.

The gap in mobile technology use of the lower socioeconomic group necessitates health care provider support to improve access to and use of mobile devices for the self-management of health. Integration with traditional health care practices involving in-person visits and phone calls must be considered.

Health care providers can support individuals in self-management of their health by directing them to mobile technologies that are most effective [25], and to devices with optimal design to engage greater proportions of the population [26]. Health care provider support appears essential but is often overlooked for mobile health technology adoption among adults across the age continuum.

Strengths and Limitations

One of the strengths of this study is the secondary analysis of a dataset collected to study mobile health technology. This study used a random sample of mobile phone users across the United States. In addition, the study was conducted in both English and Spanish to facilitate participation of the rapidly growing Hispanic population. A limitation of this study was the use of self-reported chronic conditions. This is a minor limitation, considering that no particular disease was targeted in this study. The dataset did not include information to delineate the type of health care support being sought, either general support or support for a chronic condition. Secondary analyses of existing data are limited to the existing variables in the dataset for investigation, and thus, unmeasured factors are a limitation. We examined sociodemographic variables and chronic condition variables that based on the literature were considered to be important in seeking health care support from providers on the Web. We acknowledge that the selected variables may not be sufficient to account for unmeasured factors related to our outcome variable. Other variables that may affect data and information exchange between providers and patients, such as depression and cognition, will be important to investigate in a future prospective study.

Conclusions

This is one of the first studies to report the characteristics of adults seeking Web-based support from a health care provider facilitated by mobile technology. Overall, the findings reveal that adults of all ages use mobile technology. Multiple opportunities exist for health care providers to promote self-management of health facilitated by Internet-accessible technology. Many individuals continue to seek support from health care providers by conventional means; however, mobile health technology has considerable potential to improve traditional health care by extending the reach to at-risk groups and filling the gaps between episodic clinic visits. The evolving technology has the capability to provide individualized programs that effectively meet the needs of the individual. Future study is needed to better understand the disparity in Web-based support seeking for health issues, as well as the clinicians' role in promoting access to and use of this technology to address the gaps identified in this study.

Conflicts of Interest

None declared.

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Abbreviations

OR: odds ratio
SD: standard deviation

<u>Original Paper</u>

Lack of Adoption of a Mobile App to Support Patient Self-Management of Diabetes and Hypertension in a Federally Qualified Health Center: Interview Analysis of Staff and Patients in a Failed Randomized Trial

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Abstract

Background: Thousands of mobile health (mHealth) apps have been developed to support patients' management of their health, but the effectiveness of many of the apps remains unclear. While mHealth apps appear to hold promise for improving the self-management of chronic conditions across populations, failure to balance the system demands of the app with the needs, interests, or resources of the end users can undermine consumers' adoption of these technologies.

Objective: The original aim of this study was to evaluate the effectiveness of a commercial mHealth app in improving clinical outcomes for adult patients in a Federally Qualified Health Center (FQHC) with uncontrolled diabetes and/or hypertension. Patients entered clinical data into the app, which also supported messaging between patients and providers. After a 4-month period of vigorous recruitment, the trial was suspended due to low enrollment and inconsistent use of the app by enrolled patients. The project aim was changed to understanding why the trial was unsuccessful.

Methods: We used the user-task-context (eUTC) usability framework to develop a set of interview questions for patients and staff who were involved in the trial. All interviews were done by phone and lasted 20 to 30 minutes. Interviews were not recorded.

Results: There was a poor fit between the app, end users, and recruitment and treatment approaches in our setting. Usability testing might have revealed this prior to launch but was not an option. There was not sufficient time during routine care for clinical staff to familiarize patients with the app or to check clinical data and messages, which are unreimbursed activities. Some patients did not use the app appropriately. The lack of integration with the electronic health record (EHR) was cited as a problem for both patients and staff who also said the app was just one more thing to attend to.

Conclusions: This brief trial underscores the pitfalls in the utilization of mHealth apps. Effective use of mHealth tools requires a good fit between the app, the users' electronic health (eHealth) literacy, the treatment approach, staff time, and reimbursement for services. The last 3 are contextual factors of the setting that affected the adoption of the app and context is an important factor in implementation science. We recommend that researchers address contextual factors in the trial and adoption of mHealth technologies.

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Introduction

Thousands of mobile health (mHealth) apps have been developed to support patient's management of their health [1,2], but their effectiveness remains unclear [3]. Despite reporting improved outcomes, many studies of mHealth apps are not adequately powered, have poor rates of retention, or have a high risk of bias in their methods [4]. While mHealth technologies appear to hold promise for improving the self-management of chronic conditions across populations [5-8], failure to balance the system demands of the app with the needs, interests, or resources of the end users can undermine consumers' adoption of these technologies [9-12].

This was the case in a pilot trial of a mHealth app with patients in a Federally Qualified Health Center (FQHC) who had uncontrolled diabetes and/or hypertension. The original aims of this trial were to evaluate the effectiveness of the app in improving clinical outcomes and the app's usability. However, after a 4-month period of vigorous recruitment, the trial was suspended due to low enrollment and the project aim was changed to understanding why the trial was unsuccessful. This paper briefly describes the original study to provide context and then describes the secondary study in which we focused on usability [11,12]. Lessons learned and recommendations are also discussed.

Methods

Original Study Design

Setting

Community Health Center, Inc. (CHCI) is a multisite FQHC and level III patient-centered medical home (PCMH) in Connecticut providing comprehensive primary medical, dental, and behavioral health care to 140,000 medically underserved patients in over 200 delivery locations; 75% of patients have fee-for-service Medicaid insurance. CHCI has a fully integrated electronic health record (EHR) and uses a team-based, integrated model of care. Each primary care provider (PCP) is supported by 1 medical assistant (MA) and a primary care registered nurse (RN). One nurse generally supports 2 PCPs. Most routine management of hypertension and type 2 diabetes is carried out by PCPs supported by the nurses and complemented by on-site diabetes and nutrition education. This study was approved by the Institutional Review Board (IRB) of CHCI.

Intervention

The app used for the intervention was developed by a commercial vendor to run on Mac and Windows platforms. CHCI was not involved in the development and testing of the app. Adoption of the app by CHCI was prompted by 2 studies that reported improved clinical outcomes in patients who used the app to manage their diabetes and/or hypertension [13,14].

The app provides a platform for active collaboration between patients and their primary care team between office visits. After working with the care team to develop personal goals and strategies for managing their chronic conditions, patients then enter clinical information into the app, such as weight, blood pressure, and blood glucose levels, and frequency of adhering to a treatment regimen, such as medication, diet, or exercise. The delivery interface includes charts that display trends in clinical data over time and graphics indicating patient progress toward goals. Members of the patient's care team track patients' progress toward their goals and exchange messages providing encouragement and suggestions and answering non-pressing questions.

The app can be accessed by downloading it on a mobile phone or accessing it on the vendor's website. The interface display is the same between the platforms. The end-users, which are the patients and care team members, require a profile that is visible to the vendor. The vendor created the profiles for the care team (ie, the primary care provider, nurse, and research assistants). Staff created the profiles for the patients. All data is stored in the vendor's warehouse.

Population

Patients eligible for the trial were aged 18 and over and had at least 1 visit to CHCI in the previous 6 months. Uniform Data System (UDS) measures, which CHCI reports, were chosen as the criteria for uncontrolled hypertension and diabetes because these criteria are used to develop clinical dashboards that identify patients with uncontrolled chronic disease [15]. Thus, uncontrolled hypertension was defined as having a blood pressure of either 140/90 or higher on record in the EHR at the time of the patient's last visit [15]. Similarly, uncontrolled diabetes was defined as a recorded glycated hemoglobin (HbA1c) greater than 9% at the patient's last visit [15].

Recruitment

Eligible patients were identified through a chronic conditions dashboard based on the UDS measures, and were recruited on a rolling basis from 1 CHCI primary care site. The plan was for the PCP, nurses, and research assistants to approach patients in person in the clinic, explain the app, and assist with downloading the app as needed. Research assistants also called patients, targeting those with upcoming appointments, providing assistance by phone. Patients were informed that the app is not to be used for emergencies or prescription refills and that staff would respond to messages within 24 hours of posting.

Original Study Design Results

Over a 4-month period, about 90 patients were approached either by phone or in person. A profile was created for 22 interested patients: 6 (27%, 6/22) patients had diabetes, 4 (18%, 4/22) had hypertension, and the remaining 12 (55%, 12/22) were diagnosed with both. The average age was 50 (range 31 to 69); 12 (54.5%, 12/22) were female and 10 (45%, 10/22) were male. Of the 22 patients, 7 (32%, 7/22) did not download the app. Of the remaining 15 patients who downloaded the app, 7 (47%, 7/15) were female. The patients who declined participation said they were not interested, didn't have time to learn about the app, and/or didn't have a mobile phone or computer. The trial was suspended due to low enrollment and inconsistent use of the app by those who did enroll.

Secondary Study

Overview

After the failure to recruit and retain sufficient numbers of patients to complete the trial, we evaluated the usability of the app. In light of the unsuccessful trial, we used a realist evaluation approach, which challenged us to more closely examine the unspoken assumptions behind our initiative [16]. Based on our experience, we were sure that most CHCI patients had a mobile phone; mobile phone ownership is prevalent across underserved populations [7]. But we assumed that patients would perceive that the app would help them their manage hypertension and diabetes and have the technology and proficiency to use it. Similarly, we assumed staff would be able to recruit patients, as well as use the app to collaborate with them.

We used the user-task-context (eUTC) usability framework to evaluate the results of our trial [11,12]. The eUTC has 3 dimensions and 7 domains for understanding the needs of users of eHealth technology, all within the context of healthcare (Textbox 1). In the eUTC framework, the "user" dimension refers to people who use the app, that is, patients and members of the healthcare team. The "task" dimension represents the activities involved in using technology, such as how many steps are required and how difficult it may be to navigate. Finally, the "interface" dimension is where user and task meet, and users sense the ease of and benefits of using the technology.

The eUTC is enhanced by the inclusion of eHealth literacy in the framework [17]. eHealth literacy is defined as "the ability to seek, find, understand, and appraise health information from electronic sources and apply the knowledge gained to addressing or solving a health problem" [18]. However, users of technology vary in their levels of electronic health (eHealth) literacy, such as health literacy, traditional literacy, numeracy, computer literacy, media literacy, science literacy, and information literacy [19].

It is important to note that the eUTC usability framework is used by developers of eHealth technologies in the process of designing and testing applications for consumer use and not after their implementation with end-users [11,17]. However, as CHCI was not involved in the development of the app in our pilot study, we used the eUTC framework as an evaluation tool after the fact to guide interviews with both sets of end-users: patients and staff.

Intervention

The three dimension framework noted above guided the questions asked during semi-structured interviews of participants [11,12]. Textbox 2 provides sample questions that were asked of patients; questions for staff mirrored those asked of patients. Of the 15 patients enrolled in the app, 8 (53%) agreed to be interviewed, as well as 1 PCP, 2 nurses, and 2 research assistants. All interviews were done by phone and lasted 20 to 30 minutes. Interviews were not recorded.

Textbox 1. Three dimension framework for understanding needs of users of technology.

Dimensions

- User dimension

  - Knowledge about one's own health

  - Ability to use information

  - Ability to engage with technology

- Interface

  - Feel that technology is beneficial

  - Feel in control and secure when using technology

- Task dimension

  - Access to technologies that work

  - Access to technologies that suit individual needs

Textbox 2. Sample questions for patients.

Questions

- User dimension questions

  - Tell us how you deal with your [chronic disease].

  - How do you get most of your information about your hypertension?

  - What kinds of technologies do you use? Internet? Mobile phone?

- Interface questions

  - Did you think the app was beneficial? How did your provider's opinion about the app affect your use of it?

  - How do you feel when you use technology? When you used the app?

  - What would be an ideal app for these purposes?

- Task dimension questions

  - How did you use the app?

  - What do you think about how it worked?

  - Did the app meet your needs?

Results

Quantitative Data

As noted earlier, a profile was created for 22 interested patients, 7 (32%, 7/22) of whom did not download the app. The 15 patients who enrolled in the app sent a total of 139 messages, an average of 19 per patient (range 0 to 39). Two users accounted for about half (48.2%, 67/139) of the messages. Staff sent 141 messages, spending just under 7 hours in total on the app during the trial, or about 26 minutes per patient. Two patients entered their blood pressure, as taken at home, in the first week of using the app, and both entered blood pressure again a week later, with no change. One patient entered weight twice and 5 patients entered fasting blood glucose (FBG) levels twice. Only 1 saw a drop in FBG levels, from 120 to 79. These 8 patients did not enter any further data, and the remaining 7 patients did not enter any information at all.

Qualitative Data

Patient Interviews

User Dimension

All 8 patients who were interviewed had a mobile phone, 6 (75%, 6/8) of which were mobile phones with app capabilities and 4 (67%, 4/6) used apps on their mobile phones. It was found that 63% (5/8) had a computer and 3 (38%, 3/8) reported using it routinely. For self-management of their chronic condition, most patients did "home monitoring, years of little calendars…take medication, eat right, exercise and lose weight." Others (38%, 3/8) relied on their providers as "they tell me what to do." The extent to which these patients followed through with these self-management strategies is unclear given that they had been identified as having uncontrolled disease.

Task Dimension

Several patients compared the app to the patient portal that is part of the EHR platform used by CHCI. Some found the app easier to use, while others did not.

> *[The portal] is confusing…[the app] is much easier to use than the portal.*
>
> *…[the app is] too complicated, didn't want to deal with it.*

While some reported that they got a quicker response to messages sent to the provider, others did not.

> *got answers quicker with [the app].*
>
> *[I am]…frustrated that [provider] has not been there like he was [on portal]. I could ask a question in the morning and get a response by 4:00 pm.*

Although patients were not expected to use both the app and paper logs of their blood pressure or blood glucose readings, most noted that the app "has become another step…one more thing," whereas paper logs required fewer steps. Several patients used the app to request medication refills, even though they had been advised otherwise. Some patients did not know how to download a free app when they had no credit card on file with the phone's service provider.

Interface Dimension

Several patients stated that the ideal app they would be most comfortable with would be "simple and easy". However, they did not elaborate on what that would look like, other than to note that the app in question did not quite meet those criteria. Of the patients, 3 (38%, 3/8) expressed concerns about the privacy of their health information on the app and 7 (88%, 7/8) wanted an app that connected to their EHR because:

> *the information would be private and safe….everything would be in one place [such as, requests for medication refills]…all part of your record.*

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All patients indicated ease of contact with providers is an important feature of any health-related technology.

> *Reaching the doctor anytime I could...I just need to see my doctor and be able to talk to them when I need to.*

Others (38%, 5/8) mentioned other types of functionality.

> *Liked the indication [in the app] that there is a message* [from provider]

> *...if it had a social media component, without HIPAA.* [a reference to the Health Information Portability and Accountability Act, which requires that personal health information not be shared with unauthorized persons]

> *would [like it to] remind me to take my medication.*

Staff Interviews

User Dimension

All of the staff were expert users of technology for both professional and personal purposes. The nurses and PCP reported that most disease management occurs in person with the patient during provider and/or nurse visits and by telephone. They routinely used dashboards to identify patient blood pressure or blood glucose/HbA1c levels, enroll high risk patients in care coordination, and help patients develop action plans and home monitoring.

Task Dimension

The staff noted that many patients who did not enroll did not have access to technology, were not comfortable with technology, or faced barriers to its use.

> *Many patients have a flip phone or don't use the phone other than for calls...others forgot password [to app].*

Lack of time was a major factor in usage. Downloading the app in the clinic took "too much time, the [Internet] was slow [in some parts of the building]", and when patients couldn't download the app right away they lost interest. There was not enough time for staff to explain the app during a 20-minute visit in which their priority was an acute illness, and not their chronic condition. Patients did not want to wait after their visits for the nurse or research assistant to show them how to use the app.

The app did not fit the nurses' workflow, which involves toggling among multiple screens in the EHR. To access the vendor website, the PCP and nurses had to go outside of the EHR. Echoing the patients' comments, the nurses and PCP said that the app was "one more thing to manage". The nurses reported "a lot of uneasiness" about messaging with patients, who, despite being told that staff would respond within 24 hours to a post, wanted an immediate response the nurses could not provide. The nurses and PCP also noted that patients often do not follow through with a plan of care and so were not surprised that patients didn't use the app as directed.

> *Patients have their own challenges, health is not their first priority...maybe the app was asking them too much.*

Interface Dimension

When asked to describe the ideal app, the comments of the nurses and provider echoed those of the patients. They want something that interfaces with the EHR, providing a single point of entry into patient information.

> *The technology needs to be easy to use, for programs to talk to each other and give us the information we need instead of us searching for it....[there is too much] flipping [between screens], I want a whole picture in an easier way, not searching.*

Discussion

Principal Findings

We did not test patients' eHealth literacy before beginning the trial and lack of proficiency regarding technology and chronic disease in particular may have reduced the usability of the app for patients who enrolled and dissuaded patients who were not interested. While we were fairly confident that most patients had a mobile phone, many had phones that did not support apps and those who did have mobiles phones with app capabilities were not proficient at using apps. Finally, motivation for behavior change amongst eligible patients may have been lower than we had hoped. Most had had poorly managed disease for some time and getting their chronic condition in better control did not rise to the level of urgency for them that it did for the PCP and nurses.

The recruitment approach did not fit the workflow of clinical staff as originally planned. There was not enough time in a 20-minute visit to explain the app to patients and assist with downloading it if needed. Patients left promptly following their visits and phone calls made by research assistants were not returned.

In other trials using this app [13,14], the treatment approach was to assign patients to a nurse or health coach whose job was to track and correspond with patients using the app. However, the PCP and 2 nurses at CHCI did not have dedicated time to devote solely to these activities. Rather, our treatment approach was to incorporate the app into routine practice.

In general there was a poor fit between the app, the end-users, the recruitment, and the treatment approaches in our setting. Additional usability testing might have revealed this fact prior to launch. For both patients and staff, the app became an add-on, just one more thing to attend to. Lack of integration with the EHR required staff to toggle between internal and external platforms, which took time and multiple steps. It also might have helped if staff had dedicated time to work specifically with the patients using the app; but as an unreimbursed activity, such work was not feasible. Consequently, the key feature of the app—collaboration between the healthcare team and patient—could not be achieved.

Conclusion

This brief trial underscores some of the pitfalls faced by providers hoping to utilize mHealth apps to improve chronic disease outcomes for some medically underserved patients. Effective use of mHealth tools for clinical management requires

a good fit between the app, the users' eHealth literacy, recruitment efforts, the treatment approach, and resources, especially time and reimbursement for services [5-8,20]. These last factors—treatment approach, time, and reimbursement—are contextual factors of the healthcare setting that affected the adoption of the app in this brief trial, and context is a significant

factor in implementation efforts [21]. While the eUTC is placed within the context of healthcare, we recommend that future researchers be more explicit about contextual factors in the trial and adoption of mHealth technologies in addition to factors related to the end-users.

Acknowledgments

Conflicts of Interest

None declared.

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Abbreviations

CHCI: Community Health Center, Inc.
eHealth: electronic health
EHR: electronic health record
eUTC: user-task-context
FBG: fasting blood glucose
FQHC: Federally Qualified Health Center
HbA1c: glycated hemoglobin
MA: medical assistant
mHealth: mobile health
PCP: primary care provider
RN: registered nurse
UDS: Uniform Data System

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