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Original Paper

Data Visualizations to Support Health Practitioners' Provision of Personalized Care for Patients With Cancer and Multiple Chronic Conditions: User-Centered Design Study

Uba Backonja^{1,2}, RN, MS, PhD; Sarah C Haynes³, MPH; Katherine K Kim³, MBA, MPH, PhD

¹Nursing and Healthcare Leadership, University of Washington Tacoma, Tacoma, WA, United States

²Biomedical Informatics & Medical Education, University of Washington School of Medicine, Seattle, WA, United States

³Betty Irene Moore School of Nursing, University of California Davis, Sacramento, CA, United States

Corresponding Author:

Katherine K Kim, MBA, MPH, PhD

Betty Irene Moore School of Nursing

University of California Davis

2450 48th Street, Suite 2600

Sacramento, CA, 95817

United States

Phone: 1 510 761 5461

Email: kathykim@ucdavis.edu

Abstract

Background: There exists a challenge of understanding and integrating various types of data collected to support the health of individuals with multiple chronic conditions engaging in cancer care. Data visualization has the potential to address this challenge and support personalized cancer care.

Objective: The aim of the study was to assess the health care practitioners' perceptions of and feedback regarding visualizations developed to support the care of individuals with multiple chronic conditions engaging in cancer care.

Methods: Medical doctors (n=4) and registered nurses (n=4) providing cancer care at an academic medical center in the western United States provided feedback on visualization mock-ups. Mock-up designs were guided by current health informatics and visualization literature and the Munzner Nested Model for Visualization Design. User-centered design methods, a mock patient persona, and a scenario were used to elicit insights from participants. Directed content analysis was used to identify themes from session transcripts. Means and SDs were calculated for health care practitioners' rankings of overview visualizations.

Results: Themes identified were data elements, supportive elements, confusing elements, interpretation, and use of visualization. Overall, participants found the visualizations useful and with the potential to provide personalized care. Use of color, reference lines, and familiar visual presentations (calendars, line graphs) were noted as helpful in interpreting data.

Conclusions: Visualizations guided by a framework and literature can support health care practitioners' understanding of data for individuals with multiple chronic conditions engaged in cancer care. This understanding has the potential to support the provision of personalized care.

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KEYWORDS

cancer care facilities; informatics; patient-centered care; patient-generated health data; precision medicine; visualization

Introduction

Background

About 1 out of every 4 people in the United States lives with multiple chronic conditions (MCC), which include cancer and other conditions such as hypertension, diabetes, and heart disease [1]. About 40% of individuals with cancer also live with

1 or more chronic conditions [2]. The attendant complexity and potential confounding factors in managing treatment-intensive illnesses such as cancer among individuals with MCC beg for personalized care approaches. Personalized care, as described in precision medicine and personalized medicine, involves the collaboration between health care practitioners (HCPs) and patients and considers the perspectives, experiences, and health-related data of the person receiving care [3]. A recent

Cochrane review suggests that personalized care can support the physical and psychosocial health of individuals with MCC [3], which can include those engaged in cancer care. Person-generated health data (PGHD) such as symptoms, medication use, physical activity, and health goals are important information for personalizing care of MCC. Organizations, including the United States Department of Health and Human Services [4,5] and the Healthcare Information and Management Systems Society [6], recommend that PGHD be captured and used in decision making, care planning, and coordination. Furthermore, mobile technologies can support collection and access to PGHD to support the management of chronic conditions and personalized care [7-12].

Although PGHD is quite varied, it may be collected at a different velocity and magnitude and in different and nonstandard formats [11]. To be useful to HCPs, individuals with MCC (including those engaged in cancer care), and caregivers, the cognitive burden of understanding and synthesizing this information must be minimized, and the opportunity to make good decisions must be maximized. This is particularly pertinent in the care of individuals with MCC engaging in cancer care, which is the scope of the research described in this manuscript. Coordination of cancer care involves many people—the individual engaging in cancer care, their HCPs, caregivers, family, and health care staff—who need to integrate the large amounts of data; these data are used to support understanding of an individual's health status, completion of health-related tasks, and care-related decision making [13].

Data visualization offers an approach to address this challenge of integrating and using large amounts of data collected to support the personalized care of individuals with MCC engaging in cancer care. Data visualizations are representations of data through the application of visual encodings (eg, position and color) [14-17]. Visualization can leverage a user's cognitive strengths such as pattern recognition, and it helps them overcome their cognitive limitations including calculating and remembering strings of numbers. This can ultimately support understanding, task completion, and decision making. Visualizations that are designed with guidance from potential end users can be particularly valuable. User-centered design, within the field of human-centered design, is an approach to systems development that involves potential end users to understand their behaviors, tasks, and needs, among other factors [18,19]. User-centered design can help the designer fully render the users' needs to improve the decisions that the visualizations are meant to support. User-centered design has been used previously in the development of visualizations [20,21] including visualizations of patient-reported outcomes [22,23].

The benefits of data visualizations—supporting understanding, task completion, and decision making—are especially critical in health-related settings such as cancer care facilities. In these settings, data are used to support important, critical, and time-restricted decisions that impact the health of individuals. Data visualizations are increasingly being incorporated into clinical care through integration of dashboards into health record systems. A recent review suggests that dashboards that integrate visualizations have the potential to support the cognitive work and decision making of intensive care unit clinicians [24].

However, there have been few examples of the effective use of person-generated data in personalized cancer care, particularly to enable shared decision making or care coordination [25]. A recent study found that patients with solid tumors who used a Web-based system to report symptoms experienced longer survival compared with usual care [26]. There is also little research on the value of visualizations within systems that integrate patient-generated data in cancer care. A pilot study conducted in Italy suggested that a dashboard that integrated remote monitoring and symptom-tracking data could be useful to HCPs and patients [27]. However, this work did not specifically evaluate the visualizations, and rationales for the visualization designs were not described. Therefore, a gap exists in the literature and practice regarding the development of informatics solutions that integrate and visualize person-generated data to support understanding and decision making regarding personalized cancer care among individuals with MCC.

Prior Work

OnPoint is a mobile app developed by the authors to support care coordination for individuals with MCC [25,28,29]. Previous studies by the authors' research group that were conducted to support heart failure and oncology patients resulted in the development of a mobile app that featured patient health goals, proactive symptom assessment, comprehensive medication list and medication reconciliation, and tracking for patient and caregiver use. On the basis of this prior work, researchers identified the need for visualization of data collected from the app and integrated into the electronic health record for communication to HCPs. This inspired the study described below.

Study Purpose

The purpose of this study was to assess HCPs' perceptions of and feedback regarding visualizations developed to support the personalized care of individuals with MCC engaging in cancer care.

Methods

Design, Time Frame, and Setting

This user-centered study took place from May to June 2017 at a large, urban academic medical center in the western United States.

Recruitment of Participants

We sought 8 medical doctors (MDs) and registered nurses (RNs); a sample size considered adequate for this type of qualitative user-centered design study [30-32]. HCPs were either known to the researchers or identified by referral of HCPs who had participated in previous studies in the development of the OnPoint mobile app [25,28,29]. HCPs were eligible to participate if they were potential end users of a health information system to support cancer patients with MCC and HCPs currently providing care to cancer patients.

Visualization Development

Paper mock-ups of data visualizations were developed by UB (author) guided by Munzner Nested Model for Visualization Design [17]. We applied all model constructs (italicized in the following paragraphs) except for the algorithm design construct, which is suited for software development rather than for our focus on presoftware development.

The *domain problem* addressed was the need to support the care of individuals with MCC engaging in cancer care—the problem addressed by the OnPoint mobile app [25,28,29].

For *operation and data type abstraction*, we identified operations (tasks) and data types from the previous studies [25,28,29]. These data types were blood pressure (mm Hg), weight (kg), blood glucose levels (mg/dL), medication adherence (medications not taken at the time or frequency as prescribed), and symptoms from the Canadian Oncology Symptom Triage and Remote Support (COSTaRS) practice guides [33,34].

For *visual encoding and interaction design*, mock-up encodings and designs were guided by literature on (1) visualizing data [14-17,35-44]; (2) health data visualization [23,45-47]; and (3) a mock patient persona and scenario [48,49]. The mock patient was a 56-year-old woman with uterine cancer and type 1 diabetes. She had recurrent work and personal constraints on Thursdays that interfered with taking medications as prescribed and managing her blood glucose levels. This patient also recently experienced weight gain due to fluid retention.

The following visualization mock-ups were created based on the nested model constructs: (1) a 4-week overview of medication adherence, blood pressure, weight, and blood glucose alone (Figure 1) and with pop-ups providing details on demand (Figure 2), (2) a 4-week view of line graphs indicating blood glucose readings alone (Figure 3) and with a pop-up providing details about a specific blood glucose reading (Figure 4), and (3) a 2-week view for blood pressure (Figure 5) and with a pop-up providing details about a specific blood pressure reading (Figure 6). In addition, 3 additional versions of the 4-week overviews of medication adherence, blood pressure, weight, and blood glucose were created (Figures 7-9). Finally, a visualization of self-reported symptoms generated from the COSTaRS protocols was developed (Figure 10).

Indication of target levels and ranges were shown with lines and colors. For example, in Figures 3 and 4, the gray bands indicate the target blood glucose range (80-130 mg/dL before a meal and <180 mg/dL 2 hours after the start of the meal [50]). In Figures 5 and 6, lines indicate (1) mock patient average systolic and diastolic blood pressure and target blood pressure (120/80 mm Hg [51]). Line graphs were purposefully chosen based on previous research indicating that position and color of dots on a chart (eg, individual glucose readings) can support quantitative interpretation [37-39,41]. Blue, orange, and yellow colors were used because they can be distinguished by individuals with color blindness [52-54].

Figure 1. A 4-week overview of medication adherence, blood pressure, weight, and blood glucose.



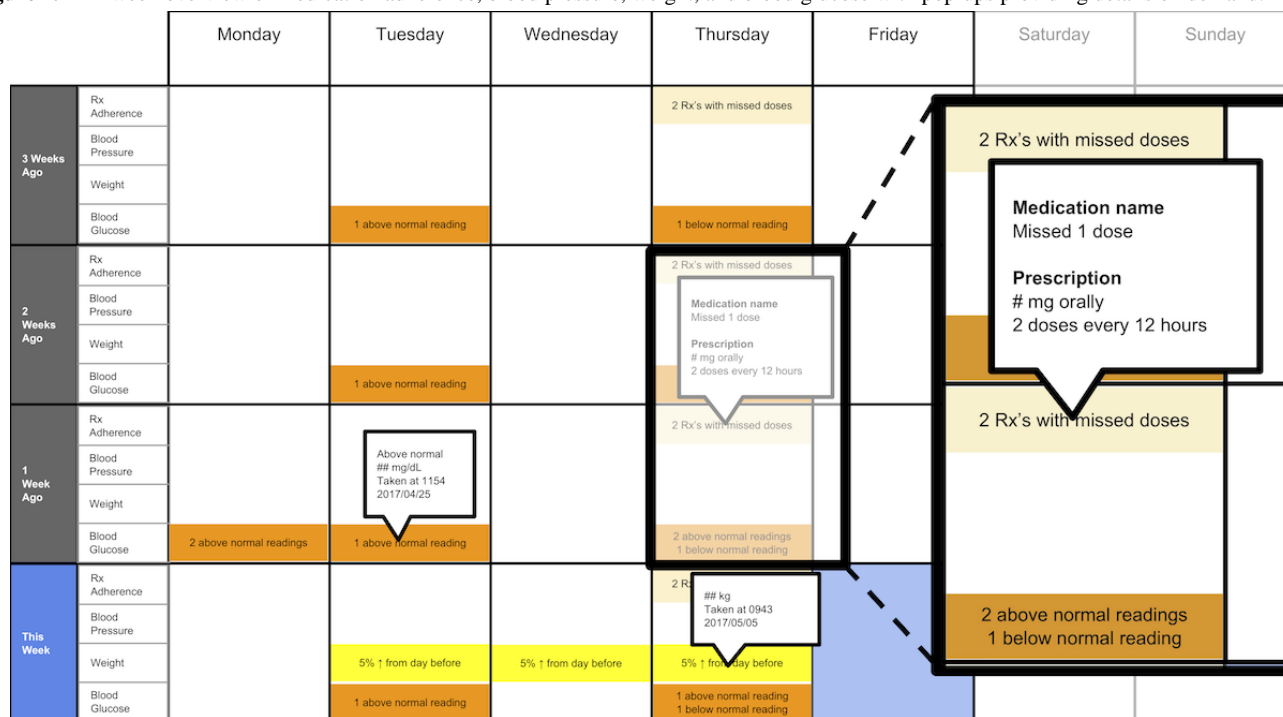
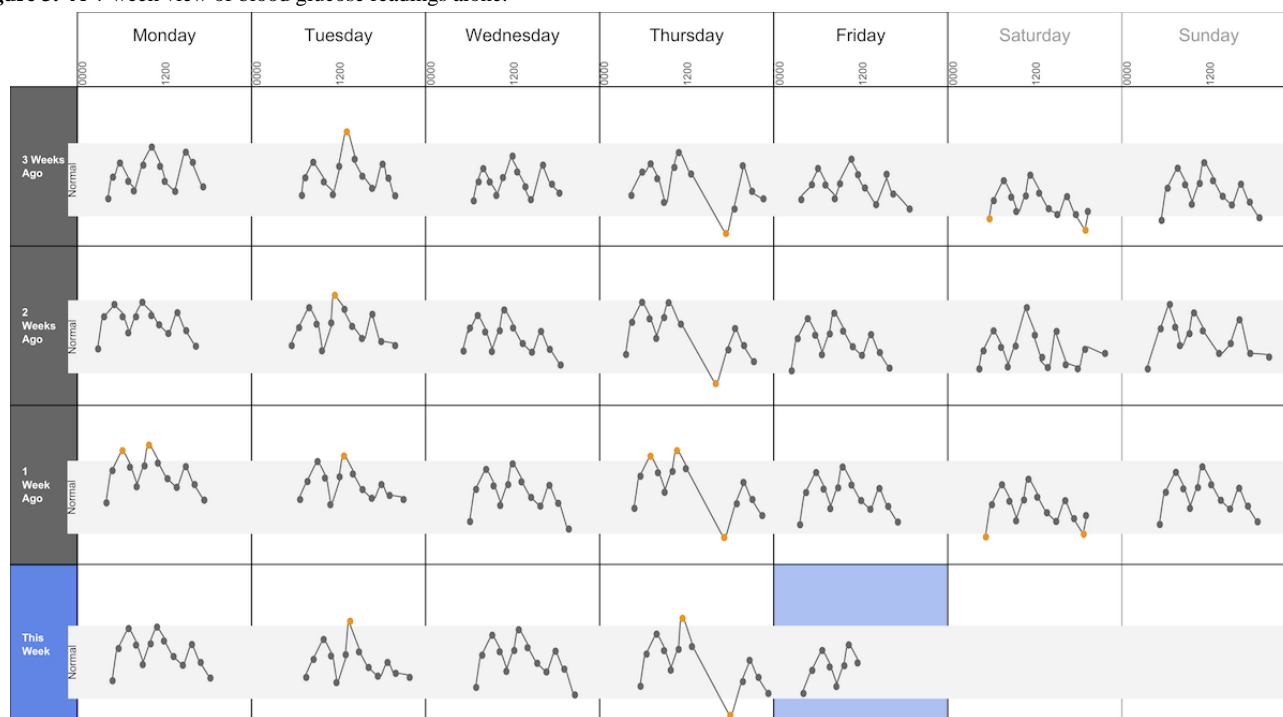
Figure 2. A 4-week overview of medication adherence, blood pressure, weight, and blood glucose with pop-ups providing details on demand.**Figure 3.** A 4-week view of blood glucose readings alone.

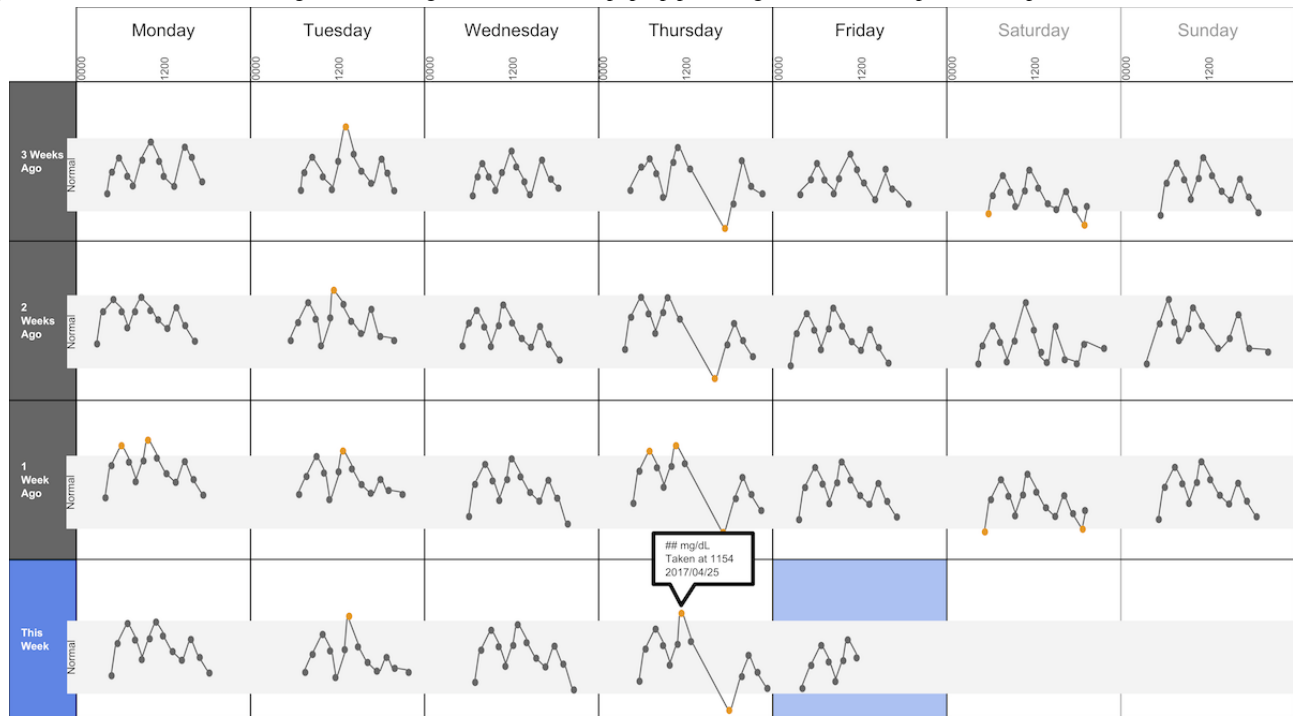
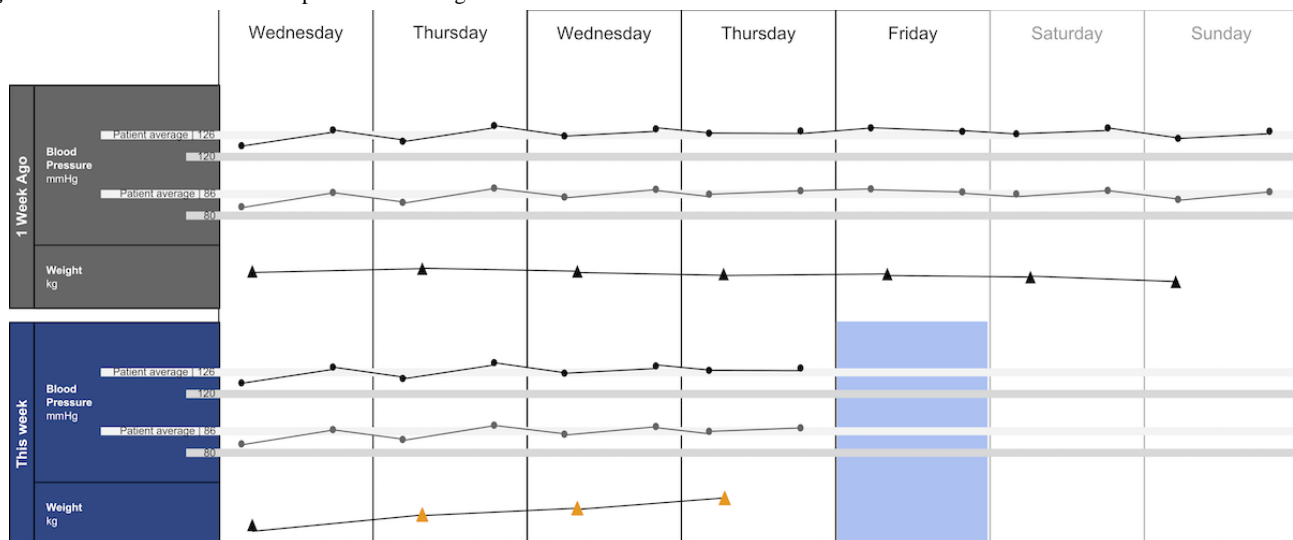
Figure 4. A 4-week view of blood glucose readings alone and with a pop-up providing details about a specific data point.**Figure 5.** A 2-week view for blood pressure and weight.

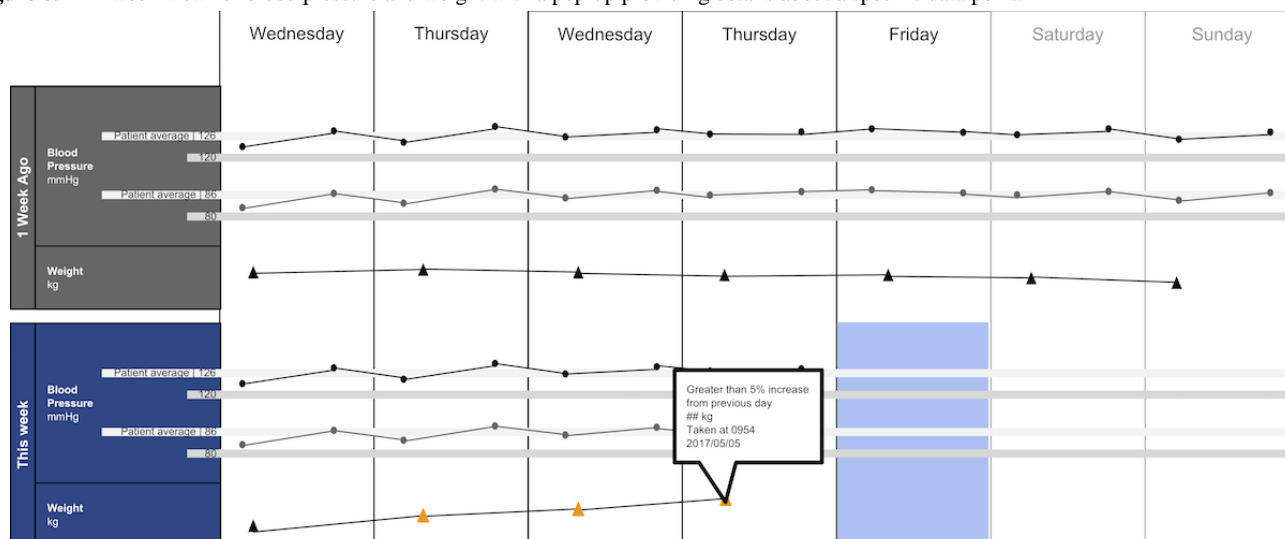
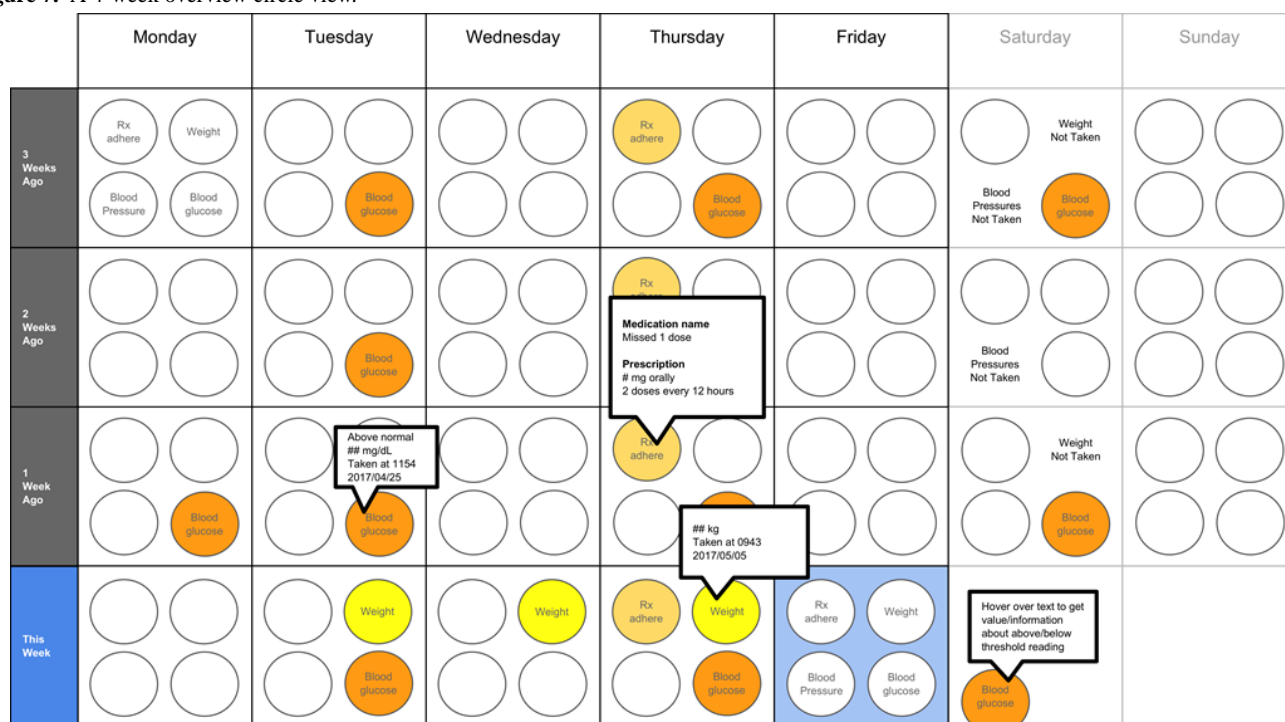
Figure 6. A 2-week view for blood pressure and weight with a pop-up providing details about a specific data point.**Figure 7.** A 4-week overview circle view.

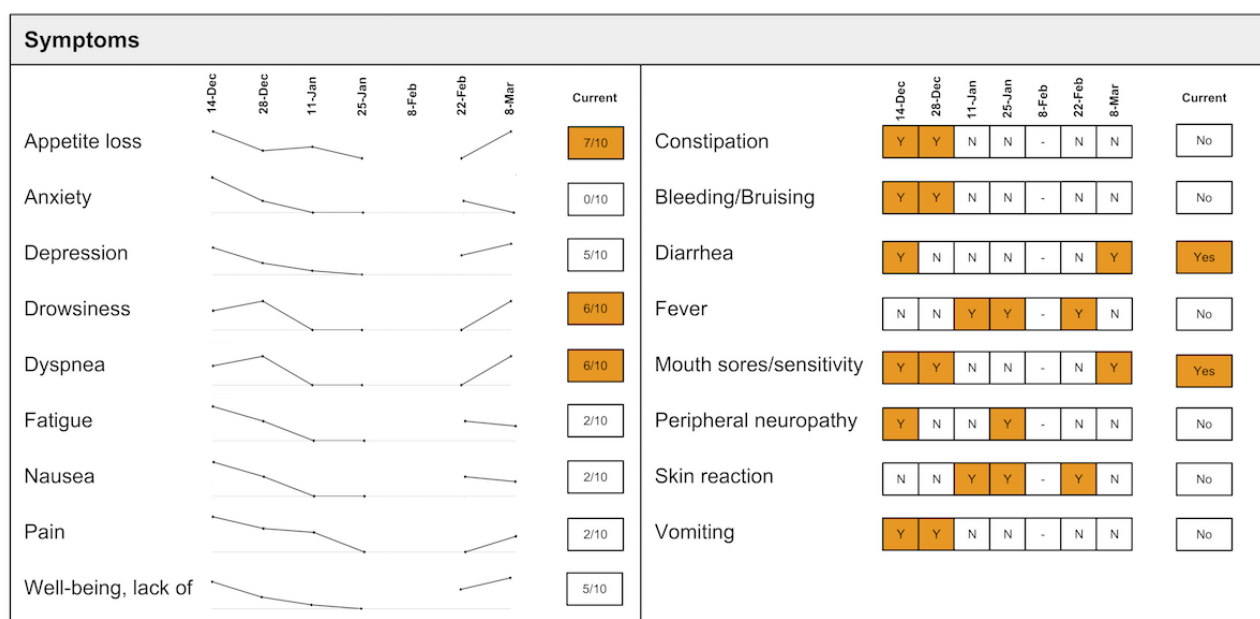
Figure 8. A 4-week overview all tab view.

	Monday	Tuesday	Wednesday	Thursday	Friday	Saturday	Sunday
3 Weeks Ago	Medication Adherence Blood Pressure Weight Blood Glucose			Medication Adherence Blood Glucose		Blood Pressures Not Taken Weight Not Taken Blood Glucose	
2 Weeks Ago				Medication Adherence Blood Glucose		Blood Pressures Not Taken	
1 Week Ago		Above normal ## mg/dL Taken at 1154 2017/04/25 Blood Glucose		Medication Adherence Blood Glucose		Weight Not Taken Blood Glucose	
This Week		Weight Blood Glucose	Weight	## kg Taken at 0943 2017/05/05 Weight Blood Glucose		Hover over text to get value/information about above/below threshold reading Blood Glucose	

Figure 9. A 4-week overview filled tab view.

	Monday	Tuesday	Wednesday	Thursday	Friday	Saturday	Sunday
3 Weeks Ago	Medication Adherence Blood Pressure Weight Blood Glucose			Medication Adherence Blood Glucose		Blood Pressures Not Taken Weight Not Taken Blood Glucose	
2 Weeks Ago		Blood Glucose		Medication name Missed 1 dose Prescription # mg orally 2 doses every 12 hours Blood Glucose		Blood Pressures Not Taken	
1 Week Ago		Above normal ## mg/dL Taken at 1154 2017/04/25 Blood Glucose		Medication Adherence Blood Glucose		Weight Not Taken Blood Glucose	
This Week		Weight Blood Glucose	Weight	## kg Taken at 0943 2017/05/05 Weight Blood Glucose	Medication Adherence Blood Pressure Weight Blood Glucose	Hover over text to get value/information about above/below threshold reading Blood Glucose	

Figure 10. Visualization of patient-generated symptoms that are self-reported using the Canadian Oncology Symptom Triage and Remote Support (COSTaRS) protocols.



Measures and Procedures

This study applied user-centered design methods to engage potential end users early in the design process to understand their needs, priorities, and values. UB and SH conducted one-on-one interviews; participants were provided with pens, colored pencils, and markers and encouraged to draw and take notes on the paper visualizations as they reviewed them. They were also prompted throughout the interview to think aloud about what they saw and thought while reviewing the visualizations [55,56].

Interviews were conducted in 3 steps: (1) going through the scenario during which they thought aloud while viewing paper mock-ups and responding to prompts (see Textbox 1 for the scenario), (2) ranking of alternative visualizations of overview mock-ups, and (3) providing overall impressions and usefulness for care coordination. This step sequence was used to guide the participants in using the visualization as they might in their clinical practice, which can help elicit reflection from participants [48].

In step 1, participants first viewed an overview of visualization (Figures 1 and 2), then specific measures (Figures 3 and 4), then sought details on demand for those measures (Figures 5 and 6). This approach aligns with Shneiderman Visual Information Seeking Mantra of “Overview first, zoom and filter, then details-on-demand” [42]. While viewing the visualizations, participants explained what they saw, the impression of the patient, what additional information they would want included,

what aspects supported their understanding of the patient, and what aspects were confusing.

In step 2, the researcher presented alternate versions of the 4-week overview (Figures 7-9). Ordering of the versions was varied from participant to participant so that the order in which the versions were presented did not influence responses. While viewing the alternate versions, participants described their overall impressions, aspects they perceived as helpful, and aspects they perceived as confusing. Then, the then researcher gave the clinicians the original 4-week overview (Figure 1) and asked participants to order this overview and the alternate versions from most helpful (ranked first) to least helpful (ranked fourth). Participants explained aloud their rationale for the ordering while sorting the versions.

In step 3, participants viewed the visualization that provided summaries of longitudinal patient-reported symptoms (Figure 10). Again, the participants were asked to describe their overall impression of the visualization, aspects that they perceived as helpful in understanding the patient, and aspects they perceived as confusing in understanding the patient. At the end of the interview, the researchers asked whether and how the visualizations could help personalize the care and asked for suggestions.

Interviews were recorded, transcribed, and supplemented by field notes taken by researchers during the interviews. This study was approved by the affiliated institutional review board. All participants provided verbal consent after receiving and reading the study consent form. Participants were provided with a US \$50 Amazon gift card for engaging in the interview.

Textbox 1. Scenario used during one-on-one interviews with clinicians to elicit feedback about data visualizations. Information in brackets indicates actions by the researcher conducting the interview.

1. You have arrived at the clinic before you start seeing patients. You want to see how your first patient of the day is doing. Her name is Deb Lee (age 56 years). Three weeks ago she completed chemotherapy for uterine cancer. She also has type 1 diabetes that was diagnosed in childhood.
2. You have done your typical chart review of Deb's clinical data using the clinic's electronic health record. After that chart review of electronic health record data, you want to see how Deb is doing at home. Recently the clinic started supporting patients in collecting data at home. Data include:
 - if the patient took her medications as prescribed
 - blood pressure (measured twice a day)
 - weight (taken once a day)
 - blood glucose (taken periodically throughout the day using a traditional finger-prick monitor)
3. These data collected by patients are provided to you first as 4-week summary. [Participant given [Figure 1](#)]
4. You want to know what's going on with some of the data. You hover over several readings reading to get more information. After you hover, you get this visual. [Participant given [Figure 2](#)]
5. You are concerned about Deb's blood glucose readings and want to see more details about her readings over the 4 weeks. You click on the most recent reading to get more information. After you click, you get this visual. [Participant given [Figure 3](#)]
6. You'd like to see some specific information about a specific data point. You hover over this orange dot. [Researcher points to dot on "This week," Thursday at 12:00 pm]
7. After you hover over it, you get this visual. [Participant given [Figure 4](#)]
8. You are concerned about Deb's weight readings and want to see details about her readings. You click on the most recent reading to get more information. After you click, you get this visual. [Participant given [Figure 5](#)]
9. You'd like to see some specific information about a specific data point. You hover over this orange dot. [Researcher points to dot for weight on "This week," Thursday]
10. After you hover over it, you get this visual. [Participant given [Figure 6](#)]

Analyses

Transcripts of participant interviews were analyzed independently by 2 researchers using directed content analysis [57]. Categories used to guide the development of codes and the content analysis were developed from the data and refined as described below. At first, 2 researchers independently coded 3 randomly selected sections of transcripts from different participants to identify themes. The unit of analysis was a distinct idea within a participant's statement. After each of 3 rounds of independent coding, the researchers discussed how content was coded and any new themes that emerged for which codes needed to be added. After the third round, the researchers concurred that the codes adequately covered all themes, thus yielding the final codebook used for the remainder of transcript coding. Inter-rater reliability was calculated using an estimate of inter-rater reliability as described by Topf [58]. The agreement was 84.5%. The researchers discussed the discrepancies in coding and ultimately came to a consensus for a final inter-rater agreement of 100%. Researchers then independently coded the transcripts using NVivo (v11.4.1, QSR International, Melbourne, Australia). Rankings for preferences

of the 4 versions of the overview visualization ([Figure 2](#); [Figures 7-9](#)) were tabulated, and mean ranks and SD were calculated for each overview version.

Results

Participants

A total of 8 HCPs participated in the interviews. Out of these, 4 were MDs; 1 was a pain management specialist (participant MD1), and 3 were oncologists (participants MD2, MD3, and MD4), and 4 were RNs (participants RN1, RN2, RN3, and RN4). Each participant provided care to cancer patients in the cancer center. Interviews lasted for approximately 25 to 42 min.

Themes

We identified 7 themes. Of these, 2 themes were not directly relevant to the visualizations; therefore, for the purpose of this paper, we report the following 5 themes: data elements, supportive elements, confusing elements, interpretation, and use of visualization. See [Table 1](#) for descriptions and specific content regarding the themes.

Table 1. Themes identified from interviews with health care practitioners while evaluating visualizations to support cancer care of an individual with multiple chronic conditions.

Theme	Description	Specific content regarding the theme
Data elements	Existing or future or potential data elements (eg, weight, blood pressure, medication adherence, and symptoms)	<ul style="list-style-type: none"> data useful for specific role in cancer care included weight and medications (Figures 1,5, and 6) and the list of symptoms (Figure 10) [MD^a1 and RN^b2] data less critical for some given job roles included blood glucose measures (Figures 3 and 4) [RN4 and MD4] suggestions for additional data elements or information included additional measures such as heart rate [MD1 and RN4], temperature [RN1 and RN2], body mass index [MD3], lab values [RN1], meal times or what eaten [RN1, RN2, MD3, and MD4], physical activity engagement [RN1], sleep [MD1], swelling [MD2], symptoms that may be particular or specific to certain cancer therapies [MD2, RN2, and MD3] patient-identified symptoms [RN2 and MD3] a legend defining the symptoms [MD1] meaning of the symptom scale ratings [MD1] reasons for missed medications [MD2, MD3, and RN1] values and description of the normal values and ranges for blood glucose and blood pressure [MD2] goals of care [RN1] treatments [RN1] patient-reported reasons for abnormal values [RN2]
Supportive elements	Aspects of the visualization that supported the participant's understanding of the patient or that they thought were helpful	<ul style="list-style-type: none"> the color orange drew attention and helped participants find data points or patterns in the data that might require attention or indicate something abnormal more easily [MD1, MD3, MD4, RN1, RN3, and RN4] icons of different shapes in Figures 5 and 6 helped participants follow the line graph progression [MD1, MD2, MD4, and RN2] gray bands indicating normal ranges (Figures 3-6) helped identify abnormal data points [MD2, MD3, RN1, and RN4] calendar format and line graphs were helpful because clinicians are accustomed to them [MD1, RN1, RN2, and RN4], are used in practice [MD1 and RN1], and help see trends [MD1-MD4 and RN1-RN4] having details on demand was helpful [MD1-MD4 and RN1-RN4] and does not lead to overpopulation of data within the visualization [MD3] suggestions for additional supportive elements included a pop-up with a numeric scale for normal ranges [MD4] or an indication of how the normal range was derived [MD3]
Confusing elements	Aspects of the visualization that the participant does not understand or finds confusing or unhelpful	<ul style="list-style-type: none"> Figure 1: Unsure if blank spaces indicated that measurements were normal or not taken [MD2, MD3, and MD4] Figures 1 and 5: Unclear about how the weight increase was calculated [MD2, MD3, and RN4] Figure 7: Circles confusing or overwhelming [MD2, MD4, RN2, RN3, and RN4] Figure 8: Unsure if the empty rectangles indicated normal readings or no measures taken that day [RN2, RN3, RN4, and MD4] Figure 10: Lack of clarity about the meaning of the numeric scale [RN3 and RN4]; unsure about threshold values for the numeric scores that led to values being highlighted in orange or whether the thresholds were the same across all symptoms [RN1]; miniature line graphs hard to interpret [MD1, MD2, MD4, and RN3]; and hard to understand, compare, and interpret the 2 different ways of quantifying symptoms [RN1, RN2, and RN4]
Interpretation	Information obtained or conclusions drawn about the patient from the visualization	<ul style="list-style-type: none"> Figures 1 and 2: Used calendar view to identify issue of missed medications of Thursdays [MD1-MD4, RN2, and RN4] Figures 3 and 4: Dips and peaks in the blood glucose line graph helped identify instances of hypo- or hyperglycemia [MD1 and MD2] or hypothesize if patient had well-controlled blood glucose [MD7 and MD8]; time indications at the top of the graph or pop-up helped hypothesize how meals may relate to dips and peaks [MD2, MD4, and RN1]

Theme	Description	Specific content regarding the theme
Use of visualization	Ways the participant would or could use the visualization	<ul style="list-style-type: none"> • visualizations could help clinicians gain an understanding of patient outside the clinic [MD1 and MD2], help them prepare specific questions regarding Thursdays [MD1-MD4, and RN4] and the cause of rapid weight gain [MD2], discuss the patient's symptom experiences or management [RN4 and MD4], make clinic time more efficient [MD1 and MD2] • visualizations could help patients remember health experiences [MD2] and empower patients to engage in health management [MD4]. Together clinicians and patients could use visualizations to support personalized cancer care [MD1-MD4, and RN1-RN4], facilitate interactions that focused more on the patient and their specific needs [MD1, MD2, RN2], and better guide conversations between clinicians and patients [RN3, RN4, MD3, and MD4]

^aMD: medical doctor.

^bRN: registered nurse.

Data Elements

There were several data elements within the visualizations that participants indicated as useful and supportive for their collaborations with patients. Participants noted the usefulness of measures and behaviors portrayed in Figures 1-6 (eg, weight) and symptoms portrayed in Figure 10 (eg, pain levels). Certain data were noted as being less relevant given their roles (see Table 1). Participants indicated several additional data elements that could be helpful (see Table 1). This included symptoms identified by patients as relevant or important (n=2). For example, MD3 suggested patient-driven modifications of the symptoms list:

Can we plan another category that I want the patient to monitor? For example, if they're having bleeding-vaginal bleeding-can they use the category of vaginal bleeding to show me...? [MD3]

Supportive Elements

Participants described several visual elements that supported their understanding of the patient. The elements included color, the calendar format, use of line graphs, and the ability to get "details on demand." All participants (n=8) stated that color supported their understanding of the data. Several indicated that icons helped differentiate graphs (n=4) and that the gray bands indicating normal ranges helped identify abnormal data points (n=4). Participants stated that the calendar format and line graphs were helpful because they are accustomed to them (n=4), are used in practice (n=2), and help them see trends (n=8):

[The line graph] gels with what practitioners could be used to...You don't want to have something too novel where you have some bizarre bar graph or some kind of odd, interesting pattern that's in 3D...that people haven't seen. [MD1]

Three participants stated that the calendar format allowed them to see trends such as missed medications on Thursdays (RN1, RN2, and RN4):

...you see a pattern...that helps you identify that there is a regimen and that there's a schedule...it enables you to see something missed in the pattern by seeing the...[entire] month. [RN4]

All participants (n=8) reacted positively to "details on demand" features such as hovering over a data point to get a pop-up with detailed information:

...it's good that it [the visualization] doesn't overpopulate the numbers right there and then because I mean I would just be overwhelmed with actual numbers, so this hovering thing is really good. [MD3]

Confusing Elements

There were several visual elements in the 4-week overviews that participants found confusing. These included not understanding the meaning of blank spaces in Figure 1 (n=3) or Figure 8 (n=4), being confused or overwhelmed by the circles in Figure 7 (n=5), and lacking clarity about how the weight increase was calculated for Figures 1 and 5 (n=3).

Several participants noted issues with interpreting visualizations for patient-reported symptoms (Figure 10). This included lack of clarity about the meaning of the numeric scale, threshold values for the numeric scores that led to values being highlighted in orange, and whether the thresholds were the same across all symptoms (n=3). Participants also found it difficult to interpret the miniature line graphs (n=4) and to understand, compare, and interpret the 2 different ways of quantifying symptoms (n=3).

Interpretation

All participants (n=8) used visual elements to interpret data—finding patterns and viewing trends—to support understanding and decision making. They identified missed medications including the pattern of missed medications on Thursday using the calendar views (n=6). When seeing the pattern on Thursdays, participants were prompted to think about what could cause the patterns:

I wonder what's going on Thursdays that she always forgets the medications. [MD3]

Identifying this pattern supported RN4's decision making to investigate the cause of the pattern:

I'm not sure why [she is missing her medications consecutively on Thursdays] so you would have to find out why is she missing her drugs on Thursday. [RN4]

MD4 similarly described how using the visualizations supported understanding of the patient, reasoning about what might be causing abnormal readings, and ruling out potential causes:

...she just is not taking her medications for some reason...I can use the visualization and the colors to figure out some of her difficulties...[about] why she may not be adherent with her health [behaviors]and medications. [MD4]

RN4 echoed how the visualizations could facilitate clinician reasoning, stating that a clinician could postulate about what might be causing the issues on Thursdays by bringing in symptoms and other data:

...you could really get I think a good picture. [RN4]

Trends in line graphs helped participants interpret temporal glucose, blood pressure, and weight data (n=5). Participants reflected on several weeks' worth of data, comparing normal and abnormal points over time as well as visual elements indicating missed medication, to formulate whether they believe the patient had well-controlled blood glucose (n=2). For example, MD4 stated:

[if the medication being missed is] related to her insulin...and her blood sugars aren't controlled, [then] the general impression probably is that her blood sugars aren't controlled and her diabetes isn't controlled. [MD4]

Participants viewed trends across different measures to infer relationships between measures. When viewing [Figures 5 and 6](#), MD1, MD2, RN1, and RN4 viewed the line graph trend for blood pressure, guided by the gray bands indicating normal readings and color coding of the data points, to inform their reasoning about what might have caused blood pressure to stay within normal range but weight to increase (as indicated by the line graph trend and color-coded data points). Participants used the calendar structure to see if weekly patterns were consistent:

I also see that the same kind of pattern I've seen on this very day and the week before. [MD3]

Use of Visualizations

Participants stated that visualizations could help gain an understanding of the patient outside the clinic and prepare specific questions to facilitate discussions with the patient about their self-management outside the clinic. This included

discussing circumstances on Thursdays that made health management challenging (n=5), asking questions to help investigate the cause of rapid weight gain (n=1); and understanding symptom experiences or management (n=2). MD2 stated that the visualizations provide insights that "might open up a door to other questions that you normally wouldn't ask if you didn't [see trends]."

In addition, participants noted that visualizations could be helpful for patients. Having the visualizations during clinic visits could help patients remember symptoms; MD2 stated that the visualizations provide "another way to understand if the patient had any symptoms but forget to mention [them] to us or we forgot to ask [about them] during the clinic visit." Visualizations could also support patients feeling empowered; MD4 stated that a visualization tool could empower patients to engage in health behaviors such as taking medications and "be more aware of their symptoms" regularly.

All participants (n=8) mentioned the use of visualization to personalize visits with patients. Visualizations helped them identify issues specific to the patient that needed to be addressed, making interactions more focused on the patient and their specific needs (n=3). Visualizations could also give a clearer and focused picture of the patient, their health status, and needs that can better guide conversations and interactions with patients (n=4):

I think it would cause us to get a good picture, get a fast picture, evaluate that with the patient so we don't walk into an assumption, but dive a little bit quicker if we needed to. [RN4]

MD3 stated that the visualization could personalize visits by bringing "attention to the important things" and focus "conversations with the patient directly to what's the issues or the problems that now I see [using the visualizations]..." RN4 stated that a benefit of the visualizations through personalizing visits with patients could be earlier identification of issues "rather than waiting until things [snowball]."

Ranking of Overview Visualizations

Participants varied in their preferences for the 4-week overviews. On average, participants ranked [Figure 2](#) as most helpful (mean 1.8 [SD 1.2]) and [Figure 7](#) least helpful (mean 3.9 [SD 0.4]; see [Table 2](#)).

Table 2. Participant rankings of the four 4-week overview versions.

Figure version	MD ^a 1	MD2	MD3	MD4	RN ^b 1	RN2	RN3	RN4	Ranking ^c , mean (SD)
Figure 2	1	2	1	1	4	1	3	1	1.8 (1.2)
Figure 9	2	1	2	3	2	2	2	2	2.0 (0.5)
Figure 8	3	3	3	2	1	3	1	3	2.4 (0.9)
Figure 7	4	4	4	4	3	4	4	4	3.9 (0.4)

^aMD: medical doctor.

^bRN: registered nurse.

^cMean rankings (and SD) across all participants for each version and ordered from most helpful (closest to 1) to least helpful (closest to 4).

Discussion

Principal Findings and Comparison With Prior Work

In our user-centered design study, we found that MD and RN participants' understanding of physiological and symptom data for individuals with MCC engaged in cancer care was supported by visualizations we developed by applying a visualization framework and relevant literature. Both MD and RN participants found that various visual encodings such as color, and familiar presentation such as calendar formats and line graphs supported their interpretation of the presented data. This research used foundational knowledge in data visualization in a novel way to develop visualizations that both MD and RN participants found helpful and effective in integrating various health-related data. Our MD and RN participants also noted the potential usefulness of the visualization in supporting personalized care. This user-centered design study offers findings from potential clinician users of the output of patient-generated health data from the OnPoint app. These results will be used specifically to inform the integration of visualizations into OnPoint system in the next phase of the project.

We demonstrated that using paper prototypes early in the design process allowed us to engage potential end users, gather useful insights, and explore suggested changes efficiently before investing in technical resources to build the system. We found that there were similar reactions by MDs and RNs to the visualizations. For example, all MD and RN participants found bands representing normal ranges and details on demand to be helpful, and they perceived the visualizations as helpful in providing personalized care. Both MDs and RNs reported that color helped them pick out important data points and that the blood glucose graph dips and peaks helped them think about what might have caused abnormal readings. This suggests that careful design of visualizations that incorporate fundamental guidance of data visualization can support a wide range of users. Although personalization and customization of a visualization interface based on different users' needs could increase usefulness and usability [59-61], it is possible to minimize the extent to which visualization versions differ when they are designed thoughtfully and purposefully.

Although we cannot assume that an interactive tool incorporating visualizations for use by individuals with MCC engaged in cancer care would necessitate the same design as a tool for clinicians, we do believe that this study offers a starting point for features to consider for users who are patients.

This study has the potential to inform the growing domain of research in integrating visualizations into informatics solutions that support personalized patient care [45,62-71]. This includes work on integrating home monitoring data for individuals engaging in cancer care [27] as well as health-related quality of life data for prostate cancer care [72].

Our study findings are congruent with guidance and best practices described in the visualization literature. Both MD and RN participants noted that color helped them see patterns in the data or pick out data that require attention, congruent with work described by Ware [44]. They also were able to use the line

graphs to identify meaningful patterns in the data; this aligns with recommendations based on work by Cleveland and McGill [37-39] and Mackinlay [41]. In particular, position rather than other data encodings (eg, area) supports more accurate interpretation of the data being represented by the encoding. Although we did not compare our line graphs with other graph types in this study, participants responded positively to our design choice that was guided by the data visualization literature.

Implications for Developing Health-Related Visualizations

On the basis of the findings from our study and the current literature of integrating visualizations into clinical care, we propose the following design recommendations: (1) applying knowledge from both health informatics and visualization domains to guide the creation of visualizations and (2) applying previous research can facilitate the development and testing of systems that integrate health data visualization. First, using Munzner Nested Model for Visualization Design [17] supported the design process by making it efficient, and it can facilitate integration of our findings with other research using the same model [73].

Second, providing users with options on how to visualize the same data may support use of the visualization. In our study, we found that among the 4-week calendar view options, there was not 1 that was consistently favored. Following 1 of Nielsen usability heuristics—flexibility and efficiency of use—visualization tool developers could allow users to customize how data and information are displayed [59-61].

Finally, engaging potential end users early in the design ideation process was feasible and insightful. To minimize time and burden on HCP participants, researchers can carefully develop study protocols so they can maximize opportunities for participants to provide insights such as using mock patient personas and scenarios to guide eliciting feedback about mock-ups. Using personas and scenarios is advocated within the human-computer interaction domain [48,49], and it has been used to support the development of health informatics tools [74,75].

Limitations

There were limitations to our study. Our sample was limited to MDs and RNs; these visualizations could be useful to other HCPs supporting individuals with MCC engaging in cancer care, such as care coordinators, dietitians, pharmacists, and social workers. In addition, inputs from patients themselves and their family members must be collected to understand their informational needs. This study was conducted at a single cancer center; therefore, it has limited generalizability to other cancer centers. Mock-ups were on paper rather than on a device that a clinician would use to view visualizations in practice (eg, computer tablet and desktop computer). The data visualization literature used to guide the development of our mock-ups has not been tested extensively and empirically within health-related apps for cancer care; our work can support the building of evidence regarding the application of the visualization literature within this health domain. Although the visualizations are intended to be delivered via the electronic health record, we did

not explicitly address how this might be accomplished. This work will be pursued in a future phase.

Conclusions

This study suggests that visualizations guided by a framework and literature can support HCPs' understanding of data to support personalized cancer care for individuals with MCC. By integrating health informatics and visualization literature and

applying user-centered design methods, we were able to develop and elicit feedback on visualizations for health-related data including person-reported data. Future research could apply these methods toward the development of visualizations to support the care of other populations and the development of functional systems integrated into clinical and personal health care.

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Conflicts of Interest

None declared.

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Abbreviations

COSTaRS: Canadian Oncology Symptom Triage and Remote Support

HCPs: health care practitioners

MCC: multiple chronic conditions

MD: medical doctor

PGHD: person-generated health data

RN: registered nurse

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Original Paper

Innovating From Within: A Process Model for User-Centered Digital Development in Academic Medical Centers

Sara Kuppin Chokshi^{1*}, DrPH; Devin M Mann^{1,2*}, MD, MS

¹Department of Population Health, New York University School of Medicine, New York, NY, United States

²New York University Langone Health, Medical Center Information Technology, New York, NY, United States

* all authors contributed equally

Corresponding Author:

Devin M Mann, MD, MS

Department of Population Health

New York University School of Medicine

227 East 30th Street

New York, NY,

United States

Phone: 1 212 263 9026

Email: devin.mann@nyulangone.org

Abstract

Background: Design thinking and human-centered design approaches have become increasingly common in health care literature, particularly in relation to health information technology (HIT), as a pathway toward the development of usable, diffusible tools and processes. There is a need in academic medical centers tasked with digital innovation for a comprehensive process model to guide development that incorporates current industry trends, including design thinking and lean and agile approaches to digital development.

Objective: This study aims to describe the foundations and phases of our model for user-centered HIT development.

Methods: Based on our experience, we established an integrated approach and rigorous process for HIT development that leverages design thinking and lean and agile strategies in a pragmatic way while preserving methodological integrity in support of academic research goals.

Results: A four-phased pragmatic process model was developed for user-centered digital development in HIT.

Conclusions: The model for user-centered HIT development that we developed is the culmination of diverse innovation projects and represents a multiphased, high-fidelity process for making more creative, flexible, efficient, and effective tools. This model is a critical step in building a rigorous approach to HIT design that incorporates a multidisciplinary, pragmatic perspective combined with academic research practices and state-of-the-art approaches to digital product development to meet the unique needs of health care.

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KEYWORDS

academic medical centers; digital health; health information technology; innovation; process model; user-centered design

Introduction

Background

User-centered design (UCD) has been applied in the development and testing of software and technology for decades; however, the application of UCD and design thinking in health care innovation and health information technology (HIT) is a more recent phenomenon [1-3]. Given that the field of UCD in HIT is relatively nascent, albeit increasingly common, a comprehensive process model is yet to be established for

applying this approach and its associated methodologies to the design of digital tools for health care delivery. In this paper, we propose an integrated and pragmatic process model for the development and testing of HIT based on our experience using a rapid cycle, iterative, user-centered approach to the development and implementation of various types of innovations for health care research and clinical delivery. Pulling from relevant academic disciplines, as well as industries outside of health care, we propose an integrated model for HIT development and implementation that incorporates and builds

upon popular trends in innovation today, offering a multiphased, comprehensive, best practices in a research-based approach to digital development in health care.

Innovation in Academic Medicine

Innovation has become a priority in many academic medical centers with leaders in health services delivery calling for increased innovation and experimentation within their organizations through new research and operational processes that are more nimble, lightweight, and iterative than the typical processes in traditional academic medicine [4-7]. Although HIT innovation has lagged, software development and other design-related industries outside of health care have incorporated strategic design processes for more than a decade, combining major elements of design thinking, lean startup, and agile development principles [8,9]. These user-centered approaches are compatible with an increasingly patient-centered health system in which the goals of development are tools and processes that work for the humans who will use them, including physicians, other types of providers, staff, as well as patients and their families [10-13].

Academic Goals and Industry Demands

Design thinking and UCD approaches, in general, have become increasingly common in scientific literature, particularly in relation to HIT, as a pathway toward the development of usable, diffusible tools, and processes [1,14,15]. Researchers in population health, as well as the computer, information, and design sciences related to HIT, have proposed models for incorporating user- or human-centered approaches and agile methods into technology development [10,16-20]. What is missing from these models, however, is the capacity to inform a variety of HIT development projects beyond mobile health and behavior change apps. In addition, other models lack the necessary specificity in approach and methods to be useful to research and operations teams at the forefront of building and implementing a wide variety of digital tools for patients, as well as clinicians and other staff in their health systems.

While design thinking and user-centricity as concepts are born out of the industry, they are relatively new concepts to academic health care [1,15]. Core tenets, such as the centrality of the user journey and the concept of “empathy,” have a rich history as cornerstone ideas in social science literature [21-23]. Anthropologists have been conducting ethnographic research on health and illness since the inception of the discipline; deep understanding of the social and organizational features of work and roles, particularly in medicine, has long been an object of the sociological imagination. It is the design thinking movement [24], however, which has pragmatized and popularized these social science research practices, lending them to wider use within scientific circles, including HIT development [22].

From the perspective of an academic health institution, any digital development process must consider the need to balance tensions between demands of HIT product development and our academic goal to contribute to the evidence-base supporting high-quality health care delivery through, for example, rigorous usability evaluation and related documentation [25]. To fulfill

the potential of technology to markedly impact the quality of health services, our process of HIT design and development integrates foundational principles and strategies from the software development industry and applies them at the appropriate time while adapting them to the complexities of health care roles and workflows with rigorous user testing [26-31].

Development of a Robust Process for Digital Innovation

Charged with establishing a pipeline for identifying and supporting innovative research and operations projects-related digital development at our institution, our group, consisting of both research and HIT innovators, created the medical center’s first lab expressly designed to support our institution’s researchers and clinicians in these types of efforts [32]. Our experience in this first year of the lab has revealed the importance of implementing a process for identifying, selecting, specifying, and supporting HIT projects at all stages. Throughout all of our projects, thus far, we have developed, employed, and refined our approach, process, and practices [33-35].

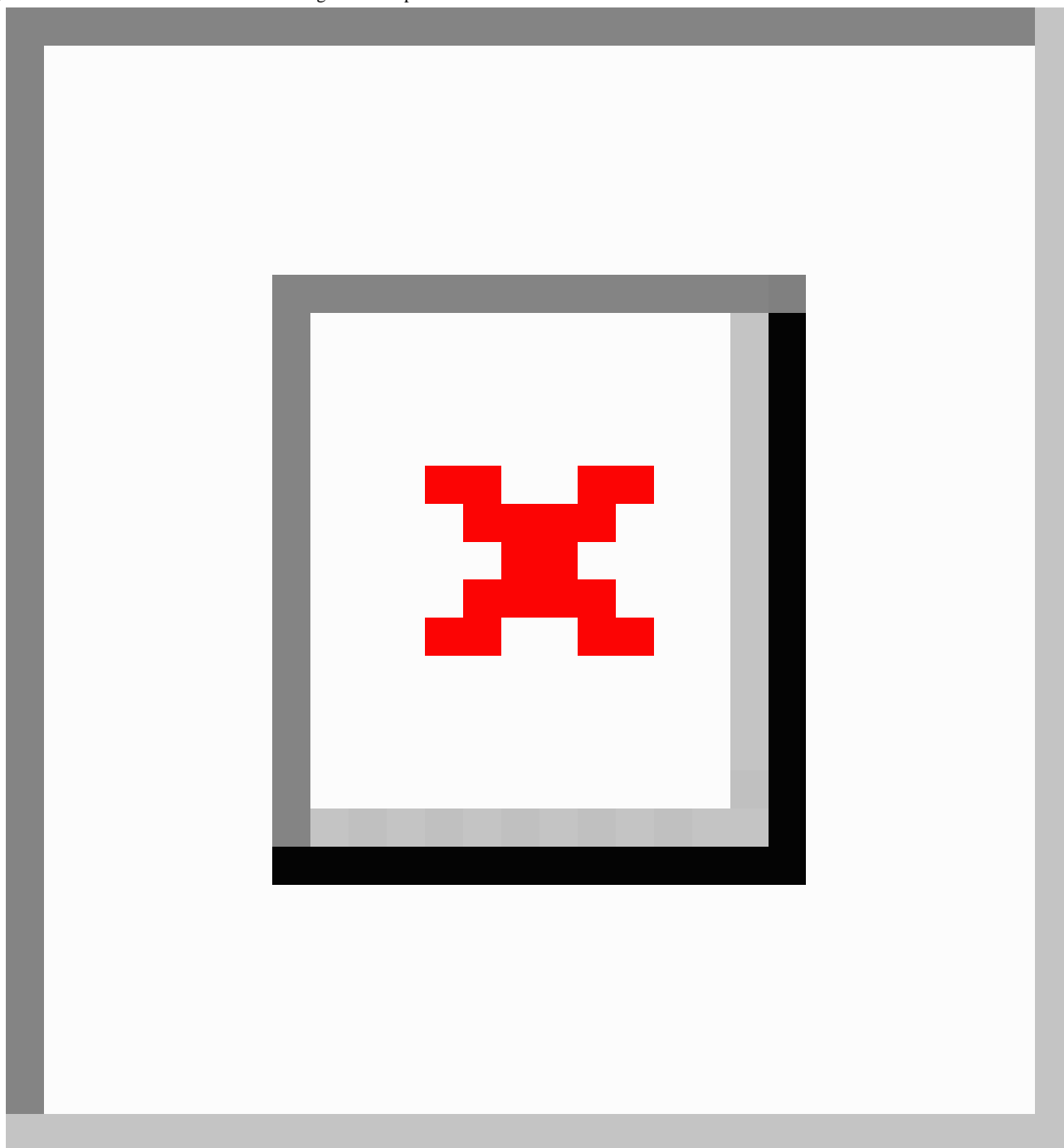
Innovating From the Inside Out

Our experience and resulting model reflect our belief in the importance of building innovation internally, acknowledging that those most likely to identify with the motivations and experiences of our users—those providing and seeking care at our institution—are, in fact, within, rather than outside of our organization. Innovation supported from within leverages the valuable “pracademic” lens—a perspective that lies at the intersection of medical practice, health care delivery, and academia. Innovation work done “in-house” is more likely to be adopted and diffused within an organization, as it is the end users themselves building and refining the tools that impact their daily work [36]. While it is common for academic medical centers to bring in external consultants, a robust internal innovation team has the potential to transform an institution’s culture, spurring greater interest in innovation, as well as institutional capacity, to support it in a more efficient, sustainable way [32]. Given the complexity of health care organizations and HIT tools, those within the institution have the institutional knowledge essential to successful innovation—a lens not easily captured by outside consultants.

This paper aims to describe the components of our resulting model, reflecting our experience establishing the internal innovation capacity that supports our medical center’s academic goals with methodological integrity and rigor, while leveraging strengths and methodologies from current trends in software development and product management (design thinking, lean, and agile development) and adapting them for efficient, sustainable, user-centered HIT development.

Methods

Our integrated process model for user-centered HIT development, as seen in [Figure 1](#), is a comprehensive picture of the entire development and testing process from concept generation to widespread deployment of an optimized tool.

Figure 1. Process model for user-centered digital development.

Leveraging applied qualitative methods, this model incorporates the popular “double diamond” representation of the design process [9], including state-of-the-art software development strategies, a phased approach to workflow analysis, usability testing, and optimization and implementation. Tangible milestones and products are noted from the intake of a new project to ongoing optimization of the HIT tool.

Results

Principal Results

We used applied design thinking strategies in the predeployment phases. In phase 1 we “discovered” concept generation and workflow analysis, followed by the further definition of the

problem and target of the proposed solution. Solution ideas are refined with user-testing feedback and developed throughout the lean-inspired phase 2. An agile approach, including “sprints” to tool development and delivery, occurs throughout phases 3 and 4. The binned approach to development that agile brings is key to the success of our model; however, the specifics of the sprint are beyond the scope of this paper.

In sum, our process consists of 4 phases as follows: (1) tool concept generation and workflow analysis; (2) prototyping with early user testing (including “think-aloud” and “near-live” methodologies) and iterative tool refinement; (3) tool development and pilot testing (including “live usability”); and (4) tool optimization, release, and scaling. Phases 1-3 are related to the predeployment tool design, development, workflow

integration, and pilot testing, whereas phase 4 occurs after tool deployment.

Phase 1: Concept Generation and Workflow Analysis

Overview

The concept generation phase features the design thinking or discovery piece of the model. The initial concept generation phase comprises the data gathering, analyses, and vetting necessary to build an initial prototype. Beginning with the very first “intake” meeting between the internal innovation and project teams, work in the concept generation phase is geared toward establishing the basic parameters of the tool to specify a minimum viable product draft of the tool. This tool will be used for the initial round of user testing with the assumption that marked iteration will occur in later phases of the process. Components of this phase include the following: extensive literature review and competitive landscape analysis of similar and related digital products on or coming to market; key informant interviews along with implementation site observation (often culminating in a design workshop aimed at producing a detailed feature list); and workflow analysis to inform phase 2 building of the initial tool “minimum viable product” prototype, as well as an initial backlog of features the project team deems as valuable but not key for the initial tool version.

Literature Review and Competitive Landscape Analysis

As with typical research endeavors, a comprehensive literature review occurs early in the process to establish the evidence-base necessary to understand what the current state of the technology in the field is, confirm gaps and use cases the tool could potentially address, and begin to identify where the opportunity exists for innovation for the tool in development. In addition, digital development projects benefit from a competitive landscape analysis, a review of similar or relevant digital products currently available or in development. The competitive analysis is essential to determining that the tool in development adds value by building upon rather than duplicating the contributions of those already available. Furthermore, it is a necessary first step in determining potential partners for codevelopment, should the development project be compatible with such an approach.

Key Stakeholder Interviews

Concurrent with the literature review and competitive analysis, interviews with key stakeholders are critical in identifying “pain points” (key needs the tool might address), identifying real-world workflow issues (and resulting opportunities for the tool to intervene or facilitate), and confirming potential use cases as identified in the literature. Individual semistructured interviews with key stakeholders typically last 60-90 minutes and are structured to elicit expert and “insider” perspectives on relevant content and workflow factors, while allowing a high degree of flexibility to capture unanticipated key issues for consideration in tool development or implementation. Documentation of interviews can range from simple detailed summaries to analyzed verbatim transcripts as is typical of rigorous qualitative research, depending on the academic versus pragmatic goals of the project.

The outcome of the literature review and key stakeholder interviews is a summary document used to drive the development of workshop materials and activities (eg, draft user profiles, value propositions, draft tool content, workflow maps, etc) and contribute material for academic manuscript development. Furthermore, results from these activities may inform the focus for site observation sessions as described below.

Site Observations and Workflow Analysis

UCD requires a deep understanding of workflow and the roles, responsibilities, and documents or data related to the tool in development [37,38]. All activities in the concept generation phase inform this understanding but typically site visits or observations (to correspond with key stakeholder interviews when appropriate) contribute greatly to the understanding of key issues or opportunities impacting tool building or implementation decisions. Hence, site observations are critical to a comprehensive concept generation phase. Using a structured approach adapted from evidence-based frameworks for workflow analysis in health care, such as the Workflow Elements Model and Agency for Healthcare Research and Quality’s Workflow Assessment for Health Information Technology Toolkit, qualitative and quantitative data on key elements are gathered throughout phase 1 and collected through usability testing and observations throughout the entire process [39,40].

Design Thinking Workshop

A design thinking workshop can happen at any point but is often a culmination of the concept generation phase, bringing together a carefully selected combination of stakeholders, including potential tool users (ideally 6-8 people) together for an extended, uninterrupted workshop (typically 4-6 hours) with an expert facilitator who guides the group through a carefully selected and sequenced body of activities designed to elicit feedback on content critical to tool development and feature specification, including exercises to create, verify, or modify (eg, user personas, opportunity statements, development exercises, value propositions, and low-fidelity prototypes of tool content or features). The design thinking workshop is key in transitioning the tool development process from the divergent ethos of the concept generation phase to the convergent cadence of the prototype development.

The types of activities conducted in a design thinking workshop vary depending on the specific needs and characteristics of an individual project, including complexity and maturity. While one project may only require 2 hours, other projects may demand an entire day’s worth of activities or multiple workshops throughout initial phases. Having representation from each of the stakeholder groups in the design workshop increases the likelihood that the resulting prototype development results in a feasible, widely acceptable tool. A typical design sprint approach in which tool development teams meet intensively for 4-5 days is rarely, if ever, feasible in the context of academic health care systems, given scheduling and logistical challenges. Maintaining the spirit of the approach and its strategies—albeit with a longer time horizon—can, from our experience, yield similar benefits [41].

Types of Design Thinking Workshop Activities

Workshop activities are designed to gather, explore, and refine the information needed for digital tool development related to specifying who is the target user; why they would use the tool; the context in which they will use it; and how the project team will gauge the success of the tool. From work done in the discovery phase prior to the workshop, the project team begins to develop clarity on these specifications; this includes mapping of workflows for integrating the new tool and related practices into current workstreams. For digital health service delivery products, a clear understanding of existing and new potential workflows is crucial to the design and implementation of a successful tool [42]. The products or “artifacts” of the workshop once consolidated and summarized will provide the foundation necessary for the development of an initial prototype in phase 2. Table 1 lists examples of workshop activities and their objectives.

Opportunity statement exercises are aimed at more clearly delineating facets of current practice that are not meeting needs to identify in what way new tools and processes can make measurable impact. In this type of exercise, participants are

often divided into pairs or small groups and asked to provide feedback on preprepared statements and offered the chance to develop new opportunity statements. Reporting back to the entire workshop group then allows for discussion, analysis, and prioritization of statements if appropriate.

Taking a user-centered approach to health services digital tool development requires a deep understanding of not just who will be using the tool (personas and user profiles) but *how* and *when* they might use the tool to derive value. User journey mapping exercises are aimed at examining current or anticipated user experiences over time, including what user groups are doing, thinking, and feeling, and how and with what they are interacting. Insights from key informants and users gathered through interviews and within workshop activities inform the journey map, which can be created during the workshop or drafted prior to the workshop with feedback and expansion being the goal of the activity in the workshop. Journey maps are essential to the workflow analysis that is crucial to building successful HIT tools; this type of exercise and the “map” it produces provides detailed insights into role responsibilities, documents, and information content necessary for prototype development.

Table 1. Examples of design thinking workshop activity types.

Activity type	Objective	Example
Opportunity statement	Identify an area in which the proposed digital tool may provide value or have an impact.	In pairs, complete this statement (followed by group discussion), “How might we improve (current process/tool) so that (users) are more successful as determined by (measurable criteria)?”
Persona development	Create specific fictional users (based on the actual user research) that feature key characteristics of the anticipated user group(s).	Participants as a large group are provided with a persona worksheet for review and subsequently asked to raise and discuss, based on the key features presented in the persona story, how this should impact tool build.
User journey mapping	Examining current or anticipated user experiences over time, including what users are doing, thinking, feeling, and interacting with over time.	Facilitator presents a different user profile to each of 3 small groups, asking them to make a journey map for that user; following, each group presents their journey map for discussion and refinement.
Service blueprint	To delineate the roles and responsibilities of actors in the health care organization and potentially outside that impact, facilitate or restrict a user journey.	Facilitator presents preprepared scenario (end-to-end user journey) to map out organizational and other decisions, activities, and influencers.
Lean canvas	An actionable “business” plan to guide product development focused on problems, solutions, key metrics, and competitive advantages.	Participants shown Lean Canvas template and led through clarifying exercises regarding 9 concepts and gaps in project maturity.

While journey mapping is often referred to as a strategy for learning about the “front-stage” user experience, service blueprint exercises are geared toward uncovering the “back-stage” and “behind the scenes” organizational factors that mirror and impact those front-stage user experiences [43]. Service blueprint activities involve the diverse group of workshop participants examining, with the help of the facilitator, scenarios of user journeys to delineate the roles and responsibilities of actors in the health care organization and potentially outside that impact what happens along the user journey; particularly the ones that, in their current iteration, restrict what can and cannot be done related to the aspects of user activities and experience of interest.

The Lean Canvas is a business plan template of sorts designed to facilitate a new project’s ability to hone in on key building

blocks of strategic development such as problem definition, solution, users, unique value added, and key metrics of success. A lean canvas exercise can be useful at this early stage to examine the maturity of the basic tool idea and identify gaps to be addressed for the project to have the focus and business case needed to drive successful development, implementation, and, importantly, sustained adoption [44,45].

The outcome of phase 1 is a synthesis document based on the “artifacts” (products of design activities, for example, opportunity statements, personas, and journey maps) and other findings from workshop activities. This document will drive the drafting of a prototype tool requirements document to drive prototype development and contribute further to the drafting of academic manuscripts.

Phase 2: Prototyping and Iterative Refinement (Including Early User Testing With “Think-Aloud” Methodology)

Lean Startup and Agile Approaches to Digital Product Development

As a project transitions to phase 2, a tool workgroup (a group of 6-8 people pulled from the research team, representative users, key stakeholders, and members of the digital development team) is convened to solidify plans for the initial prototype and make any last tweaks to the tool or the workflow integration plan before the tool build after which the project moves to the iterative refinement phase characterized by rounds of user-testing, tool building, and implementation refinement.

In this model, as is typical in a lean startup approach, the initial prototype is refined through a multiphase, preclinical user-testing process, which serves as a clinical laboratory for building successful workflow-integrated tools with a high likelihood of adoption and adherence. Focused on the space between initial product ideation and actual building of software, lean startup as a strategy contributes a rapid, user-focused approach to idea validation with user testing [41,46,47]. In the lean approach, ideas generated by users or with the input of key stakeholders in the initial product ideation stage are validated and refined iteratively with multiple rounds of user feedback, often using prototyping with varying degrees of fidelity. If appropriate, initial user testing can occur with low fidelity (eg, paper or low-resolution wireframes) prototypes to test key assumptions before moving on to costlier and time-intensive, high-fidelity software when the tool team is more confident and committed to features and design elements to include.

Subsequent rounds of multidisciplinary workgroup sessions are interspersed with usability sessions to iteratively refine the tool, beginning with cycles of “think-aloud” usability testing sessions in which users are asked to verbalize all thoughts as they interact with the tool following a carefully scripted series of tasks of interest. The think-aloud approach is particularly well suited to exploring adoption and implementation issues [48]. Following think aloud, usability testing transitions to “near-live” testing in which users are observed carrying out representative tasks of interest with the tool during simulated clinical encounters [49-51].

Similar to the use of flight simulators for vetting new designs in the airline industry, usability testing and research is an essential part of HIT development [52]. As in aviation, clinical conditions in health care are often stressful and difficult to recreate. The lighter-weight processes for innovation in consumer digital development are frequently not sufficient in the high stakes and regulated health care environment. In addition, in HIT, there is often more than one user group; one technology may need to meet the needs of multiple clinical providers (eg, physicians, nurses, and medical assistants), as well as patients in some instances. Hence, multiple rounds of usability testing in our model reflects the unique nature of HIT compared with consumer digital development. Although data saturation is a goal, the lean philosophy takes a rapid iterative approach to user testing, which values a “good enough” level

of feedback to move to the next iteration over conclusive evidence favored in traditional academic research [50]. After the tool building and implementation plan has incorporated user feedback from predeployment usability testing, the tool is ready for pilot testing in phase 3.

Workbook

The outcome of phase 2 is the culmination of work to date in a “workbook” designed to inform building and implementation of the tool. A workbook contains curated content and artifacts gleaned from the first 2 phases and is designed to provide a detailed, yet concise picture of the project process, as well as feature and design decisions to date and the work that informs them. This document represents an important moment in the product life cycle when project teams can use the workbook to assess gaps as well as the health and viability of the project before deciding to move on to the resource-intensive building phase. Serving as both evidence of the work to date (useful for demonstrating efforts to institutional leadership, as well as program officers, in the case of grant-funded projects), as well as a “pitch deck” for project teams to secure funding for the next phase, the workbook is a critical product in this process.

Phase 3: Pilot Testing (“Live Usability”)

Phase 3 features pilot-testing of the tool combined with “live” usability testing prior to large-scale deployment. Pilot testing in this phase, similarly to typical research pilots, is designed to examine tool impact on workflow, uncover usability issues, and identify educational needs to be considered for inclusion by the tool workgroup before larger-scale implementation. Through the gathering and addressing of real world, *in situ* user feedback from “live” usability testing, the development team increases the likelihood that the final iteration released is likely to be acceptable and usable [53]. While it can be useful at any phase, the time-blocked binning of work in agile “sprints,” where very specific and deliberate allocation of work is binned into 2-week blocks, becomes a key characteristic of the work in phases 3 and 4.

While the Lean approach is designed to produce validated use cases and value propositions, agile techniques, such as “sprints” facilitate flexibility and efficiency, by offering strategies to support the likelihood that software will be delivered on time containing the key features that satisfy user needs [54-56]. Given the challenging environment health care poses to IT development, the lean process incorporates a sustained user-centered approach that is essential [29]. While the promotion of design thinking, prototyping, and rapid iteration is increasingly common in the health care innovation and HIT literature, coverage of these strategies tends to be superficial and isolated from the foundational principles of the lean startup and agile methodologies from which they originate.

Phase 4: Tool Optimization, Release, and Scaling

Phase 4 focuses on ongoing training and organizational and peer support to improve acceptability and adoption of the tool postdeployment. Throughout this phase, the tool workgroup continues to meet as needed to examine and discuss tool utilization and user feedback to determine any further modifications needed to the tool itself or the implementation

plan. For example, a tool built by researchers at our institution for delivering preappointment digital health assessments to patients features built-in reporting of process metrics, which are regularly reviewed by the project team in addition to ongoing user experience research for continuous improvement of tool features, functionality, and engagement.

Although additional modifications may be made to the tool itself in this later phase, our model prioritizes the role of training and organizational and peer support in the successful implementation of a digital tool [57]. Training support may consist of ongoing outreach to assess and meet training needs; organizational support may include regular contact with site leaders to assess implementation and engage in ongoing optimization to the evolving workflows; peer support may be facilitated through identification of high-volume users of the system and engaging them as implementation champions at their site.

Discussion

Principal Findings

A rigorous process for UCD and implementation of HIT is critical to supporting digital innovation and contributing to evidence-based medicine. Our experience developing and refining this process through multiple clinical decision support and other HIT projects yields a unique model for design in health care that, while particularly well suited to HIT development, applies to nondigital innovation as well. While design thinking and user-centered approaches are referred to with increasing frequency in the academic literature, few explicit models for HIT development exist that foster a holistic understanding to apply to both clinician- and patient-facing tools [23,58,59]. Given the value placed on holistic understanding of roles and workflows involved in the design and implementation of a new tool, future research will examine how the systematic approach put forth in the model lends itself to generating evidence to support design and implementation

of HIT tools generally. High-quality user research, usability evaluation, and implementation pilot research offer value to the HIT community as a whole.

While existing models espouse the importance of design thinking, prototyping, and rapid cycles of iterative feedback, fidelity to the principles and practices of lean and agile approaches to digital development from which they came is not evident [17]. Similarly, the crucial role of usability testing both pre- and posttool deployment is not specified or emphasized. Given the complexities of health care roles and workflows, successful implementation necessitates rigorous usability testing pre- and postdeployment to truly grasp a health care user journey [48,53,60]. While recognizing the centrality, first and foremost, of the user perspective and experience and deep knowledge and consideration of the ways in which health care professionals and patients, as humans, interact with digital tools, this model incorporates strategies that also address the need for digital clinical delivery tools to incorporate the business goals and processes of the academic health system for diffusion and sustainability.

Conclusion

A result of experience and reflection, this model is a comprehensive approach to digital tool development and implementation that promotes UCD and development, while being uniquely equipped to account for and mediate the challenges and tensions posed by the complex, highly regulated, and high stakes health care environment and the need in academic medicine to be first and foremost evidence-based. As the culmination of diverse innovation projects, this process model for user-centered digital development represents a multiphased, high-fidelity process for making HIT and other types of innovation more creative, flexible, efficient, and effective. This model is a critical step in building a rigorous approach to HIT design that incorporates a multidisciplinary, pragmatic perspective, combined with academic research practices and cutting-edge approaches to digital product development to meet the unique needs of health care.

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Authors' Contributions

All authors have made substantial contributions to conception and design, acquisition of data, and analysis and interpretation of data and drafting and critical revisions of the manuscript.

Conflicts of Interest

None declared.

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Abbreviations

HIT: health information technology

UCD: user-centered design

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Original Paper

Usability Testing of a Mobile App to Report Medication Errors Anonymously: Mixed-Methods Approach

Doris George¹, MPharm; Mohamed Azmi Hassali¹, MPharm, PhD; Amar-Singh HSS², MSc Community Paediatrics, MBBS, MRCP, FRCP (Glasg)

¹Social & Administrative Pharmacy, School of Pharmaceutical Sciences, Universiti Sains Malaysia, Penang, Malaysia

²Clinical Research Center, Department of Paediatrics, Raja Permaisuri Bainun Hospital, Ipoh, Malaysia

Corresponding Author:

Doris George, MPharm
Social & Administrative Pharmacy
School of Pharmaceutical Sciences
Universiti Sains Malaysia
Minden
Penang, 11800
Malaysia
Phone: 60 052085555 ext 5293
Fax: 60 2538400
Email: doris.moh.gov@gmail.com

Abstract

Background: Reporting of medication errors is one of the essential mechanisms to identify risky health care systems and practices that lead to medication errors. Unreported medication errors are a real issue; one of the identified causes is a burdensome medication error reporting system. An anonymous and user-friendly mobile app for reporting medication errors could be an alternative method of reporting medication error in busy health care settings.

Objective: The objective of this paper is to report usability testing of the Medication Error Reporting App (MERA), a mobile app for reporting medication errors anonymously.

Methods: Quantitative and qualitative methods were employed involving 45 different testers (pharmacists, doctors, and nurses) from a large tertiary hospital in Malaysia. Quantitative data was retrieved using task performance and rating of MERA and qualitative data were retrieved through focus group discussions. Three sessions, with 15 testers each session, were conducted from January to March 2018.

Results: The majority of testers were pharmacists (23/45, 51%), female (35/45, 78%), and the mean age was 36 (SD 9) years. A total of 135 complete reports were successfully submitted by the testers (three reports per tester) and 79.2% (107/135) of the reports were correct. There was significant improvement in mean System Usability Scale scores in each session of the development process ($P < .001$) and mean time to report medication errors using the app was not significantly different between each session ($P = .70$) with an overall mean time of 6.7 (SD 2.4) minutes. Testers found the app easy to use, but doctors and nurses were unfamiliar with terms used especially medication process at which error occurred and type of error. Although, testers agreed the app can be used in the future for reporting, they were apprehensive about security, validation, and abuse of feedback featured in the app.

Conclusions: MERA can be used to report medication errors easily by various health care personnel and it has the capacity to provide feedback on reporting. However, education on medication error reporting should be provided to doctors and nurses in Malaysia and the security of the app needs to be established to boost reporting by this method.

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KEYWORDS

mobile app; usability; medication error reporting; anonymous

Introduction

Patient safety incident is defined as a situation that resulted or did not result in unnecessary harm to a patient due to the health care process, procedures, or medications given to the patient. Harm to patient can be further classified based on type of harm and extent of harm, including social and economic implications [1]. The theme of the third Global Patient Safety Challenge launched in 2017 by the World Health Organization (WHO) is medication safety [2]. The WHO reports that all medication errors potentially can be avoided by improving health care systems and practices of medication ordering, prescribing, preparing, dispensing, administering, and monitoring. Therefore, all health care personnel involved in any medication process should be committed to continuous improvement in health care systems and practices.

Medication error reporting is one of the essential mechanisms to identify risky health care systems and practices, and information regarding medication errors should be shared among health care professionals for learning purposes and prevention of further errors [3]. In Malaysia, medication error reports to the national database revealed reports of medication errors were substantially by pharmacists (98%) with 76% of the medication error reports involving the prescribing process [4]. In the United States, 80% of hospitals estimated that only a few adverse event reports were reported by doctors [5]. This indicates there are unreported medication errors from certain professions such as doctors. Every unreported medication error is a chance lost to identify trends, risky systems, and practices for improving health care [6]. Encouraging various groups of health personnel in medication error reporting would give a better perception of medication error occurrences at the institution.

The roadblocks in medication error reporting can be divided into three major categories based on recent literature reviews: attitudes of reporters, the error involved, and the reporting system [7,8]. Attitudes of reporters include fear of impending actions as a result of reporting and simply not seeing the need of reporting. Error severity also influences reporting. A reporting system that is laborious along with lack of education on reporting, nonsupportive management, and lack of feedback discourages reporting. The reporting system is a modifiable category that can be improved to encourage reporting. This leads to the idea of creating a medication error reporting method that is user-friendly, a fast mode of reporting, requires little training to use, is available at all times, preserves anonymity, and—importantly—is able to provide feedback on a large scale instantaneously.

Therefore, the aim of this paper is to report the usability testing of a mobile app for reporting medication errors with the ultimate aim to design an anonymous, user-friendly app for reporting medication errors.

Methods

Study Design

Usability is a measure of how easy a product such as website or app is to use. It can also be defined as methods for improving

ease of use during the design process as described by Jakob Nielsen [9]. This usability testing involved a mixed methodology of both quantitative and qualitative data collection conducted from January 2018 to March 2018. Task performance and rating of app methods were used to retrieve quantitative data. Qualitative data were retrieved through focus group discussion methods on completion of tasks. A series of three sessions were conducted in the meeting room of the hospital where a hotspot was created for internet connectivity.

Medication Error Reporting App

The design of the Medication Error Reporting App (MERA) was developed by an independent pharmacist to run on two mobile phone operating platforms, the iOS and Android. Content of MERA was adapted from the current Medication Error Reporting System Form (BPF/104/ME/02) in Malaysia. Based on analysis of the current reporting database (2013-2015), common missing and incorrect information were recorded. Two public hospital verifiers of medication error reports were interviewed to discuss the content of MERA. Changes incorporated into MERA based on these are explained here.

Domains that were appended were location of error (inpatient or outpatient for errors that occur at hospital settings), initial medication process that error occurred (labeling, filling, preparing, and monitoring), types of error (subcategorized as shown in [Multimedia Appendix 1](#)), and possible contributing factors (categorized based on an extensive literature search as shown in [Multimedia Appendix 2](#)).

The age of patient domain was categorized into neonates, infants, children, adolescents, adults, and geriatrics because data in this category were mostly missing from the current reports.

A drop-down list of medication available for Ministry of Health (MOH) use for quick entry was also incorporated into the app.

Information on type and size of container and manufacturer details are not included in MERA. Features to upload images such as a prescription or a photo of the label and any other relevant materials were not included due to cost implications.

Selection of Testers

Testers' Characteristics

Testers were selected based on potential users of MERA in the MOH, which included doctors, pharmacists, and nurses. Testers were conveniently selected from a large 990-bed public hospital, Raja Permaisuri Bainun Hospital, in Ipoh, Malaysia. Testers included both experts in the field of medication error reporting or related works and users or novices of the current medication error reporting form or website. Testers were categorized into two categories: (1) user or novice and (2) expert or nonexpert. Experts for the study were defined as health care professionals who encounter medication errors in practice and are involved in patient safety meetings for department, facility, or state, or are involved in medication error-related research. Users were defined as health care professionals who have reported medication errors using manual forms more than once in the past year or are involved in verifying medication error reports for facility or state. Health care professionals who have their

subordinates fill in the medication error reports were considered novice.

Other criteria for selecting testers included those that owned mobile phones with an iOS or Android operating system and had been using it for not less than 3 months.

Sample Size

It has been concluded that five testers are typically enough to discover 80% of the problems in a test [10] and 15 testers is enough to discover 90% of the problems in a test [11]. In this study, the sample size for each session was set at 15 to obtain 90% of the problems encountered with MERA. Assuming more than two sessions of testing would be required to obtain a usability score for the app, power analysis was conducted using G*Power version 3.1.9.2 software [12] by setting 80% power to detect the difference among means versus the alternative of equal means using an *F* test with a .05 significance level. A total calculated sample size of nine was obtained by assuming the standard deviation to be 5, expected usability score to rise from 60% to 80%, and the calculated effect size to be 1.63. Similarly, by assuming mean time to complete a medication error report reduced from 10 minutes to 5 minutes, a standard deviation of 5, and calculated effect size of 1.03, the minimum sample size required was 15.

Testing Procedure

Procedure 1

The testers were briefed on the background and purpose of the app before starting the session. Consent was obtained from each tester prior to starting the sessions and basic demographic data such as profession, age, and gender were recorded. Testers for each session were all different.

Procedure 2

Each tester downloaded MERA by scanning a quick response (QR) code to retrieve the app onto their mobile phones and were given time to go through the app. MERA has two major functions: to report medication errors and to provide feedback of medication error reports. Testers were presented with three medication error scenarios involving medication errors initiated in three main medication processes (prescribing, administering, and dispensing) for reporting (Multimedia Appendix 3). The scenarios were randomly selected from real cases reported from the hospital. They were required to read the scenarios and submit medication error reports using the app. During the task, the problems encountered and the step(s) testers sought help for were evaluated. Testers were told to record the time they attempted to fill in the report and the time they completed submission of the report using MERA. Immediately after the testers completed submitting the three reports, they were asked to rate the perceived usability of MERA based on the System Usability Scale (SUS; Multimedia Appendix 4).

Procedure 3

Once the testers completed rating using the SUS, a focus group discussion was conducted to discuss the challenges and problems encountered using the app, any good points regarding the app, suggestions to improve the app, and potential use of MERA by all health care professionals. A checklist of focus group

discussion question points was used to conduct the session (Multimedia Appendix 5). The focus group discussions were conducted by the same researcher, who is a practicing hospital pharmacist and has experience in reporting medication errors, compiling medication error reports for the state, and is involved in various research involving medication errors. This researcher also underwent qualitative interview training.

Evaluation and redesign of app functions and interface were done based on the feedback obtained during the discussions.

Tools and Data Collection

Quantitative Data

The quantitative data collected consisted of time taken to complete the medication error report, total medication error reports successfully submitted, number of incorrect reports submitted, and the SUS score to measure perceived usability.

The SUS is a validated tool that is simple and easy to evaluate how one perceives the usability of a system or app [13]. The SUS is a set of 10 questions with a Likert-scale rating of 1=strongly disagree to 5=strongly agree. The scale of odd questions (1, 3, 5, 7, and 9) are deducted by 1, whereas for even questions (2, 4, 6, 8, and 10), 5 is deducted from the scale. The SUS score calculation is done by summing the modified scale and multiplying it by 2.5; the score has a range of 0 to 100. For a score higher than 80.3, the app is considered excellent, a score of 80.2 to 74 considers the app is usable, a score of 73.9 to 68 considers the app is usable but could improve, a score of 67.9 to 51.9 considers improvement is recommended, and a score of 51 or less considers the app should be fixed. For this study, improvement and usability testing was done until a score of 74 or higher was achieved.

Qualitative Data

Themes for questions used in the focus group discussion were derived from seven theoretical domains frameworks as suggested in a literature search [14,15]: usability, visual design and layout, content, potential user engagement, security, validation of report, and other comments. A semistructured question guide was prepared as a checklist to ensure all topics were covered and probing questions could be asked when necessary (Multimedia Appendix 5). Discussions were continued until no new themes and issues emerged. Discussions were conducted for approximately 45 to 60 minutes. All discussions throughout the sessions and consent for focus group discussion participation was recorded.

Data Analysis

There were three rounds of usability testing done with redesigning of the app after each round.

The collected data were analyzed using Stata version 13. Findings are presented as descriptive statistics of frequencies. The null hypothesis for this study was there was no significant difference between mean SUS scores and mean time to complete a medication error report across the three sessions and between testers' characteristics. Analyses of variance (ANOVA) and *t* tests were used to make a decision on whether to reject or accept the null hypothesis.

Verbatim reports of each recorded focus group discussion was transcribed by two independent research assistants. The verbatim reports were counterchecked for accuracy by the research assistants by switching their transcripts. The reports were then coded based on the seven theoretical themes by a researcher.

Ethics Approval

This study was reviewed and approved by the National Medical Research and Ethics Committee of Ministry of Health, Malaysia (registration ID: NMRR-15-1445-27125[IIR]). The respondents were informed about the voluntary nature of participation. Participants were only served snacks during the focus group discussion and no other incentives were given. The results do not mention names of the participants. A formal letter of invitation to participate was issued to testers through their respective department heads.

Funding

This research received no specific grants from any funding agency in the public, commercial, or not-for-profit sectors.

Results

Participant Characteristics

A total of 45 testers were available for testing, including 23 pharmacists, 13 doctors, and 9 nurses (Table 1). The ratio of

selected pharmacists to doctors to nurses was 3:2:1. The majority of testers were female (35/45, 78%) and the mean age of testers was 36 (SD 9) years. Most testers were nonusers of the current medication error reporting system and nonexperts in medication errors.

Quantitative Data

A total of 135 complete reports were successfully submitted by the testers (three reports per tester). Although all reports submitted were complete, there was deviation in answers provided in three domains: 12 of 135 (8.8%) in stage of medication process that error occurred, 8 of 135 (5.9%) in outcome of medication error, and 5 of 135 (3.7%) in drug involved in error (Table 2). Incorrect reports involving drugs were due to selection of the wrong drug form and only occurred in session 1. A note was included to inform users that drug names can be modified based on the drug involved in the error after session 1.

There was significant difference in mean SUS scores between the three sessions ($P < .001$; Table 2). The mean SUS score increased each session based on feedback from the testers. Experts rated lower SUS scores with a mean score of 72.8 (SD 2.4) compared to nonexperts (mean 80.1, SD 2.0, $P = .03$) and comparison of SUS scores between users and nonusers revealed no significant difference (Table 3).

Table 1. Characteristics of testers (N=45).

Characteristics	n (%)
Gender	
Female	35 (78)
Male	10 (22)
Age (years)	
≤20 to <30	13 (29)
≥30 to <40	17 (38)
≥40 to <50	11 (24)
≥50	4 (9)
Profession	
Pharmacist	23 (51)
Doctor	13 (29)
Nurse	9 (0)
Expertise in medication error	
Experts	18 (40)
Nonexperts	27 (60)
Users of current medication error reporting system	
Users	14 (31)
Novice	31 (69)

Table 2. Quantitative data by sessions conducted.

Variables	Session 1	Session 2	Session 3	Overall	<i>P</i> value
Reports submitted, n (%)	45 (100)	45 (100)	45 (100)	135 (100)	— ^a
Complete reports, n (%)	45 (100)	45 (100)	45 (100)	135 (100)	—
Correct reports, n (%)	28 (62.2)	39 (86.7)	40 (88.9)	107 (79.2)	—
Drug name inaccurate, n (%)	5 (11.1)	—	—	5 (3.7)	—
Outcome of medication error incorrect, n (%)	4 (8.9)	2 (4.4)	2 (4.4)	8 (17.8)	—
Initial medication error process incorrect, n (%)	5 (11.1)	4 (8.9)	3 (6.7)	12 (26.7)	—
Time per report (mins), mean (SD)	6.5 (2.6)	7.1 (2.6)	6.5 (1.9)	6.7 (2.4)	.70
SUS score (%), mean (SD)	65.8 (10.2)	79.9 (4.5)	86.0 (3.8)	77.1 (10.8)	<.001

^aNot applicable.**Table 3.** Quantitative data of System Usability Scale (SUS) score by testers' characteristics.

Variable	Mean (SD)	<i>P</i> value
Age		.10
≤35 years	74.4 (12.3)	
>35 years	79.7 (8.8)	
Gender		.50
Female	77.8 (9.9)	
Male	75.0 (13.8)	
Expertise on medication error reports		.03
Expert	72.9 (10.2)	
Nonexpert	80.1 (10.4)	
Experience in current medication error reporting system		.91
User	76.9 (9.7)	
Novice	77.3 (11.4)	

Table 4. Quantitative data on mean time per report submitted by testers' characteristics.

Variable	Mean (SD)	<i>P</i> value
Age		.61
≤35 years	6.90 (2.4)	
>35 years	6.54 (2.3)	
Gender		.13
Female	6.4 (2.5)	
Male	7.7 (1.6)	
Expertise on medication error reports		.51
Expert	7.0 (2.3)	
Nonexpert	6.5 (2.4)	
Experience in current medication error reporting system		.02
User	5.5 (2.0)	
Novice	7.3 (2.3)	

Overall, the mean time to submit a report was 6.7 (SD 2.4) minutes. There was no difference in mean time to submit a report using the app between the three sessions ($P=.70$; [Table](#)

[4](#)). There was no difference in mean time for testers who were experts in medication errors to submit medication error reports compared to nonexperts ($P=.51$). However, users of the current

medication error reporting system required a shorter mean time of 5.5 (SD 0.5) minutes compared to nonuser mean time of 7.3 (SD 0.4) minutes to submit a report ($P=.02$).

Qualitative Analysis

Seven key themes were apparent from the group discussions: usability, visual design and layout, content, potential user engagement, security, validation of report, and other comments. The qualitative analysis will be summarized based on these themes.

Usability

In general, testers agreed that the app was easy to use and they required only a few tries to be familiarized with the functions in the app. However, several comments were provided by testers to improve navigation of MERA such as guided flow of upcoming field to fill, a “pop-up” box to proceed to the subsequent fill, a “next page” icon to proceed to the subsequent fill, and a summary of the filling guide at the beginning of the app. In the first session, nearly all the users struggled to identify how to add drug and medication process of error. It only required them to tap the bar, but it was not apparent to the testers.

The sequence of the questions needs to be guided like numbering of the questions. [Doctor, male, nonexpert, novice]

A summary in the beginning of the app explaining which part to “tap” or “click” to fill would be useful instead of having to try on our own now. [Nurse, female, nonexpert, novice]

After filling one data, the next data filling can appear in a “pop-up” manner so that users can know what to fill next. [Pharmacist, female, expert, user]

I would prefer if it would be good if there is a next button to move to the next page. Now I am struggling to scroll up and down. [Pharmacist, female, expert, novice]

When asked if they would require technical assistance to use the MERA, all unanimously agreed that would not be necessary.

Once you get the hang of it, it's pretty easy to use. [Nurse, female, nonexpert, novice]

Despite the challenges mentioned subsequently, all testers managed to submit complete reports in the first session of testing concluding that the app can be learned without guidance, but a guided app would ease users further.

Visual Design and Layout

The testers agreed that the design was simple and met its purpose. The majority of pharmacists understood the color selection was to match the color of the current medication error reporting form in the country. Although the font size was set at a standard 12 pixels, testers still preferred a larger font size. Testers also continued to comment on difficulty in identifying space to tap or click to fill in data and the design was improved based on their comments. When asked if the design flow of MERA was appropriate, most testers had positive comments and were satisfied with the design flow. Comments regarding the visual design and layout mentioned by testers are:

I would like the fonts to be bigger. [Pharmacist, male, expert, novice]

If we want doctors to report, the font must be larger as most senior doctors are long and short sighted. [Pharmacist, female, expert, user]

The colors are similar to the current medication error form from Ministry of Health: dark purple and light purple. I would prefer a contrast color in the rows that I need to fill in. I don't know which place to key in data; this row should have an eye-catching color. [Pharmacist, female, expert, user]

I would like to suggest that once data is keyed in, the row changes color indicating row already answered for the ease of users. This is because currently it is not obvious that you have filled that row. [Pharmacist, female, nonexpert, novice]

In order to address the comments and problems faced, app layout was modified to standardize the color scheme (dark purple) for rows that were required to be tapped to fill in data and each section was numbered as illustrated in Figure 1. Once the selection was done, the row changed to light blue as illustrated in Figure 2. Information about use of the app was located at the beginning of the app as illustrated in Figure 3 and information that drug names can be modified and more than one drug can be added was placed in the drug involved in error section as illustrated in Figure 4.

Figure 1. Screenshot of the final design of Medication Error Reporting Application (MERA) with each of the 12 steps of reporting medication error numbered.

Figure 2. Screenshot of the final design of Medication Error Reporting Application (MERA). Purple bar changes to blue once tapped to fill report.

MY MAXIS 6:19 PM 54%

MERA info

What Happened to the Patient

No harm; correcte

Step 7: Medication Error In Detail ⓘ

Paracetamol 500 mg Tablet Delete

+ Add Drug(s) Involved In Error

Step 8: Stage(s) of Medication Process & Type of Error(s) ⓘ

Prescribing-Wrong Dose(500mg QID 1000mg QID) Delete

+ Add Stage of Medication Process Error Occured

Step 9: Contributing Factor(s)

No Double Checking Delete

+ Contributing Factors

Step 10: Relevant Materials

➤ Submit

MERA Medication Safety News

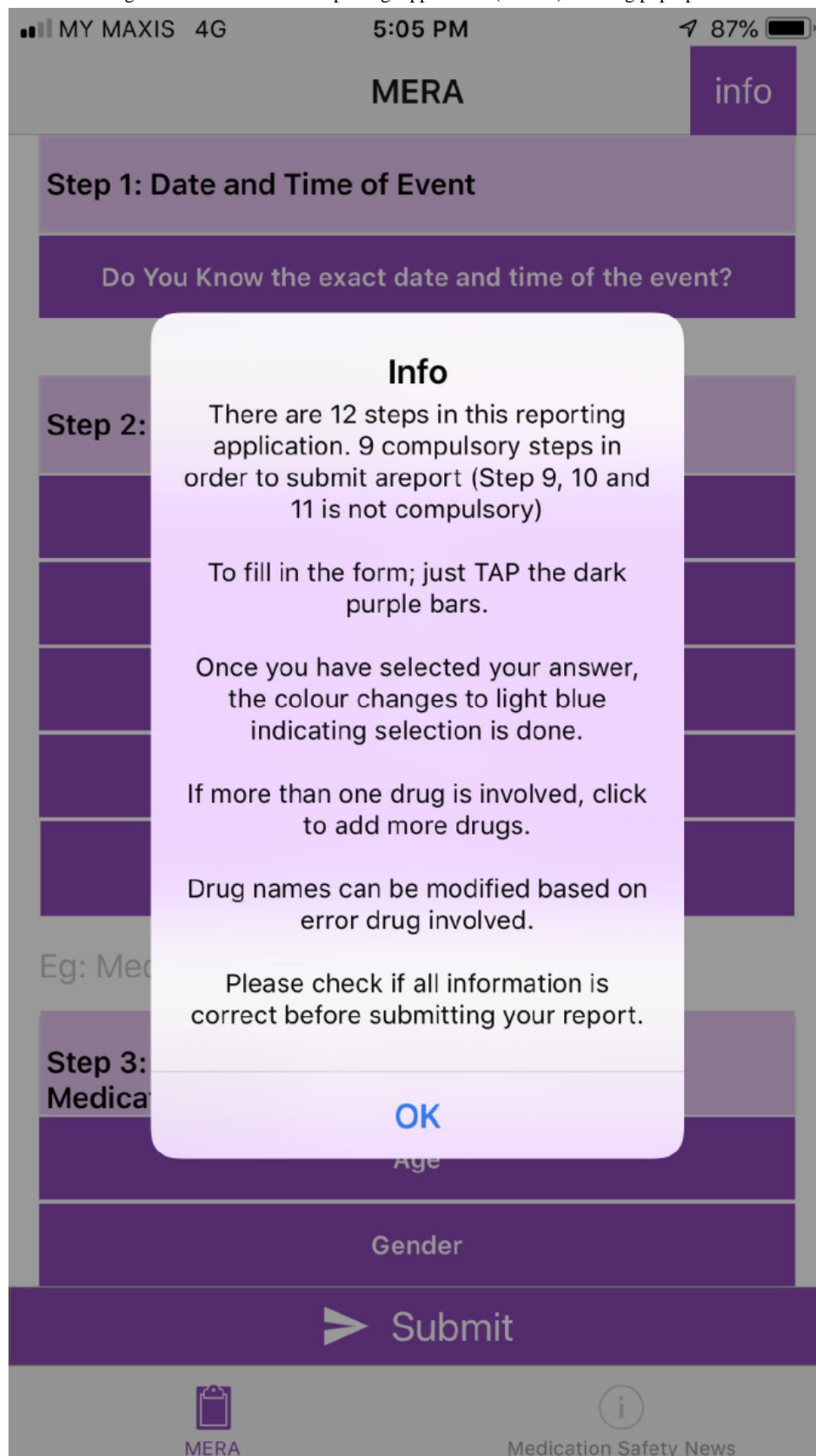
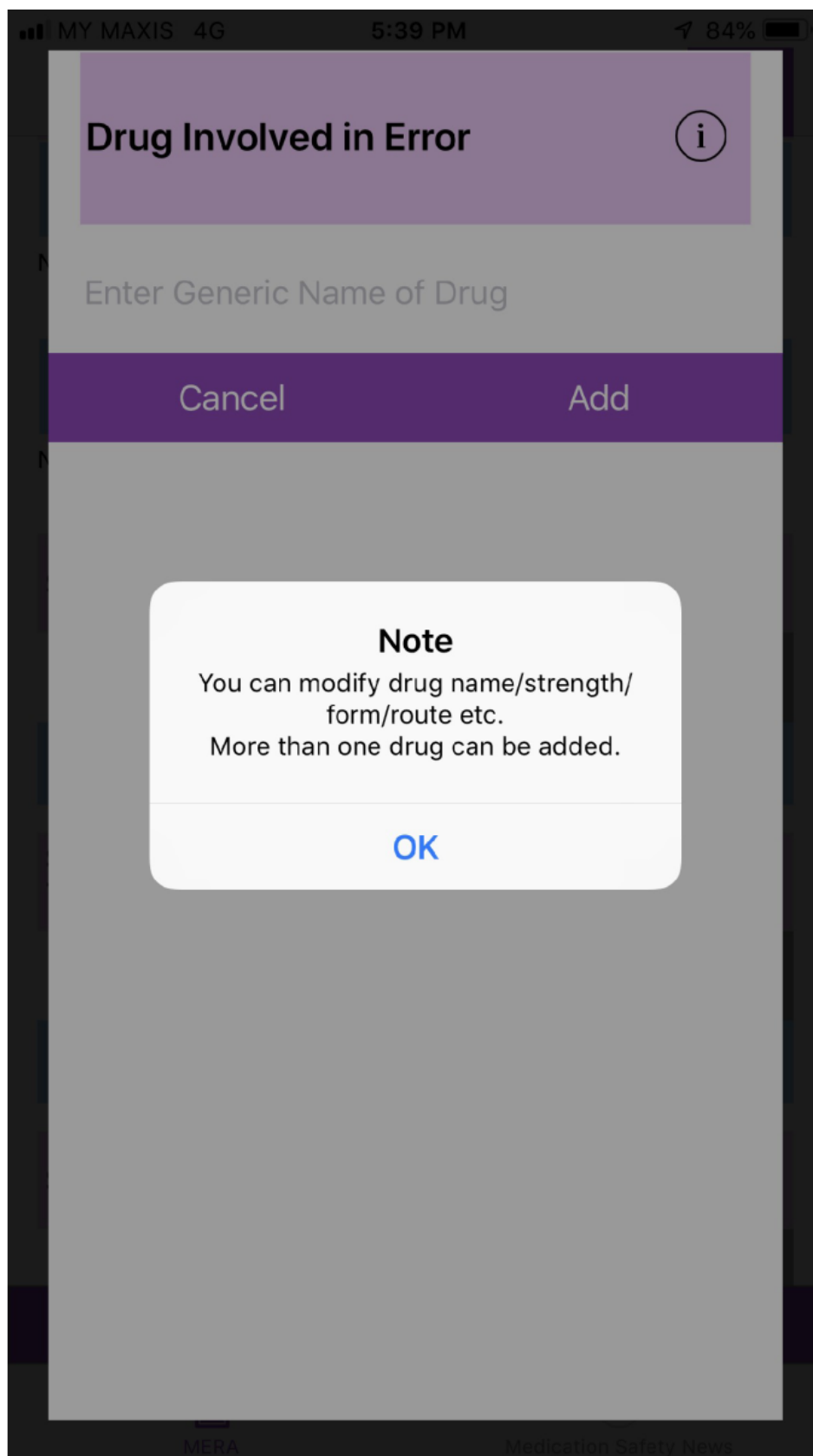
Figure 3. Screenshot of the final design of Medication Error Reporting Application (MERA) showing pop-up information of reporting instructions.

Figure 4. Screenshot of the final design of Medication Error Reporting Application (MERA) showing pop-up information about adding drug involved in error.



Content

There were many comments from the testers regarding content. Testers perceived that MERA itself was a simple, easy, and

self-learnable app; however, filling in MERA required training especially on outcome of error, initial medication process that error occurred, and type of errors. Many testers requested to omit time of event.

Comments on Outcome of Error

Most of the testers, especially nonusers of the current medication error reporting system, were not sure how to code outcome of error. Pharmacists who were experts in medication error reporting commented that outcome of error in certain medication errors were difficult to determine and options were not provided to illustrate this in the medication error forms:

This is the first time I seen the outcome of error classification, maybe it's my own ignorance. And I don't know how to fill this column...Don't get me wrong. It's not the app; that's straightforward. But the outcome of error is new at least to me. [Doctor, female, expert, novice]

Can one of the options used in the outcome of error classification be UNKNOWN as patients are not traceable after an error at times? [Pharmacist, female, expert, user]

Understand why our doctor counterpart, have difficulties categorizing outcome of error because even pharmacists face similar difficulties especially if patient succumbs to death. It's difficult to relate if medication error was the cause of death indirectly. [Pharmacist, female, expert, user]

Errors that reach patient or did not reach patient is not included. It's important to quickly identify near miss or actual error. [Pharmacist, male, expert, user]

Comments on Type of Medication Error and Initial Medication Process That Error Occurred

The type of errors and initial medication process that error occurred appeared as jargon to doctors and nurses. Pharmacists in general understood the terms and some even requested more precise information. Here are some of the common cited issues as commented by testers:

The app can be used by everyone, so the process can't be complex like type of error. [Doctor, male, expert, novice]

App is easy but the data to key in especially type of error is not easy. [Doctor, male, nonexpert, novice]

User-friendly terms maybe be useful. [Doctor, female, nonexpert, novice]

Only the part to click the relevant medication error is not easy for me. [Nurse, female, nonexpert, novice]

It depends how the tedious reporting person is; pharmacists are generally tedious and doctors are not when it comes to reporting...I am impressed that the app even has wrong formulation as an error category. [Pharmacist, female, expert, user]

Transcribing process is missing as this is a common medication error process that is not captured in the current form and best included in MERA. [Pharmacist, female, expert, user]

I think doctors would not be able to differentiate labeling, filling, or dispensing, so why not just stick to three major medication processes: prescribing, dispensing, and administration. We can identify the

exact process during RCA [root cause analysis]. [Pharmacist, female, expert, novice]

I'm sure even my specialists are not familiar with the term used especially the terms such as labeling and preparation. [Doctor, female, nonexpert, novice]

Some of the terms used are very pharmacy-based terms. That is why better to ask the pharmacist to report; they would better understand what to report. [Doctor, male, nonexpert, novice]

A blank space to type briefly on medication error outcome and medication error event in the reporter's own words was included. The administrator can then compare the filled-in outcome error and medication process with the brief description and correction can be made where appropriate. Time of medication error occurrence also had an option to select (weekday, weekend, public holiday, or on call) if users were not sure of exact time of medication error occurrence was also included.

Potential User Engagement

NERA is intended for all health care professionals and testers were asked if NERA could be engaged well by them; most doctors had negative responses compared to pharmacists.

If you need to engage doctors to use NERA, the app should be idiot-proof or else they might not use it. [Doctor, male, nonexpert, novice]

If I am clinician and I have encountered medication error in my clinic, I might still not report using the app because I might forget the error. [Doctor, male, nonexpert, novice]

I already have many apps on handphone already; I am not sure if I want another app. [Doctor, female, nonexpert, users]

The NERA is smooth and fast and easier than manual for sure. [Pharmacist, male, nonexpert, novice]

CME [continuous medical education] is definitely required before doctors and nurses can use NERA. [Pharmacist, female, expert, novice]

Pharmacists were concerned about documentation of medication errors if reporting done via NERA because this would disrupt the statistics that is required for audit purposes:

In our government hospital setting, documentation for auditing is required. If we have manual and app; we of course go for the manual. This is for the purpose of the documentation part. That is why I don't think we should use this app frequently. Unless we don't need documentation, we can use apps only. [Pharmacist, female, expert, user]

If it's possible to print or save report; the app can be used. [Pharmacist, female, nonexpert, user]

Security

At present, the app does not require any mode of registration before it can be used by users to ensure anonymity of users.

In each session, concerns about security of the app was questioned. Security of NERA was questioned in two aspects: security of medication error report data stored and news of the

medication error reports. News on the app was suggested to be informative rather than just providing statistics on reported medication errors. A careful consideration on the feedback provided by MERA was recommended:

I assume...this app would be made available in AppStore and Google Store...it will be available to public as no registration is required. Public should not access to the statistics of reports in the News section of app. [Pharmacist, male, expert, user]

The News section of app does it also post statistics of medication error reports? If so, the data can be misused if it falls in the wrong hands and can be misinterpreted. The MOH staffs can also misinterpret the statistics. [Pharmacist, female, expert, user]

Any app can be hacked these days, even if its data secured to the MOH server. [Doctor, male, expert, novice]

This app allows reporting error done by another staff; can this be misused? [Nurse, female, nonexpert, novice]

Validation of Reports

The validation of reports posted some concern to testers. The current system is usually filled in manually and data are verified and the form is ensured complete by a local verifier. The medication error report then goes through a double verification process before the medication error report is accepted. A compulsory process for submission of medication error reports online requires identity of reporter:

How do administrators ensure that medication error reports via app is a genuine report? [Pharmacist, female, expert, user]

What if more than one reporter reports the same medication error? How is this situation handled or identified? [Doctor, male, nonexpert, novice]

If the reporter has selected the wrong selection by mistake; and report is submitted. This will be a problem, because as all required field is selected and filled, report is submitted. [Doctor, female, expert, novice]

Other Features

Other features requested for MERA to make it more attractive were an indication of the compulsory questions to be filled and a pop-up to alert users if all data keyed in were accurate once Submit was tapped. This was to ensure that reporters were aware that once submitted, reports could not be amended. Users would like to save the reports in portable document format (PDF) to allow printing of reports to submit to any relevant authorities as required.

Another suggestion was to have some form of registration process to ensure that the app was only for health care professionals.

Discussion

Principal Findings

This usability testing using mixed methods provided vast informative input from testers in improving the MERA design. Improvements made to the design based on input provided clearly satisfied testers in the subsequent sessions as evidenced by the increasing SUS scores.

The app, from the discussion and tasks performed by the testers, proved to be simple and self-learnable. The design and layout were modified based on the useful insights from the testers.

The difficulty of reporting medication errors seems to lie in the three major parts of the medication error reporting as identified in this research: outcome of medication error, medication process when medication error initially occurred, and type of medication error. Outcome of medication error coding was an obstacle for all health care professionals, whereas medication process when medication error initially occurred and type of medication error were an obstacle to professionals other than pharmacists. Outcome of medication error used in MERA is the National Coordination Council for Medication Error Reporting and Prevention (NCC MERP) classification of outcome of error similar to the current reporting system in the country. A survey conducted among users of MEDMARX, an internet-based anonymous reporting system subscribed to by hospitals in the United States, reported kappa value of 0.61 (95% CI 0.41-0.81) among participants who rated error outcomes of 27 scenarios. This indicates only substantial interrater agreement among participants categorizing error outcome using NCC MERP. The overall percentage of participants that categorized error outcomes accurately based on the gold standard set was only 74% [16]. Testers in this study also faced the dilemma of correctly coding outcomes of medication errors resulting in incorrect reports submitted. It is essential therefore for MERA users to be trained regarding terms and classifications used in medication error reporting similar to the current reporting method. MERA app training may not require extensive training for reporting medication errors. The wide range of selection of initial medication processes when the error occurred and the type of error were maintained in the app. This wide range of categories are not available in the current manual reporting form. Incorporating a wide range of options for these two allows for quick verification of medication errors and report generation in the future. Incorrect submission of these two categories can be counterchecked with comments provided by reporters. Free text for outcome of error was included after the testing of the app. It also became apparent that doctors would rather have medication error reporting performed by pharmacists or nurses, as was reported in a recent literature review [7]. Doctors, nurses, and medical assistants who encounter medication errors in government hospitals and clinics in Malaysia must be prioritized for medication error reporting education. Nurses, and medical officers lack knowledge on medication error reporting process as mentioned in a qualitative study conducted recently [17].

In Malaysia, there are three reporting systems: adverse drug reaction reporting, medication error reporting, and incident

reporting. All three reporting can be incorporated into one system. An app to report all three reporting can be considered for future use in Malaysia.

The major concern of reporting medication errors using a mobile phone app was validation of the reports. Should this mode of reporting be accepted in the future, similar verification methods as the current verification methods of medication errors can be employed, especially medication errors that have reached patients and caused harm. Each institution can have a local verifier who can trace patients based on location of error and basic patient details. A detail on location of error should be emphasized, such as a specific ward or clinic, and unique to the institution. Timely reports of actual medication error also should be emphasized during education sessions so that appropriate action can be undertaken, such as root cause analysis when required. Duplication of medication error reports also can be sorted out after cross-checking details of patients, drug involved in error, and type of error encountered by verifier.

Security of data stored was the major concern of the experts' resistance to using the mobile app for reporting. News on the app that will be provided to users was another concern among experts as data obtained from new section can be subject to abuse by particular health personnel or institutions. This could be a major drawback in obtaining permission to use the app for reporting medication errors and this issue needs to be addressed appropriately. There were also similar concerns shown among testers in an app to report adverse drug reactions [18]

In regard to limitation of access to the app to health care personnel to safeguard information on medication reports to the public, various methods can be implemented which may incur cost and are not feasible at the moment for the purpose of this study. One such method is to assign a specific code that needs to be keyed in to launch the app. Codes will be issued to health

care professionals by the administrative authorities of the institutions.

Future Research

A mobile app to report medication errors has been successfully developed through usability testing and feedback of testers. Future work can be done to validate the use of MERA in a real clinical work setting to improve medication error reporting.

Limitations

Features such as time of occurrence of medication error and details such as registration phase, consultation phase, admission phase, ward stay, or discharge phase can be incorporated into MERA. This would provide valuable information about which part of the health system is the weakest in the organization. This was not included throughout the design testing period and will be considered in the final design.

The study was not powered to analyze differences of SUS scores and time to report a medication error between experts and nonexperts, and users and novices.

Finally, the testers were all from one health institution; therefore, their views are not representative of personnel from other health institutions.

Conclusions

MERA, the anonymous mobile app for reporting medication errors, can be used to report medication errors by various health care personnel conveniently with minimum user training. Security of the app, validation of reports, and abuse of feedback featured in the app seem to be of concern when using MERA. To encourage doctors and nurses in Malaysia to report medication errors, education on medication error reporting should be prioritized.

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Conflicts of Interest

None declared.

Multimedia Appendix 1

Type of medication error classification in Medication Error Reporting App (MERA).

[PDF File (Adobe PDF File), 22KB - [humanfactors_v5i4e12232_app1.pdf](#)]

Multimedia Appendix 2

Possible contributing factors appended in MERA based on an extensive literature search.

[PDF File (Adobe PDF File), 24KB - [humanfactors_v5i4e12232_app2.pdf](#)]

Multimedia Appendix 3

Task scenarios for usability testing.

[PDF File (Adobe PDF File), 25KB - [humanfactors_v5i4e12232_app3.pdf](#)]

Multimedia Appendix 4

System Usability Scale (SUS).

[PDF File (Adobe PDF File), 23KB - [humanfactors_v5i4e12232_app4.pdf](#)]

Multimedia Appendix 5

Question guide for focus group discussion.

[PDF File (Adobe PDF File), 16KB - [humanfactors_v5i4e12232_app5.pdf](#)]

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Abbreviations

MERA: Medication Error Reporting App

MOH: Ministry of Health

SUS: System Usability Scale

WHO: World Health Organization

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Original Paper

Easier and Faster Is Not Always Better: Grounded Theory of the Impact of Large-Scale System Transformation on the Clinical Work of Emergency Medicine Nurses and Physicians

Elaine Zibrowski¹, MSc (Neuroscience), MSc (Epidemiology); Lisa Shepherd², MD, MHPE; Kamran Sedig^{3,4}, PhD; Richard Booth⁵, RN, PhD; Candace Gibson⁶, PhD

¹Health Information Science, Faculty of Information & Media Sciences, University of Western Ontario, London, ON, Canada

²Division of Emergency Medicine, Department of Medicine, Schulich School of Medicine & Dentistry, University of Western Ontario, London, ON, Canada

³Department of Computer Science, University of Western Ontario, London, ON, Canada

⁴Faculty of Information & Media Sciences, University of Western Ontario, London, ON, Canada

⁵Arthur Labatt Family School of Nursing, University of Western Ontario, London, ON, Canada

⁶Pathology & Laboratory Medicine, Schulich School of Medicine & Dentistry, University of Western Ontario, London, ON, Canada

Corresponding Author:

Elaine Zibrowski, MSc (Neuroscience), MSc (Epidemiology)

Health Information Science

Faculty of Information & Media Sciences

University of Western Ontario

FNB Room 2050

London, ON, N6A 5B9

Canada

Phone: 1 5196417196

Fax: 1 5196613506

Email: emzibrow@alumni.uwo.ca

Abstract

Background: The effectiveness of Lean Thinking as a quality improvement method for health care has been contested due, in part, to our limited contextual understanding of how it affects the working conditions and clinical workflow of nurses and physicians. Although there are some initial indications, arising from prevalence surveys and interviews, that Lean may intensify work performed within medical environments, the evidence base still requires detailed descriptions of the changes that were actually introduced to individuals' clinical workflow and how these changes impacted health care professionals.

Objective: The aim of this study was to explore ways in which a Lean intervention may impact the clinical work of emergency medicine nurses and physicians.

Methods: We used a realist grounded theory approach to explore the clinical work of nurses and physicians practicing in 2 emergency medicine departments from a single teaching hospital in Canada. The hospital has 1000 beds with 128,000 emergency department (ED) visits annually. In 2013, both sites began a large-scale, Lean-driven system transformation of their practice environments. In-person interviews were iteratively conducted with health care professionals from July to December 2017. Information from transcripts was coded into categories and compared with existing codes. With repeated review of transcripts and evolving coding, we organized categories into themes. Data collection continued to theoretical sufficiency.

Results: A total of 15 emergency medicine nurses and 5 physicians were interviewed. Of these, 18 individuals had practiced for at least 10 years. Our grounded theory involved 3 themes: (1) organization of our clinical work, (2) pushed pace in the front cell, and (3) the toll this all takes on us. Although the intervention was supposed to make the EDs work easier, faster, and better, the participants in our study indicated that the changes made had the opposite impact. Nurses and physicians described ways in which the reconfigured EDs disrupted their established practice routines and resulted in the intensification of their work. Participants also identified indications of deskilling of nurses' work and how the new push-forward model of patient care had detrimental impacts on their physical, cognitive, and emotional well-being.

Conclusions: To our knowledge, this is the first study to describe the impact of Lean health care on the working conditions and actual work of emergency medicine nurses and physicians. We theorize that rather than support health care professionals in their

management of the complexities that characterize emergency medicine, the physical and process-based changes introduced by the Lean intervention acted to further complicate their working environment. We have illuminated some unintended consequences associated with accelerating patient flow on the clinical workflow and perceived well-being of health care professionals. We identify some areas for reconsideration by the departments and put forward ideas for future research.

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KEYWORDS

health care; emergency medicine; grounded theory; workflow; hospital

Introduction

Background

One outcome of encouraging health care systems to consider interdisciplinary approaches has been the overhaul of patient care environments with the use of the Lean Principles model. Lean Principles (commonly referred to as Lean Thinking or Lean) is a continuous method of process improvement pioneered by Toyota Motor Company for their car manufacturing production lines [1-6]. In brief, Lean is a customer-driven, continuous method of process improvement that asks an organization to focus on and reconsider how they are delivering what is of value to their customers [1-3,5]. Value is determined not only by what customers desire but also how fast what they desire is delivered to them [2]. Activities that are not contributing to value are considered to be wasteful in time and motion, and therefore, they are to be removed [1,2]. In contrast to other process improvement strategies, Lean is a bottom-up approach that relies on the input and engagement of both management and workers [1,3].

Although the state of the discourse on Lean in health care has been described as being relatively new [5], a systematic review by Moraros et al [6] concluded that the current evidence base is not strong enough to support upholding Lean as an effective quality improvement method for health care. Among the reasons underlying this assertion is that we have limited, contextual understanding of how Lean affects the multitude of internal and external variables [6] that exist within any health care setting.

Holden [4] and Rees and Gauld [7] advocated that efforts to enhance our contextual understanding must include exploration of the impacts of Lean-driven intervention on the working conditions and the actual work of individuals who are involved in the delivery of health care. There are some initial indications that Lean can intensify work performed within medical environments. Work intensification manifests under expectations that employees expend greater work effort by spending more time working, take on greater responsibility and/or more duties, or cope with fewer staff [7-9]. These pressures, in turn, can incubate increased levels of job-related stress and strain [10].

As part of a multiple case study by Rees [11], managers, nurses, physicians, and other support workers were interviewed about their involvement in the implementation of Lean interventions conducted in 3 hospital-based emergency departments (EDs) in New Zealand and found that employees from 2 of the 3 sites experienced work intensification. Although details regarding the nature and scope of duties that were affected by these interventions were not presented, individuals attempted to

manage their elevated workloads with strategies including prioritizing duties related to patient care and using unpaid time to complete their work. Two Canadian studies reported on the experiences of nurses and clinicians and also of managers, with the widespread implementation of Lean across the province of Saskatchewan. Although the specifics of the interventions were not described by these studies, a random survey of 1173 nurses found that 49.5% reported that they experienced heavier workloads and greater levels of stress (rate ratio=0.29, 95% CI 0.24-0.35) and 58.2% reported feeling less engaged and had weakened morale (rate ratio=0.30, 95% CI 0.25-0.36) after Lean-driven changes were introduced into their workplaces ([12]; data described by Moraros et al). Clinicians and managers who participated in the provincial implementation of Lean health care acknowledged, in hindsight, that interventions were overwhelming for their staff [13]. Hung et al surveyed 1333 health care professionals in the United States, including physicians and clinical support staff, before and after their ambulatory care clinic had undergone a Lean-based redesign of their clinical processes [9]. Although the details of interventions undertaken by individual clinics were not presented, these authors noted that Lean redesign included the composition of care teams and their workflow. The surveys probed aspects of worker engagement and teamwork, and participants were also asked to complete a measure of occupational burnout. After the redesign, nonsignificant increases were observed in both groups in terms of their scores on measures of engagement and work satisfaction. Despite these improvements, Lean changes did not appear to mitigate job-related stress as statistically significant increases in emotional exhaustion were reported by both groups (physicians parameter estimate=0.39, $P<.01$, clinical staff parameter estimate=0.365, $P<.05$ for nonclinical staff).

Objectives

If we are to more fully advance our contextual understanding of Lean in health care, including how it may be linked to work intensification, we will need to disseminate more granular levels of description of the changes that were introduced to clinical activities within local settings and the impacts, both intended and not, these modifications have on the professionals who practice within that working environment. The purpose of this study was to explore the ways in which a Lean intervention may enhance or disrupt clinical work and within what contexts.

Methods

Study Design

We utilized a grounded theory approach with a realist lens. Pawson [14] contends that when we explore any intervention, we must attend to contexts in which it is situated. Context is not merely unwelcome noise nor a confounding variable to be controlled for [14]. Any context will have embedded within it socially interactive factors, including the individuals who are experiencing the intervention, their interpersonal relations, the institutional setting of the intervention, and the impact of its greater infrastructure. These factors will act to support or constrain how well an intervention is taken up in a given setting. In sum, Pawson [14] describes the realist mantra is one that attends to what works, for whom, and in what circumstances.

We selected grounded theory because it is a methodological approach that seeks to explore how persons experience and give meaning to events [15,16]. Rather than focus on testing of specific hypotheses or theories, grounded theory seeks to describe social processes from data that are systematically collected or grounded in their participants, and data are analyzed throughout the course of the study [15,16]. This methodology has been recognized to be particularly useful for exploring phenomena about which little is known [17,18].

Hospital Sites and Participants

From July to December 2017, we recruited 20 emergency medicine professionals (15 nurses and 5 physicians) from 2 sites of a teaching hospital in Ontario, Canada. Eighteen of these individuals had been practicing emergency medicine for at least 10 years. The hospital has 1000 beds with 128,000 ED visits annually. The reported wait times for the hospital's ED were among the worst for the province, and in response to this, in 2013, both sites began a large-scale, Lean-driven, system transformation of their practice environments.

Data Collection

We recruited professionals using an email that was sent to the official, hospital accounts of emergency nurses and physicians by the ED on behalf of our team. To be eligible for participation in this study, a professional needed to have been practicing at the hospital for a minimum of 1 year, beginning no later than a specified date which preceded the ED's planning for the Lean transformation. Nurses and physicians were asked to directly contact EMZ via her official, university email account. Interviews were arranged at a time/location convenient for the professional, and these meetings were audio-recorded for later transcription into verbatim, anonymized documents by a professional service. The department was not informed of participants' identities. Interviews were scheduled for 1 hour, which is consistent with grounded theory [18]. Participants received a Can\$ 20 gift card as an honorarium. Both university and hospital health research ethics boards approved the protocol for this study. Consistent with a realist focus, the interview guide probed the physical structure of the ED, organization of patient flow, individuals' clinical workflow, opportunities for nurses and doctors to collaborate during patient care, and the impetus and planning around the transformation of the ED. Data

collection was organized around a constant comparative process that hallmarks grounded theory [15,16,19].

Data Analysis

After each interview, notes were written about dialogue with the professional, and the interview guide was refined to probe emerging ideas across successive participants. Once a transcript was received from the professional service, its accuracy to the original recording was reviewed. As the interviews proceeded, their transcripts were first coded into categories with the use of MAXQDA software (Version 11.2.5, VERBI Software, Sozialforschung GmbH, Berlin, Germany). We checked on the consistency of coding across 3 team members (EMZ, RB, and LS) for 2 of the transcripts. Coding continued alongside data collection so that new information was compared with existing codes. Through repeated review of the interview transcripts and our evolving coding, we organized categories into themes. Our data collection continued to theoretical saturation of meaning at which point we felt that the amount of information we gathered was sufficient to support our understanding of participants' perspectives and that any additional interviews were not likely to introduce major modifications of our understanding of the data gathered in our study [20,21]. For our study, we sensed theoretical sufficiency after 20 interviews.

Results

Themes

The results of our study illuminated the impact of large-scale, system transformation on emergency medicine nurses and physicians with 3 themes: (1) organization of our clinical work, (2) pushed pace in the front cell, and (3) the toll it all takes on us. In the following sections, we describe the clinical practice environments of the ED both before and after their redesign and our 3 themes in greater detail. As is consistent with grounded theory, we have supplemented our results with anonymized, illustrative quotes from our participants [16]. Quotes with a generic identifier beginning with "N" are from an emergency nurse, whereas generic identifiers beginning with a "P" are from an emergency physician.

The Clinical Practice Environments

Original Model

The original practice configuration of the ED involved a triage area that triaged patients to 3 pods (labeled A, B, and C). Pod A housed patients with the most acute care needs. Less ill patients were triaged to the other 2 pods. Patients requiring major resuscitation, mental health assessment, or special emergency procedures, such as an eye examination, were included in ED spaces outside the 3 pods.

Pod A was configured with 10 beds each spaced with surrounding curtains. A central desk with computers and a departmental, landline telephone was available for use by registered nurses and unit clerks, whereas physicians had a desk area off to 1 side of pod A. Medical supplies for all patient care areas were distributed from a central supply.

In terms of staffing, 2 nurses were assigned for triage duties, 3 to 4 nurses for pod A, and other nurses in the additional care

areas. Aside from overnight hours, 3 emergency physicians attended to patients throughout the ED. Nurses worked in 12-hour shifts and physicians worked in 8-hour shifts. In the event that a nurse was called in for additional coverage in the ED, she/he would work 8 hours. Physicians working overnight in the ED were scheduled for a 6-hour shift. At the end of their shift, it was common for physicians to wrap up patient care on their own time.

Reconfigured Model

In 2013, both sites began an emergency department system transformation (EDST) involving both the reconstruction of their physical environment along with changes made to their patient care processes. The plans for the transformation were developed in collaboration with an international consultant with expertise in Lean health care, front-line staff, and management. The overall goal, and resulting byline, for the transformation was that it would make the ED easier, faster, and better. All patient care areas were reconceptualized into 3 bubbles or cells. Pod A became the front cell and it was split into 3 zones (blue, green, and orange). Each colored zone was equipped with 3 beds and 6 chairs. The physicians, nurses, and learners assigned to each colored zone were allocated portable, battery-operated, computer, workstations on wheels (WOW) clustered around their stretchers. The staff was encouraged to use the WOWs in a standing posture. The unit clerk was situated at a central hub that included a photocopier/fax/printer as well as a landline telephone. Portable phones were assigned to nurses and physicians in each zone. Although supplies were still provided from central supply areas, medical supplies stocked for each cell were reconfigured.

During each shift, the reconfigured ED was staffed with a total of 13 nurses (2 nurses at triage, 1 primary assessment nurse [PAN] and 2 nurses for each of the 5 patient areas across the cells) and 3 emergency doctors (1 assigned to each colored zones in the front cell). In addition, a communications clerk and ED technician would be working with these professionals. In terms of operating schedules, the 3 zones were opened during the day and evening and overnight with reduced staff working in 1 or 2 of the zones depending upon patient volumes and staffing. The number of scheduled hours for nurses' and physicians' shifts in the ED did not change.

Organization of Our Clinical Work

Original Model: Physicians

In the original model, physicians explained that the ED was organized by patient acuity. At triage, an emergency nurse assigned a Canadian Triage Acuity Scale rating to every patient that categorized one's medical priority to be seen [22]. A patient would be brought to their assigned bed by a nurse and would remain there until their point of disposition. Using a computerized boarding system, physicians selected or pulled patients specifically into their care. Physicians were not assigned to a particular pod within the ED, and they would move or float around to provide care.

Even during periods of high patient volume, physicians described that the original ED model allowed them to generate an overall, comfortable cadence of patient flow. This was

primarily afforded through opportunities for physicians' to make one or more strategic patient pulls during their shift. Interviewees explained that, during a given shift, they were able to review the ongoing list of triaged patients and use this list to make decisions regarding the type and number of patients they should pull into their care. By making some strategic patient pulls, doctors perceived that they were able to maximize their clinical efficiency:

We would just kind of do the sickest people first, it'd go to the sickest person, usually by triage code. And sometimes you would do, just for efficiency as well, so if there was a sick person and a not sick person in one of the three rooms, I would often grab two of them. Because one would be quick and one would be longer, but I'd only walk in there once as opposed to twice. What it also gave you the chance to, like, if you saw three sick people in a row and had a lot of things going on, the sensible thing to do is to see that twisted ankle, sew up the finger, in between, so that there's kind of a self-driven load or control the amount. But it also allowed you to, you know, you know you've got 10 minutes so you can call out some of the quick ones and not at the expense of the others. So it was self-driven movement. [P201]

Strategic patient pulls were also used to support the efficiency of other doctors, and participants described using strategies including pulling specific patients into their care so that another colleague was not caring for too many complex patients at one time, and as this participant explained, streamlining your cases to avoid issues at the time of handover for the next doctor coming on shift:

We'd always had an agreement in the last two hours of the shift, that you could clearly go ahead and pick out cases that you felt were likely to be simpler so that you would have to, less likely to hand over those cases. There's really limited utility in seeing somebody 15 minutes before you're supposed to leave. You're just going to have to hand it over right to another person who is basically going to have to start over anyway. [P202]

Moreover, doctors felt that because they were able to float across the 3 pods they were able to band together and support one another by covering for colleagues during their breaks and checking in on another doctor's patient if they were already heading over to a particular pod:

You could say, "There's that really urgent person that just came into bed 2, can you go see that person?" And we would work, the physicians who worked together would work as a team. [P204]

Original Model: Nurses

In the original model, nurses explained that their work was organized by designated bed assignments, that is, during their shift, a nurse would be assigned to a specific block of beds within a pod and it was understood that:

Those were my patients regardless. And if I'm going on break, I have to make sure that there's coverage

for them, and if I have to leave the room. I'm primarily responsible for them. [N106]

Nurses explained that the process of assigning them to bedsides held several advantages to the delivery of patient care. As a nurse was likely to be the first provider a patient encountered in a pod, she/he played a very important role in the critical assessment and monitoring of that individual. As 1 of the nurses explained:

It was good because you could see them from the beginning to the end. You could tell if treatments and interventions were making them better or not having any effect at all. If they're coming in and they're in their worst possible presentation, I need to know if what we have done has helped them. And if it's not, then I need to report that to the physician so we could try something else because it's not working. [N109]

Second, both doctors and nurses asserted that nurses at bedsides often freed up physicians' time, which, in turn, often allowed a doctor to be able to spend more time with other patients or to be able to pull more patients into their care during a shift:

The best part was the continuity of care. So when we're assigned a bed (for the patient), that nurse stayed with them. There weren't multiple handovers and you kind of knew where they were. You could plan your movements in the department knowing they were there. You had a consistent nurse assessing changes, physiologic changes, anything that came up was picked up, the orders were consistently carried out, and you didn't have to worry about that. [P201]

Furthermore, nurses viewed that being with patients throughout their trajectory meant that they had an important opportunity to establish rapport with patients and their families. Nurses were valuable in answering their questions, comforting them, and gaining information from family members that was relevant to the patient's condition:

I find you had more time to speak with patients, the families, getting to know just some little nuances that could tip you off. You had the time to talk with them. I also found you had more time to build a relationship with your patients. [N110]

Finally, nurses perceived that the original configuration afforded nurses working together in a pod to develop a strong sense of camaraderie. In pressing moments, nurses recalled uniting together to work as a team. A nurse recalled what it was like to practice in the pod A of the original model, which was used to treat the most urgent cases:

I liked it. I didn't mind working in Pod A. It was nice, to have people around, to have people helping. Everybody would know what was going on, in a general sense, of all the patients in the Pod A area. Everyone else was right there that could come and help you deal with it at that time. If someone came in with a heart attack, per se, you had them with you the whole time. [N111]

Reconfigured Model: Physicians

During their interviews, doctors perceived that their site had shifted from an acuity-based model to one that was orientated toward maximizing the number of patients their ED sees daily. One of the physicians summed up the new situation as:

Time management was very different than it is now. We are now in a push-forward model. [P200]

The system transformation generated a new staff role in the ED, the PAN whose primary job is to direct patients into a colored zone of the front cell. Once a patient has been directed to one of these zones, the physician will assess the patient. Ideally, this will occur within a targeted period. In the event that a patient requires further assessment and/or treatment, they will be physically moved from the front cell to the middle and/or back areas. Although the patient is still cared for by the same physician after they are moved to another cell, the physician attending is required to begin working with a new set of nurses.

Physicians were frustrated about how the reconfigured model had decreased the level of control they had over their clinical workflow, and therefore, they had less ability now to control the cadence of the ED. Assigning physicians to particular zones of the ED also diminished their abilities to interact and support one another. Rather than be able to float from pod to pod:

In the new system, the physicians are like islands. We do not work with each other. We do in a very minimalistic fashion. [P203]

They also sensed that their department expected more as they were, essentially, now required to see one-third of all the patients that were pushed forward from triage during their shift. An interviewee admitted:

It can be a very overwhelming system to work with because it basically puts all the pressure on you. So, if you are really tied up with someone who's very ill or a very complex patient, then you are constantly, like "Oh my god, I've got these other patients that are mine that no one else is going to see them. [P202]

Given that patient flow was delegated to the discretion of a PAN, interviewees noted that their ability to make strategic patient pulls was diminished, and as a doctor who was interviewed noted, the PAN did not always understand why an attending would want, or even request, that they not be given several complex patients within a short period:

In the old model, I had more choice over who I was going to see. You could allot your time easier and pick the patients you wanted to see. You don't want a PAN nurse to give you five critically unwell patients in a row. You want them to put in a few easier ones to help you with your flow of patients and sometimes they don't do that, they keep putting them in. [P200]

Finally, physicians highlighted that being assigned to a particular zone did not mean that they would remain stationary during a shift. It was common for an attending to move back and forth, and even repeatedly so, within and between the front, middle, and back cells. A variety of examples were given of why they needed to do this including moving back and forth between

front and middle cells to check on several patients, needing to retrieve medical supplies, changing out a dead battery on a WOW, and needing to move a patient out from a chair in the front cell so that they could speak with the individual in a more private manner.

As a participant explained, some doctors perceived that the reconfigured model had diminished the overall role of the physician in the ED because:

Emergency physicians are used to multi-tasking. We're used to a busy environment. We're used to an unpredictable environment. But what we're not used to is not having control with regard to how we manage our environment. And that is the salient difference. It's taken the complete autonomy and leadership quality that a physician provides in the emergency department completely out. So now we come to work and you're just assigned a little zone and a little box and you're told what to do. [P203]

Reconfigured Model: Nurses

Nurses also perceived that the reconfigured ED diminished their opportunities for collaboration. First, the new configuration relies on fewer nurses to provide care, and if fully staffed, there are 2 nurses working within a cell. However, as participants explained, in situations such as when a nurse calls in sick for their shift, the individual may not be replaced by another colleague:

So, yeah, sometimes there are two nurses, but a lot of times, particularly on nights, there's now one. Sick calls have gone through the roof, so, like, Saturday night they were five nurses short, last night there was three. So we find ourselves working with one nurse. [P201]

Second, nurses noted that aside from times of patient handover, there could be little, if any, interaction among the nurses practicing in other cells:

You interact very differently because now you are assigned to a cell. You're focusing on the cell. You're not focusing on if you're one cell and just the way the cells are. Your back is turned towards one cell and you don't know what they're doing, you don't know if they need help. But you can't help them either because you're working at a cell and you might have one to two doctors, you might have residents and if you're short staffed you're now working in the cell by yourself. [N103]

Opinions were split amongst nurses and physicians about the impact of the reconfigured ED on the quality of nurse-doctor interaction. Some doctors felt they had better opportunities to establish a working rapport with nurses in the new model, whereas others expressed they worked better with nurses in the original configuration. Although nurses generally acknowledged that it was easier to keep track of an attending in the reconfigured ED, it did not necessarily mean that you would be working collaboratively with them.

Some nurses felt that the reconfigured ED increased the power differential between nurses and doctors:

It now means that it's one physician, he's like, "Dah, dah, dah," so now you're his robot. "Do this, do this, I need that, you need to go give that, you need to do this." [N108]

Nurses asserted that, by pushing all patients through the front cell, the new configuration had fundamentally changed the nature of their duties. Nurses working in the front often carried heavier workloads, involving more physical work. As this interviewee explained:

I would say work for nurses, to give you an idea, in the new model, where most of the blood work, IVs and everything else is all done in the front bubble. Every patient is seen in the front bubble. And I'm not saying that middle and back bubbles are easy to work, but at the same time, I wouldn't say you're doing as much work in those areas. So, physical work-wise, definitely there's a lot more imbalance. I would say that would be the main thing, is that, in the older system, there was a lot more equalization. [N114]

Moreover, nurses viewed that the redistribution of physical work to the front cell, in turn, diminished the purpose of a registered nurse in the reconfigured ED away from being a key actor involved in ensuring continuity of care.

Pushed Pace in the Front Cell

Although interviewees noted there were times when the reconfigured ED worked well to meet patient demands, there were times that both sites struggled with high patient volumes:

Some days I feel like there's a bus that drops them all off at the same time. That's what it feels like. It's every day. It's not weekends. It's every day. [N112]

Doctors and nurses viewed factors that were contributing to ongoing patient volume pressures included the sites receiving greater numbers of complex cases including those transferred from smaller communities along with increased demand for mental health and addictions treatment:

Acuity-wise, I am finding patients are sicker, in general. There are fewer beds [everywhere], so people are sicker before they come into the hospital, and also just the sheer numbers. We are averaging 200 to 230 patients in 24 hours. [N110]

During times of high patient volume, interviewees were aware that the reconfigured ED model emphasized flowing them through:

We've got to get people moving. We've got to do this. We've got to do that. There's push from all over. There's push from the physicians in the front. There's push from management. There's push from PAN or charge nurse, either one. Keep it moving. Keep it moving. [N113]

The front cell was identified as the primary area where professionals experienced the brunt of the impact of high patient volume. Although a PAN was viewed as being involved in the

ongoing flowing of patients, some interviewees perceived the role as being one that did not require the same skill set as the other registered nurses in the ED:

[Role of a PAN] Is to push them and to keep them going and keep the flow. One of our co-workers said, "a monkey could do that job." [N109]

The PAN nurses, they call them primary assessment, but they don't really do it. It's us, but they're the ones who are pushing. [N108]

Several participants recalled incidents during which they served as a PAN in the front or they interacted with one that involved tension with other staff:

For me, I like to go and talk to everyone face-to-face. And I'll say, "I'm PAN nurse today." And some people roll their eyes because I'm a mover, organizer, shaker, and I do the rob Peter to pay Paul. I'll move and shuffle people like a Jenga. [N112]

Push the pace. And you'll say to the PAN nurse, "Can you just give my zone a 10-minute reprieve? I have a bunch of reassessments to do and then I really need to go eat something." And they'll still fill your beds up because they were told by management that they needed to continue to fill beds up. [P204]

Professionals perceived that a crowded ED amplified the challenges that the new configuration already introduced to their clinical work. First, there were capacity issues associated with flowing all patients through the front. As a nurse who was interviewed counted, the front cell typically contained a minimum number of people that would need to be working within that space:

You used to have, you know [in the old model], if you had three physicians on, there might be two people seeing a patient in Pod B, and there might have been one doctor seeing a patient in Pod C. There might not have been anyone in Pod A, which is where the front bubble is now. But everybody now, there is one doctor per each cell they could have upwards to three learners. If the two nurses are there, which is great, there are two nurses, so that could be five to six people per area. So you're upwards to 18 to 20 people before you're even involving the patients, in that area. [N105]

Add to this mix, patients and any family members that may have accompanied them to the ED and the front became very congested:

It's like a hornet's nest. It's the best way to describe it. [N110]

As the ED filled, so did the need to keep moving patients around the ED. Interviewees asserted that figuring out where to move patients could be complex and time-consuming:

We're always behind. We can't keep up and whereas, previously, we really could. So, it's like this constant Rubik's Cube. Like, move this person here and move that person there. And it's like never-ending. You could be moved around several times because of the

fact that there is somebody else competing for your stretcher who is iller than you. And then, it's eventually deemed, okay, you can't have a stretcher anymore, you've got to sit in a chair. [P202]

Participants recalled being interrupted more, struggling to keep up with what needed to be done for their patients' care, and often feeling overwhelmed while working. In a crowded front cell, some nurses also admitted that their clinical workflow could become very fragmented to the point that they could not complete everything to the standard they desired:

What happens often too I find is that there is a lot of pressure to get these people in and be seen that they just bring them all in. Charts get disorganized. There's no kind of methodical movement to all of this stuff because "Oh, this person needs this and that." They may need that done, but the policy procedure as far as nurses go, they need vitals after. They might need to be fully disrobed. You need to listen to a chest. There are all these little bits that have to occur based on standards of care that don't always happen in this environment because of the movement of people so quickly. [N103]

On a similar note, some physicians recalled moments in the front when they needed to be more vigilant about what nurses were doing (and not doing). During times when they sensed a nurse could actually miss an order, they needed to make an effort to verbally push that nurse more to ensure that the work was actually carried out. As a doctor explained:

I've had to change my practice in the bubble to say, "Do not move that person until this, this, and this are done." Because if I don't do that I will go to a room two hours later, three hours later, and things aren't done. [P203]

Participants noted that during periods of high volume, eventually, patient movement would stop due to bottlenecks in the front cell or the hospital had become bed-blocked, meaning that the number of patients requiring admission had exceeded the number of beds that were available.

The Toll This All Takes On Us

Participants admitted that working in the front cell was often a stressful experience that impacted them physically, cognitively, and emotionally:

We are in an area where it is so high stress that sometimes...last night we had a [complaint anonymized] case come in. I've been there for [number anonymized] years and I felt like I was going to have a panic attack. That's the kind of environment. It is stressful, stressful, stressful. [N114]

I just find most shifts I just keep my head above water. Like, you feel like you're drowning constantly. [N105]

Interviewees identified several conditions of their working environment including the constant movement required from doctors and nurses in the front cell during patient care, difficulty finding the time and place to take a nutrition break during a

shift, and being required to stand for long periods often resulted in doctors and nurses feeling very physically fatigued:

Our legs are tired. Every nurse, guys and girls alike, even the docs, we're all wearing the compression stockings. Before we had chairs where we could sit down and chart. Now we're standing up at the computer doing our charting. You're standing your full 12 hours. [N112]

Professionals also recalled moments where they felt cognitively overextended. During these times, they described having difficulty maintaining attention, needing information to be repeated to them, forgetting patient names, second-guessing whether they had completed a task fully (or not), and using moments where they used a more menial task, such as retrieving supplies, as an opportunity to take a cognitive respite. Moreover, some interviewees admitted that to try to cognitively decompress after working a shift in the ED, they needed to be socially isolated for some period from family and friends:

It's just sensory overload. You're constantly, in the front bubble, you're constantly being pushed to get patients in, get patients out, get patients in, and get patients out. For me, and this doesn't happen all the time, so I don't want to paint a bad picture, but I shouldn't go home so mentally tired that I don't want to socialize with people. [N102]

Some days you physically feel fine, but, mentally, you are drained. And it's because you have ninety patients' information running through your mind. [N101]

Most interviewees recalled incidents where they had been on the receiving end or witnessed moments of pushback from patients to staff (and vice versa). These incidents were difficult to experience and witness, and most times, these events seemed to catalyze from patients' frustration with wait times:

We [the general public] don't seem to control our tempers anymore. We [the general public] don't seem to control our outlets. We [the general public] want instant gratification, we [the general public] want this and they get angry and they feel it's acceptable to become angry, yelling, threatening to hit. Lives have been threatened in the emerg. You hear some events that have happened and the nurses are becoming angry at the patients as well. [N108]

Overall, participants sensed that colleagues' morale had declined at work and, as evidenced by the following statements, showing awareness of colleagues that were contemplating leaving their position at their site or had recently quit their job:

Of the heavily trained people, the people that I perceive as the strongest up-and-comers, a lot of them are peeling off. [P201]

I don't know where it's heading, but I just know that something has to change because we're going to lose more. At least, from a nursing aspect, we're going to lose more. I have been in this department for (number anonymized) years. I love emergency medicine but I

hate what is happening. Five years ago, I wouldn't have even looked at the job board to get out. [N110]

Discussion

Principal Findings

Emergency medicine is a highly complex medical discipline characterized by fast pace, interruptions, multitasking, overcrowding, and unpredictability [23-29]. Although the EDST was supposed to make the ED work easier, faster, and better, the participants in our study described that the Lean-driven changes made to their practice environment, most especially with the design of the front cell, had the opposite impact.

Physicians and nurses spoke about how assigning them to work within the front cell fundamentally disrupted routine patterns of how they interacted with patients and with each other. Doctors noted that despite the responsibility they held within the reconfigured ED, they had diminished autonomy over their work. The physicians in our study found it especially disruptive to have reduced opportunities over the course of their shift to plan and execute as many strategic patient pulls as they judged necessary. This should not be surprising given that Kovacs and Croskerry [23] posited that the most important type of information used by emergency physicians in their clinical decision making relates to their patients' acuity, and moreover, that Schubert et al identified time management as one of the defining features [29] that distinguishes expert emergency physicians from novices. By limiting their ability to make strategic patient pulls, the ED was unintentionally disrupting physicians' ability to exercise their professional expertise. Therefore, any moments of tension between PAN and attending, where a physician requests that patient flow be slowed (or even halted), are very likely important signals of physicians' heightened situational awareness. Moulton et al [30-32] observed that surgeons often experience transitional moments during patient care when they feel the need to slow down. These transitions may be routine or unplanned and can result from factors including recognition of the need to deal with distractions and sensing one's fatigue. Moulton asserts that slowing down is the "crucial part of expert surgical judgment, and failing to transition during critical moments may lead to medical error and patient harm" [31]. Given that physicians recalled moments where they felt they needed to slow down patient flow for reasons similar to that observed by Moulton, rather than continuing to push the pace, we suggest that the ED should reframe these requests as important opportunities for assessment of potential risks. Future exploration of the potential relationship of emergency physicians' strategic patient pulling and requests to slow down patient flow with expert physicians' judgment and distributed cognition is warranted.

Although a nurse may still be the first provider whom a patient encountered within the front cell, the quality of that nurse-patient interaction may have shifted significantly. The nurses who participated in our study did not indicate that their department had intentionally restricted their involvement in certain clinical activities, but they did perceive that they held diminished value within their department after the reconfiguration of the ED. Nurses viewed that the front cell required less use of their critical

assessment skills, they were less involved in monitoring patients, were being pushed toward carrying out more general tasks that often involved physical work, and they had fewer opportunities to develop a rapport with patients and their families. Although some physicians perceived their working relationship with nurses had improved after the reconfiguration, nurses did not share this opinion. Nurses felt they had fewer opportunities to collaborate with physicians and, compared with the original model, they were now working less with physicians and more for them. In the United Kingdom, intentional narrowing and standardization of workers' duties under Lean has been associated with deskilling of taxation civil servants [33] and automotive manufacturing employees [34]. We found that the PAN, a role that was directly borne out of the EDST, was viewed by some professionals as being a position that did not draw on the same skill set as required by other registered nurses within the ED. This observation taken together with other above-mentioned perceptions of nurses' work suggests that some unintentional deskilling may have been introduced in the ED with Lean. As such, the relationship between clinical workflow redesign and deskilling of nurses requires further attention.

An argument can be made that as emergency medicine is highly complex, by definition, the clinical work performed by its nurses and doctors will always be intense. That being said, the acceleration of patient flow to the front cell appeared to further ramp-up the existing pressures faced by health care professionals in the ED. The participants in our study described how several years after their department underwent a Lean redesign, their clinical workloads were intensified. They reported greater pressure to keep patients flowing, spent time moving patients around the front cell, were more likely to be interrupted while working, carried out more menial tasks that added to their workload, and were not always confident that their work was completed to the desired standard. They also admitted feeling emotionally and physically exhausted, noted more of their colleagues requested sick time away from work, were aware of incidents of tension between colleagues and patients, and knew that other professionals had already or were contemplating leaving their jobs. It has been estimated that at least 60% of emergency medicine physicians and nurses have experienced symptoms of burnout syndrome [35-37]. Although we are unable to estimate the prevalence of symptoms in our study, the ways in which our participants described how their work impacted them physically, cognitively, and emotionally suggest that they are at risk for developing burnout syndrome. Similar to the results of Hung et al, we did not find that Lean redesign mitigated levels of job-related stress perceived by nurses and physicians [9]. Unlike these authors, we did not find that our participants were more engaged and more satisfied with their work after the reconfiguration of their practice environment. Our findings suggest that the ED revisits and re-evaluates its

Lean-informed design of the front cell including its relationship with work intensification, workplace stress, and worker burnout.

Lean has been described as a quality improvement approach that depends on worker engagement and input [3,4]. Although in this study we have not addressed our participants' conceptual understanding of Lean or their involvement in the planning and implementation of the ED's reconfiguration, we did not sense any unwillingness from them to try to ensure that the intervention was successful for their department and hospital. Rather, despite the ergonomic challenges they faced, our interviewees seemed to be quite passionate about their work and commitment to patient care. It is unclear, at present, how the perceptions of the nurses and physicians who deliver patient care in the reconfigured ED resonate and align with what hospital management expected the intervention would achieve. Future exploration of what constitutes success in Lean-driven health care is warranted.

Limitations

As our study involved 2 sites of a single teaching hospital, its findings are representative of our local context. Further research into the impact of Lean health care on the clinical work of nurses and physicians practicing in other emergency medicine departments and in other medical settings is necessary to explore the transferability and resonance of our findings.

Conclusions and Implications

To our knowledge, this study is the first grounded theory regarding the impact of Lean on the working conditions and actual work of emergency nurses and physicians. We theorize that rather than support health care professionals in their management of the complexities that characterize emergency medicine, the physical and process-based changes introduced by the Lean intervention acted to further complicate the environment under which they delivered patient care. Our research has illuminated some unintended consequences associated with accelerating patient flow on the clinical workflow and perceived well-being of health care professionals. Nurses and physicians described several ways in which the new model disrupted their established practice routines and resulted in the intensification of their clinical work. Participants also identified indications of the deskilling of nurses' work and how the new, push-forward model of patient care had detrimental impacts on their physical, cognitive, and emotional well-being. On the basis of our findings, we advocate for future exploration of the relationships between emergency physicians' use of strategic patient pulls and requests to slow down patient flow with expert physicians' judgment and distributed cognition, clinical workflow redesign, work intensification and deskilling, and Lean health care and burnout symptoms experienced by nurses and physicians.

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Authors' Contributions

EZ conceptualized the study, interviewed participants, and was the primary data analyst. LS and RB provided feedback on the interview guide and reviewed ongoing data analyses. EZ wrote the draft manuscript, and all the other authors contributed edits and feedback toward the final version.

Conflicts of Interest

None declared.

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Abbreviations

ED: emergency department
EDST: emergency department system transformation
PAN: primary assessment nurse
WOW: workstations on wheels

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Original Paper

An Optimization Program to Help Practices Assess Data Quality and Workflow With Their Electronic Medical Records: Observational Study

Mavis Jones¹, PhD; Reza Talebi¹, MSc; Jennifer Littlejohn¹, BA; Olivera Bosnic¹, BA; Jason Aprile¹, MA

OntarioMD, Toronto, ON, Canada

Corresponding Author:

Mavis Jones, PhD

OntarioMD

Suite 900

150 Bloor Street West

Toronto, ON, M5S 3C1

Canada

Phone: 1 4166231248 ext 5388

Email: mavis.jones@ontariomd.com

Abstract

Background: Electronic medical record (EMR) adoption among Canadian primary care physicians continues to grow. In Ontario, >80% of primary care providers now use EMRs. Adopting an EMR does not guarantee better practice management or patient care; however, EMR users must understand how to effectively use it before they can realize its full benefit. OntarioMD developed an EMR Practice Enhancement Program (EPEP) to overcome challenges of clinicians and staff in finding time to learn a new technology or workflow. EPEP deploys practice consultants to work with clinicians onsite to harness their EMR toward practice management and patient care goals.

Objective: This paper aims to illustrate the application of the EPEP approach to address practice-level factors that impede or enhance the effective use of EMRs to support patient outcomes and population health. The secondary objective is to draw attention to the potential impact of this practice-level work to population health (system-level), as priority population health indicators are addressed by quality improvement work at the practice-level.

Methods: EPEP's team of practice consultants work with clinicians to identify gaps in their knowledge of EMR functionality, analyze workflow, review EMR data quality, and develop action plans with achievable tasks. Consultants establish baselines for data quality in key clinical indicators and EMR proficiency using OntarioMD-developed maturity assessment tools. We reassessed and compared postengagement, data quality, and maturity. Three examples illustrating the EPEP approach and results are presented to illuminate strengths, limitations, and implications for further analysis. In each example, a different consultant was responsible for engaging with the practice to conduct the EPEP method. No standard timeframe exists for an EPEP engagement, as requirements differ from practice to practice, and EPEP tailors its approach and timeframe according to the needs of the practice.

Results: After presenting findings of the initial data quality review, workflow, and gap analysis to the practice, consultants worked with practices to develop action plans and begin implementing recommendations. Each practice had different objectives in engaging the EPEP; here, we compared improvements across measures that were common priorities among all 3—screening (colorectal, cervical, and breast), diabetes diagnosis, and documentation of the smoking status. Consultants collected postengagement data at intervals (approximately 6, 12, and 18 months) to assess the sustainability of the changes. The postengagement assessment showed data quality improvements across several measures, and new confidence in their data enabled practices to implement more advanced functions (such as toolbars) and targeted initiatives for subpopulations of patients.

Conclusions: Applying on-site support to analyze gaps in EMR knowledge and use, identify efficiencies to improve workflow, and correct data quality issues can make dramatic improvements in a practice's EMR proficiency, allowing practices to experience greater benefit from their EMR, and consequently, improve their patient care.

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KEYWORDS

chronic disease; electronic medical records; primary care; quality improvement

Introduction

Electronic medical record (EMR) adoption among Canadian primary care physicians has grown steadily; 75% now use EMRs, with some provinces—including Ontario—reporting adoption rates >80% [1]. Compared with paper-based practices, EMR-based practices show substantial improvements in population health management [2]. Research investigating the implementation of meaningful use criteria associated with the Health Information Technology for Economic and Clinical Health Act in the United States furthers the argument that care improvements require advanced EMR use. Studies on the quality of diabetes and cancer care in that context suggested that primary care practices need support to redesign work processes with population health management targets in mind [3-6].

However, the benefits of an EMR for patient care and population health cannot be realized unless practices become proficient [7,8], and studies have indicated that practices approaching EMR implementation as a complex change management project would have the greatest success [3,9]. Even in terms of practice management, supports such as workflow optimization [10] and resolution of workarounds [11] are necessary to help a practice realize the full benefit of their EMR.

In Ontario, community-based physicians using a certified EMR have access to OntarioMD's EMR Practice Enhancement Program (EPEP). The program deploys consultants who provide on-site analysis of a practice's current EMR proficiency, identify their priorities, and provide recommendations for concrete steps to achieve them. The EPEP was established in early 2016, and at the time of writing this paper had provided in-person support to >1000 clinicians and practice staff.

Methods

Electronic Medical Record Practice Enhancement Program

The EPEP is available to all community-based physicians using a certified EMR in Ontario, at no fee, and is promoted to physicians through health care sector conferences and services provided by OntarioMD (eg, regional field staff members who help physicians connect with provincial and local health care information systems). Clinicians often present to the EPEP with the knowledge that their EMR can help them with quality improvement projects but requiring additional knowledge or support on how to get the most from this tool.

Electronic Medical Record Maturity Model

A foundation of the EPEP method is the EMR Maturity Model (EMM) [12]. The EMM was developed in line with international

best practices for measuring the EMR proficiency (eg, the Healthcare Information and Management Systems Society Electronic Medical Record Adoption Model [13]) and validated through engagements with clinical practices. It articulates 6 levels of proficiency ranging from paper-based to fully digital (Figure 1).

Electronic Medical Record Progress Assessment

The EMM provides the foundation for the EMR Progress Assessment (EPA) [14], an Web-based self-assessment tool that allows EMR users to identify their level of proficiency in the functional areas of Practice Management, Information Management, and Diagnosis and Treatment Support, and corresponding key measures (Figure 2).

The EPA is available over the Web [14] to any EMR user who wishes to conduct a self-assessment but is also used within the context of an EPEP engagement. Consultants administer the EPA to assess a practice's baseline maturity level for each key measure a practice has identified as a priority. Consultants similarly conduct a data quality review (DQR) to establish a baseline for data completeness in areas directly related to the priority key measure (eg, assessing whether blood sugars are recorded for people with diabetes, as associated with complex care/chronic disease management). These baselines and a clinic workflow analysis help consultants develop a diagnostic profile and generate recommended actions targeted at the practice's goals.

Electronic Medical Record Practice Enhancement Program Engagement

Generally, an EPEP engagement consists of the following:

- *Current state assessment* using the EPA and a gap analysis to help the practice identify priority areas for improvement;
- *Analysis of data quality and workflow* to determine causes of data discrepancies and establish baselines for specified clinical measures and identify ways to improve the efficiency of workflow;
- *Customized action plan* development that provides concrete, achievable tasks designed to improve data quality in identified practice priority areas and overall practice management;
- *Postengagement evaluation* using the EPA to measure EPEP-driven improvements in EMR data quality and proficiency; depending on the amount of work required in the action plan, postengagement evaluation can be done at 3 or 6 months postbaseline (and again at 12 months to assess the sustainability of improvements).

Figure 1. OntarioMD's electronic medical record maturity model. EMR: electronic medical record.

Level	Criteria	Capabilities
5	INTEGRATE	Use of portals, hubs, attachment to provincial e-health platforms sharing data from the EMR.
4	POPULATION DATA USE	Dashboard of whole populations, acting upon the whole, performing population analysis at the practice level.
3	LOOK AHEAD / PREDICT	Reminders and alerts are used at the point of care. Searches are done regularly and scheduled for review.
2	EARLY DATA USE	Acting upon the output of episodic searches, quick entry tools, forms, calculators, etc.
1	ENTER DATA	Documentation occurs electronically. Progress notes, forms, and other documents are entered into the EMR.
0	PAPER	Processes are primarily paper-based.

Figure 2. Functional areas and key measures on the EMR (Electronic Medical Record) Progress Assessment.

PRACTICE MANAGEMENT	APPOINTMENT SCHEDULING PRACTICE BILLING COMMUNICATION & MESSAGING
INFORMATION MANAGEMENT	ENCOUNTER DOCUMENTATION DATA QUALITY & NOMENCLATURE CONSISTENCY DOCUMENT MANAGEMENT
DIAGNOSIS AND TREATMENT SUPPORT	RESULTS MANAGEMENT REFERRAL & CONSULTATION TRACKING PREVENTION & SCREENING COMPLEX CARE

EPEP consultants tailor their approach according to each practice's unique characteristics, priorities, and pain points. Each consultant in the program is asked annually to provide a detailed account of one engagement they identified as demonstrating typical challenges faced by primary care practices and how the EPEP method was customized to the practice's priorities. (Note: the collection of data at the baseline and post encompasses, at least, a year to assess the sustainability of the change, and the program had celebrated its second anniversary at first writing; these examples were selected from a limited cohort, and we look forward to providing further examples in future as the cohort grows.) Three of the authors of this paper (RT, JL, and OB) are consultants who developed the first 3 examples. They selected these from their engagement roster for their distinct priorities and problems, as well as their ability to reflect common challenges. In this paper, we provide a high-level description of the approach taken by consultants, the engagement's timeline, and additional actions prescribed and taken. The success of any engagement is typically measured by progress against multiple indicators; for this paper, we limit the

discussion to indicators on priority areas shared by all 3 practices (and, indeed, representative of primary care practice priorities). Please note that as an artefact of data collection procedures over time, not all n values were available. We elected to omit all for consistency's sake. Requests for more information can be directed to the corresponding author.

Finally, in the discussion section, we contextualize these examples within the larger cohort of EPEP-assessed maturity data, consider limitations to the EPEP approach and our analysis, and discuss next steps for assessing the impact of the program over time.

Results

Practice 1

Current State Assessment and Priorities

An EPEP consultant met with Dr. A at Practice 1 in April 2016 to discuss his EMR concerns. The physician identified concerns with the amount of time it was taking to search for certain

information on a patient such as test results and prior examinations for chronic conditions.

Data Quality Review and Workflow Analysis

To review the quality of data captured within Dr. A's EMR, the consultant ran queries on (1) roster size; (2) preventive care coverage; (3) the number of diabetic patients based on the diagnosis code; (4) the number of diabetic patients based on the diagnosis noted in the problem list; (5) patients with glycated hemoglobin (HbA_{1c}) >7 without a diagnosis in the problem list; (6) the number of diabetic follow-up visits based on the billing code; and (7) the smoking status based on the notation in the risk factor section of the cumulative patient profile (CPP).

The consultant's data analysis revealed that the documentation captured in the EMR was not accurately reflecting Dr. A's provision of care. For example, there were 44% more patients with a diabetes diagnosis in the problem list than were billed for diabetic visits. Moreover, 9 patients with high HbA_{1c} did not have a diabetes diagnosis indicated in their problem list and showed insufficient clinical visits in the log.

The consultant documented clinic workflow processes, using participant observation, interviews, and activity diagrams. Interviews revealed an onerous workflow problem preventing Dr. A from using the EMR's diabetic flowsheet feature. The clinic was not receiving laboratory results through the EMR, relying instead on paper, scans, or faxes. As a result, diabetes notes were being manually recorded in the record's chart section. Dr. A's clinical documentation was precise and accurate, but searching for patients' information during visits was inefficient.

Action Plan

The EPEP consultant presented Dr. A with their findings from the DQR and workflow analysis and proposed the following action plan:

1. Follow-up with the EMR provider to address technical issues in the transfer of laboratory results.
2. Periodically run and review a cumulative preventive care report.
3. Periodically run reports on patients due for screening or diabetic follow-ups, to ensure critical procedures are tracked.
4. Focus on recording diagnosis in the problem list section.
5. Adopt and adhere to the agreed nomenclature to ensure accuracy of reminders and reports.

Postengagement Evaluation

Dr. A executed the action plan, and the consultant provided coaching and reviewed progress. The laboratory interface issue was resolved quickly, and a staff member was assigned to handle the manual download still required for one provider. Dr. A began running diabetic population reports to compare diagnoses and billings. The practice updated charts to resolve discrepancies, reviewed reminders and added new ones, and retooled their workflow to contact diabetic and other patient populations proactively.

With better control over his workload, Dr. A began scheduling follow-ups for screening and diabetes care and set up access for

this patient population to self-care supports like nutritional counseling.

In December 2016, the consultant conducted a follow-up review with Dr. A, and postengagement figures were compared with the initial DQR (Table 1).

All indicators are evidence of a positive change in the completeness of documentation, from the most dramatic (cervical cancer screening) to the least (smoking status captured).

Practice 2

Current State Assessment and Priorities

In June 2016, EPEP consultants met with 4 physicians—Drs. B, C, D, and E—working in a group practice, who had been using their EMR for several years. The practice was motivated to engage with the EPEP through a desire to ensure they were providing high-quality care to their patients, including preventive services such as screening.

Data Quality Review and Workflow Analysis

To review the quality of data captured within this practice's EMR, the consultants ran queries on (1) roster size; (2) preventive care coverage; (3) the smoking status based on the notation in the risk factor section of the CPP; (4) the number of patients prescribed diabetic medication with the diabetes diagnosis in the problem list; (5) the number of patients with suspected diabetes based on the HbA_{1c} count with the diagnosis in the problem list; and (7) the number of diabetic follow-up visits based on the billing code.

The DQR revealed variances in each physician's roster. Investigating further, they found that the clinic had not been aware of the roster capitation reports available from the Ministry of Health and Long-Term Care (MOHLTC) as a resource to monitor enrolled patient populations. The consultants inferred that roster variances were also causing inaccuracies in the reports the clinic generated to identify subpopulations for targeted interventions and confirmed this in reviewing the practice's preventive care data.

In addition, the DQR showed that the smoking status was not consistently recorded in the CPP, and not all diabetic patients were identified as such in the problem list (despite the presence of diabetic billing codes or diabetic medications prescribed).

Action Plan

Consultants met with each physician to review their DQR and current workflows and proposed the following action plan: (1) request MOHLTC roster reports; (2) reconcile roster data; (3) review preventive care data post roster reconciliation; (4) develop prevention and screening management protocols; (5) complete the smoking status in CPP for all patients; (6) onsite and remote coaching on monitoring and tracking diabetes billing codes; and (7) the implementation of a diabetic toolbar within the EMR.

Using the MOHLTC roster reconciliation report, the consultants identified roster discrepancies ranging in variance from 11% to 33%. Keen to improve, the physicians agreed to work on all

recommendations to improve roster reconciliation, preventive care screening, and diabetes management.

Postengagement Evaluation

After approximately 6 months of work on improving their data quality, the practice reengaged with the consultant to work on

prevention and screening and chronic disease management. Pre- and postengagement assessed figures for data quality against these indicators, for each clinician's patient population, are shown in [Tables 2-5](#).

Table 1. Postengagement data quality review—Dr. A.

Data quality indicator	Pre-engagement (May 2016)	Postengagement (December 2016)
Breast cancer screening, %	61.00	65.00
Cervical cancer screening, %	44.29	65.83
Colorectal cancer screening, %	48.79	61.81
Smoking status captured, %	61.35	61.36
Patients with high glycated hemoglobin without diabetes on the problem list, n	10	1

Table 2. Postengagement data quality review—Dr. B.

Data quality indicator	Pre-engagement (June 2016)	Postengagement (May 2017)
Breast cancer screening, %	51.97	53.97
Cervical cancer screening, %	49.00	60.00
Colorectal cancer screening, %	35.00	35.02
Smoking status captured, %	2.01	17.02
Patients with high glycated hemoglobin without diabetes on the problem list, n	65	13

Table 3. Postengagement data quality review—Dr. C.

Data quality indicator	Pre-engagement (June 2016)	Postengagement (May 2017)
Breast cancer screening, %	64.01	70.00
Cervical cancer screening, %	61.02	68.98
Colorectal cancer screening, %	38.03	41.97
Smoking status captured, %	3.00	18.98
Patients with high glycated hemoglobin without diabetes on the problem list, n	63	20

Table 4. Postengagement data quality review—Dr. D.

Data quality indicator	Pre-engagement (June 2016)	Postengagement (May 2017)
Breast cancer screening, %	50.99	55.98
Cervical cancer screening, %	48.00	58.00
Colorectal cancer screening, %	39.03	45.99
Smoking status captured, %	16.03	29.96
Patients with high glycated hemoglobin without diabetes on the problem list, n	4	7

Table 5. Postengagement data quality review—Dr. E.

Data quality indicator	Pre-engagement (June 2016)	Postengagement (May 2017)
Breast cancer screening, %	62.99	67.99
Cervical cancer screening, %	65.01	72.99
Colorectal cancer screening, %	34.99	43.99
Smoking status captured, %	47.01	48.99
Patients with high glycated hemoglobin without diabetes on the problem list, n	142	55

As shown, data quality improved against most indicators for all clinicians. The level of improvement depended in part on the baseline assessment. For example, the smoking status was a significant improvement for Drs. B, C, and D. However, Dr. E already had a comparatively high rate of capture for smoking status. Similarly, where the direction of change was opposite from expected—namely, Dr. D's patients with high HbA_{1c} without diabetes on the problem list—this is still the result of improvement in overall data quality. Notably, identifying the problem allows the practice to correct it.

Consultants continued to coach this group on optimizing their EMR use. They developed and implemented a diabetic toolbar to assist with data entry, display a chronic disease management flowsheet, and provide appropriate information at the point of care. Together with the practice, they implemented a preventive care window and smoking status toolbar to streamline information capture.

Practice 3

Current State Assessment and Priorities

An EPEP consultant met with Dr. F in January 2016. The practice acknowledged they were not consistently entering data into the EMR and recognized that improving data quality and the consistency with which they entered data would help the practice measure the quality of care they provided. In addition, they were looking for guidance on changes to the MOHLTC's reporting requirements and how to be better prepared for them.

Data Quality Review and Workflow Analysis

Based on discussions with Dr. F, the consultant focused on reviewing EMR data associated with preventive care screening and diabetes. The data collection was completed in May of 2016, during which time the consultant conducted EMR queries and produced reports on (1) preventive care; (2) the number of diabetic patients (based on diagnosis code 250); (3) the number of diabetic patients (based on diagnosis noted in the problem list); (4) patients with the last eye exam recorded; and (5) the smoking status (based on the notation in the risk factor section of the CPP).

The consultant conducted interviews with Dr. F and staff to better understand practice workflow and the role of the technology in their clinic to help address their issues.

Action Plan

In April 2017, all findings were presented to Dr. F and the clinic manager; as in other examples discussed here, the consultant proposed action plans focused on “quick wins” to improve data quality:

- Review rules for reminders; remove unnecessary ones, and add missing ones (coaching provided).
- Ensure the completion of required activities when a reminder becomes active.
- Periodically run and review a cumulative preventive care report.
- Implement a reminder to capture smoking status in risk factors if none is there (patients aged >15 years).
- Periodically run reports on patients due for screening or diabetic follow-ups.
- Enhance existing Diabetic Stamp to capture data in the EMR.
- Implement a diabetes prevention window showing summary of lab values.

Postengagement Evaluation

In this engagement, 2 baselines were collected—in March 2016, and again in June of that year after some initial data quality work. Owing to unforeseen factors (a new physician joined, entailing a data migration that interrupted the course of the engagement), the consultant was able to follow the practice for a longer period than is typical for the EPEP. Table 6 shows the improvement in data quality from the first baseline to the final assessment.

As this was one of the first EPEP engagements, this engagement provides the best picture of the sustainability of an EPEP-driven change. At the first assessment taken 6 months after the engagement began, we observed improvements in all areas; however, an even greater improvement in data quality is observed more than a year later, as the clinic had implemented recommendations and demonstrated their ability to sustain, and improve upon, the change.

Following the engagement, Dr. F reported increased efficiency in his clinic's workflow and confidence in the quality of his EMR data. He believes he is seeing a benefit to his patients from these improvements. He encouraged other physicians in the group to engage with the EPEP, which they did.

Table 6. Postengagement data quality review—Dr. F.

Data quality indicator	Pre-engagement (January 2016)	First assessment (June 2016)	Postengagement (September 2017)
Breast cancer screening, %	66.00	67.00	76.00
Cervical cancer screening, %	59.30	62.00	69.00
Colorectal cancer screening, %	14.70	16.00	23.00
Smoking status captured, %	46.00	60.00	85.00
Patients with diabetes captured on the problem list ^a , n	201	226	231

^aThis indicator is reported differently in this engagement compared with the others; as one of the first Electronic Medical Record Practice Enhancement Program engagements, consultants were still refining the metrics they used for reporting and later revised the indicator to reflect those who were missing from the identified diabetes mellitus population, rather than those who were included.

Discussion

Principal Findings

As noted earlier in the paper, and born out in the literature, the EMR implementation alone does not guarantee proficiency—even with the passage of time [8,10]. Practices that engage in change management supports—including training, workflow analysis and corrections, resolution of data quality issues, and implementation of standards—are those that are most likely to realize a return on their digital health investment and improvement to patient outcomes [2,8,9,10,11]. The EPEP was designed to address these challenges, and consultants take a continuous quality improvement approach both in the context of engagement and in their practice and method.

In each case, we can see from pre- and postengagement DQR that improvements were achieved across most measures. These advances are further borne out by EPA assessments run at the baseline and postengagement for each practice. As noted in the Methods section, while the EPA is primarily a self-assessment tool, it is also used by EPEP consultants in the context of engagement—that is, EPAs are administered to determine a consultant/expert (rather than self) assessed maturity level. The resulting EPEP-assessed EPA dataset is separate from the larger self-assessed EPA cohort. At the time of writing, EPEP consultants had collected pre- and postengagement maturity assessments on over 200 completed engagements.

In Figures 3 and 4, the baseline (current) maturity level for each practice here is shown to be similar to or higher than the median of the cohort of clinicians in this EPEP-assessed group (nb. the consultant-assessed n can differ between questions, as consultants use the EPA to assess only the areas a practice identifies as priorities). These figures show consultant-assessed maturity for each practice using the EPA, at baseline and

postengagement, compared against the median of the entire cohort of consultant-assessed EPAs for the Complex Care key measure and Prevention and Screening key measure. At postengagement, 2 practices reported in this paper scored higher-than-median on their achieved proficiency for complex care; all 3 scored higher-than-median in prevention and screening.

Limitations

The assessment approach used in this program, while mixed in its methods, relies heavily on human observation. It is thus vulnerable to subjectivity biases, but that potential limitation can be the price of applying expert interpretation to factors that influence the sustainability, or “stickiness,” of change.

With that qualification, several limitations could be expected to affect the reproducibility of results in applying an intervention of this nature. These include (1) variability in the nuances of executing the EPEP approach, across consultants; (2) variability of efficacy in implementing an action plan, across clinics (including supporting resources); and (3) variability in available functionality and supports, across EMRs.

An additional limitation concerns the EPA. As with the other assessment methods used in the EPEP, applying the EPA requires consultants to judge the level of proficiency they observe, which involves subjective as well as objective measurement. In the collective experience of EPEP consultants, movement up the maturity scale may be relatively straightforward with uncomplicated key measures like appointment scheduling. However, as for other key measures, like complex care and prevention and screening, gaining proficiency is more challenging, assessment of the maturity model may show very little movement from pre- to postengagement.

Figure 3. Maturity levels for Complex Care (includes chronic disease management).

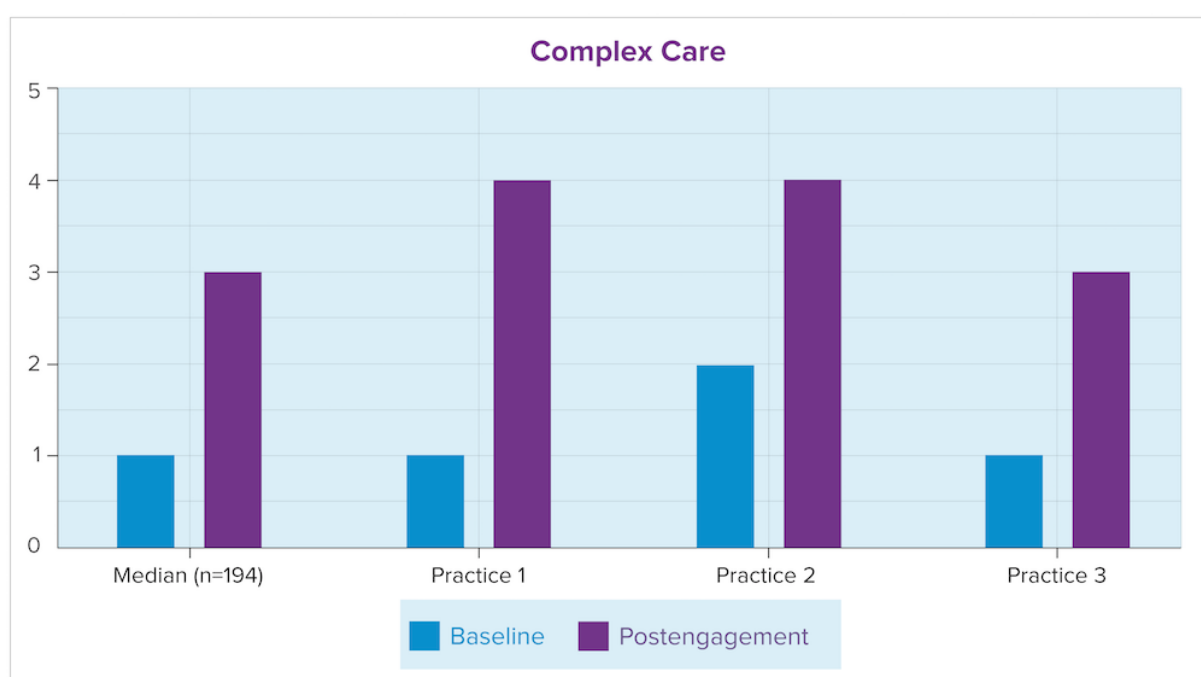
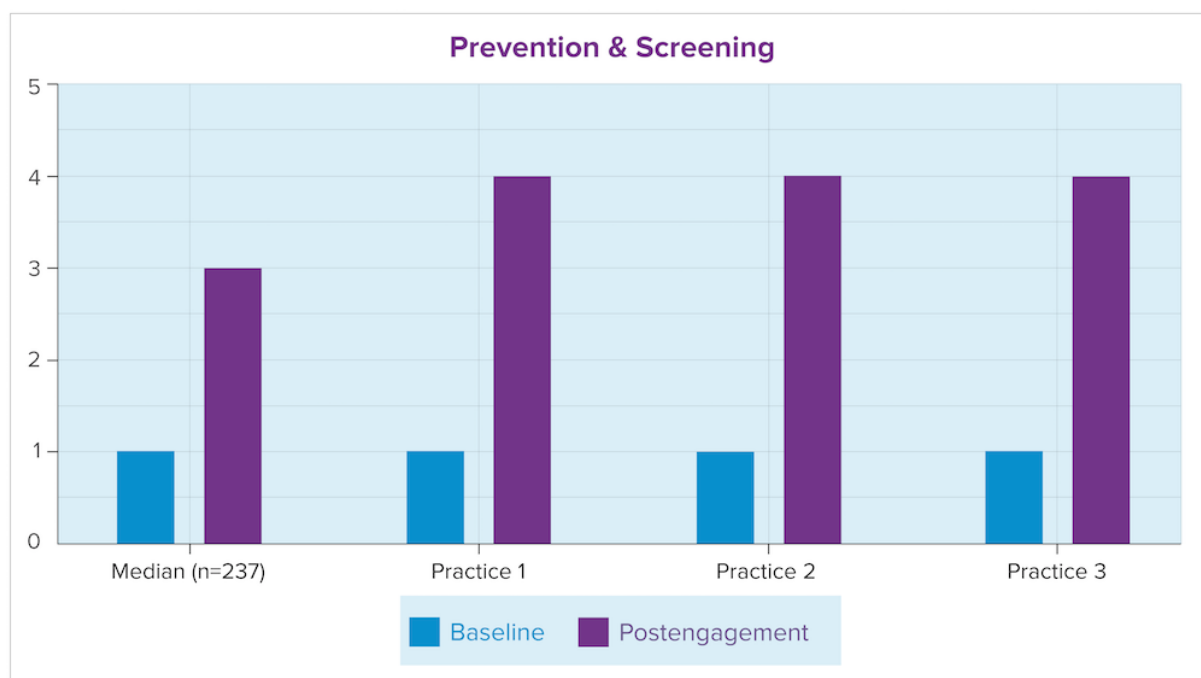


Figure 4. Maturity levels for Prevention and Screening.

Interestingly, it is in these challenging-to-move key areas where, we believe, the value of the EPEP is most clearly demonstrated. Key measures where it is easier to advance—such as appointment scheduling—are more easily improved with use. In areas where improvement is more difficult to achieve, as noted at this paper's outset, change management support, such as those delivered by the EPEP, can help a practice overcome these challenges, become more proficient, and sustain that level of proficiency.

Implications for Future Analysis

Given these results, the next question might be—what factors lead to success in achieving EMR proficiency? Consultants routinely report that these successes are primarily because of the dedication of clinicians and staff at the practice, who embrace the process and understand that undertaking the recommended actions will result in tangible improvements in practice management and their capacity to provide quality care to their patients. Motivation to improve is a critical success factor. We note, for example, that at the baseline, Dr. A's assessed maturity in complex care was a 1, but the desired level of maturity he reported for that measure was 5—considerably higher than the median. As has been found elsewhere [15], the knock-on effect of motivation to improve is the decision to seek supports—in this case, engagement with the EPEP—to achieve the desired changes.

Although the data presented here is limited to EPEP-assessed maturity, our collection of self-assessed EPA data (including measures matched across the EPA and its predecessor, the EMR Progress Report) now totals >1000 discrete respondents. From these data, we see a picture of steady progress in maturity across the province. As we continue to accrue macro-level data on the EMR maturity across Ontario, in combination with micro-level data from practice engagements, we will increasingly be able

to characterize the factors that contribute to EMR proficiency and success at achieving quality improvement goals.

In the context of a large number of ongoing and future engagements for this relatively young program, these few examples cannot represent the program's efficacy. Recognizing the importance of providing a clear account of the EPEP's impact, consultants are routinely collecting pre- and postengagement data. As engagements accumulate, we will not only strengthen our ability to characterize the factors that contribute to EMR proficiency but also develop a better understanding of the EPEP's impact, including the extent to which improved data quality and EMR proficiency postengagement correlates with better patient outcomes.

Conclusions

The challenges described in these engagements are not unique to Ontario primary care practitioners. Technology adoption and implementation introduce disruption to clinical workflows, and the promise of a benefit may not be enough to embrace the change in a sustainable way fully.

The EPEP was established in recognition that to be sustainable, change requires support. Best practices in change management informed the EPEP method, and the program's consultants operate as a team that regularly reflects on practice, shares new knowledge, and understands the value of consistency and rigor in their method and data collection.

With this customizable approach, EPEP consultants can virtually help any practice uncover gaps, achieve more efficient workflow, and improve data capture. Our previous analysis suggested that steps to improve EMR proficiency (maturity) can lead to improvements in care [16]. The examples described here add further layers to our understanding of EMR maturity—measurable improvements in data quality and ability

to monitor patients can be achieved by individual practices as they work to improve EMR workflow and data quality. To be clear, while the achievement of objectives at the level of the practice is the goal, program consultants and clinicians involved in an engagement are serving system-level priorities as well. In Ontario, the Primary Care Performance Measurement Framework [17] identifies cancer screening, chronic disease (eg, diabetes) monitoring, and risk factor (eg, smoking) management as both system- and practice-level priorities for population health. As the EPEP program continues to spread and collect data from its engagements, we will be able to build a richer picture of the benefit of this change management

approach for clinicians (practice-level) and the health system (system-level) alike.

The EMR use is a continuing journey of learning and improvement. Practitioners involved in our engagements have access to the supports necessary for sustainable change and continued progress. EMRs can improve population health management, enable public health interventions, and support evidence-based policy. Rather than focusing on the universal EMR adoption, resources should be aimed at moving the needle among existing EMR users to build capacity for better population health management. With appropriate help to improve EMR proficiency, practices can achieve their population health goals—to their patients' benefit.

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Conflicts of Interest

None declared.

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Abbreviations

CPP: cumulative patient profile
DQR: data quality review
EMM: EMR Maturity Model
EMR: electronic medical record
EPA: EMR Progress Assessment
EPEP: EMR Practice Enhancement Program
HbA_{1c}: glycated hemoglobin
MOHLTC: Ministry of Health and Long-term Care

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Original Paper

Bridging the Gap Between Academic Research and Pragmatic Needs in Usability: A Hybrid Approach to Usability Evaluation of Health Care Information Systems

Devin M Mann^{1,2*}, MD, MS; Sara Kuppin Chokshi^{1*}, DrPH; Andre Kushniruk^{3*}, PhD, FACMI, FCAHS, FIAHSI

¹Department of Population Health, School of Medicine, New York University, New York, NY, United States

²Medical Center Information Technology, NYU Langone Health, New York, NY, United States

³School of Health Information Science, University of Victoria, Victoria, BC, Canada

* all authors contributed equally

Corresponding Author:

Devin M Mann, MD, MS

Department of Population Health

School of Medicine

New York University

227 East 30th Street

New York, NY, 10016

United States

Phone: 1 212 263 9026

Email: devin.mann@nyulangone.org

Abstract

Background: Technology is increasingly embedded into the full spectrum of health care. This movement has benefited from the application of software development practices such as usability testing and agile development processes. These practices are frequently applied in both commercial or operational and academic settings. However, the relative importance placed on rapid iteration, validity, reproducibility, generalizability, and efficiency differs between the 2 settings and the needs and objectives of academic versus pragmatic usability evaluations.

Objective: This paper explores how usability evaluation typically varies on key dimensions in pragmatic versus academic settings that impact the rapidity, validity, and reproducibility of findings and proposes a hybrid approach aimed at satisfying both pragmatic and academic objectives.

Methods: We outline the characteristics of pragmatic versus academically oriented usability testing in health care, describe the tensions and gaps resulting from differing contexts and goals, and present a model of this hybrid process along with 2 case studies of digital development projects in which we demonstrate this integrated approach to usability evaluation.

Results: The case studies presented illustrate design choices characteristic of our hybrid approach to usability evaluation.

Conclusions: Designed to leverage the strengths of both pragmatically and academically focused usability studies, a hybrid approach allows new development projects to efficiently iterate and optimize from usability data as well as preserves the ability of these projects to produce deeper insights via thorough qualitative analysis to inform further tool development and usability research by way of academically focused dissemination.

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KEYWORDS

software design; user-computer interface; medical informatics

Introduction

Background

Technological solutions are a dominant modality for improving health care delivery and are increasingly embedded into the full

spectrum of health care workflows—patient, provider, system, and population. The growing integration of technology into health care has benefited from the application of software development practices such as agile development, user-centered design, human-computer interaction, and usability testing [1-4].

Usability testing has emerged as an important methodology in health informatics [5-8]. Although it can take various forms, usability testing refers generally to the evaluation of a digital tool involving the observation of end users as they interact with that tool to carry out representative tasks [9,10]; for example, a clinician (representative user) may be observed while interacting with a clinical decision support (CDS) module in the electronic health record (EHR) system [9,11]. Observations are recorded and analyzed for the purposes of gathering feedback for user-centered tool development.

Observations made during the testing and the recorded user interactions (typically captured using screen-recording software) are analyzed to varying degrees of depth to identify specific usability issues, such as problems with navigation or “pain points” with regard to tool compatibility with user workflow [9,12]. These practices are applied in both commercial or operational and academic settings; however, the relative importance placed on rapid iteration, validity, reproducibility, generalizability, and efficiency differs between the 2 settings, as do the needs and objectives of academic versus pragmatic usability evaluations [6,7].

Serving the Needs of Academic Usability Evaluation

With interest increasing in conducting and reporting data from usability studies from an academic perspective, the relevant literature has seen a growing number of publications proposing best practices and minimum standards of rigor for usability research [5,13-17]. Statement on Reporting of Evaluation Studies in Health Informatics principles, for example, provide proposed guidelines for conducting and reporting evaluation studies, including explicit consideration of scientific background, study context, detailing of methods, results, and the discussion of implications and limitations [14,18-20]. Peute and colleagues have extended these ideas to the creation of guidelines for usability evaluations for academic reporting, adding descriptive data on study participants and discussion on the generalizability and reproducibility of the study [15].

These guidelines and practices can be seen as supporting a move toward a culture of “evidence-based” human factors work in health care, as described by Marcilly and other authors [5,13,15,17]. Many of these practices, such as including a minimum number of representative users that would allow for statistical analyses and conducting objective and replicable analyses of the resulting data, are documented in the academic literature [15]. However, despite these established practices, software development projects in real clinical contexts continue to routinely minimize the role of truly rigorous evaluation [15,18,21].

Agile Development and Pragmatic Usability Evaluation

Although academically oriented usability studies value validity, reproducibility, and generalizability, those usability studies

conducted in primarily pragmatic settings (eg, commercial or clinical settings) prioritize speed, efficiency, and the ability to inform rapid, agile development cycles [22]. Agile development refers to a set of software development practices that, in contrast to more linear and traditional “waterfall” approaches, value rapid, flexible, and iterative processes that heavily incorporate end user feedback [23,24]. Agile and user-centered techniques are increasingly written about in relation to person-centered health information technology (HIT) design [3,24-27]. Although the increased attention paid to usability research is indicative of its potential value, details on how to conduct usability research in a way that is agile and iterative while aligned with the goals and demands of academic research remain sparse [28]. This gap in knowledge as to how to balance or reconcile objectives in academic and pragmatic usability engineering in health care represents an important knowledge translation problem, which may be at the root of a number of issues regarding the lack of usability of systems and lack of end user adoption of many HIT systems [2,29-32].

Academic Versus Pragmatic Usability: A Comparison of Features

Academic and pragmatic usability studies may employ similar methods but as described above, can be characterized by several key differentiating features reflecting differing priorities [12]. The differences in priorities reflect differences in both the goals of each type of project as well as the funding source of academic (typically grants) versus pragmatic usability studies. Importantly, these differences can create tension within teams seeking to meet both academic and pragmatic research and development goals, including many teams at academic health centers with a mandate to produce effective and timely production systems for real-world use in clinical contexts [2,12,20].

Table 1 compares and contrasts features of more rigorous academic usability with those of a purely pragmatic usability approach. As highlighted above, there are shortcomings to using each of these approaches alone; purely pragmatic projects tend to sacrifice the potential for producing evidence useful to the wider HIT community, whereas purely academic usability evaluation may produce some interesting findings but risk long, costly timelines that are incompatible with the pace of digital innovation today. Although the table illustrates essential differences and potential tensions between the 2 perspectives, it is important to acknowledge that in reality, usability evaluations vary widely and differences in features between academic and pragmatic approaches may not be clear-cut. The priorities listed for each approach can help research and development teams understand the trade-offs involved when making these decisions regarding usability evaluation design.

Table 1. Comparison of features of academic versus pragmatic usability testing.

Feature	Academic usability	Pragmatic usability
Objectives	<ul style="list-style-type: none"> • Production of evidence regarding adaptation and development of tool types (eg, clinical decision support) and workflows for academic publication and dissemination • Priority: rigor and reproducibility 	<ul style="list-style-type: none"> • Rapid iterative design and testing cycles to provide user feedback to product owners and developers • Priority: speed and cost-effectiveness
Methodological approach	<ul style="list-style-type: none"> • Direct observation • Think-aloud • Near-live • Live testing 	<ul style="list-style-type: none"> • Direct observation • Think-aloud • Near-live • Live testing using low-cost approaches
Setting	<ul style="list-style-type: none"> • Variable (laboratory to <i>in situ</i>) • Priority: high-fidelity, representative testing environment and tasks 	<ul style="list-style-type: none"> • Variable (laboratory to <i>in situ</i>) • Priority: convenience over fidelity
Number of participants	<ul style="list-style-type: none"> • 10-15 participants (representative of end users) per user group for usability testing (potentially more if conducting statistical analyses) • Priority: representativeness of user 	<ul style="list-style-type: none"> • <10 participants (typically minimum=4) • Priority: convenience and managing time constraints
Data capture	<ul style="list-style-type: none"> • Note taking • Audio recordings • Video recording • Screen capture • Data captured and transcribed for detailed analyses 	<ul style="list-style-type: none"> • Observational note taking • Notes on debriefing interviews • Real-time analysis of user-screen interaction
Termination criteria	<ul style="list-style-type: none"> • Termination with data saturation for current iteration 	<ul style="list-style-type: none"> • Termination based on consensus, cost, and time constraints
Data analysis	<ul style="list-style-type: none"> • Detailed qualitative analyses (including inter-rater reliability) of data captured: usability testing transcripts, screen captures, etc • Quantitative analyses (eg, error rates, System Usability Scale scores, measures of clicking, eye tracking, etc) 	<ul style="list-style-type: none"> • Concise, structured summaries of findings based on notes from usability sessions and debriefings and notes from anecdotal and stakeholder feedback
Output	<ul style="list-style-type: none"> • Detailed data tables and results reporting 	<ul style="list-style-type: none"> • Simple summary or table of problems and solutions
Dissemination	<ul style="list-style-type: none"> • Publication of findings in peer-reviewed journals • Priority: generalizability of results and scientific value 	<ul style="list-style-type: none"> • Final summary report presented to developers and management • Priority: local (vs wider) distribution of findings for use to improve a specific system or interface
Time frame	<ul style="list-style-type: none"> • Varies from weeks to months 	<ul style="list-style-type: none"> • Feedback from testing immediately or within days of testing

Methodological Approaches, Setting, and Number of Participants

Although differing in objectives, data collection may be similar across the 2 approaches, including direct observation, the think-aloud method (users are asked to provide real-time, out-loud feedback while carrying out representative tasks), and near-live (observed use of the tool in a clinical simulation in realistic settings) and live usability testing (observed use of the tool postdeployment to discern outstanding issues with design or integration with workflows before wider implementation) [33,34]. The tools and methods used in more rigorous academic usability are very the similar to those used in academically oriented qualitative research otherwise. Although knowledge and comfort with the principles of usability research are

important, internal team members capable of implementing a high-quality qualitative research protocol can adapt those tools and skills for usability evaluation. Additionally, more quantitative methods, such as user-reported usability scales or analytics (eg, click counts), collected on the back end of a software program, shed insight into how users interact with a tool [6,35-37].

The setting used for testing may be more elaborate for academic versus pragmatic usability testing; the former tends to reflect an emphasis on the representativeness of the testing environment, whereas the latter indicates the tendency to prioritize time and cost concerns over the achievement of a high-fidelity testing environment [36]. The number of participants also typically varies between academic and

pragmatic usability with the recommendation for academic usability being a minimum of 15 participants, deemed representative of the intended end users, whereas in pragmatic usability testing, fewer participants may be considered sufficient to inform design decisions, particularly if testing is integrated into numerous rapid iterative and agile development and testing cycles [15,20]. Furthermore, academic usability studies may require enough subjects to be able to carry out meaningful statistical analysis or reach saturation of data, whereas this is typically not a requirement for pragmatic testing.

Data Capture, Analysis, Reporting, and Dissemination

Although the methodologies employed may be similar across approaches, data capture and analysis is a key area of difference with the academic approach requiring more involved data capture to inform a level of analysis appropriate for an academic publication. Even though the pragmatic goals of a usability study can be met with detailed field notes, academic objectives may demand a full transcription of usability sessions reflecting a variety of types of data captured (eg, video, audio recording, screen captures, etc). Termination of data collection is based on the achievement of saturation for that iteration of the tool, as is common in traditional academic qualitative research, rather than on time and cost considerations [12,37].

Similarly, analytic methods differ across the 2 approaches. On one end of the spectrum, purely pragmatic projects might use only field notes, which may be loosely organized into practical usability themes and issues used in real time to inform build recommendations. On the other end of this spectrum is a heavily academic project with copious amounts of raw data to be analyzed systematically, as in a typical academic qualitative project; these data may even be combined with the analysis of more quantitative assessments for a mixed-methods approach to usability evaluation. Instant data analysis has emerged as a solution to reduce time and cost related to traditional (academic) usability evaluation while maintaining a systematic approach. However, while offering strategies for providing usability feedback to development teams efficiently, the data capture and analysis phase remain pragmatically rather than academically focused [12].

User feedback can be a useful marker indicating potential areas of focus for deeper learning during more rigorous qualitative analysis in the case of academically oriented studies. Although time-consuming, the depth and rigor of this type of data collection and analysis are necessary to uncover more subtle usability patterns and insights as well as produce high-quality findings fit for peer-review academic publication [38]. Given this, the depth of data capture and analysis as well as the format of reporting and dissemination are warranted. From the pragmatic perspective, summary reports highlighting usability issues and build recommendations suffice. Real-time summary documents can also be used to ensure the capture of key quotations from direct user feedback to be used to improve the tool at hand and drive changes in system design more broadly and therefore, they may be useful for academic objectives as well.

The choice of method and level of data analysis are the primary drivers of the difference in the time frame between academically

versus pragmatically focused projects. An academically focused usability study may see value in conducting multiple rounds of various types of usability testing to achieve data saturation and analyzing audio, video, and screen capture data to uncover evidence to support findings relevant to the academic community. More pragmatic projects that incorporate usability testing may conduct just 1 cycle of 1 type of testing (eg, 1 cycle of think-aloud testing) with summary memos for prototype iteration but no further analysis of usability data [12,39].

Hybrid Approach to Usability Testing

We believe the needs of both academic and pragmatic usability evaluation can be served by a hybrid approach. As described above, key drivers of differences in the features and cadence of academic versus pragmatic usability studies are the depth of data capture and analysis. With a hybrid approach, usability testing is tackled in the spirit of rapid, agile iteration while planning for the documentation needs required for deeper academically focused analysis. With attention paid to rigorous systematic data capture with a sufficient number of end users to meet academic objectives, in-depth qualitative or mixed-methods analysis can occur later in the product development lifecycle, although ideally before wide release of the optimized system, to ensure the opportunity for any later findings to find their way into final product iterations [21,38].

Teams best able to conduct this type of hybrid work are multidisciplinary and cross-functional, featuring some expertise in design thinking, agile product development, user interaction design, rapid pilot testing, and iteration in addition to team members with more traditional research HIT backgrounds [40]. While research and development teams conduct multiple usability testing cycles systematically, each session can be concisely summarized in a rapid fashion for tool iteration and to serve as a growing body of key feedback for the design team throughout the development process. This combined approach allows new development projects to efficiently iterate and optimize from usability data while preserving the potential for these projects to produce deeper insights via thorough qualitative analysis to inform further tool development and usability research by way of academically focused dissemination.

Our experience suggests that combining strategies for testing and evaluation provides a feasible approach equipped to meet academic objectives while also satisfying real-time needs of pragmatic usability evaluation. In this paper, we reviewed 2 case studies to demonstrate its feasibility and illustrate how this approach can be operationalized to build tools in a pragmatic, agile way while serving academic goals [32,41,42].

Methods

Using a hybrid approach as a framework, we describe our experience incorporating usability evaluation in 2 HIT development projects [42-46]. These 2 case studies are used to illustrate the operationalization of a hybrid approach and demonstrate its potential value and feasibility. In the first case, we describe the adaptive design of an EHR CDS tool designed to reduce inappropriate antibiotic prescribing for upper respiratory infections. In the second case, we outline the design

and development of a decision support tool-embedding goal setting into primary care EHR workflows. After a brief description of the project, we complete a side-by-side evaluation of each case study with regard to the key dimensions to consider in the design of a usability evaluation as outlined in [Table 1](#).

This research did not involve human subjects. An institutional review board approval was not required because it did not involve a review of previously published data and did not involve data collection.

Results

Case Study 1: The Integrated Clinical Prediction Rule Decision-Support Tool

The objective of the Integrated Clinical Prediction Rule 2 (iCPR2) project, a National Institutes of Health (NIH)-funded research study, was to employ a user-centered approach to adaptively design an EHR CDS tool to reduce inappropriate antibiotic prescribing for upper respiratory infections and assess the adapted tool's adoption and effectiveness [41,42]. By design, this project required relatively rapid incorporation of end user input and delivery of academic products related to lessons learned for the user-centered design of CDS tools.

The first phase of the study involved conducting laboratory-style usability testing of 12 clinician users who interacted with the guidelines embedded in the EHR by following a script driven by the experimenters. The participants were asked to verbalize their thoughts while interacting with the EHR and guidelines. While carrying out this study, technical staff was involved in implementing the guidelines observed the sessions. Based on their notes, they were immediately able to arrive at important modifications to the EHR and guidelines, satisfying pragmatic goals of the project. In addition, the study then moved to further phases in which more rigorous testing in near-live contexts was conducted prior to the actual release of the guidelines in the EHR for real use. This involved having users interact with a simulated digital patient to observe how the guidelines would be triggered in real-life contexts, followed by a formal clinical trial to assess the uptake of the guidelines. These latter objectives of the same study met the academic usability goals of providing publishable and useful knowledge that could guide further studies and other researchers in the future [31,32]. Thus, the approach could be considered to be hybrid in that it was designed to address both pragmatic short-term goals and objectives as well as longer-term scientific objectives for publication and knowledge dissemination.

Case Study 2: The Avoiding Diabetes Thru Action Plan Targeting Tool

The Avoiding Diabetes Thru Action Plan Targeting (ADAPT) tool, also the product of an NIH-funded decision-support trial, was designed to support the integrated care counseling of prediabetes by providing templates within an EHR to guide physician-patient dialogues [44,45]. This study also involved conducting usability testing of clinician users as they interacted with the template embedded in the EHR, where they were asked to think aloud while interacting with the system and the templates. All the computer screens and audio were recorded and analyzed at the surface level for quick-fix problems and at a more detailed level of sufficient quality and reliability to lead to publishable journal results (to fulfill the goals of both pragmatic and academic usability engineering within the same study design).

With academic objectives in both cases, the decisions regarding methods used, setting, and the number of participants were made accordingly; data capture also reflected the downstream plan to transcribe and apply rigorous qualitative analysis; for example, in iCPR2, full-screen capture and audio were recorded for each think-aloud, near-live, and live usability session using Morae (think-aloud and near-live) and Camtasia (live) software. Researchers trained in usability methods also took detailed field notes [33]. The depth of data capture allowed researchers the ability to subsequently conduct a synchronous review of audio and video files together, allowing deeper analysis and results for the production of academically oriented findings suitable for dissemination in the scientific literature. Simultaneously, pragmatic objectives were recognized and addressed, as field notes were turned into summaries with recommendations to be considered for rapid tool modification.

In the case of ADAPT, pragmatically oriented summaries from usability session observations revealed that limited text length in the patient instruction field contributed to generic, nonpatient-specific content. A deeper qualitative analysis of the session data, including of the information entered in this field, further revealed that this content was uncondusive to goal setting. Additionally, the in-depth analysis revealed a number of workflow issues, such as incompatibility of flow with encounters not focused on diabetes [44]. Both of these findings were important to the design of ADAPT but are also valuable for informing the design of other technologies with similar functionalities. [Table 2](#) is a side-by-side comparison of the usability evaluation features of each of these two case studies.

Table 2. Case study comparison of usability evaluation features.

Feature and usability type	Case study 1 (Integrated Clinical Prediction Rule 2)	Case study 2 (Avoiding Diabetes Thru Action Plan Targeting)
Objectives		
Academic	<ul style="list-style-type: none"> To generate evidence on the optimal adaptation of clinical decision-support tools 	<ul style="list-style-type: none"> To generate evidence on the clinical impact of an electronic health record-enabled prediabetes counseling tool
Pragmatic	<ul style="list-style-type: none"> Tool adaptation and identification of issues in tool build before widespread deployment 	<ul style="list-style-type: none"> User feedback for recommendations to tool developers
Methods used: Academic and pragmatic	<ul style="list-style-type: none"> Direct observation Think-aloud Near-live Live testing Semistructured group interview (postdeployment) 	<ul style="list-style-type: none"> Direct observation Think-aloud Near-live Live testing
Setting: Academic and pragmatic	<ul style="list-style-type: none"> Laboratory and <i>in situ</i> 	<ul style="list-style-type: none"> Laboratory and <i>in situ</i>
Core team: Academic and pragmatic	<ul style="list-style-type: none"> 9 members (expertise: primary care, clinical decision support, informatics, electronic health records, usability, qualitative research, and graphic design) 	<ul style="list-style-type: none"> 6 members (expertise: primary care, health psychology, diabetes education, nutrition, informatics, usability, and graphic design)
Number of participants: Academic and pragmatic	<ul style="list-style-type: none"> Think-aloud=12 clinicians Near-live=12 clinicians (same) Live=3 clinicians and 6 encounters Postdeployment=75 clinicians and 14 sites (group interviews) 	<ul style="list-style-type: none"> Think-aloud=7 clinicians Near-live=6 clinicians
Data capture: Academic and pragmatic	<ul style="list-style-type: none"> Note taking Audio recording of sessions Video recordings Screen capture 	<ul style="list-style-type: none"> Note taking Audio recording of sessions Screen capture
Termination criteria: Academic and pragmatic	<ul style="list-style-type: none"> Termination with data saturation for current iteration 	<ul style="list-style-type: none"> Termination with data saturation for current iteration
Data analysis		
Academic	<ul style="list-style-type: none"> Qualitative thematic analysis by 2 independent coders 	<ul style="list-style-type: none"> Qualitative thematic analysis by 2 independent coders
Pragmatic	<ul style="list-style-type: none"> Thematic analysis of observational field notes 	<ul style="list-style-type: none"> Thematic analysis of observational field notes
Output		
Academic	<ul style="list-style-type: none"> Detailed data tables and results reporting 	<ul style="list-style-type: none"> Detailed data tables and results reporting
Pragmatic	<ul style="list-style-type: none"> Summary reports from field notes 	<ul style="list-style-type: none"> Summary reports from field notes
Dissemination		
Academic	<ul style="list-style-type: none"> Publication of protocol and usability findings from think-aloud, near-live, and live testing in peer-reviewed journals 	<ul style="list-style-type: none"> Publication of protocol and usability findings from think-aloud and near-live testing in peer-reviewed journals
Pragmatic	<ul style="list-style-type: none"> Research team Electronic health record development team 	<ul style="list-style-type: none"> Research team Electronic health record development team
Time frame		
Academic	<ul style="list-style-type: none"> Think-aloud or near-live usability 16 months from the beginning of data capture to the publication of findings 	<ul style="list-style-type: none"> Think-aloud or near-live usability 11 months from the beginning of data capture to the publication of findings
Pragmatic	<ul style="list-style-type: none"> Think-aloud or near-live usability 2 months from the beginning of each phase of data capture to the completion of all summary reports 	<ul style="list-style-type: none"> Think-aloud or near-live usability 1 months from the beginning of each phase of data capture to the completion of all summary reports

Discussion

Principal Findings

We reviewed 2 case studies to demonstrate the feasibility of a hybrid approach and illustrated how the approach could be operationalized to build tools in a pragmatic, agile way while serving academic usability research objectives. In both case studies, research teams were presented with pragmatic and academic objectives, necessitating the delineation of an approach to resolve what initially seemed to be a tension between the 2 approaches to usability research. While approaching the iCPR2 project, for example, with purely pragmatic usability methods, we would not have been able to produce and disseminate findings worthy of academic publication, missing the opportunity to enrich the body of evidence for the larger CDS and usability community. However, a purely academic approach to usability would have extended the development timeline of the iCPR2 tool, cutting into the time available to make and study tool iterations and the effects on process and clinical outcomes. When consideration of the needs of both perspectives are recognized and addressed, as in the hybrid approach, priorities can be negotiated upfront to produce a usability evaluation designed to produce a quality tool as well as usability findings of maximum value to the project team and the usability community at large.

As the need for rapid, user-centered HIT grows, efforts to develop effective technology tools to support evidence-based health care require an approach to systematic usability research that addresses both the pragmatic as well as academic needs of a project. At the crux of this hybrid approach is the collection of detailed audio and video data amenable to longer-term in-depth analysis, while rapidly collecting and summarizing information to drive system improvements in a short time frame (ie, within hours or days rather than weeks or months). The pragmatic, postsession summary memos and subsequent group solutioning supported agile development timelines, whereas the deeper qualitative analysis of the transcribed audio and video data generated more complex and orthogonal observations and insights for academic dissemination. Results from the in-depth qualitative analyses were applied prior to widespread system release in both projects but did not impede or preclude an agile development process or timeline.

This deeper analysis of data revealed additional important findings not apparent from the initial session summary memos obtained from observation as well as provided the data necessary for the rigorous analysis and reporting suited to addressing the

project's academic goals. This is evident in our publication of usability findings and implications from the ADAPT study in peer-reviewed publications [44-46]. Similarly, in the case of iCPR2, near-live session data captured workflow-sensitive usability problems missed in both the (pragmatic) field note summary document as well as in the think-aloud usability research cycle [33]. This finding indicates both the value of multiple rounds of usability testing with a variety of methods as well as the potential value added by the transcription and deeper analysis of session data. More complex analyses and insights, though more time-consuming to generate, have been valuable for optimizing our overall approach to developing similar CDS systems and thus provided generalizability of findings essential in academic research.

Limitations

This evaluation of case studies prioritizes observational, qualitatively-focused methods over quantitative methodologies. This is not to negate the value of quantitative data sources to either academic or pragmatic usability research because a mixed-methods approach can be valuable to the objectives in both cases. Given the role that qualitative data capture and analysis play in the tension between academic and pragmatic usability evaluation, a focus on more qualitative usability research methods was deemed appropriate. This paper reports on 2 case studies in which the authors were leaders in the design and implementation, potentially limiting the generalizability of the finding that our approach is readily feasible for other teams in different contexts. Additionally, the data capture methods used were the same in both cases; analysis of cases with only a subset of data capture methods would offer additional insight into the application of the hybrid approach.

Conclusions

We observed that the hybrid approach outlined in this paper was a feasible way to address the needs of academic usability and pragmatic usability objectives. Borrowing from industry usability testing practices common outside of academia and from our experience as illustrated by these 2 case studies, we have demonstrated that a hybrid approach can meet the needs of both by leveraging the rigor of academic usability testing along with the flexibility and rapid, agile characteristics of pragmatic usability methods. These studies provide novel examples of a hybrid approach that meets the needs of system developers charged with building and optimizing systems as well as academic usability researchers tasked with furthering our knowledge and perspective on the role of usability testing in health care technology.

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Authors' Contributions

All authors have made substantial contributions to conception and design, acquisition and analysis or interpretation of data, and drafting or critical revision of the manuscript. All listed authors have approved the final version of the manuscript to be published.

Conflicts of Interest

None declared.

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Abbreviations

ADAPT: Avoiding Diabetes Thru Action Plan Targeting

CDS: clinical decision support

EHR: electronic health record

HIT: Health Information Technology

iCPR2: Integrated Clinical Prediction Rule

NIH: National Institutes of Health

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Original Paper

The Service User Technology Acceptability Questionnaire: Psychometric Evaluation of the Norwegian Version

Astrid Torbjørnsen^{1,2}, MSc; Milada C Småstuen¹, PhD; Anne Karen Jenum², PhD; Eirik Årsand^{3,4}, PhD; Lis Ribu¹, PhD

¹Department of Nursing and Health Promotion, Faculty of Health Sciences, OsloMet – Oslo Metropolitan University, Oslo, Norway

²General Practice Research Unit, Department of General Practice, Institute of Health and Society, University of Oslo, Oslo, Norway

³Norwegian Centre for E-health Research, University Hospital of North Norway, Tromsø, Norway

⁴Department of Clinical Medicine, Faculty of Health Sciences, UiT The Arctic University of Norway, Tromsø, Norway

Corresponding Author:

Astrid Torbjørnsen, MSc

Department of Nursing and Health Promotion

Faculty of Health Sciences

OsloMet – Oslo Metropolitan University

Postboks 4 St. Olavs plass

Oslo, 0130

Norway

Phone: 47 92633075

Email: astridto@oslomet.no

Abstract

Background: When developing a mobile health app, users' perception of the technology should preferably be evaluated. However, few standardized and validated questionnaires measuring acceptability are available.

Objective: The aim of this study was to assess the validity of the Norwegian version of the Service User Technology Acceptability Questionnaire (SUTAQ).

Methods: Persons with type 2 diabetes randomized to the intervention groups of the RENEWING HEALTH study used a diabetes diary app. At the one-year follow-up, participants in the intervention groups (n=75) completed the self-reported instrument SUTAQ to measure the acceptability of the equipment. We conducted confirmatory factor analysis for evaluating the fit of the original five-factor structure of the SUTAQ.

Results: We confirmed only 2 of the original 5 factors of the SUTAQ, *perceived benefit* and *care personnel concerns*.

Conclusions: The original five-factor structure of the SUTAQ was not confirmed in the Norwegian study, indicating that more research is needed to tailor the questionnaire to better reflect the Norwegian setting. However, a small sample size prevented us from drawing firm conclusions about the translated questionnaire.

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KEYWORDS

acceptability; factor analysis; health care; mHealth; telemedicine

Introduction

Patients' perceptions are important components of any health technology assessment when developing and introducing technological devices for self-management. Scientific and robust methods are necessary in the evaluation of the technology, including the use of a framework such as the Model of Assessment of Telemedicine [1,2].

In previous research, both qualitative and quantitative research methods and log data from self-monitoring have been used in the evaluation of acceptability. Many published studies use questionnaires [3,4], which are often self-constructed and not validated [4], making the comparison of results across studies difficult. Further, many of these studies are small, with few participants, and have methodological limitations [4]. In particular, limitations related to the development phase and psychometric evaluation of questionnaires measuring patient

satisfaction are present, with evaluations lacking data on factor structures, reliability, and validity [5].

There is no consensus related to the definition of the acceptability in mobile health (mHealth) research, although a long list of definitions exists, combining technology and health [6] with users' perspectives [7]. Previous research has defined users' perspectives within telemedicine as "issues related to the perception of the patient or the relatives of the telemedicine application including the patients' and relatives' acceptance of the technology" [1]. However, we have not been able to find the user perspective defined in terms of mHealth. The *acceptability* of digital solutions in health care is often used synonymously with the concept of satisfaction [7]. In the development of the acceptability questionnaire Service User Technology Acceptability Questionnaire (SUTAQ), Hirani et al aimed to investigate the concept of technology acceptance in more detail [8].

The aim of this study was to assess the validity of the translated Norwegian version of the SUTAQ acceptability questionnaire. This was tested on participants who used an mHealth tool, namely, a digital diabetes diary app running on a mobile phone and a blood glucose meter transferring blood glucose measurements to the app by Bluetooth in the intervention groups of a randomized controlled trial (RCT).

Methods

European Union Project

The European Union (EU) project, REgions of Europe WorkINg toGether for HEALTH (RENEWING HEALTH), was a research collaboration between 9 regions in Europe working with designing and implementing telemedicine services. The data used in this paper were drawn from the Norwegian study that was a part of this EU project. The acceptability of the equipment was measured at the one-year follow-up in an RCT (NCT01315756).

Participants and Setting

Persons with type 2 diabetes were randomized to 3 groups. The 2 intervention groups received a diabetes diary app that they had for 1 year, and one of the groups also received health counseling for the first 4 months. In addition, the study had a control group. The participants lived at home and were recruited from primary health care. Of the 101 participants who were randomized to the 2 intervention groups, 74.3% (75/101) completed the SUTAQ questionnaire. Other results from the RCT are reported in detail elsewhere [9-12].

Service User Technology Acceptability Questionnaire

The SUTAQ was developed for the Whole Systems Demonstrator (WSD) study in the United Kingdom, to measure acceptability and identify the characteristics of persons who were likely to reject technological health services (see [Multimedia Appendix 1](#)) [8]. The questionnaire has 22 items, measured on a Likert-scale from 1 to 6, reflecting more or less agreement with the item statements, respectively. The questionnaire has 5 subscales, where each contains between 3 and 9 items. The subscale containing 9 items was further divided

into 2. The original items and the subscales are presented later in the paper. The original questionnaire was found to be reliable and valid [8].

As the partners in the RENEWING HEALTH study in 2011 had decided to include answers to SUTAQ in the minimum common dataset, the questionnaire was also used in the Norwegian trial, even though our data collection had already started. The questionnaire was not available in Norwegian when this study started. However, the translation process followed the procedure recommended by the European Organization for Research and Treatment of Cancer Quality of Life Group [13] and the published guidelines for cognitive interviews [14,15]. Two professional translators translated the SUTAQ questionnaire from English to Norwegian. The Norwegian research team considered the discrepancy between the 2 translated versions and the English version. We achieved equivalence with regard to aspects such as the meaning of words, expressions, concepts, and cultural context. A cultural adaptation of the questionnaire had to be done only for a few statements.

A native English speaker, a bilingual person, without any initial knowledge of the SUTAQ, backward translated the final Norwegian version. The research team, also with a good command of English, compared the backward translation with the original questionnaire, and no further changes were made.

Finally, we conducted cognitive interviews with 10 random participants who had answered the SUTAQ questionnaire. According to these interviews, the items were understandable to the participants, although some found the language somewhat cumbersome, leading us to make a few adjustments.

The report from the translation process can be obtained from the last author (LR).

Statistical Analysis

The sample was described using descriptive statistics. To assess the construct validity of the present domains in the SUTAQ questionnaire from the WSD study, we conducted a confirmatory principal component factor analysis on the 22 items, with Varimax rotation and with a fixed number of 5 factors in accordance with the WSD study [8]. To assess the internal consistency of each domain or extracted factor and for the entire questionnaire, we calculated Cronbach alphas. All analyses were performed using IBM SPSS Statistics v23 (IBM Corp, Armonk, NY, USA).

Results

Sample Characteristics

In total, we analyzed data from 75 participants, of whom 56% (42/75) were female. The age range was 35-80 years, with a median age of 59 years, and 49% (37/75) had ≥ 12 years of education. There were no differences between the 2 intervention groups for the SUTAQ findings. We found no differences in the baseline measures between the 75 participants included in the analyses and the 26 who dropped out during the study. More details concerning demographic and clinical results from the study sample are published elsewhere [16].

The median values for the original SUTAQ domains are presented in Figure 1, indicating that the participants accepted the equipment to a high degree within the 3 areas of *privacy and discomfort*, *care personnel concerns*, and *satisfaction*. This implies a high degree of acceptability regarding beliefs about the security of the monitored data, the impact of the equipment on the user, beliefs of the continuity and skills of the health care personnel facilitating the equipment, and acceptance and satisfaction with the equipment and the given service. The median value between 1 and 6 constitutes the middle value in the figure. The two categories, *privacy and discomfort* and *care personnel concerns* are based on items with negative statements, where high values reflect a high degree of agreement with the negative statements in these two categories, which means that low values represent a positive score. The remaining factors consist of positive statements. High values reflect a high degree of agreement. The participants reported being slightly more than medium positive concerning whether the equipment could improve their care or increase their access to health care within the domain *perceived benefit*. Results from the domain *kit as substitution* indicated that the participants were most critical

about the statements concerning this digital solution replacing usual care.

Factorial Reliability and Validity

The measurement properties of the SUTAQ are presented in Table 1. Overall, the amount of missing data was minimal, no more than 8% for all items. The floor effect was small; only 4 items were far above 15%, considered to be problematic [17]. However, the number of items with ceiling effects was higher, with only about half of the items below the limit of 15%, and for 5 of the items, around 50% (34-40/75) of the participants reached the highest possible score.

The confirmatory factor analysis revealed that only factor 1 and factor 3 were consistent in the original study and this study (Table 2). The first factor, *Perceived benefit*, had 9 items in the original factor structure. Of the items in the Norwegian dataset, 7 loaded >0.400 , which was the limit within the factors in the WSD study [8]. In the third domain, *Care personnel concerns*, all 3 items loaded >0.400 . The Cronbach alpha coefficient for all 22 items was .851, which demonstrates good internal consistency [18]. Cronbach alpha values for each factor are listed in Table 2.

Figure 1. Median reported scores of the Service User Technology Acceptability Questionnaire domains.

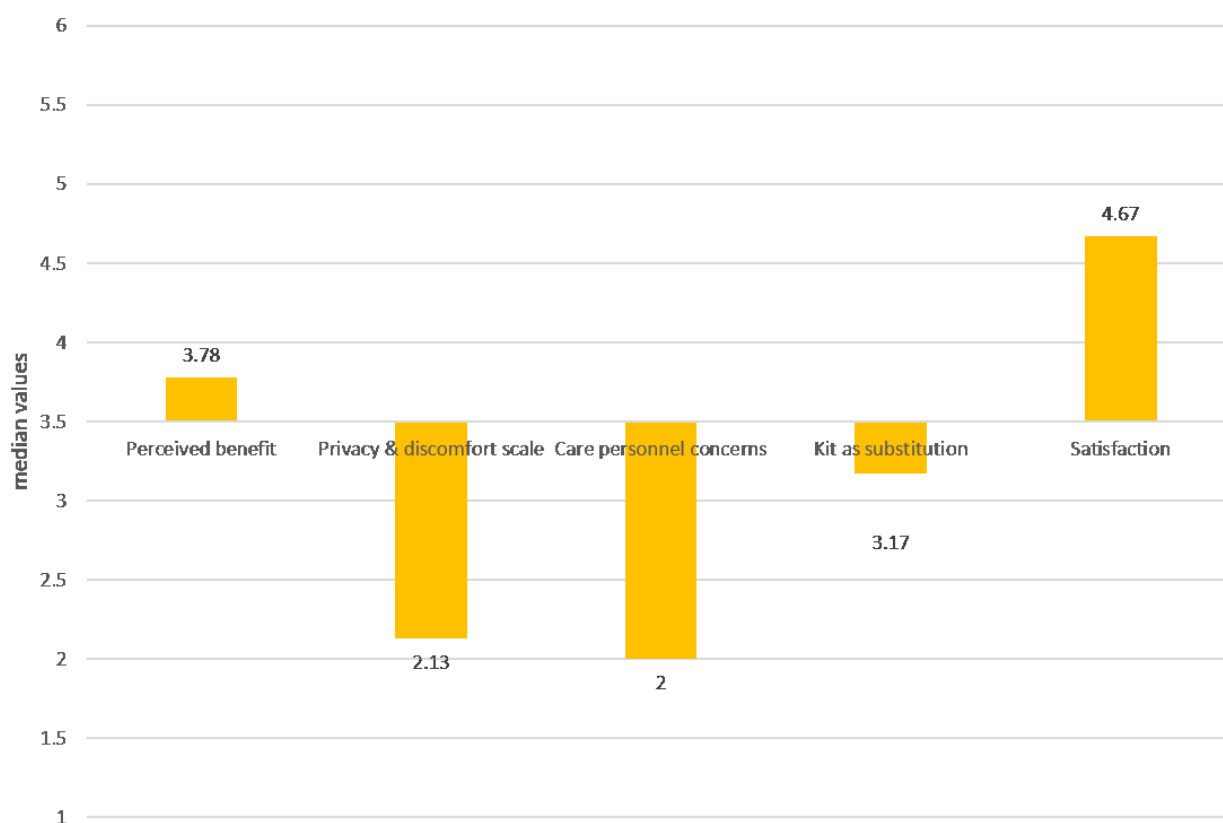


Table 1. Service User Technology Acceptability Questionnaire item descriptors.

Items (range 1-6)	Median	Missing, n (%)	Floor, n (%)	Ceiling, n (%)
The kit I received has saved me time in that I did not have to visit my GP clinic or other health/social care professional as often	4	4 (5)	1 (1)	17 (23)
The kit I received has interfered with my everyday routine	5	3 (4)	2 (3)	35 (47)
The kit I received has increased my access to care (health and/or social care professionals)	5	4 (5)	4 (6)	24 (33)
The kit I received has helped me to improve my health	3	3 (4)	7 (10)	8 (11)
The kit I received has invaded my privacy	5	4 (5)	2 (3)	23 (32)
The kit has been explained to me sufficiently	2	3 (4)	26 (35)	2 (3)
The kit can be trusted to work appropriately	2	3 (4)	17 (23)	10 (14)
The kit has made me feel uncomfortable, eg, physically or emotionally	6	3 (4)	2 (3)	40 (54)
I am concerned about the level of expertise of the individuals who monitor my status via the kit	6	5 (7)	0 (0)	40 (56)
The kit has allowed me to be less concerned about my health and/or social care	3.5	5 (7)	4 (6)	9 (13)
The kit has made me more actively involved in my health	3	5 (7)	7 (10)	8 (11)
The kit makes me worried about the confidentiality of the private information being exchanged through it	5	5 (7)	5 (7)	34 (47)
The kit allows the people looking after me, to better monitor me and my condition	3	5 (7)	11 (15)	8 (11)
I am satisfied with the kit I received	2	4 (5)	11 (15)	10 (14)
The kit can be/should be recommended to people in a similar condition to mine	2	5 (7)	18 (25)	7 (10)
The kit can be a replacement for my regular health or social care	4	5 (7)	5 (7)	17 (24)
The kit can certainly be a good addition to my regular health or social care	2	5 (7)	20 (28)	6 (8)
The kit is not as suitable as regular face to face consultations with the people looking after me	3	4 (5)	13 (18)	4 (6)
The kit has made it easier to get in touch with health and social care professionals	4	5 (7)	4 (6)	19 (26)
The kit interferes with the continuity of the care I receive (ie, I do not see the same care professional each time)	5	6 (8)	1 (1)	34 (48)
I am concerned that the person who monitors my status, through the kit, does not know my personal health/social care history	5	6 (8)	3 (4)	22 (31)
The kit has allowed me to be less concerned about my health status	3	5 (7)	6 (8)	11 (15)

Table 2. Confirmatory factor analysis showing Cronbach alpha values.

Item	Factor 1: perceived benefit	Factor 2: privacy and discomfort	Factor 3: care personnel concerns	Factor 4: satisfaction	Factor 5: kit as substitution
The kit can be/should be recommended to people in a similar condition to mine	.880 ^{a,b}	.146	.060	-.077	.079
The kit can certainly be a good addition to my regular health or social care	.821 ^{a,b}	.065	-.022	-.101	.220
I am satisfied with the kit I received	.815 ^a	.257	.028	-.121 ^b	.093
The kit has made me more actively involved in my health	.779 ^{a,b}	.202	-.026	.253	-.098
The kit I received has helped me to improve my health	.709 ^{a,b}	.276	-.132	.181	-.098
The kit has allowed me to be less concerned about my health status	.693 ^a	.125	.050	-.168	-.005 ^b
The kit has allowed me to be less concerned about my health and/or social care	.676 ^{a,b}	.201	.057	.028	-.194
The kit can be trusted to work appropriately	.682 ^a	.103	-.165	.066 ^b	-.263
The kit allows the people looking after me to better monitor me and my condition	.650 ^{a,b}	.292	.043	-.395	.072
The kit has been explained to me sufficiently	.505 ^a	-.022	-.084	-.394 ^b	.443
The kit I received has saved me time in that I did not have to visit my GP clinic or other health/social care professional as often	.291 ^b	.751 ^a	-.057	.006	.100
The kit has made it easier to get in touch with health and social care professionals	.402 ^b	.721 ^a	-.004	.134	-.067
The kit I received has increased my access to care (health and/or social care professionals)	.246 ^b	.668 ^a	.205	.042	-.131
The kit can be a replacement for my regular health or social care	.411	.612 ^a	.169	-.243	-.117 ^b
I am concerned that the person who monitors my status, through the kit, does not know my personal health/social care history	.119	-.048	.824 ^{a,b}	.204	.234
The kit makes me worried about the confidentiality of the private information being exchanged through it	-.070	.130 ^b	.791 ^a	.095	.116
I am concerned about the level of expertise of the individuals who monitor my status via the kit	.038	-.040	.738 ^{a,b}	.210	-.341
The kit interferes with the continuity of the care I receive (ie, I do not see the same care professional each time)	-.199	.383	.656 ^{a,b}	.122	.318
The kit I received has invaded my privacy	.051	-.069 ^b	.281	.774 ^a	.065
The kit I received has interfered with my everyday routine	-.118	.187 ^b	.336	.606 ^a	.159
The kit is not as suitable as regular face to face consultations with the people looking after me	-.154	.287	-.223	-.138	-.722 ^{a,b}

Item	Factor 1: perceived benefit	Factor 2: privacy and discomfort	Factor 3: care personnel concerns	Factor 4: satisfaction	Factor 5: kit as substitution
The kit has made me feel uncomfortable, eg, physically or emotionally	-.031	.420 ^b	.243	.359	.536 ^a
Cronbach alpha	.892	.721	.701	.766	.295
Explained variance, %	31.3	16.4	8.2	5.5	5.1

^aItalicized values indicate loading in the present Norwegian data.

^bOriginal loading in the Whole Systems Demonstrator study.

Discussion

Principal Findings

The Norwegian version of SUTAQ revealed good internal consistency, with a Cronbach alpha of .851. However, the original five-factor solution was not confirmed. On the contrary, our results indicated that a one-factor solution, or at most a three-factor solution, was sufficient, as the explained variance increased by <6% when adding more factors (Table 2). Moreover, only 2 items were loaded on each of the last factors (factors 4 and 5), indicating that they were superfluous. In addition, we found that the SUTAQ questionnaire had some items with a floor effect and even more items with ceiling effects.

Limitations

One limitation of this study was the low number of participants, as over 250 or at least 10 participants per item is recommended to enable precise conclusions from factor analysis [19]. Further, a factor loading above 0.7 per item is preferred according to Kaiser's criteria [20]. Thus, the small sample size might be one of the possible explanations for the lack of confirmation of all factors. Exploratory factor analysis would have been a suitable statistical method to explore the potential of the questionnaire in our Norwegian setting, although demanding a larger number of participants.

Differences in study contexts, health issues, and equipment could also contribute to the lack of common factors in the original study and this study. In the WSD study, interventions were given to patients with long-term conditions, not only diabetes but also chronic obstructive pulmonary disease, heart failure, and social needs [21]. Further, a far broader range of equipment was used in the WSD study: both telehealth and telecare. In this study, only persons with type 2 diabetes used the self-management app, and no telemonitoring was involved. Outdated equipment was also a problem in the Norwegian study because of a long inclusion process [10].

Our data were slightly skewed (Table 1), and to our knowledge, there are no references to an acceptable level of floor and ceiling effects in similar technological studies. Quality criteria available in the literature suggest that floor or ceiling effects over 15% will reduce the reliability of the item in health status questionnaires. In addition, such an item cannot distinguish between the groups of responders scoring at either end of the scale [17]. Only 6 of the 22 items had an acceptable level (≤15%) of both floor and ceiling effects. Other SUTAQ studies [8,22] did not report on the floor and ceiling effects of each item

but did present histograms and means for the domains. It seems that the data on the domains *Satisfaction* and *Privacy and discomfort* were skewed in those studies [8,22]. Hirani et al [8] explained the skewedness of items as being linked to the dropout rate from their study, as persons dropping out could have scored somewhat different from the remaining participants, possibly leading to bias and reduced generalizability. The responders were expected to be more satisfied than nonresponders; this explanation could also be relevant for our Norwegian study. However, even if the remaining participants were more satisfied, the questionnaire did not capture details of their satisfaction.

Using an unvalidated questionnaire is a limitation as described by Streiner [18]. This refers both to the development of the questionnaire and to the generalizability of the translated version, which may lack equivalence with the original questionnaire. Being part of a large EU study, we agreed upon the selection of common questionnaires. Before our one-year follow-up, the partners decided to introduce the SUTAQ. At that time, we translated the instrument according to standardized procedures for translation [13]. This gave us knowledge about the participants' conceptual and semantic understanding of the items. If we had the opportunity to perform a questionnaire validation of the SUTAQ ahead of the study, this would have improved reflections about its validity. Another aspect is that SUTAQ was developed for the WSD study evaluating different technologies and measuring the acceptability of telehealth and telecare interventions, with a closer follow-up from health care personnel than that in the Norwegian self-management study. The differences in the content of the interventions between the original [8] and this mHealth study could have affected the validation analysis, as the SUTAQ might be more suitable for a different type of intervention than the one implemented in this study. Finally, even though we carefully followed the translation procedures, we cannot rule out the risk that the translation from English to Norwegian could have changed the understanding of the initial meaning of the statements in SUTAQ.

Originally, we aimed to perform a test-retest analysis to measure reliability, which would require data on 40-50 participants. Unfortunately, we did not reach the sufficient number of participants because of financial and logistical difficulties. We measured acceptability at the last point of follow-up in the study, making it difficult to collect additional retest questionnaires. Given that we had only 12 retest responders, we realized that we did not have enough statistical power to perform a meaningful test-retest analysis.

Implications for Future Research and Clinical Practice

In the diverse reality of technology and health, it is challenging to measure patient perception. Nevertheless, we are still in need of a questionnaire that measures the acceptability of digital interventions, given the current development and implementation of many new apps and Web solutions in health care. Health technology assessment as a systematic evaluation contributes

to the evaluation of various impacts of health technology [23], so there is a need for validated measurements of the acceptability of the technology among users. The SUTAQ measures several such relevant aspects, such as the impact on relations to health care personnel, privacy, etc. A relatively small sample size has restrained us from drawing any firm conclusions. SUTAQ should be validated using a larger sample and possibly a modified version developed for use in the Norwegian setting.

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Conflicts of Interest

None declared.

Multimedia Appendix 1

The Service User Technology Acceptability Questionnaire (original version; published with permission from Shashi Hirani).

[PDF File (Adobe PDF File), 402KB - [humanfactors_v5i4e10255_app1.pdf](#)]

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Abbreviations

EU: European Union

mHealth: mobile health

RCT: randomized controlled trial

RENEWING HEALTH: REgionNs of Europe WorkINg toGether for HEALTH

SUTAQ: Service User Technology Acceptability Questionnaire

WSD: Whole Systems Demonstrator

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Original Paper

Developing Culturally Sensitive mHealth Apps for Caribbean Immigrant Women to Use During Pregnancy: Focus Group Study

Hana AlJaberi¹, PhD

Department of Computer Graphics Technology, Purdue Polytechnic Institute, Purdue University, West Lafayette, IN, United States

Corresponding Author:

Hana AlJaberi, PhD

Department of Computer Graphics Technology

Purdue Polytechnic Institute

Purdue University

Knoy Hall

401 N Grant St

West Lafayette, IN, 47907

United States

Phone: 1 765 494 7505

Email: aljaberi.hana@gmail.com

Abstract

Background: A valuable addition to the mobile health (mHealth) space is an exploration of the context of minorities in developed countries. The transition period postmigration, culture, and socioeconomic uniqueness of migratory groups can shed light on the problems with existing prenatal mHealth apps.

Objective: The objectives of this study were to (1) use the theoretical concept of pregnancy ecology to understand the emotional, physical, information, and social challenges affecting low-income Caribbean immigrant women's prenatal well-being practices and (2) develop a deep understanding of challenges worthy of consideration in mHealth design for these women.

Methods: This qualitative interpretive approach using analytical induction presents the findings of 3 focus group sessions with 12 Caribbean immigrant women living in South Florida in the United States. The study took place from April to September 2015.

Results: The participants revealed problematic tiers and support needs within the pregnancy ecology including emotional stressors caused by family separation, physical challenges, information gaps, and longing for social support.

Conclusions: mHealth interventions for low-income Caribbean immigrant women must be designed beyond the conventional way of focusing on the events surrounding the unborn child. It can be tailored to the needs of the expecting mother. Pregnancy information should be customized on the basis of the variability of lifestyle, cultural practices, socioeconomic status, and social ties while still being able to deliver appropriate guidelines and clear cultural misconceptions.

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KEYWORDS

mHealth; human computer interaction; prenatal health; Caribbean; immigrant women; mobile phone

Introduction

Background

Caribbean immigrants represent 9% of all immigrant populations in the United States [1]. More than half of the Caribbean immigrants are women. Pregnant women in the United States do not have their first medical visit until between 8-13 weeks into their pregnancy [2,3]. Immigrant women, in particular, do not initiate any type of medical visits because of additional access challenges, including the cost of health care, lack of health insurance, or its limitations [4,5]. Caribbean immigrant

women face the risk of giving birth to very low birth weight children (<1500 g) at 2.4% compared with 0.7% for white American women [6]. In addition, they are susceptible to illnesses such as heart disease, asthma, poor breast health, and illnesses related to sexual intimacy [7]. Although their native tradition includes healthy foods, many are at risk of chronic type II diabetes for having to improvise their native diet in unhealthy ways when migrating to the United States [4]. The transition period postmigration can be especially challenging for the health of pregnant women. Added challenges for this minority group include limited knowledge of available medical resources in the new host country, lack of tailored care that

considers culture and language barriers [5], and stigmas associated with seeking mental health [8]. Medical and information gaps in care lead immigrant women to tap into informal resources of information [4,9], which introduces incorrect, conflicting, and misguided information [3].

One way to address health disparities is through the use of mobile phones (mobile health, mHealth) as opposed to traditional means, such as pamphlets and brochures, which are impersonal and often easily lost and forgotten [2,3,10]. It can ensure the delivery of accurate and timely information along with support capabilities for better pregnancy management. Nonetheless, disparities in mHealth technology adoption are evident in lower-income minority populations in the United States because of the lack of tailored interventions [2,5]. Several models of mHealth, for example, use text messaging prompts [11], birthing chat rooms [3], and activity tracking with extensive input commands [12]. However, the impact of body changes and unpredictable energy levels during pregnancy might not be represented well through traditional designs of mHealth activity promoting tools. In addition, existing pregnancy mobile apps focus on topics surrounding the birthing event such as fetal development, countdowns to delivery, generic nutritional tips, and birthing complications [3]; it does not facilitate culturally and socioeconomically personalized information.

Aims of the Study

During such vulnerable time, pregnancy can make women more receptive to interventions, which can arm them with health habits to extend beyond pregnancy [5,13-15]. The relationship between health outcomes for pregnant women and technology, in part through the creation of the term *pregnancy ecology* [3], seeks to create a nuanced understanding of the needs of pregnant women, who are often reduced to a series of data points and objectified as the adult carrying a baby to term. The term was specifically formed to emphasize the uniqueness of every pregnancy [3] and attempts to make clear the real value technologies can provide in aiding women with pregnancy health-related issues [2,3]. Therefore, the goal of this study is to develop a comprehensive understanding of the pregnancy ecology of low-income Caribbean immigrants that are deemed worthy of consideration in mHealth design.

Methods

Qualitative Study

This qualitative study adopted an interpretive paradigm that used an inductive analysis approach of its data collected from 3 semistructured focus group interviews. Focus groups were used to promote reflection among women for richer data [16] and for better time management with hard to recruit and busy participants. The focus group interview questions revolved around participants' ideas of what it takes to have a healthy pregnancy, what they found challenging, and where they obtained their pregnancy information. The study was approved by the Human Research Protection Program's Institutional Review Board at Purdue University.

Recruitment

Recruitment occurred concurrently while conducting focus group sessions taking place in April to September 2015. Four women were enrolled per session, for a total of 12 participants distributed among 3 sessions. Recruitment was successful through the process of snowball sampling [17]. The study's purpose and eligibility requirements were sent out via email to the contact list of Healthy Mothers Healthy Babies in West Palm Beach. In addition, they were posted on flyers along college and grocery store boards in South Florida and pitched in-person to potential participants through personal connections.

Sampling

One way of strengthening rigor was recruiting a representative sample using a criterion-based sampling strategy where a predetermined set of criteria is used to identify appropriate participants for the goals of the study [17]. Eligibility criteria were (1) low-income Caribbean immigrant women living in South Florida, (2) able to communicate in English, (3) at least one full-term pregnancy between the ages of 18 and 30 and within the last 5 years in the United States, (4) familiarity with basic technologies such as the use of cell phones and the internet. No participant-specific demographic information was collected to make women feel comfortable and safe. The study involved a small sample size of 12 female participants partly because of the extensive effort and time it took to recruit and motivate participants to enroll and then schedule the sessions with them.

Procedures

Each session took 1 hour to complete. The first 30 minutes were dedicated to reading the consent forms and familiarizing participants with the session rules. Each session was audiorecorded to help represent participants in this study accurately instead of relying on memory or the time-consuming process of note-taking. However, participants were advised that they could skip any question they do not want to answer or ask to stop recording at any time. A single copy of the audiorecordings was stored in a portable hard drive in an encrypted password-protected file that was destroyed within 2 months of transcribing the audiorecordings. No personally identifying information was audiorecorded. At the beginning of each focus group session, participants were asked to pick a fictitious name by which the moderator and other participants can use to communicate with them while the audiorecordings are in effect. After that, the focus group interviews took an average of 30 minutes to complete. Participants were asked to reflect on their pregnancy experiences as immigrants related to the following keywords: pregnancy, relationships, and technology (Multimedia Appendix 1). In addition, the questions provoked discussions of the important relationships influencing their pregnancy understandings, the technologies they used during pregnancy, and technologies used to interact with relationships affecting their pregnancy; furthermore, these questions probed participants to talk about their values indirectly. This was achieved by asking participants about common everyday events, obstacles, and behaviors in which they engage and which are important to them [18]. Even though this research focused on preventative mHealth care

interventions, it did not lend itself to investigating a specific wellness initiative in prenatal health care for immigrant women. Per examination of previous research [3], women were more receptive to discussing their subjective perceptions of prenatal health versus discussing objective medical initiatives such as healthy weight gain during pregnancy.

Data Analysis

The author transcribed audiorecorded focus groups immediately following each session, and an initial set of codes was developed. At that time, each transcription was supplemented with notes detailing the researcher's initial reflections on possible themes. After that, transcripts were reviewed, compared, and coded using inductive constant comparative method [19-21], and then coded using an iterative coding process. Inductive coding was used to summarize the raw data into key themes that emerge from the data itself as opposed to being implied beforehand. Within each transcript session, the researcher used tentative short descriptive codes to describe excerpts of text. The process of rereading the transcripts and refining the descriptive codes was repeated several times. As subthemes emerged, the researcher consulted with past literature [3] to help make sense of them. Then, the researcher tried to establish connections between the subthemes. Later, these subthemes were combined into a broader theme. For example, subthemes such as family separation and abandonment were combined with the broader category of emotional stressors as the headline theme. All transcriptions and a rough draft of chosen quotes, paraphrased materials, and analysis were made available to the participants for review. Therefore, participants were given an opportunity to clarify any misrepresentation, and approve of the accuracy of the data as an approach to strengthen the rigor of this qualitative research through respondent validation. Of note, this work is also part of a dissertation paper that involved the cross-checking of analysis and interpretation strategies by committee members.

Results

Overview

The following sections reveal themes and subthemes of problematic tiers and support needs within the women's pregnancy ecology (Figure 1). Portions of the transcripts are quoted in numbers that reference either focus group 1, 2, or 3 and then either 1, 2, 3, or 4 for each of the participants within each focus group. For example, Participant 2.3 refers to participant number 3 within focus group 2.

Emotional Stressors

This section aims to understand the emotional needs and stressors influencing the immigrant women's ability to engage in health-promoting behaviors.

Family Separation

Acclimating to a new country during pregnancy is challenging because of the absence of family and social support system to lift some of the burdens during this time. Participants described pregnancy to be a family affair, as illustrated in the following quote:

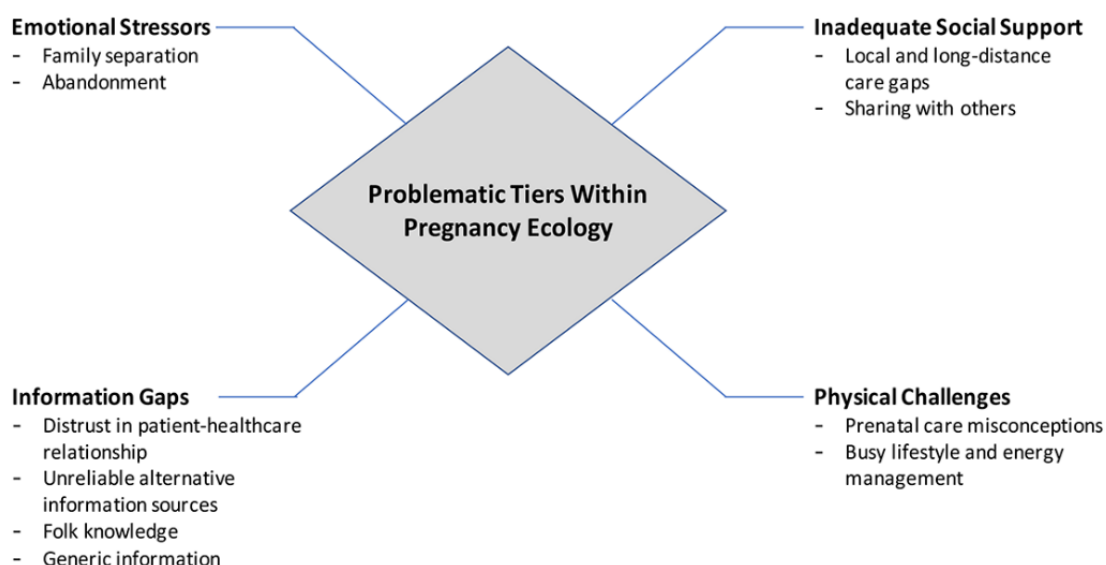
The pregnant journey for me is about family, the family connection. With mother, sisters, cousin friends, and friends. We talk about it, we plan it together, we make decisions together, you need each other. [Participant 2.3]

Consequently, women endured emotional stress during pregnancy triggered by homesickness.

Abandonment

Migration is a challenging time that is aggravated further during pregnancy, causing tensions between a woman and her partner. According to participants, pregnancy is celebrated among female members in Caribbean cultures. Despite such dynamic, separation from family support imposed lifestyle changes that require the expecting father to adapt and contribute.

Figure 1. Problematic tiers within pregnancy ecology.



When that does not happen, participants are left feeling abandoned and neglected, as illustrated in the following quote:

My husband like a ghost. He drink his beer and watch the tv without lifting na finger to help. Typical man...he can't be bothered. I don't need him anyway. What a man know? Na cook, na clean, na watch his own children to help me. [Participant 3.1]

The resulting emotional stress and added burdens on their time leaves the pregnant women without the right frame of mind to pursue available prenatal resources and good dietary and fitness behaviors. However, participants with an understanding partner found pregnancy to be an easier process. A supportive partner predicts their mood and takes care of house chores so that they may rest or have time to pursue health activities, as illustrated in the following quote:

My husband know when I am pregnant is his turn to get the girls ready in the morning for school. Its more for him because if I get me time I am in better mood because when you pregnant you know you can loose it sometimes in the head. [Participant 2.2]

Physical Challenges

This section addresses the physical challenges influencing the immigrant woman's prenatal health-seeking perceptions and behaviors.

Prenatal Care Misconceptions

During the focus group interviews, there were debates over several circulating prenatal guidelines. For example, there was a collective agreement among participants that deemed diet as one of the pillars to a successful pregnancy. However, there was confusion about appropriate diet and fitness guidelines. One major debate is the idea of eating for two without accountability, as illustrated in the following quote:

You eat for the baby and for you. Right now to be anorexic and worry too much about looking like supermodel better wait. [Participant 1.3]

Another participant objected, as illustrated in the following quote:

You should eat your craving but in moderation. You should not want to be skinny of course, but you don't just eat everything like you never going to have cake again. No, I am sorry, not good obviously. [Participant 1.2]

Some women believed that such control could lead to a birthmark deformity and, therefore, the expecting mother must submit to the demands of her pregnant body, as illustrated in the following quote:

...if you don't eat what you crave, your baby will have the blue with green marks somewhere in the body...I have cousins like that because my aunt man didn't eat what she was craving. You don't want your baby to live like that. [Participant 1.1]

In addition, there was debate over appropriate and safe levels of exercise. Several participants were not into the idea of

engaging in exercises once the physical appearances of pregnancy started to show, as illustrated in the following quote:

...walking is very good but not exercise especially when you start to show. You need enough rest and sleep. [Participant 2.1]

However, when one participant expressed approval over the benefits of fitness during pregnancy, as illustrated in the following quote:

People say is not good to exercise when you start to show. Before you show is ok? Really? I use to think the same but walks ok only. But you have all celebrities exercise when pregnant, so I am curious now ok? I Googled, and find out it is good for you. It will make your mood better, and delivery of your baby so much easier. [Participant 1.4]

Another participant interjected with sarcastic disapproval, as illustrated in the following quote:

...so you are one of the crazy Instagram pregnant woman with six abs. [Participant 1.3]

Busy Lifestyle and Energy Management

The women's migratory circumstances imposed lifestyle changes such as limited financial resources, changing roles in the household, and feelings of abandonment. Thus, some struggled with fatigue due to demanding responsibilities during pregnancy, as illustrated in the following quote:

I heard about exercising but my feet hurt too much after work and then I have to cook and clean. My sister helps but I'm just so tired! [Participant 3.3]

Despite struggling with energy management during pregnancy, very few women recognized the benefits of exercising to improve energy levels, as illustrated in the following quote:

I also like walking and squatting every day when I am pregnant. Sometimes I do it first thing in the morning before I go to work, gives me good energy. Or before sun go down after work. Helps me with stress and give me some energy to cook and spend time with my family before bed. [Participant 2.2]

However, some expressed that it was challenging to stay active because of their busy schedule, as illustrated in the following quote:

Think about it. Some of us might have two jobs. This city is not made for walking. Back home you walk a lot to get from a to b. But here if you take the bus, commute can be more than one hour, you sit on your ass. [Participant 1.1]

Information Gaps

This section discusses the participants' perceived access challenges to prenatal information as a result of their migratory lifestyle.

Distrust in Patient-Health Care Relationship

Participants felt rushed during hospital visits and described doctors as impersonal and nurses as rude and impatient, as illustrated in the following quote:

I ask the nurse at the clinic and she turn her nose up at me. The doctor don speak in a language I understand then push me out. [Participant 3.1]

Others accused the health care system of being a scam because of overused and unnecessary tests, as illustrated in the following quote:

They tell you all these things you need that you don't need, or something wrong with you to charge you for tests you don't need. [Participant 2.2]

Unreliable Alternative Information Sources

As participants felt abandoned by medical professionals, they tapped into informal resources like Web-based search engines, family members, and mom friends. Search engines such as Google provided a platform for self-guided help. In addition, Google provided a discrete element for private use, as illustrated in the following quote:

Sometimes some of the questions you have is embarrassing to ask your mom or doctors. So I just go on Google. [Participant 1.2]

Even though helpful, the women found such mediums yield at times conflicting and overwhelming information, as illustrated in the following quote:

But, many times I get very stressed because there is too many opinions to choose from. Or sometimes the language is very medical. [Participant 1.3]

Because of these disqualifying characteristics, participants turned to family members and social circles for help, as illustrated in the following quote:

My mom and my sisters. We all have children so we talk about it all the time and we share advice when anyone is pregnant. [Participant 1.4]

Folk Knowledge

There were many culturally and socially informed health tales during the focus group discussions. One participant recalled an encounter with her mother, as illustrated in the following quote:

When she came to see me first time I was pregnant, she never been to our apartment before, right? She freaking because the floors are tile, naaa you can't walk inside your house without shoes because having bare foot on the tile hurt the baby. Actually, the bedrooms she thought were hardwood so can't walk on either. But, ma these are, you know what you call them, you know, laminate, right? Yea yeah man laminate. I'm just dying laughing, she don't know the difference. [Participant 2.1]

Another participant recalled a story from her mother, as illustrated in the following quote:

My mom even tell me to cook the meat rare because the blood help the baby grow. What?! Eat anything red like red fruits because it is good blood for the baby. [Participant 2.4]

Participant 2.1 expressed disapproval of such folk discourses as illustrated in the following quote:

I love my mom, I don't know what I would do without her ever especially when I get pregnant. But, just there are some times she really get on my nerve and stress me out because she still old school, like the thinking. [Participant 2.1]

...while Participant 2.3 expressed approval and belief in such discourses:

How about eating spicy food? Is that not good for the baby? I believe when people tell me things like that. [Participant 2.3]

Generic Information

Participants disliked generic pregnancy print, Web, and mobile apps that focus mostly on the unborn child and the birthing event versus meeting the health and well-being needs of the expecting mother, as illustrated in the following quote:

Most apps about the baby. But, what about me? Even when is about the baby, is out of touch, you know. I am homesick when pregnant, I need a flavor of home there. Otherwise, I am just bored. It has stupid things like your baby now is this fruit size. I also want things for me, how I can manage emotion, exercise, eat good, dress comfortable, lotion, spanx, whatever to help me have healthy baby and also feel good. [Participant 2.2]

For these immigrant women, other dislikes stemmed from information resources being insensitive to their socioeconomic status and cultural practices. Some women acknowledged wanting to take care of their diet. However, they were discouraged because existing prenatal resources do not factor their socioeconomic challenges into dietary and nutritional guidelines. Their socioeconomic status affects their perceptions of what is realistically attainable, which, in turn, discourages them from pursuing a healthier lifestyle, as illustrated in the following quote:

Okay think about it. You can want to be healthy all you want, is just wishes. The real life is a different story. Eating healthy food is very expensive. [Participant 2.4]

In addition, existing resources lacked sensitivity over their cultural food preferences, as illustrated in the following quote:

I don't trust what dem website say. People are different. I need answers from my own people, that why I ask family. All dem white lady doin the yoga, drinkin the Starbucks, and eatin like them bunny rabbit nothing but vegetables and blogs. These apps don't tell me na ting new! I dun need pictures of how a white lady baby grow in her belly! Me want rice and beans, that brown stew, and leave me be. [Participant 3.1]

Social Support

In this section, the perceived social support capability gaps by immigrant women in existing systems are discussed.

Local and Long-Distance Care Gaps

Participants pointed out specific members of their social circle as sources of support for their emotional or informational needs when dealing with pregnancy stressors. For example, participants used social media, video, and group texting technologies to maintain ties in their home country during pregnancy, as illustrated in the following quote:

I always communicate with my mom when pregnant, more than the usual. She stays in my country. So, it's hard to talk on phone whenever I like. But, she knows how to use Internet now, we use Whatsapp and Skype whenever we can. [Participant 1.3]

In addition, participants wanted to see the role of the husband addressed, as illustrated in the following quote:

Also, this just funny, but help women know how to get their husband more involved since some have issues with that. [Participant 2.2]

In expressing why they were not the intended match for existing apps, one participant argued that these were mostly designed for American women who might relate to pregnancy differently, as illustrated in the following quote:

It's good for them maybe because you find some cute things like special dates in pregnancy, when your baby gets fingers and whatever, kicks or what that kick means. For some woman, maybe pregnant is hard, so maybe it can help you connect with emotion with your baby that you don't know him or her. It can make it more fun when you are feeling not so good, your body hurts. I'm thinking, maybe... The pregnant journey for me is about family, the family connection. With mother, sisters, cousin friends, and friends. We talk about it, we plan it together, we make decisions together, you need each other. I'm too busy with that side of things, making memories. [Participant 2.3]

Sharing With Others

Participants were comfortable sharing with a tight circle of parents and siblings, followed by few very close friends. The same courtesy was not extended to other family members and acquaintances, as illustrated in the following quote:

Ultrasound only for my mother and sisters and very close friends. Not even for the rest of the family...no ultrasound for everyone to see. If you have haters, you need to be careful. [Participant 1.3]

The findings revealed that the women's sharing habits in their personal social media profiles proceeded with caution during pregnancy. One reason for such cautious, limited practices is cultural beliefs. Some believed that people's jealousy or envy might cast a curse, leading to misfortune, and that some might inflict harm on you through acts of witchcraft and voodoo practices, as illustrated in the following quote:

I myself scared to share too much happy pictures because there are haters, people you know, and I don't want something bad to happen to my baby. [Participant 1.1]

When participants did encounter pregnancy Web or mobile tools, they recalled social capability features such as chat rooms that grouped women together with the same birth month. Participants disliked such tools and cited reasons of observing bullying incidents, receiving conflicting information, and responses that go out on irrelevant tangents, as illustrated in the following quote:

If you have a good question, no one answer, no one care. Only if you a drama queen question, like my baby daddy drama, I don't know what. [Participant 2.1]

A participant went so far as to describe such mediums as an episode of "bad girls club" [Participant 2.1], a reality television series of clashing personalities living under one roof.

Discussion

Design for the Expecting Mother

Participants did not find something specifically directed at their needs as expecting mothers other than generic pregnancy mobile and Web apps focusing on the relationship to the unborn child, birthing, and postbirthing events. These solutions fail to be relevant in addressing prenatal health care challenges faced by recent immigrant women. Several women acknowledged wanting to manage pregnancy and adopt a healthier lifestyle but admitted to not having the proper information and circumstances to do so. Therefore, the study advocates for interventions that focus on the expecting mother by providing support with immigrant women's physical, information, social, and emotional stressors.

Tailored Interventions

One crippling access challenge to prenatal medical information for the interviewed immigrant women is not mapping information to align with their demanding day-to-day lifestyle, and lacking sensitivity to their cultural practices. For example, dietary guidelines and nutritional suggestions do not consider minorities' cultural connections [4,22-24] that affect their food preferences and choices. As the results revealed, there is a disconnection between medical information and the realities these women live. For immigrants, there is an emotional connection with familiar food, especially when acclimating to a new unfamiliar environment [4]. In addition, the study calls for sensitivity to the women's low-income socioeconomic status when recommending nutritional guidelines. The case in point here is not solely over what the recommended cuisine should be. From a design perspective, the bigger picture is that participants would adopt technologies that support their lifestyle. Participants felt excluded from prenatal health tech solutions, perceiving them as designed exclusively for "white rich ladies [Participant 2.3]." Thus, interventions must deliver information in a way that supports their busy day-to-day lifestyle, cultural practices, and socioeconomic status to achieve successful practice and adoption.

Clear Cultural Misconceptions

Because of medical access challenges, the immigrant women seek guidance from their social circles and the internet instead. Women are then exposed to conflicting, misguided, and false information. The debates reported earlier surrounded topics such as safe fitness levels and practices, ideal food consumption habits, and healthy weight management; these are similar misguided topics reported for low-income pregnant American women [3]. However, the study's findings added cultural discourses unique to this demographic. In this case, examples included narratives linking birthmarks to unfulfilled cravings, red foods and baby animals for fetal development, wood floors to miscarriages, and so on. The design of mHealth interventions should address not only common misconceptions but also culturally and socially specific folk wisdom discourses specific to a targeted demographic. This is an area in which mHealth design can make a significant contribution to pregnant immigrant women's health.

Include Social Circles

The findings revealed the significant other, whether compassionate or indifferent, plays a major role in a woman's pregnancy. Another example was revealed in the role of family and close friends play in an immigrant pregnant woman's life. Because of the long-distance separating families and the idea that pregnancy is a family affair, facilitating a platform for the family to participate in an immigrant's pregnancy practices presents an opportunity for mHealth design. While previous studies [3] emphasized the role of the spouse alone in a woman's pregnancy, this study introduces the mother and siblings who are just as important. Mothers especially seem to play a dual role, in which they are a reliable support system, while at the same time a source for folk misconceptions. The mother's role is something that has been ignored in past mHealth literature. Such relationships represent indirect stakeholders that might affect whether the woman decides to adopt a technology or not. Thus, designs should prompt others to participate in the intervention to aid in supporting the user. This type of interaction engages the intimate relationships in a pregnant immigrant's

life and provides a platform for rebuilding social support with relationships that affect their health behaviors. In previous health communication human-computer interaction and social networking research [25-27], pregnant women have been described as being comfortable sharing pregnancy and motherhood information on Web-based social settings, even with strangers; this certainly contradicts with the findings in this study and a previous study on low-income pregnant American women by Peyton et al [3].

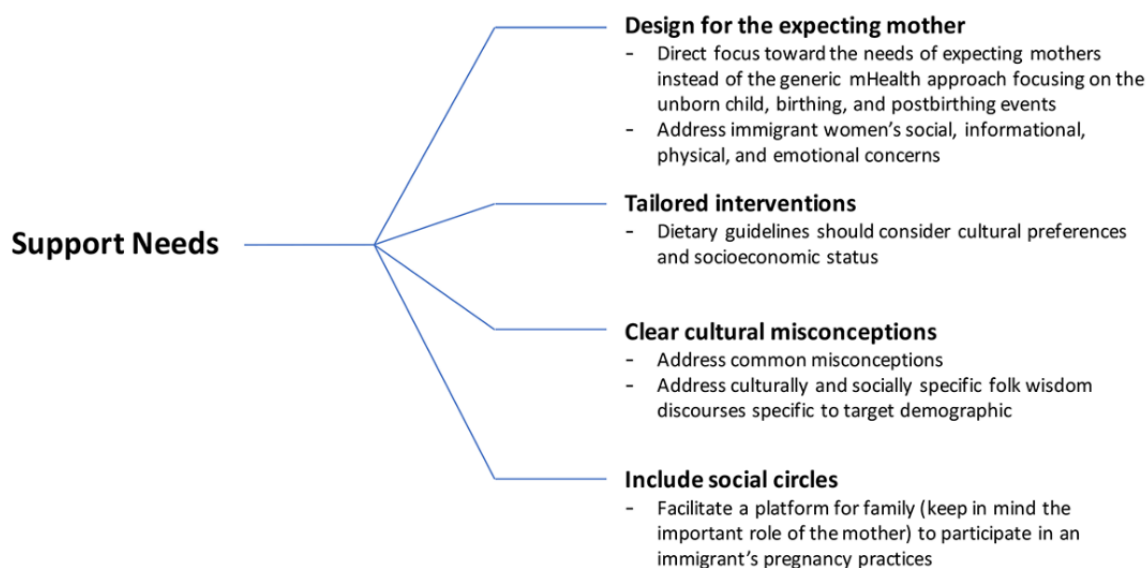
The author takes a more in-depth view of this aspect in a recently published work [28]. The study expands the discussion on the social theme that emerged from the focus groups here and uses codesign workshops under a participatory action framework to propose social and organizational design needs and recommendations for effective mobile tools for the women. In addition, it explores the immigrant women preferred interaction scenarios in mHealth design.

Stemming from the study's findings, an alternative approach to designing prenatal mHealth technologies that can be explored and expanded further in future studies is set forth with the following recommendations: design for the expecting mother's needs, design tailored interventions, clear misconceptions, and consider the role of social circles (Figure 2).

Limitations

Those who could not communicate in English were excluded from the study. In that sense, the study did not take into account language barriers as part of a comprehensive picture of understanding the barriers to accessing available technologies. In addition, the small sample size in this study presents a challenge to the generalizability of the study findings. However, the inductive exploratory nature of this research warrants and benefits from the use of small sample sizes. A small sample size allows the researcher to assume an active role in recruitment and engagements with participants, which can help generate richer multidimensional data. It is also convenient to attain continual access with participants to validate the data and strengthen its reliability [29,30].

Figure 2. Design recommendations.



Conclusions

Migration stressors can impose health challenges on a pregnant woman. As this study joins others in addressing the health needs of minority groups, it advocates designing of appropriate prenatal mHealth interventions that explore the multidimensional ecology of pregnant low-income immigrants. Thus, the study's methods aimed to understand how immigrants view their ecological gaps that challenge and influence technology design

and adoption. Prenatal mHealth interventions must be explored beyond the traditional way of focusing on the events surrounding the unborn child. They must tap into the needs of the expecting mother and beyond by, for example, considering the role social ties play as motivators or challengers to her pregnancy well-being. Furthermore, it must explore ways that customize pregnancy information based on the variability of lifestyle, cultural practices, and socioeconomic status, and yet be able to deliver appropriate guidelines.

Conflicts of Interest

None declared.

Multimedia Appendix 1

A script of focus group questions.

[[PDF File \(Adobe PDF File\), 24KB](#) - [humanfactors_v5i4e29_app1.pdf](#)]

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Abbreviations

mHealth: mobile health

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Original Paper

Applying Persuasive Design Techniques to Influence Data-Entry Behaviors in Primary Care: Repeated Measures Evaluation Using Statistical Process Control

Justin St-Maurice^{1,2}, PhD; Catherine Burns¹, PhD; Justin Wolting³, BSc (Hons)

¹Systems Design Engineering, University of Waterloo, Waterloo, ON, Canada

²Applied Health Information Science Program, School of Health & Life Sciences and Community Services, Conestoga College Institute of Technology and Advanced Learning, Kitchener, ON, Canada

³Guelph Family Health Team, Guelph, ON, Canada

Corresponding Author:

Justin St-Maurice, PhD
Systems Design Engineering
University of Waterloo
200 University Avenue West
Waterloo, ON, N2L 3G1
Canada
Phone: 1 5198884567
Fax: 1 5197483563
Email: jstmaurice@conestogac.on.ca

Abstract

Background: Persuasive design is an approach that seeks to change the behaviors of users. In primary care, clinician behaviors and attitudes are important precursors to structured data entry, and there is an impact on overall data quality. We hypothesized that persuasive design changes data-entry behaviors in clinicians and thus improves data quality.

Objective: The objective of this study was to use persuasive design principles to change clinician data-entry behaviors in a primary care environment and to increase data quality of data held in a family health team's reporting system.

Methods: We used the persuasive systems design framework to describe the persuasion context. Afterward, we designed and implemented new features into a summary screen that leveraged several persuasive design principles. We tested the influence of the new features by measuring its impact on 3 data quality measures (same-day entry, record completeness, and data validity). We also measured the impacts of the new features with a paired pre-post *t* test and generated XmR charts to contextualize the results. Survey responses were also collected from users.

Results: A total of 53 users used the updated system that incorporated the new features over the course of 8 weeks. Based on a pre-post analysis, the new summary screen successfully encouraged users to enter more of their data on the same day as their encounter. On average, the percentage of same-day entries rose by 10.3% for each user ($P < .001$). During the first month of the postimplementation period, users compensated by sacrificing aspects of data completeness before returning to normal in the second month. Improvements to record validity were marginal over the study period ($P = .05$). Statistical process control techniques allowed us to study the XmR charts to contextualize our results and understand trends throughout the study period.

Conclusions: By conducting a detailed systems analysis and introducing new persuasive design elements into a data-entry system, we demonstrated that it was possible to change data-entry behavior and influence data quality in a reporting system. The results show that using persuasive design concepts may be effective in influencing data-entry behaviors in clinicians. There may be opportunities to continue improving this approach, and further work is required to perfect and test additional designs. Persuasive design is a viable approach to encourage clinician user change and could support better data capture in the field of medical informatics.

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KEYWORDS

data collection; data entry; data accuracy; health care; persuasive design; persuasive systems design framework; user interface

Introduction

Background

Technology can be designed to trigger emotional responses in humans, which can lead them to interact with technology as if it were a social actor. Behavior change techniques, such as persuasive design, can be used to intentionally design technology to change people's attitudes and behaviors by leveraging social processes [1,2].

There are many advantages to using technology to influence behavior change: technology can automatically deploy persuasion strategies in real-time as users are performing a task; technology is persistent and consistent; technology can be deployed anonymously; and technology can exist in locations and contexts that are not possible for humans. Persuasive design can also quickly adapt to large amounts of data, simultaneously attempt several modalities to influence people, and can quickly scale once successful [1-3]. To date, the use of persuasive design in health care has focused primarily on consumer-facing mobile apps and has aimed to improve health outcomes [4]. In contrast, there are few examples of using persuasive design to influence clinician behavior within clinical systems, such as within an electronic medical record system.

Despite an absence of studies exploring the use of persuasive design to change clinicians' behaviors, several studies have shown that basic social processes, such as persuasion and social comparisons, can successfully initiate behavior change. For example, a successful approach called audit-based education consisted of group meetings and presenting comparative data to individual physicians [5] and was described as the most successful change agent for influencing clinicians' attitudes and habits regarding data entry [6]. More recently, a data quality feedback tool generated comparative data quality metrics between practices; data recording behavior and data quality improved significantly through the use of social comparisons between users [7].

Since clinicians can be influenced to change data-entry practices through social comparisons, and since persuasive design is intended to allow technology to emulate and facilitate these types of social processes, we hypothesize that persuasive design is a suitable approach to motivate clinicians to enter higher quality data into electronic systems. Conceptually, persuasive design can be leveraged to change clinician attitudes and behaviors regarding data-entry tasks.

Data Entry in Primary Care

Primary care is an important part of the health care ecosystem. Primary care data is unique because it includes a patient's entire health history and may extend from the patient's birth until their death. As such, primary care data can be used for secondary purposes such as auditing, quality improvement, health service planning, epidemiological study, research, and measuring care quality [8,9]. Primary care data has also been used in novel ways to investigate challenging and broad health system problems [10-13]. However, the effective secondary use of this data is contingent on its quality.

There are many barriers to entering high-quality structured data into an electronic medical record. These barriers include user skill gaps, task time, and professional and organizational priorities [6,14]. The crux of the challenge with data quality in primary care is that clinicians are often asked to structure their data by clinic managers and consultants, but prefer writing unstructured narratives [15]. Entering structured data is also challenged by a lack of perceived value for future uses by clinicians. In many cases, clinicians do not fully accept the merit of entering structured data [16], and this negatively impacts data quality for secondary uses. One important finding in the literature is that the completeness and accuracy of primary care data often rely on the enthusiasm of clinicians [17]. The user interface for structured data entry is often simple and can facilitate the creation of structured data with minimal training; entering usable data requires appropriate entry behaviors and attitudes of clinician users.

In a previous study [18], several data quality benchmarks were developed based on the historical analysis of entries in a system designed to measure the effectiveness and costs of services. The study found that while 97.4% of the entries were valid (ie, logically consistent), only 21.7% of the entries were considered complete (ie, users had entered all the necessary information). As well, only 50.7% of the entries had been recorded on the same day as the clinical encounter. The study also described corollaries between data validity, data completeness, and data timeliness and concluded that entries were more likely to be valid and complete if they had been entered on the same day as the clinical encounter.

As health care reforms aim to improve the efficiency of care, organizations need to find ways to track the effectiveness, quality, and cost of care and services. This data is critical and cannot be accurately captured through free text and unstructured narratives. Organizations must continue to ensure that clinical documentation exists to serve patients, and they must also find ways to capture high-quality data for secondary use. Information systems and human processes need to adapt to evolving requirements and data needs.

Systems Analysis and Persuasive Design

Cognitive work analysis (CWA) is a systems analysis framework that facilitates the analysis of the environment at various levels of detail and assesses how the environment impacts and shapes the human-information interaction. CWA is a systematic method that can be used to examine work activities of participants in workflows and processes with environmental, organizational, and social lenses [19].

CWA is well suited to consider the sociotechnical relationships between information systems and human processes and is an effective tool for designing systems for changing environments. CWA is broken down into 5 stages of analysis: work domain analysis, control task analysis, strategies analysis, social organization and co-operation analysis, and work competencies analysis [19]. Each stage of CWA provides a different level of detail for a complete analysis of a domain.

Oinas-Kukkonen and Harjumaa developed the persuasive systems design framework [3,20] to facilitate the identification

and incorporation of persuasion principles into effective designs. Persuasive system design uses the idea of a persuasion context to define *how* users could be persuaded. Persuasive system design does not, however, link directly to a specific systems analysis framework; a designer needs to identify *who* the users are and *why* the change is required before they can build an effective persuasion context.

Recently, efforts have been made to link CWA to the persuasive system design framework [21,22]. Since the CWA framework provides a systematic approach to understanding ecology and cognition, it easily addresses many of the information requirements described by Oinas-Kukkonen and Harjumaa [3,20]. As well, the idea of tying CWA to Fogg Behavior Model [23] and persuasive system design has previously been explored by Rezai and Burns [24], though with only a few phases of the CWA framework.

Importantly, current literature has recently started to draw a link between CWA and the persuasive system design framework, providing a set of tools covering the complete analysis-to-design spectrum of persuasive design.

Study Objective

Previous studies have shown that entries are more valid and complete if they are entered on the same day. However, only 50.7% of entries were recorded on the same day [18,21]. Thus, there is a need to find ways to influence clinician's behaviors around data entry and data quality. The required behavior changes include encouraging users to enter their data on the same day as their patient encounter, encouraging users to enter a complete entry within the structured form, and encouraging error-free entries. Our objective was to expose clinicians to persuasive design in order to modify their data-entry behaviors.

Methods

Study Design

During our study, we analyzed the persuasion context of a primary care data-entry task. Following the analysis, we designed and implemented an updated user interface that implemented new persuasive features. Finally, we tested the influence of the new user interface on clinicians' data recording behaviors and its impact on data quality.

Study Context

In Ontario, there are over 200 family health teams. These organizations are Ontario's implementation of team-based care. Family health teams employ allied health professionals, such as nurses, dietitians, social workers, and pharmacists. Allied health professionals provide supplementary services (such as one-on-one counseling and group therapy classes) to patients in the community. Patients are referred to allied health professionals by their family doctor at no cost. Family health teams are intended to improve the quality of primary care services and access to primary care physicians.

Family health teams must report the activities of their allied health professionals to the Government as a condition of

funding. Though some of this information is available within medical records, extracting the information in a format that aligns with the reporting requirements is challenging. As well, electronic medical records are not easily adapted to new reporting requirements. Furthermore, if organizations have more than a single electronic medical record for documentation purposes, the challenges associated with collecting consistent data is compounded. In this context, family health teams with numerous allied health professionals working in multiple locations have opted to create separate systems to collect data for reporting purposes. These types of systems require allied health professionals to answer short survey questions for each clinical encounter. The collected data is aggregated to generate reports for the government and internal process improvement.

One family health team (the "organization") uses a separate data collection system (the "reporting system") to collect data from its allied health professionals. The organization's reporting system is an excellent example of a structured data-entry prompt, and it parallels the processes and use-cases of structured data entry in electronic medical records. Since the reporting system is incorporated into normal workflows, the tool is an interesting opportunity to explore data-entry behaviors in clinicians and benchmark data quality [21]. The organization's current data-entry screen is shown in Figure 1.

The organization had a staff of approximately 110 and served 20 different family practices and 90 doctors in the community. A total of 53 employees were active users of the reporting system and used the system at least once per month. The organization was interested in finding ways to improve data quality in its reporting system. Based on a previous study, only 50.7% of the entries within the data collection system were recorded on the same day as the clinical encounter by allied health professionals [18]. As a primary goal, the organization wanted to introduce persuasive design to increase the number of entries that were entered on the same day as the clinical encounter. The organization saw improving the validity and completeness of the data in the reporting system as secondary objectives.

We worked with the organization to understand the sociotechnical context of the allied health professionals' data recording task and developed a new user interface for the reporting tool to improve data quality. Over the course of several months, we measured the impact of the user interface changes.

Analysis of Persuasion Context

To describe the persuasion context, we linked the CWA systems analysis framework to the persuasive system design framework. We used data from a CWA conducted over the course of another study [21], where a CWA was completed regarding the reporting system's data-entry tasks. Based on the results of the work domain analysis phase, we had access to several abstraction hierarchies that showed relationships between the organization's goals, benchmarks, professional norms, and impacts on population health outcomes [14].

Figure 1. Screenshot of the reporting tool data entry screen.

RECORD INDIVIDUAL ENCOUNTERS

*** Denotes a required field**

Appointment Date*

Clinic

Office ▼

Type of Encounter*

Initial Visit ▼

Referral Date ☒ I know the date the referral was received

Referral Source*

▼

ARRIVAL STATUS

☒ On Time
 ☐ Late
 ☐ Cancellation
 ☐ Late Cancellation
 ☐ No Show

PATIENT INFORMATION

Patient*

test, sdoh - Birthdate: 2015-08-05

Presenting Problem*

COPD ▼

☐ Show list of other topics discussed

APPOINTMENT OUTCOME

Visit Outcome*

Referred to Psychiatry ▼

☐ Show list of secondary outcomes

Duration Of Encounter(minutes)*

Other Patient Specific Time (minutes)

Comments

Spent 30 minutes trying to call psychiatry.

Based on the results of the control task analysis and strategies analysis phases, which described decision making regarding data entry and strategies employed by users to accomplish the work, we had decision ladders and information flow maps to describe user decision making and strategy adoption [14,21]. Each CWA model helped identify the user's ecosystem and elements that would influence their behavior.

In persuasive system design, several principles are intended to support persuasive design. To identify which principles would be appropriate within the persuasion context, we used a CWA to inform a who, what, where, when, how (WWWWH) paradigm. Our ecological approach to persuasive design takes advantage of the strengths of each framework: CWA provides insight about *context, ecology, and cognition*; Fogg Behavior Model provides information about *when* the change will occur; and persuasive system design provides *tools and design* ideas

that can create a change in behavior. The combination of these frameworks filled the analysis-to-design spectrum with a series of useful tools and sources of information. This was a novel approach to filling the analysis-to-design gap and generated a useful design concept to implement and test.

To link our models from CWA to the persuasive system design framework, we took previous work [22,24] a step further by adopting the WWWWH paradigm to map the spectrum of the persuasion context to our CWA. This use of a WWWWH approach is similar to a previous approach by Mohr et al. [25] but establishes a link to a full ecological framework and toolkit from a well-known systems analysis framework. For each of the questions of the WWWWH paradigm, we linked appropriate sources of information from the CWA. We also captured *when* a change would occur by mapping information from the CWA to inform Fogg Behavior = Motivation + Ability + Trigger model [23]. Our WWWWH approach linked specific sources of information to describe the persuasive context, which could then be used by the persuasive system design to develop an effective design. The mapping of each framework to the WWWWH paradigm is shown in Table 1.

Development of Persuasive Design

After defining the persuasion context, we identified several persuasive design principles that could help change the data-entry behavior [21]. These principles were selected from the persuasive system design framework [3] behavior. The persuasive design principles were incorporated into several different user interface designs and discussed with the organization. A final design was developed over the course of several months, during which drafts and comments were sent back and forth between our team and the organization until the design was acceptable to all parties. The design was then implemented and tested by the organization's application developers.

Evaluation of Impacts

The new design was published as an update to the organization's reporting system. We measured the impact of the new design to measure the impact persuasive design had on user behaviors related to data entry.

Table 1. Linking cognitive work analysis to the persuasive system design's persuasion context.

WWWWWH ^a paradigm and Fogg Behavior Model	Persuasive system design framework			Analytical need	Cognitive work analysis context	Cognitive work analysis phase(s) and outputs
	Intent	Event	Strategy			
Who	Persuader	User	N/A ^b	Identify the persuader and the user or class of users who are the target of the persuasive intervention.	Ecological	Work domain boundaries (Phase 1) and social organization models (Phase 4)
What	Change type	Technology	N/A	Identify what behaviors need to change and what the new target action or behavior looks like.	Cognitive	Descriptive decision-making logic trees (Phase 2)
Why	N/A	Use	N/A	Contextualize the reasons for the task in the complex system. Why did old behaviors develop and what are the constraints on new behavior?	Ecological	Hierarchical relationships between ecological factors (Phase 1)
When						
Motivators	N/A	N/A	N/A	Identify motivating factors within the ecology.	Ecological	Hierarchical relationships between ecological factors (Phase 1)
Abilities	N/A	N/A	N/A	Identify user abilities and capabilities. Identify constrained resources (eg, time, money, etc).	Cognitive	Descriptive decision-making logic trees (Phase 2) and skill taxonomy (Phase 5)
Triggers	N/A	N/A	N/A	Identify reasons users adopt specific behaviors or strategies.	Ecological	Descriptive decision-making logic trees (Phase 2) and strategies analysis (Phase 3)
How	N/A	N/A	Message route	How will we create a change? What design principles and strategies would be appropriate?	N/A	N/A

^aWWWWWH: who, what, where, when, how.

^bN/A: not applicable.

Ethics

The study was submitted to the University of Waterloo Ethics Board and approved before the deployment of the new design and before the collection of data. To measure the impact of the new design, the study was positioned as a secondary analysis of data, as the organization was opting to independently deploy a suggested design. Data were collected by the organization, and users were not required to opt into the study because the change was implemented as part of the organization's normal software revision and update cycle. We served a consultancy role to assess the impact of the change as a third party. All data shared for the study was deidentified, and we had no direct contact with users.

In order to collect direct feedback and comments, the organization identified contacts to discuss the results in semistructured interviews. These contacts completed consent forms. Users were also invited to complete an anonymous survey and consented to their participation.

Throughout the study, the new design did not endanger the availability of patient data or risk the organizations' ability to report its activities. The design changes were considered passive and posed negligible risks to the organization, its users, and patients.

Measures

To measure the impact of the summary screen on data entry, we calculated measures of record validity, completeness, and timeliness. These measures were developed collaboratively with the organization during a previous study of the same system [18]. Each of our measures is defined in Table 2.

Statistical Analysis of Measures

To measure the effectiveness of the intervention, the field study was set up using a repeated measures experimental design. We analyzed data spanning a period of 16 weeks by looking at data before and after the new design was deployed. Each data quality measure was calculated for each user 8 weeks prior and 8 weeks after the implementation of the new summary screen. The measures for each user were averaged for the pre- and postperiods. The total number of entries (ie, patient visits) were compared between periods to ensure that the visit volume was not significantly different. Data from the premeasurement and postmeasurement periods were analyzed with a paired *t* test. *P* values, Cohen *d*, and power were calculated.

Statistical Process Control

We expected noise within the dataset and assumed it could skew results positively or negatively. Noise in our measures, which were generated from a real-world, dynamic, sociotechnical system over the course of 16 weeks, would not be abnormal. For example, management meetings, programming changes, organizational behavior, strategic direction, and management priorities could easily change behaviors during the study. As well, it should be expected that patient volumes and care needs fluctuate seasonally and over the study period (eg, higher volumes for the flu in the winter and lower volumes for assessments around the holidays as staff use vacation time). We wanted to ensure that our statistical results were not attributed to normal changes or noise.

Measuring changes to variables within a "noisy" complex system is not a unique challenge in health care. This issue is often encountered when evaluating quality improvement initiatives in health care and is supported by the use of statistical process control (SPC) [26,27]. Thus, in our study, we contextualized the impact of our intervention by using SPC techniques to measure variance over time.

The notion of SPC is to measure process variance in 2 categories. The first type of variance in SPC is chance variation (also known as common cause variation). This category of variation is caused by phenomena that are always present within a system. Chance variation is anticipated noise associated with normal system operations. The second type of variance in SPC is assignable cause variation (also known as special cause variation). This category of variation is caused by phenomena that are not typically or historically present in a system. Assignable cause variation is associated with changes to the system's operation [28].

A common display tool for SPC, the XmR chart, consists of 2 graphs. The first graph in the chart is a measure of a variable over time (*X*). This graph shows the mean calculated value for the analysis period, an upper control limit, and a lower control limit. A line graph is shown over a period of time. If values are above or below the control limits, they represent assignable cause variation. Values between the control limits represent chance variation. The second graph in the chart shows the moving range (*mR*) between each value in the *X* graph. A mean value for the period and an upper control limit are also shown. These graphs represent the absolute value of the change from period to period and can be used to identify significant variation. Variation above the upper control limit is abnormal [28].

Table 2. Data quality measures.

Measure name	Definition
Percent same-day entry	The percentage of entries that were entered on the same day as the appointment.
Percent complete	The percentage of entries that were measured as complete. An entry was considered complete if all fields had data and if the reason for the visit was not specified as "other." If the visit was an initial encounter, the referral source was required.
Percent valid	The percentage of entries that were measured as valid. An entry was considered valid if the appointment date occurred before the entry date, if the appointment date occurred after January 1, 2008, and if the amount of time between the appointment date and entry date was <4 months. If the time between the referral date and the appointment date was greater than 6 months, it was considered invalid.

SPC is intended to be used when measuring change within a complex system with many sources of noise. Normally, SPC is used to measure quality improvement by a team and becomes part of an overarching quality improvement philosophy; teams use SPC during weekly or monthly meetings to track progress, identify potential signal changes and causes, and improve processes. To analyze behavior change in data entry, SPC lends itself well to putting any observed changes into context.

We created SPC XmR charts for each of our data quality measures. We generated XmR charts with the *R* statistical software and the qicharts package. The chart generation was scripted and automated to take data directly from a secondary Structured Query Language database that performed the data grouping. To give context to the results, the XmR charts were generated with data including 7 months before the intervention and used all available data following the intervention. All data points were used to calculate the average, upper control limit, and lower control limit values. The implementation of the user interface change was graphically marked on the XmR chart with a black line and the note “UI CHANGE.” Charts were created by breaking down the data by month.

Feedback and Comments

After 8 weeks, users were invited to complete a survey. The survey included 3 free-text response questions, including Question A, “Do you have any comments about the reporting system?”; Question B, “Do you have any comments about the new summary screen?”; and Question C, “How could you be motivated to enter accurate, complete, and timely data into the reporting system? Did the summary screen help?”

Two managers who were familiar with the organization, its culture, and its initiatives were asked to comment on the patterns and changes visible in the XmR charts. Semistructured interviews and email correspondence took place after the design change had been deployed for 8 weeks.

Results

Persuasion Context

The results of our combination of CWA and the persuasive system design framework to define the persuasion context are shown in Table 3.

Table 3. Persuasion context.

Question	Answer	Referenced framework
Who	Our target users are health professionals entering data into the family health team reporting tool. There are no complex team dynamics as users enter data. The exercise is individual.	Described and modeled in the abstraction hierarchy phase of cognitive work analysis
What	At the alert level of the control task analysis, we want users to enter their data into the system after they have finished a patient encounter.	Described and modeled in the control task analysis phase of cognitive work analysis
Why	Summarizing the data is related to benchmarks and norms of the organization. The task will help the organization be accountable. Timely data will allow the organization to respond to needs more quickly. Professional values and training provide potential insightful constraints on the change. Building and moderating behavior through a sense of “duty” or by developing the sense of a professional norm could be a valuable approach to persuasive design.	Described and modeled in the abstraction hierarchy phase of cognitive work analysis
When		
Motivation	Users have professional values which will lead them to input data. Users are responsible for meeting organizational benchmarks; failing to report data could result in disciplinary action.	Described and modeled in the abstraction hierarchy phase of cognitive work analysis
Abilities	Users need to prioritize their time and engage in time management to change this behavior. They need time and time management abilities.	Described and modeled in the skill, rule, and knowledge taxonomy phase of cognitive work analysis
Triggers	Users are triggered and influenced to record data by organizational policies, workload requirements, experience, technical abilities, and practice workflows.	Described and modeled in the strategies analysis phase of cognitive work analysis
How		
Message	Persuasive messages should encourage users to enter data on the same day. The messages should appeal to each user’s sense of professional duty and desire to meet professional norms. Users need to be encouraged to think about entering data right away and avoid the bulk entry strategy. Users need to be encouraged to use the same-day workflow strategy.	Described and modeled in the strategies analysis phase of cognitive work analysis. Application of persuasion context analysis
Route	The persuasive route can be direct or indirect.	Persuasion context analysis
Strategy	To reduce entry delay, a dialogue-based persuasion strategy could be appropriate. Effective approaches might include praise, rewards (computer-based), or suggestions. Reduce entry delay, a persuasion strategy based on social support, could also be appropriate. Effective design principles might include social comparison, normative influence, and social facilitation.	Persuasive system design framework

Persuasive Design

Design Description

The organization wanted an unobtrusive design that did not involve amending entry fields in the system's input screen (see [Figure 1](#)). In the final design, the persuasive elements were introduced to the system through a new summary screen that was displayed after each user entered data. Whereas users normally clicked "RECORD ENCOUNTER" and were brought to a blank form, the change would now show a summary screen and ask users to click "RECORD ANOTHER ENCOUNTER" after reviewing the new content in the new design. The design of the summary screen was divided into 3 sections. A screenshot is shown in [Figure 2](#).

Section 1: "Your Updated Data Based on Your Entry"

The first section of the screen is linked to the data validity and data completeness measures. This section supports data accuracy and completeness by inviting users to edit their submission, if anything is missing or incorrect, after showing a summary. An "Edit Entry" button was placed below the text to support the editing workflow; users can go back and make changes if an error was recorded or if something was missed.

This section was an adaptation of the verifiability and trustworthiness principles of the persuasive system design. In this context, users see what data they have inputted into the system and can see how it will be counted in reports. It aims to clarify how the data they inputted will be used.

Section 2: "How did This Change Your Current Reporting Statistics?"

Previous studies have found a positive relationship between use and data quality. For example, audit-based education proved to be an effective tool for improving data quality in primary care by providing users with a baseline during meetings, educating users about how data is used and recorded, and establishing goals [5]. Thus, increased attention and focus on data, engagement of stakeholders, and comparisons had positive impacts on data quality. Facilitating these processes would be a good use of persuasive design. In a previous study, there was a positive relationship between use and completeness for the reporting tool [18], suggesting that encouraging use would have positive impacts on data within the reporting tool.

This section aims to engage users with their data. As an alternative to users "using" their data through a report, the screen automatically shows important graphs, and in a sense, forces them to "use" their data. The design includes information that was deemed to be most important by the organization; a pie chart that broke down the user's no-show rate from the last 3 months, the user's follow-up ratio from the last 3 months, and a graph of scheduled visits (no-shows and actual encounters) over the last 2 weeks. Beneath these charts, users could click "Review My Stats" and generate more complex reports in the report module.

By engaging users with their data, the design aims to improve timeliness (ie, keep the data up to date for proper graphing) and encourages users to input valid and complete data to correctly display their data. The sentence "How did this change your current reporting statistics?" refers to how the user's action and inputted data changes their statistics in reports. This was an implementation of the task support self-monitoring principle from the persuasive system design model.

Section 3: "Badges and Awards"

In the persuasive system design framework, the praise principle states that "by offering praise, a system can make users more open to persuasion" [3]. The section uses badges to encourage and normalize entering data on the same day. The persuasive design encourages users to think about keeping their statistics and encourages them to change their workflows and data-entry strategies accordingly.

The final iteration of the badges section shows a "same day" badge, which is programmed to display and reward the percentage of same-day entries. Different badges are presented with 70%, 80%, and 90% marks. The text provides a current same-day percentage measure. As long as a user remains between 90% and 100% same-day, they will keep the "top" badge available to them. This section also displays the percentage of users that enter their data on the same day. The message at the bottom is an implementation of the praise dialogue principle and the social facilitation principle from the persuasive system design model. This section aims specifically to encourage same-day entries.

Impact Measures

Statistical Results

We collected data from all active users of the system (53 users), paired for the pre- and postperiods. We compared the number of entries completed in the 8 weeks prior to the change and the 8 weeks after the change. The average number of entries per user for the preperiod was 336.62 and for the postperiod was 314.31. The difference of 22.31 entries was not significant ($P=.23$). Thus, the pre- and postperiods were similar in terms of the volume of patient visits and data collection. The results of the paired t test of each data quality measure are presented in [Table 4](#).

According to the pre-post analysis, the intervention increased the percentage of same-day entries by 10.3%. The test was statistically significant ($P<.001$) with a power of 0.999. The Cohen d of 0.70 would be considered a large effect.

According to the pre-post analysis, the intervention decreased the percentage of complete records by 4.8%. The test was statistically significant ($P<.001$) with a power of 0.957. The Cohen d of 0.505 would be considered a large effect.

According to the pre-post analysis, the intervention increased the validity measure by 0.7%. The test was (marginally) statistically significant ($P=.05$) with a power of 0.537.

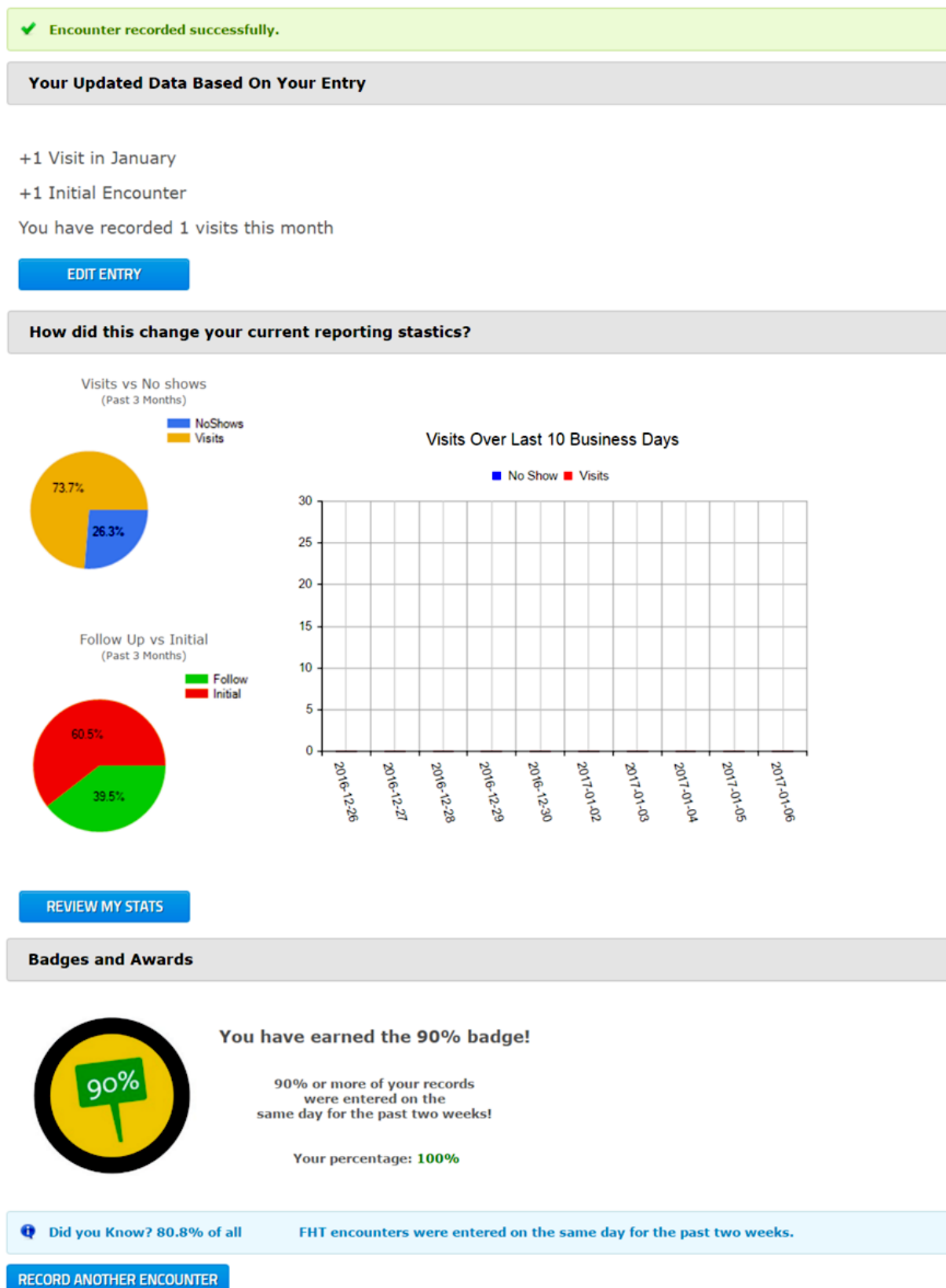
Figure 2. Screenshot of the persuasive summary screen.

Table 4. Pre versus post results with paired *t* tests.

Records	Pre (%)	Post (%)	Change (%)	<i>P</i> value	Power	Cohen <i>d</i>
Same-day entries	62.8	73.2	+10.3	<.001	0.996	0.632
Complete records	86.3	81.6	-4.8	<.001	0.978	0.545
Validity measure	98.9	99.6	+0.7	.05	0.537	0.282

Control Charts

To understand the changes to the data measures in the context of noise, we created XmR charts for same-day percentage, completed percentage, and validity percentage. Data for the XmR charts were grouped into months. Data from 7 months prior to the change and 3 months afterward were included to contextualize historical system noise and put the changes after the design change into a larger context. The user interface change took place in the last week of November 2016.

As shown in Figure 3, the same-day percentage average rose above the upper control limit after the change. For 3 months after the change, the same-day percentage were almost all above the upper control limit, which can be attributed to assignable cause variation and was not associated with normal variation or “noise” in the system. The mR (eg, the change from month to month) was high immediately after the change. The perceivable increase in the timeliness measure is consistent with the statistical results.

As shown in Figure 4, the complete percentage did not rise above the upper control limit after the change. In fact, the values dropped below the lower control limit. As the values dropped below the control limits, the changes represent assignable cause variation and were likely caused by the change. By the third month after the change, the completeness measure returned to

a midrange point. The mR (eg, the change from month to month) was very high immediately after the change. This indicates that the change to the user interface impacted and changed the measure in a significant way. The perceivable drop in the completeness measure is consistent with the statistical results.

As shown in Figure 5, the validity percentage average rose above the upper control limit after the change. For 3 months after the change, the validity percentage stayed within the control limits and could be associated with normal variation or “noise” in the system. The mR did not rise above the upper control limit or below the lower control limit. Based on this chart, the change did not impact the data’s validity. The changes in the validity measure were consistent with the statistical results, which were marginal with a *P* value of 0.5.

Feedback and Comments

User Feedback

A total of 17 users completed the survey that was distributed, and 13 of those users provided comments to Question B, “Do you have any comments about the new summary screen?” and Question C, “How could you be motivated to enter accurate, complete and timely data into the reporting system? Did the summary screen help?” Relevant responses to each question are shown in Table 5 and Table 6. A complete set of responses are available in a published dissertation [21].

Figure 3. XmR chart of timeliness measure. CL: control limit; UI: user interface; UCL: upper control limit.

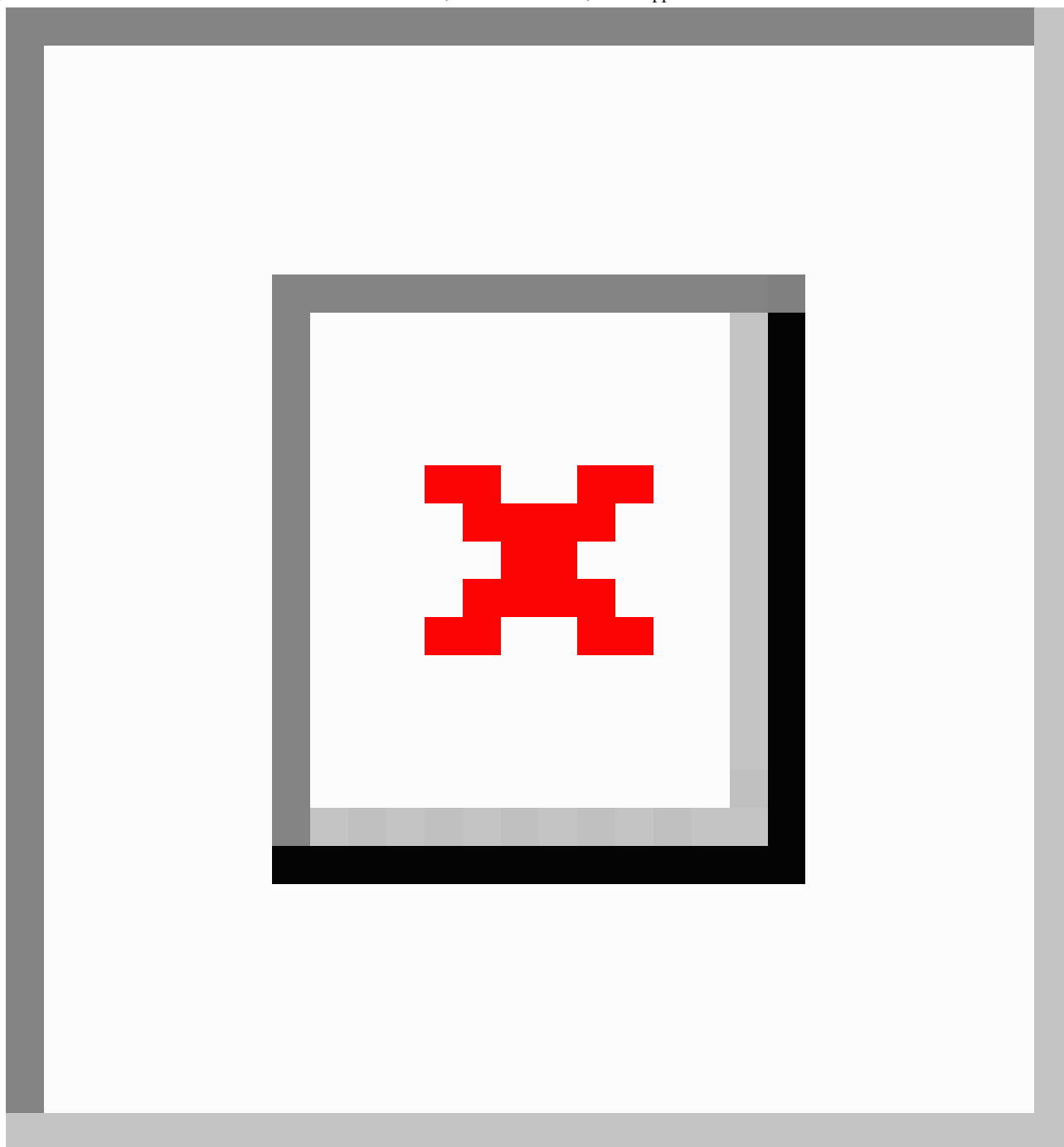


Figure 4. XmR chart of completeness measure. CL: control limit; UI: user interface; UCL: upper control limit.

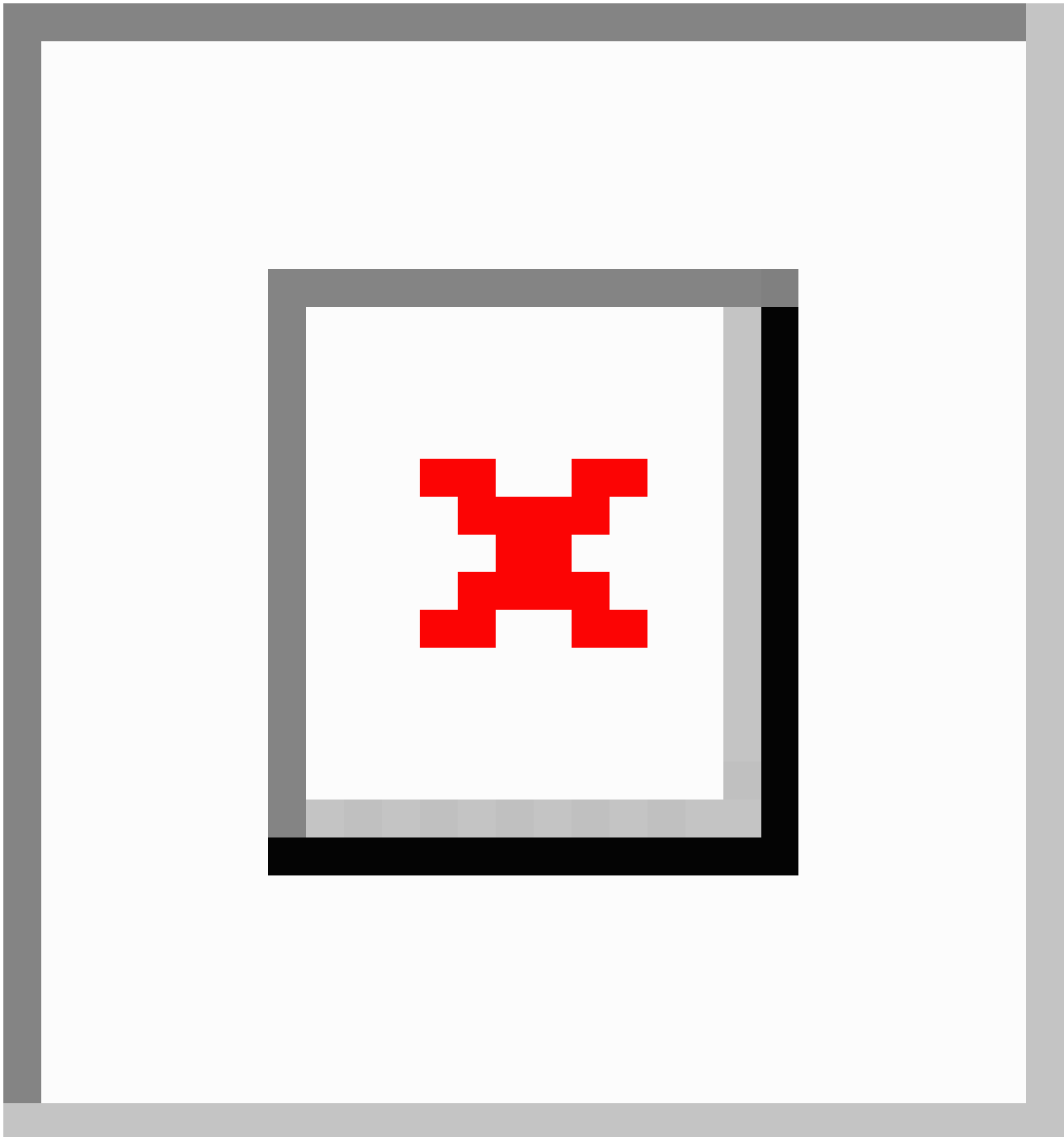


Figure 5. XmR chart of validity measure. CL: control limit; UI: user interface; UCL: upper control limit.

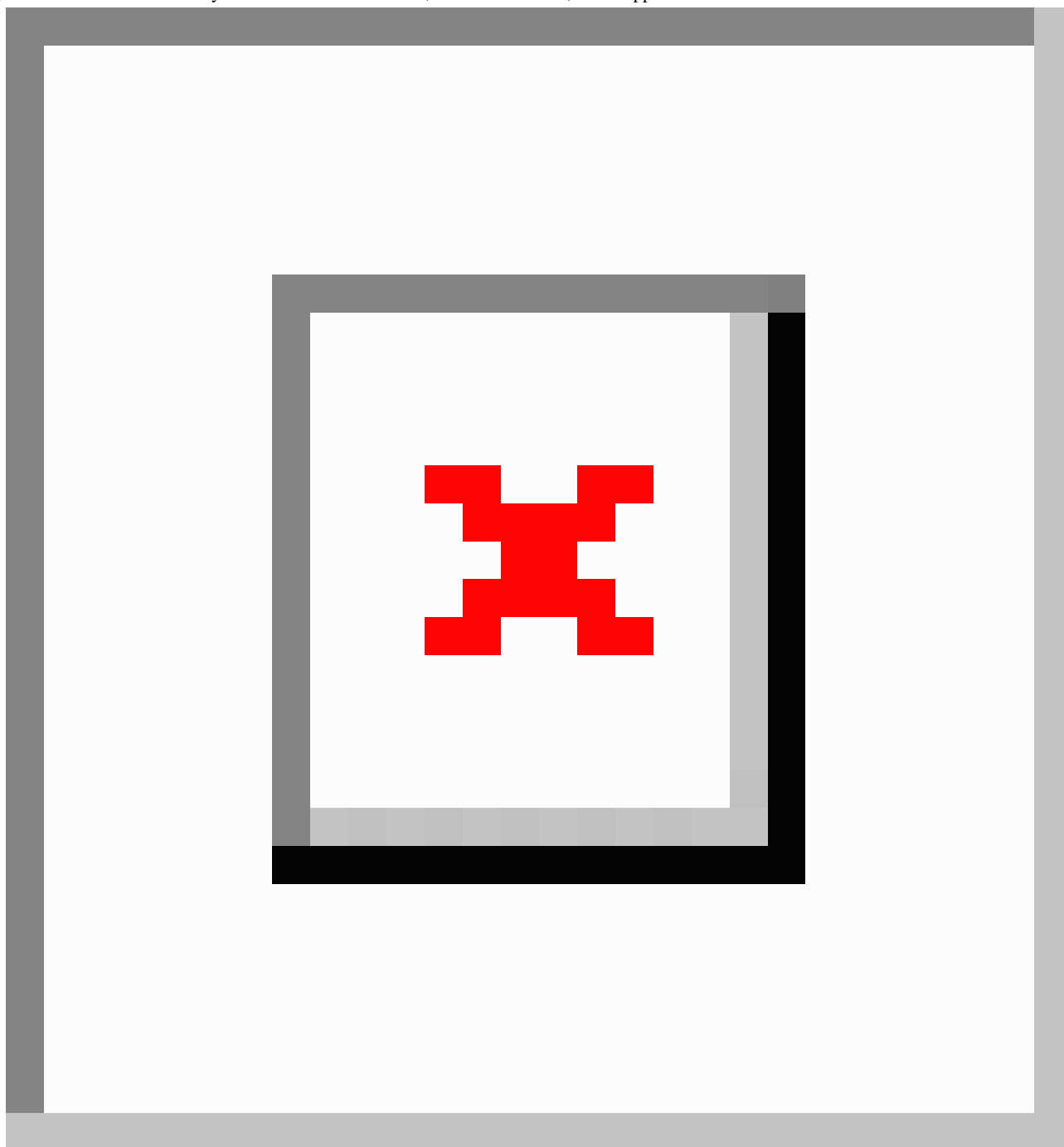


Table 5. Responses to Question B.

Respondent	Comment
5	It makes me feel anxious and unhappy to see a lot of no shows.
6	The new screen data seems to put more unnecessary pressure on data entry.
8	Even though it only takes a few seconds for the new screen to load and then a few more seconds to click “record encounters” and for that screen to load, it really adds up! [Entering data] seems to take way longer now.
9	I like seeing the graphs — I’m a visual person, and this helps to summarize what I view as important info about my practice.
10	Please remove — adds time to data entry and doesn’t change practice.
11	I would prefer to see the summary screen once only when I start to enter data [...]
14	Seems unnecessary.
15	I don’t need to see my percentages page after entering each client encounter. Could be used as a summary page of day/week/month. Easy to read and understand.
16	The summary needs only to come up when I have completed all entries, not after every [patient] encounter [because it] takes too much time.
17	The new summary screen added lag time to inputting stats, and [has made] the process [more] cumbersome.

Table 6. Responses to Question C.

Respondent	Comment
5	I always have entered my data on the same day. Summary screen just makes me anxious.
6	I have usually recorded data on the same day. The new screens seem to discourage that.
7	I personally did not see any difference.
8	It helped slightly. I find I am now entering stats every 7-9 days instead of every 9-14 days.
9	I’m not sure it provided extra motivation; I’m a pretty organized person so have always wanted to keep on top of doing stats.
10	Monetary rewards [would be motivating]. [...] The summary screen did not help [motivate me].
11	At first [the new screen] helped somewhat; now I again rely on my own motivation to keep up to date, which ebbs and flows with the demands of my schedule.
13	[The new screen helped] a bit.
15	I was already entering data on daily basis, but I do feel it could act as a motivator to those who have not in recent past.
16	I know I need to enter my work into [the reporting tool] but I am not particularly motivated to do so, not sure what would motivate me.
17	It was nice to see incentives on the screen of reaching goals and receiving badges, but other incentives would likely help motivate.

Comments by Management

The 2 managers designated as contacts were asked to comment on the drop in the completeness measure. The Information Systems Manager responded as follows:

It appears it is because of the referral issue.

There is an option where you can [click] ‘I do not know when the referral source was’ [and the system, therefore, records] the date of 1900-01-01.

[We implemented this feature because] staff pushed back saying that they do not always have the referral date handy so they need [the ‘I do not know’] option...

If [users] leave the default option of ‘I know when the referral date is’ [the system] forces [users] to [enter] a date’. Based on the data, it seems that more users have started to click the ‘I do not know the referral date’ option, which seems to explain the change in the completeness measure. [Information

Systems Manager, personal communication, February 16, 2017]

The managers were also asked to comment as to whether or not other interventions, meetings, or policies around data entry had changed over the course of the study period. They noted that there was no formal or direct intervention around data entry in the reporting system other than the user interface change.

Discussion

Objective

Our objective was to find a way to influence clinician behaviors around data entry and to improve data quality. Our approach was to expose users to a new design that adopted persuasive design principles in order to modify their data-entry behaviors. Based on our results, there is evidence that a behavior change took place for users of the reporting system as a result of the design change.

Impact of Design Change

Data Quality Measures

There were changes immediately after the new design was deployed in each of the 3 data quality measures used to measure the impact of the design change. Though these measures were not perfect representations of timeliness, completeness, and validity, they were suitable proxies. In a previous study, the improvement of these measures represented measurable enhancements to data quality [18].

Obviously, there may be questions about whether the observed changes can be attributed to the changes to the user interface. The organization had an interest in improving data quality, and various meetings, staff instructions, or other events over the study period could have contributed to the improvement. We attempted to contextualize this potential problem by using SPC control charts and by discussing this potential problem with the management contacts.

The SPC control charts are intended to help differentiate changes related to noise and “normal” changes within the system. We attribute any meetings, staff instructions, or other events related to data quality as “normal” system noise. The SPC chart contextualizes normal changes when values occur between the control limits. Based on the data available for the previous year, any events that could have changed data quality fell within these bounds. The user interface change was a unique event and pushed the measures above the upper control limits, meaning that something occurred outside the normal system “noise” and that the values were significant and could be assigned a cause. Since management commented that there were no other events during the study period that could have influenced the measures, there is good evidence that the user interface design change very likely impacted the measures. These conclusions are supported by the *t* tests and significant statistical inferences.

The impacts of the design change did not work exactly as intended. The timeliness measure improved, the completeness measure worsened, and the validity measure showed a marginal (if any) change.

Timeliness Measure

The XmR chart for the timeliness measure tells a compelling story. Before the change, the system signal was relatively stable. Small spikes occurred before the end of each quarter, which managers associated with peak reporting periods and seasonal organizational pressures. Before the implementation, there were no other obvious trends and no out-of-control signals. After the change, all values were above the upper control limit. There was a significant change after the user interface change, based on the mR graph. Based on the results of the XmR charts and the paired *t* test, the evidence is compelling that the intervention increased the number of same-day entries within the system.

Completeness Measure

The XmR control chart for the completeness measures shows that the completeness measure was a relatively stable measure over the previous 7 months. There were no noticeable spikes or changes, and no trends or out-of-control signals were seen. The month before the implementation, the completeness measure

hit a high point. A significant impact on the completeness measure can be seen when the intervention was deployed. The impact was significant, as shown in the mR graph. Interestingly, it appears that after the initial “shock” of the change, the completeness variable appears to be returning to normal. The results of the *t* test and XmR are consistent.

Based on the comments from the organization’s managers, it appears that immediately after the summary screen introduction, the completeness measure was reduced because there was a significant change in a number of entries recorded with the “I don’t know the date” instead of entering the referral date for initial encounters. It is very interesting that a passive change to the user interface (a noninteractive summary screen) changed user behavior in this way. The summary screen appears *after* users enter the information and select referral details. It appears that a statistically significant number of users responded independently to the intervention in the same manner. This may represent a reaction to the “same day” badge on the summary screen: to hit this metric as quickly and easily as possible, users abandon the referral date to optimize their time. This tradeoff is consistent with behaviors modeled in the CWA [21]. To counterbalance this adaptation, a “completeness” badge may be appropriate.

Validity Measure

Interestingly, the results of the validity values are comparable to the results from other medical registry case studies, which have reported 98% accuracy (ie, validity) based on a gold standard [29]. The data show that there was a significant change in the percentage of valid records.

It is important to put these improvements in context, as they were relatively small. The paired *t* test did not have a strong statistically significant result compared with the other measures. The Cohen *d* of 0.282 would be considered a small-to-medium effect. Though the validity measure in the XmR chart shows an improvement, rejecting the null hypothesis and concluding that there was a significant impact should be cautiously done.

User Comments

Several users articulated positive feedback and gave the intended behavior change heuristics that the summary screen was intended to encourage. For example, “I find I am now entering stats every 7-9 days instead of every 9-14 days,” “I like seeing the graphs — I’m a visual person, and this helps to summarize what I view as important info about my practice,” “It was nice to see incentives on the screen of reaching goals and receiving badges,” and “I feel it could act as a motivator to those who have not [been timely] in the past.” Some users suggested there was only an initial impact with comments such as “At first it helped somewhat; now I again rely on my own motivation.” These comments align with the persuasive system design proposed by Oinas-Kukkonen and Harjumaa [3]: there are different kinds of behavior change (eg, one time, short-term, long-term), and different kinds of interventions are appropriate for each. While it is clear that the summary screen introduced a change in behavior and influenced the users, further work will be required to properly categorize the change as either short-term or long-term.

Other comments in the survey were concerning. One user reported that it felt like there was new pressure on data entry. This is not an incorrect impression, but associating pressure to enter data with the summary screen was unexpected. It appears some users saw the summary screen as an accentuation of historic management reminders to enter data on time and had a negative reaction. This is further described by another respondent who said the summary screen made them feel “anxious and unhappy” and complained that “the summary screen just makes me anxious.”

Anxiety and unhappiness from users are very strong words. However, the true cause of anxiety is not the summary screen or the data, but the user’s performance and statistics. Specifically, the user complained that the summary screen caused anxiety because the system reminded them that they had no-show visits on their record. This would be akin to a student expressing anxiety over seeing their grades posted on a learning management platform. Regardless, if users feel that the summary screen is tracking their progress closely as a proxy manager, it is understandable that performance tracking could cause anxiety.

Contrasting responses were provided regarding the summary screen. Whereas some users expressed seeing a carrot, others saw a stick. Based on the data and outcomes, this would be an example where performance and preference are not correlated; it appears performance is occurring where preference is not.

Design Improvements

The final design used in the study was developed in collaboration with the organization. As it is in many cases and was also in this case, certain compromises were made, and the organization was the best expert on what kind of solutions should be provided for their employees and how to make changes without causing any problems. Having said this, there are several possible iterations for the design.

Five comments mentioned concerns about the performance impacts of the summary screen, including “adds time and doesn’t change practice”, “The summary screen added lag time and [made the process] more cumbersome,” “[The extra time required] really adds up!”, and “It feels slower to load pages and enter data.” Based on these comments, there does appear to be a concern about the performance of the system. The organization has since taken this feedback and adjusted their queries with table-valued functions to reduce the load time by 80% (Information Systems Manager, personal communication, February 16, 2017).

In other comments, users provided suggestions for user experience and user interface adjustments to the summary screen. For example, 2 users suggested having the summary screen appear only once a day, instead of after every encounter, or enabling a daily, weekly, and monthly view. These suggestions are not unreasonable and could be implemented by the organization in a software revision. Taking the summary screen out of the workflow would address most of these concerns, but it is not clear if this would continue to provide the same effect on user behavior.

In terms of improving the summary screen, a few design heuristics may help alleviate some of this anxiety. Currently,

the data provided is only a measure of a single user’s data. Comparisons between groups and users might help alleviate performance anxiety by normalizing their results. If a user is worried about their performance, would it not be helpful for them to see the performance of other similar users? A comparison paradigm could help build a user’s confidence, compliance, and engagement and reduce potential anxieties about their own data. Further work and study would be required, however, as there is also the possibility that comparisons could increase anxiety by making users defensive about their performance and feel inadequate about their statistics compared to peers. The comparison concept is part of the persuasive system design model, which describes normative influence and social facilitation as design principles. This idea would not be difficult to incorporate into the new summary screen and design change.

Contributions

There are many studies in the literature demonstrating that persuasive design can be useful for changing patient attitudes and behaviors through mobile devices. However, there are few examples of persuading clinical users to change their behavior. Knowing that primary care data recording behaviors impact data quality and its secondary uses and that these behaviors are impacted by the enthusiasm of clinicians [17], our study demonstrates a novel path forward. Our study is a unique contribution, demonstrating that persuasive design techniques are viable tools for changing not only patient behaviors in the health care system but also clinicians and system users.

Knowing that social, intraclinician comparisons have been effective approaches for changing clinician data-entry practices [5-7], our work shows the viability of using persuasive design to emulate those types of social mechanisms with technology. In the future, persuasive design could be used to encourage adoption and use and manage the organizational and social aspects of successful clinical system implementations. The use of persuasive design with clinicians is an exciting and interesting area for further study. It will be very interesting to vendors and developers in the health care ecosystem.

Importantly, this work makes a major contribution by describing *how* persuasive design can be used in design to achieve a specific goal. This was done by combining the persuasive system design model and CWA with a WWWWH paradigm and extending previous work [22,24]. Our research showed that building a persuasion context using a detailed systems analysis framework can facilitate the deployment of effective interventions and that these interventions can influence behaviors in users in intentional ways.

Limitations

Our study is unique because it involves a combination of theoretical work and a real-world “in the wild” evaluation of the design. This combination introduced constraints to the study, which could be improved and extended in several ways.

One area that would have been interesting to explore is variation between users and groups of users. Unfortunately, we were limited to 53 users in our study. Because these users worked in multiple locations and could be categorized into 1 of 8 different

professions, any comparisons would rely on very small groups and would not permit meaningful, statistically significant comparisons. In the future, if the reporting system were deployed into additional organizations, these types of comparisons could be both possible and quite interesting.

The length of the postperiod is limited to 8 weeks for the *t* test comparisons and 3 months in the XmR charts. The issue of short-term versus long-term impacts on behaviors is obviously of interest to the academic community [3], and an evaluation of long-term impacts of the design change and comparisons to short-term impacts would be valuable. Unfortunately, the scope and funding of the study did not allow for a longer-term evaluation of the metrics and the long-term impacts of the design change. Future work will involve exploring and evaluating the

long-term impacts in greater detail as well as assessing iterative improvements to the design.

Conclusions

The reporting tool used by allied health professionals in a family health team provided us with an interesting opportunity to explore the use of persuasive design to change clinician attitudes and behaviors regarding data entry. We demonstrated that informing persuasive design with CWA can be effective in designing an intervention that can change data-entry behavior and reduce entry delay. Our study demonstrates merit to the use of persuasive design for changing data-entry behavior in clinicians. Further work is required to perfect and test additional designs. Persuasive design is a viable approach for designing and encouraging behavior change and could support effective data capture in the field of medical informatics.

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Conflicts of Interest

None declared.

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Abbreviations

CWA: cognitive work analysis
mR: moving range
SPC: statistical process control
WWWWH: who, what, when, where, how

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Original Paper

Usefulness and Relevance of an eHealth Tool in Supporting the Self-Management of Chronic Obstructive Pulmonary Disease: Explorative Qualitative Study of a Cocreative Process

Malin Tistad^{1,2}, PhD; Sara Lundell¹, MSc; Maria Wiklund¹, PhD; André Nyberg¹, PhD; Åsa Holmner³, PhD; Karin Wadell^{1,4}, PhD

¹Unit of Physiotherapy, Department of Community Medicine and Rehabilitation, Umeå University, Umeå, Sweden

²School of Education, Health and Social Studies, Dalarna University, Falun, Sweden

³Department of Radiation Sciences, Umeå University, Umeå, Sweden

⁴Department of Public Health and Clinical Medicine, Division of Medicine, Umeå University, Umeå, Sweden

Corresponding Author:

Malin Tistad, PhD

Unit of Physiotherapy

Department of Community Medicine and Rehabilitation

Umeå University

901 87

Umeå,

Sweden

Phone: 46 90 786 50 00

Email: mti@du.se

Abstract

Background: New strategies are urgently needed to support self-management for people with chronic obstructive pulmonary disease (COPD) in primary care. The use of electronic health (eHealth) solutions is promising. However, there is a lack of knowledge about how such eHealth tools should be designed in order to be perceived as relevant and useful and meet the needs and expectations of the health professionals as well as people with COPD and their relatives.

Objective: The objective of this study was to explore the aspects of an eHealth tool design and content that make it relevant and useful for supporting COPD-related self-management strategies from the perspective of health care professionals, people with COPD and their relatives, and external researchers.

Methods: Data were collected during the development of an eHealth tool. A cocreation process was carried out with participants from two primary care units in northern Sweden and external researchers. Individual interviews were performed with health care professionals (n=13) as well as people with COPD (n=6) and their relatives (n=2), and focus group discussions (n=9) were held with all groups of participants. Data were analyzed using qualitative content analysis.

Results: The overarching theme, *reinforcing existing support structures*, reflects participant views that the eHealth tool needs to be directly applicable and create a sense of commitment in users. Moreover, participants felt that the tool needs to fit with existing routines and contexts and preferably should not challenge existing hierarchies between health care professionals and people with COPD. Important content for health care professionals and people with COPD included knowledge about self-management strategies. Videos were regarded as the most effective method for communicating such knowledge.

Conclusions: The cocreation in the development process enables participant perspectives and priorities to be built into the eHealth tool. This is assumed to contribute to a tool that is useful and relevant and, therefore, adopted into clinical practice and everyday life. Findings from this study can inform the development of eHealth tools for people with COPD in other contexts, as well as the development of eHealth tools for self-management support of other chronic diseases.

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KEYWORDS

COPD; eHealth; cocreation; self-management; primary care, chronic disease

Introduction

Pulmonary rehabilitation programs for people with chronic obstructive pulmonary disease (COPD) include exercise training and self-management strategies. These have been shown to decrease dyspnea; improve physical capacity, physical activity level, and health-related quality of life [1-4]; and be cost effective [5]. Self-management strategies include physical activity and appropriate food intake, recognizing and taking action if symptoms worsen, sputum evacuation, and breathing techniques. Each of these requires relevant knowledge and skills to be effective [1]. However, only a small proportion of people with COPD participate in pulmonary rehabilitation [6-9]. This may partly be due to insufficient adherence to nonpharmacological COPD guideline recommendations in primary care [10]. Furthermore, strenuous travel, exacerbation of symptoms, lack of motivation, and high costs have been reported as barriers to participation [6]. Since self-management is a core component of COPD management [1], a considerable proportion of people with COPD are at risk of insufficient access to support for these evidence-based interventions. Consequently, there is an urgent need to find new strategies to promote self-management support to people with COPD in primary care.

Electronic health (eHealth) includes digital technologies to inform, track, and monitor health in order to improve health and health services [11]. eHealth solutions have been suggested to have the potential to deliver support for self-management strategies to people with COPD [1,12], but the effectiveness and favorable features of such solutions remain to be determined. A recent meta-review of telehealth interventions to support self-management in COPD showed inconsistent effects [13]. In addition, recently published studies have report no difference in COPD-related health status after the use of a self-management platform [14] or the use of a system of monitoring and self-management support compared with usual care, apart from beneficial general health outcomes [15]. However, the functions and features of eHealth applications vary significantly and more research is needed.

Implementation of eHealth solutions has often proven to be challenging [16,17]. Implementation research concludes that the characteristics of the innovation to be implemented, the context, the recipients, and the method used for supporting the implementation influence whether the innovation is adopted [18]. In addition, studies have suggested that user involvement is important for understanding user needs, and it facilitates the use of eHealth solutions [16,19,20], whereas a lack of fit between users and the technology might hamper the adoption of technologies [17]. Both people with COPD and physiotherapists (PTs) have been shown to perceive an eHealth self-management application that intends to increase physical activity by goal-setting, advises on how to perform physical activity, and presents physical activity in steps to be stimulating and beneficial. However, PTs reported a low use of the eHealth application because of time constraints and costs [21]. More knowledge is needed about how eHealth tools should be designed to support the aspects of self-management other than physical activity that will meet the needs and expectations of health professionals and people with COPD and their relatives.

We decided to develop an eHealth tool in the form of an interactive website, the COPD web, directed toward two user groups—people with COPD and health care professionals providing primary care for these patients. The aims of the eHealth tool were to support people with COPD in their self-management strategies and facilitate the implementation of health care professionals' support for these strategies. To meet user needs and requests and contextual conditions while also following an evidence-based approach, we invited the user groups, that is, health care professionals and people with COPD and their relatives in primary care, as well as external researchers within the area of COPD to a cocreation process. The purpose of this study was to explore the aspects of the content and design of an eHealth tool that would make it relevant and useful for supporting COPD-related self-management strategies from the perspective of health care professionals, people with COPD and their relatives, and external researchers.

Methods

Study Design

This explorative qualitative study is part of a larger research project based on cocreation and user involvement [22,23]. The study utilizes data from all of the individual interviews and focus group discussions carried out in the course of the development of an eHealth tool, the COPD web, aiming at supporting self-management strategies in people with COPD (Figure 1 and Table 1).

Setting and Sample

Two primary care units in northern Sweden were invited to participate in the study, one situated in a city with a population of 120,000 inhabitants and one in a rural area with 2500 inhabitants. The urban primary care unit had about 7500 people enrolled and the rural unit had 2500 people. The primary care units provide outpatient care and, like almost all health care services in Sweden, are publicly funded.

The conditions for the use of eHealth solutions in Sweden in general are beneficial, and almost 100% of the population has access to the internet at home [24,25]. The possibility of reaching the older population is also relatively good as approximately 56% of those aged above 75 years use the internet [25].

Recruitment of Participants

Participants for Individual Interviews

The nurses specialized in COPD care (henceforth denoted “COPD nurses”) at the primary care units were asked to participate in individual interviews. They were asked to suggest 1 or 2 additional nurses and physicians who met people with COPD in their clinical practice. Furthermore, all PTs, occupational therapists (OTs), dieticians, and medical social workers (MSWs) employed or engaged as consultants at these units were asked to participate. In total, 16 health care professionals were invited and 13 were finally included (Table 2). Due to very limited working time at the unit, illness, or no experience with COPD, 1 OT and 2 MSWs declined participation.

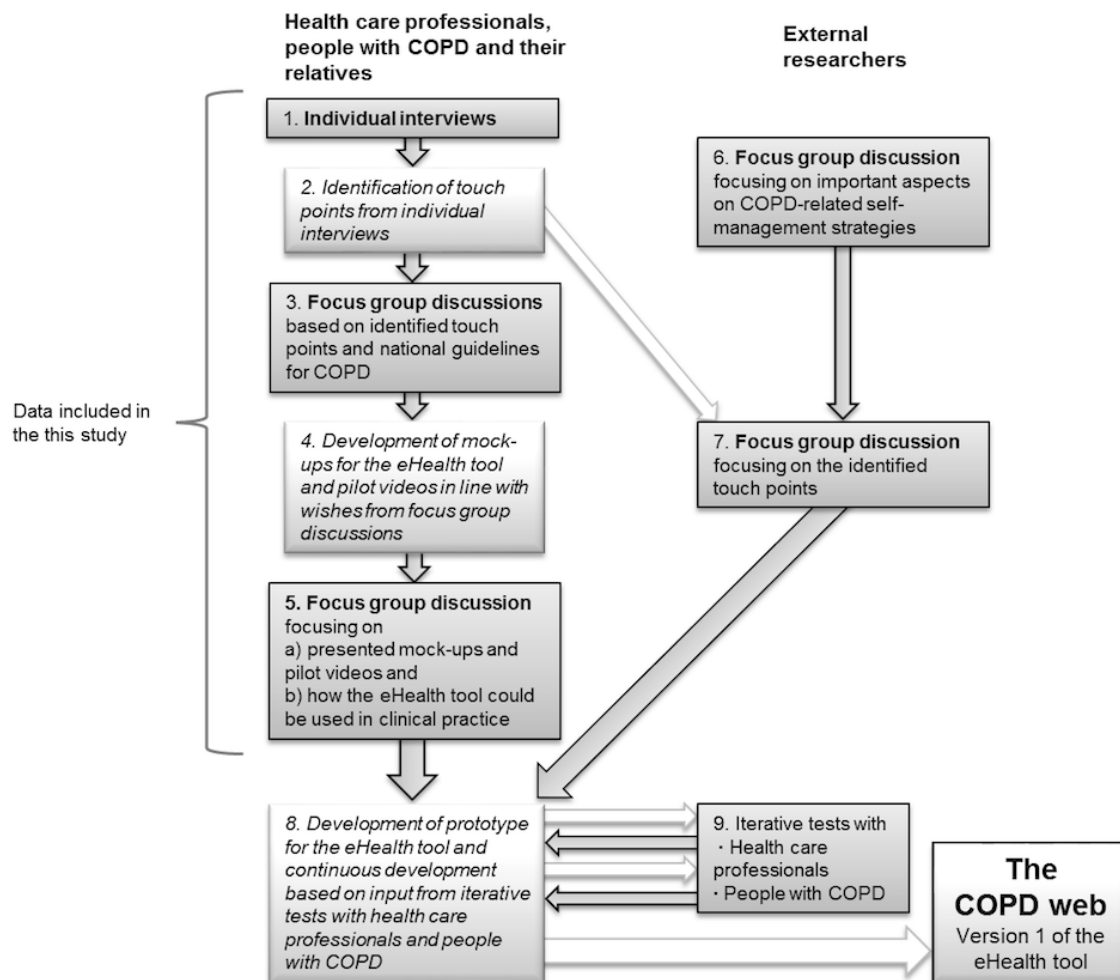
Figure 1. Structure of the development process of the eHealth tool. COPD: chronic obstructive pulmonary disease.

Table 1. Description of the components in the development process and data collection.

Component in the development process	Group of participants and number of individual interviews (n) or focus groups (FG)	Content
1. Individual interviews ^a	<ul style="list-style-type: none"> Health care professionals (n=13) People with COPD^b (n=6) / relatives (n=2) 	Semistructured interviews with health care professionals and people with COPD and their relatives.
2. Identification of touch points from individual interviews	<ul style="list-style-type: none"> Intermediate work by the researchers 	Identification of touch points (ie, topics that seemed crucial or were mentioned by several of the interviewees).
3. Focus group discussions ^a	<ul style="list-style-type: none"> Health care professionals (FG=2) People with COPD and their relatives (FG=2) 	The identified touch points and self-management strategies that were highly prioritized in the National Guidelines for COPD were presented to the participants. The participants were encouraged to reflect on the topics that were presented and particularly on how an electronic health (eHealth) tool could facilitate provision of, or give support for, such self-management strategies.
4. Development of mock-ups for the eHealth tool and pilot videos in line with wishes from focus group discussions	<ul style="list-style-type: none"> Intermediate work by the researchers 	Based on the wishes and needs expressed during the individual interviews and focus group discussions, mock-ups for the website and pilot videos were developed showing breathing techniques for stair climbing and muscle strength training.
5. Focus group discussions ^a	<ul style="list-style-type: none"> Health care professionals (FG=2) People with COPD and their relatives (FG=1) 	The mock-ups and the pilot videos were presented. The participants were encouraged to reflect on the basic structure, the colors, wordings, and how well the pilot films served their purpose. Moreover, the participants were asked to reflect on how the website could be introduced to people with COPD and how the use of the website should be followed up.
6. Focus group discussions ^a	<ul style="list-style-type: none"> External researchers (FG=1) 	Based on their scientific knowledge about COPD, the external researchers were encouraged to identify and reflect on important interventions and self-management strategies that would be important to include on the website.
7. Focus group discussions ^a	<ul style="list-style-type: none"> External researchers (FG=1) 	A summary of the suggestions, wishes, and needs brought up by the health care professionals and people with COPD and their relatives were presented. The researchers were asked to reflect on how the interventions and self-management strategies should be presented considering both scientific correctness and the need to allow for adaptations to local conditions. Moreover, the researchers were asked to prioritize between the suggestions, wishes, and needs.
8. Development of prototype for the eHealth tool	<ul style="list-style-type: none"> Intermediate work by the researchers 	A prototype for the eHealth tool was developed based on input from the individual interviews and focus group discussions. The iterative tests (9) led to further development.
9. Iterative tests	<ul style="list-style-type: none"> Health care professionals (n=6) People with COPD (n=6) 	Iterative tests focusing on what words to use in the menu structure and the navigation of the website were performed.

^aData for this study was collected during this component.

^aCOPD: chronic obstructive pulmonary disease.

The COPD nurses at both units were also asked to assist in identifying 3 people with COPD—with variations in disease severity and sex—for participation in the individual interviews. A total of 6 people with COPD were invited, and all of them agreed to be interviewed (see Table 2). The people with COPD were asked to nominate a relative who the researchers could contact and ask for participation in the interviews. Accordingly, 3 relatives were asked and 2 agreed to participate (see Table 2).

Participants for Focus Groups

In order to avoid traveling of the participants, the focus groups (Table 3) were formed separately in urban and rural areas. Our

intention was to include 1 COPD nurse, 1 PT, and 1 physician from the individual interviews at each unit in the focus groups for health care professionals. However, because the physicians were unable to participate due to time constraints, a district nurse with extensive experience in the care and support for people with other chronic diseases at the primary care unit and a physician with a special interest in COPD employed at another primary care unit joined one focus group each. Thus, one group consisted of 2 nurses and 1 PT, and the other group consisted of 1 COPD nurse, 1 PT, and 1 physician.

Table 2. Description of participants in the individual interviews.

Participants	Value
Health care professionals	
Nurse, n	5
Physician, n	3
Physiotherapist, n	2
Occupational therapist, n	1
Dietician, n	2
Professional experience (years), mean (range)	20 (3-31)
People with chronic obstructive pulmonary disease	
Sex, n	
Male	2
Female	4
Age (years), mean (range)	74 (65-80)
FEV ₁ % ^a predicted, mean (range)	58 (32-91)
Relatives (roles), n	
Son or daughter	1
Spouse	1
External researchers	
Nurse, n	1
Physician, n	1
Physiotherapist, n	1
Dietician, n	1
Professional experience (years), mean (range)	24 (15-32)

^aFEV₁ %: Forced expiratory volume in 1 second.

Table 3. Composition and number of participants in the focus groups.

Participants in the focus groups	n
Health care professionals	
Focus group 1 (nurse, physician, and physiotherapist)	3
Focus group 2 (nurses and physiotherapist)	3
People with chronic obstructive disease and relatives	
Focus group 1	4
Focus group 2	3
External researchers	
Focus group 1 (nurse, physician, or physiotherapist and dieticians)	4

The people with COPD and their relatives who had participated in the individual interviews were asked to partake in focus groups, among whom, 5 people with COPD and 2 relatives agreed. Thus, one group consisted of 2 individuals with COPD and 1 relative, but one of the individuals with COPD never turned up. The other group consisted of 3 individuals with

COPD and 1 relative. Moreover, 4 external researchers—including a physician, a PT, a COPD nurse, and a dietician—who were engaged in both research and clinical practice within the field of COPD were invited to a separate focus group. All of the researchers agreed to participate.

Table 4. Theme, categories, subcategories, and groups of participants.

Theme, categories, and subcategories	Group of participants
Reinforcing existing support structures	
Supportive and noninterfering	
Handling the disease	<ul style="list-style-type: none"> • People with chronic obstructive pulmonary disease (COPD) and their relatives
Applying evidence-based care	<ul style="list-style-type: none"> • Health care professionals • Researchers
Fitting into the current routines	<ul style="list-style-type: none"> • Health care professionals • People with COPD
Keeping control	<ul style="list-style-type: none"> • Health care professionals • Researchers
Meaningful and urgent	
Visualized messages that enable self-identification	<ul style="list-style-type: none"> • Health care professionals • People with COPD and their relatives • Researchers
Easily accessible and distinct messages	<ul style="list-style-type: none"> • Health care professionals • People with COPD and their relatives • Researchers
Creating engagement	<ul style="list-style-type: none"> • Health care professionals • People with COPD • Researchers

Process of Data Generation and Cocreation

All individual interviews and focus group discussions were carried out between January and May 2015 as part of the development of the eHealth tool (Figure 1 and Table 1). One of the authors (MT) performed the individual interviews with health care professionals, and 2 of the authors (MT and SL) performed the interviews with the people with COPD and their relatives. Health care professionals were interviewed at their work places with the exception of one interview performed at a restaurant. The interviews with people with COPD and their relatives were performed at their homes (n=3), at the university (n=3), at a restaurant (n=1), and at their primary care unit (n=1) in accordance with their wishes. The interviews lasted between 30 and 60 minutes. MT moderated the focus group discussions with people with COPD and health care professionals with support from SL and KW, who raised follow-up questions and added reflections. SL or MT moderated the focus group discussions with the external researchers with support from KW. All of the focus group discussions lasted approximately 1 hour. Interviews and focus group discussions were audiorecorded and transcribed verbatim by a professional transcriber, and the transcripts constitute the data for this study. All data were continuously analyzed during the development of the prototype for the eHealth tool. For this study, we accumulated all of the data in order to summarize and deepen the analyses.

Analysis

The transcribed interviews were analyzed using qualitative content analysis [26]. Initially, the transcripts were read through

in order to get a “sense of the whole” [26]. In the next step, all data derived from the individual interviews and focus groups with health care professionals were inductively coded using software Open Code 4 [27]. Codes with similar content were grouped into subcategories that were abstracted into higher-order categories. Thereafter, the same process was carried out with all of the data derived from the individual interviews and focus groups with people with COPD and their relatives and with external researchers, separately. To complete the analysis, categories and subcategories from the different groups of participants were collated at a higher interpretive level, and after discussions and reflections, the authors agreed on a set of 7 subcategories, 2 categories, and 1 theme (Table 4). The analysis was performed by MT in close collaboration with SL and involved continuously going back and forth between the whole empirical data and parts thereof. Credibility was strived for through recurrent triangulation between all of the authors with various competencies and perspectives regarding the most credible analysis and interpretation of the findings [26].

Ethics

Approval was granted by the regional ethical review board of Umeå, Sweden (Dnr 2014/319-31). Written informed consent was given by all participants, and their confidentiality was ensured throughout the whole research process, including the storage, publication, and dissemination of results.

Results

Reinforcing Existing Support Structures

The analysis resulted in the theme *reinforcing existing support structures*, which, together with the interrelated categories and subcategories (Table 4), represents the participants' overall view on how an eHealth tool could have the potential to improve existing support for self-management. It was seen as being able to reinforce the information and interventions from the health care professionals and could provide easier access to information and support for people with COPD and their relatives. All of the involved groups emphasized that the content should be directly applicable and must create engagement among its users. Moreover, they emphasized that the eHealth tool should fit with existing routines and contexts and preferably not challenge existing hierarchies between health care professionals and people with COPD.

Supportive and Noninterfering

The category supportive and noninterfering refers to the content of the eHealth tool that focuses on the practical and concrete level in the management of COPD. For people with COPD, this meant content linked to everyday challenges that could decrease the consequences of the disease in daily life. For the health care professionals and researchers, this meant a tool that could support patients' self-management and increase their readiness to act as well as support health care professionals' knowledge and way of working while fitting into their prevailing routines.

Handling the Disease

People with COPD described a responsibility for handling the disease, and they perceived pressure to stay physically active, to do breathing exercises, or to quit smoking. A common view was that COPD was a disease that was ignored by physicians and the entire health care system. Furthermore, with the exception of smoking cessation, nonmedical issues were not viewed as something you should "bother" the busy primary care with. Because relatives were not always involved, expressed as "COPD is nothing you talk to relatives about," the responsibility for patients' body and lifestyle choices was foremost perceived as their own:

Because I've had COPD for many years, and no one cares. But I have a responsibility to my own body—a great responsibility in order for me to be able to survive. And I don't want to become this big lump who just lies on the floor...so I just have to get myself out of the house... [Participant with COPD]

At the same time, the people with COPD had only limited knowledge about the disease and self-management. Furthermore, they had scarce knowledge about what kinds of support were available through health care services or when to contact the primary care. Therefore, the eHealth tool could, according to both people with COPD and their relatives, contribute valuable information and deeper understanding about, for example, exacerbations, nutrition, or strategies for sputum evacuation. The eHealth tool was also considered to have the potential to support exercise training by providing videos of exercises suitable for a home environment for people who were motivated

because training at a gym was expensive and might require strenuous travel. A possibility to send questions to the COPD nurse through the eHealth tool and have them answered was raised as a suggestion.

Handling the disease in everyday life also involved feelings of self-blame and worthlessness as well as hiding the self-inflicted disease by saying things like "I am just a bit out of breath" instead of naming the disease. The eHealth tool was seen as a tool that could deal with the urgent "blame-yourself question," and one suggested strategy for doing that was to produce short videos of critical situations such as getting the diagnosis or chatting about the disease with friends.

Applying Evidence-Based Care

The subcategory applying evidence-based care captures the views of the role an eHealth tool could play in supporting the application of guideline recommendations and evidence in clinical practice. Health care professionals suggested that the eHealth tool could offer knowledge and support for self-management strategies in order to meet their needs for knowledge. They expressed great variability in their COPD-related knowledge, and while some perceived a need for very basic knowledge, others expressed a need for knowledge related to their own professional practice. For example, the PTs who primarily catered to patients with musculoskeletal disability in their daily practice expressed needs for knowledge about breathing techniques and about how much one could "dare to push them" during physical training. Moreover, easy access to screening tools, material for patient education, and updated information about local exercise groups was highly desirable.

The eHealth tool was considered by both researchers and health care professionals to have the potential to support people with COPD in self-management strategies and to strengthen their ability to influence their health, interpret symptoms, and take relevant actions such as contacting the health care system. Portraying people with COPD who had succeeded in, for example, increasing their level of physical activity as role models on the eHealth tool was thought to support other patients in their use of self-management strategies. A common view was that people with COPD are a low-powered group that neglects important symptoms such as weight loss and symptoms indicating an exacerbation of their disease. However, as people with COPD might be "stigmatized and depressed and feel bad" and have bad experiences from previous contacts with health care services, the researchers also acknowledged that they might find it difficult to ask for services.

A crucial issue in the researchers' discussion was how the newly published, evidence-based National Guidelines for COPD care [28] and other evidence should be applied in primary care. The eHealth tool could, for instance, provide concrete advice on how people with COPD could start increasing their level of physical activity and how health care professionals could use the recommended screening tools and interpret the results in order to identify patients with the greatest needs. Furthermore, questions related to how the guideline recommendations could be adapted to clinical contexts and how this was described on the eHealth tool were seen as essential. This can be exemplified

through a discussion among the researchers related to the 6-minute walking test, which is highly prioritized in the national guidelines but requires a 30-meter corridor in order for cut-off values to be valid.

But I still think that we need to come out with the recommendation that if you only have ten meters, then that's what you should use to do it. If you then do it the same way every time. [External researcher]

Another issue that might demand contextual adaptation, raised by the researchers, was how work was organized. Contributions from the eHealth tool could be to describe what interprofessional collaboration and evidence-based practice included but not to define “who should do what.”

Fitting Into the Current Routines

The subcategory fitting into the current routines reflects the participants' view that the eHealth tool had to fit the contextual conditions in the primary care and the habits and interest of people with COPD in order to be used regularly. The health care professionals pointed to the dilemma that the use of a website would require access to computers in a way that was not in concordance with the present situation. Flexible use of the eHealth tool without being tied to a desktop seemed helpful, and wishes to “have an iPad in my room” were expressed. Time was another resource that was emphasized because the introduction of the eHealth tool might require longer visits.

Furthermore, a challenge related to the use of the eHealth tool was variation in interest, motivation, and computer skill among the people with COPD. Even though almost all the people with COPD and their relatives owned a computer, some experienced a lack of knowledge about how to use it, as well as a lack of interest. The use of computers could be associated with previous work, and one relative had made a promise “to never sit by the computer when retired.”

Regarding an eHealth tool as support for exercise training, a common view was that participating in a group together with other people with COPD for exercise training seemed more fun compared with doing exercises at home. Doing exercises at home was considered to require strong motivation, and participating in a group and having an inspiring instructor was seen as the best support for physical exercise. Limited opportunities to participate in such groups in the rural area was also put forward.

Keeping Control

Even though the health professionals' and researchers' ambition to strengthen the patients was prominent, the subcategory keeping control captures how the eHealth tool could potentially challenge the well-established hierarchy between health care professionals and patients. A few thoughts were brought up among them, suggesting that patients could be unable to handle all of the information and that patients who were too knowledgeable might induce a risk of “being questioned.” Therefore, it was suggested that the patients should not be able to access information primarily directed to the health care professionals on the eHealth tool, such as how to organize team-based care and alternative interpretations of symptoms. Furthermore, encouraging people with COPD to ask for specific

health services, such as support for physical exercise, was not always appreciated because the primary care unit's right to prioritize the services offered was considered important.

No one else should get involved. Because that's how the financial conditions are. So I don't think you should promise [on the eHealth tool] that someone else will do something. [Health care professional]

Furthermore, the national guidelines were seen as tools for health care professionals that were difficult to communicate to the public.

Meaningful and Urgent

The category meaningful and urgent reflects the participants' perspective that the eHealth tool should be designed so that it speaks distinctly and directly to its target groups. A straightforward message and wording that included all groups of health care professionals was seen as crucial in order to promote its use.

Visualized Messages That Enable Self-Identification

All groups of participants viewed visualized messages that enable self-identification on the eHealth tool as an advantageous way to communicate information, instructions, and advice. People with COPD and their relatives perceived that videos would be “more efficient” and “informative” compared with text or instructions on paper. The health care professionals suggested several issues that could be communicated through videos such as the handling of positive expiratory pressure devices and energy conservation techniques. To make the messages meaningful, people with COPD suggested that the videos should allow them to identify themselves with the people in the videos. This could be done by showing people with COPD instead of actors and by including “young, old, white, and black people; persons with disabilities; and those who are able-bodied.” In order to further enable identification, the health care professionals put forward that both positive and negative experiences of using self-management strategies, as well as different stages of the disease, could be represented in videos.

Easily Accessible and Distinct Messages

The importance of communicating easily accessible and distinct messages on the eHealth tool with a focus on short bits of information written in an “understandable language” was brought up by all groups. Health care professionals, people with COPD, and their relatives emphasized that the eHealth tool should be easy to find on the internet, that the written information should be illustrated with pictures, that one should be able to listen instead of having to read, and that the information should be printable. When pilot videos were shown during the focus group discussions, both health care professionals and people with COPD pointed out the importance of instructions that specified the purpose and benefits of, for example, breathing techniques and physical exercises.

Either I was very inattentive...but the instructions...well, I understood what to do with the rubber band and all that, but what's the point of it? [Participant with COPD]

Health care professionals also thought that the eHealth tool would be accessed to a greater extent if registration and log-in could be avoided or at least be voluntary.

Creating Engagement

The subcategory creating engagement captures the participants' view that the eHealth tool would need to arouse interest among its potential users, which involves both aspects of the content and the introduction of the tool. The choice of wording was thought to influence health care professionals' motivation to use the eHealth tool, and the researchers suggested that the expression "pulmonary rehabilitation" was not the most suitable in order to engage all groups of health care professionals.

Rehabilitation is so focused on physiotherapy. But if you call it 'health-promotion,' then it includes, like, all of the professions in this line of work. It supports interprofessional collaboration. [Researcher]

The people with COPD perceived that a face-to-face introduction, preferably by the COPD nurse, would be most advantageous. Some type of written information was considered unavoidable, even though "being flooded by leaflets" was a common experience, and a small card with the address to the website or a leaflet was preferred. Health care professionals suggested printed material with information about the eHealth tool to hand over to both people with COPD and their relatives in order to involve them as well.

Because many people with COPD also suffered from comorbidities, it was considered important to meet the needs of a specific patient in order to create engagement and make the eHealth tool relevant.

When you have COPD, you often have many other illnesses too, and do you take those into account? Well, the patient certainly asks himself that "But I have heart failure, too. Or diabetes, or..." ...When you're supposed to do what they say in this video. It just isn't accurate. Click. Delete. And then you forget the video [Health care professional]

Individualization was considered to be possible if information and videos on the eHealth tool targeted different stages of the disease. Health care professionals then could pick information considered relevant for a specific individual during the introduction of the tool.

Discussion

Principal Findings

The number of eHealth solutions that are being developed has increased rapidly in recent years. In order to enable implementation, it is important that the development of such solutions is informed by the needs and preferences of the potential users and by contextual conditions [16,17,19,20]. Accordingly, data for this study were collected during the cocreation process of an eHealth tool aimed at supporting self-management strategies in people with COPD. Key findings, reflecting study participants' perspectives and captured in the theme *reinforcing existing support structures*, suggest that an eHealth tool aiming to support self-management strategies

should facilitate the adaptation of guideline recommendations and evidence into everyday practice. Furthermore, the eHealth tool should reflect the urgency of self-management issues and communicate this in a distinct message while fitting into the existing routines and not threatening the existing hierarchy between health care professionals and patients.

Interpretation of Findings

Insufficient knowledge about how to apply guideline recommendations and other evidence-based interventions in primary care was described by health care professionals, and similar findings have also been reported in previous research [10,23,29,30]. Insufficient knowledge has also been reported as a barrier to guideline adherence in COPD care [10,23,29,31]. Furthermore, having a thorough understanding of what a new practice entails and the relevant skills has been described as crucial for the successful adoption of a new practice [18,32-34]. Consequently, as captured in the subcategory *applying evidence-based care*, the study participants emphasized that an eHealth tool should provide concrete examples and suggestions on how to adapt and apply guideline recommendations in order to facilitate evidence-based practice. An eHealth tool alone cannot be expected to make up for insufficient knowledge and skill, but it might have the potential to facilitate an implementation process.

The eHealth tool was considered to have the potential to strengthen the people with COPD and increase their readiness to act and to be more involved in their own care. The emphasis on patients' involvement is in line with the national and international development toward person-centered health care systems [35,36] that include sharing of information and knowledge in order to create a common understanding and to build a partnership between patients and health care professionals [37-39]. On a national level, efforts that help patients become experts on their conditions are imperative and have been called for by the Swedish authorities [40]. However, as illustrated in the subcategory *keeping control*, patients taking up the role of experts—who ask for services and interpret their own symptoms—might be perceived as a challenge to the health care professionals' authority. This is supported by a previous review in which an unwillingness and reluctance to encourage patient participation and to delegate power to patients was reported [41], and limiting the amount of information given to patients was one way of maintaining control. In the context of COPD, a study of health care professionals involved in providing pulmonary rehabilitation ranked the importance of patients' adherence to medical advice considerably higher than having the patient involved as a team member or having the patient be an independent information seeker [42]. Even though most health care professionals seem to welcome more active and involved patients, the fact that not everyone embraces this shift in the patient's role must be acknowledged and challenged.

An important finding is that people with COPD only turned to primary care when faced with strictly medical issues and not issues related to self-management. One explanation for this, supported by previous research, is insufficient knowledge about self-management [43,44], including insufficient knowledge about what services and support are available from primary

care. Another explanation might be the experience of guilt and shame associated with a self-inflicted disease that was described by the people with COPD in this study and also reported in other studies [45-48]. Such feelings might lead to a situation where patients distance themselves from their symptoms and minimize their needs, thus, avoiding seeking advice and instead adapting to a life with unnecessary disabilities [46,48]. Because self-management plays a prominent role in the treatment of COPD, there is an obvious need to provide easily accessible support for self-management, including information on when to contact primary care and information on what support might be available. The internet and eHealth solutions seem to be appreciated and valued sources of information and support for people with COPD [47,49], and consequently, it is important that such support, based on the needs and wishes expressed in this and similar studies, is available.

In this study, videos were suggested as important measures for communicating the self-management interventions as well as for addressing questions about the shame associated with a self-inflicted disease. Previously reported eHealth interventions have involved persuasive technologies such as remote monitoring of physical activity [21] and self-monitoring of health values [50], but no such components were suggested by the people with COPD in our study. However, the absence of such proposals and desires is hardly surprising as it might be necessary to have knowledge about such interventions in order to propose them. The use of videos for demonstration of self-management intervention is in accordance with “modeling,” which is one of the ingredients described to enhance self-efficacy for self-management in chronic conditions [1,51]. Modeling can be accomplished through the use of videos or pictures that reflect the population of concern [51] and might thereby have the potential to influence people’s behavior. However, the use of only videos and written information as methods for supporting self-management strategies on an eHealth tool might be insufficient, and additional persuasive technologies might be needed in order to promote behavior change.

Strengths and Limitations

In the research process toward an eHealth tool for enhanced self-management, a major strength of this study is its focus on user involvement and cocreation. Trustworthiness has been strived for by involving health care professionals representing different professions, people with COPD and their relatives, and external researchers, who have provided several perspectives on the relevance and usefulness of the eHealth tool. Furthermore, the fact that the sample included both rural and urban areas and people with COPD at different stages of their disease is essential because the perceived needs and relevance for eHealth solutions might differ based on the distance from health care services and severity of the disease. The authors’ broad range of competencies and perspectives, and recurrent reflection during the process of analysis, further added to the trustworthiness. The limited number of people with COPD and their relatives in the study must be considered a weakness as this might have limited the variation in the findings. Furthermore, a greater representation of physicians in the health care professionals’ focus groups, as well as representation of OTs, dieticians, and MSWs, would have been beneficial. However, as the findings represent a broad range of experiences from 3 groups of participants, we assume that the results could be generalized to similar health care contexts.

Conclusions

Self-management is an ongoing and never-ending task for many people with chronic diseases, and the development of tools that are accessible and meet the needs of the users, including both health care professionals and patients, is imperative. The findings of this study, such as the need for knowledge about how to apply guideline recommendations, the need for more knowledge among people with COPD, how to create engagement among the users, and eHealth tools as potential threats to hierarchies, are presumably generic and can inform the development of eHealth tools for self-management support in other chronic diseases. The involvement of the user groups and the careful analysis of their views and perceptions enable their perspectives and priorities to be built into the eHealth tool and will most likely contribute to a tool that has the potential to be adopted in clinical practice and in everyday life.

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Authors' Contributions

MT has made direct and substantial contribution to this work by playing a leading role in the design of the study, data collection, analyses, interpretation of data, and drafting of the manuscript. SL made a direct and substantial contribution to this work by contributing to data collection and played, in close collaboration with MT, a significant role in analyses and interpretation of data and in drafting of the manuscript. MW made a direct and substantial contribution to this work by playing a significant role in the analysis and interpretation of data and by providing critical revisions that are important for the intellectual content of the manuscript. AN contributed to the analysis and interpretation of data and provided critical revisions that are important for the intellectual content of the manuscript. ÅH contributed to data collection and provided critical revisions that are important for the intellectual content of the manuscript. KW is the principal investigator and has made a direct and substantial contribution to this work by

providing the project idea; contributing to data collection, conception, and design of the study; and providing critical revisions that are important for the intellectual content of the manuscript. All the authors have read and approved the final version of the manuscript.

Conflicts of Interest

None declared.

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Abbreviations

COPD: chronic obstructive pulmonary disease

eHealth: electronic health

MSW: medical social worker

OT: occupational therapist

PT: physiotherapist

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Review

Clinically Excellent Use of the Electronic Health Record: Review

Leah Wolfe¹, MD; Margaret Smith Chisolm², MD; Fuad Bohsali³, MD

¹Division of General Internal Medicine, Johns Hopkins Bayview Medical Center, Johns Hopkins University School of Medicine, Baltimore, MD, United States

²Department of Psychiatry and Behavioral Sciences, School of Medicine, Johns Hopkins University, Baltimore, MD, United States

³Department of Medicine, School of Medicine, Duke University, Durham, NC, United States

Corresponding Author:

Leah Wolfe, MD

Division of General Internal Medicine

Johns Hopkins Bayview Medical Center

Johns Hopkins University School of Medicine

5200 Eastern Avenue, Mason F Lord Building

Center Tower, Suite 2300

Baltimore, MD, 21224-2780

United States

Phone: 1 410 550 0512

Fax: 1 410 550 3403

Email: lewolfe@jhmi.edu

Abstract

Background: The transition to the electronic health record (EHR) has brought forth a rapid cultural shift in the world of medicine, presenting both new challenges as well as opportunities for improving health care. As clinicians work to adapt to the changes imposed by the EHR, identification of best practices around the clinically excellent use of the EHR is needed.

Objective: Using the domains of clinical excellence previously defined by the Johns Hopkins Miller Coulson Academy of Clinical Excellence, this review aims to identify best practices around the clinically excellent use of the EHR.

Methods: The authors searched the PubMed database, using keywords related to clinical excellence domains and the EHR, to capture the English-language, peer-reviewed literature published between January 1, 2000, and August 2, 2016. One author independently reviewed each article and extracted relevant data.

Results: The search identified 606 titles, with the majority (393/606, 64.9%) in the domain of communication and interpersonal skills. Twenty-eight of the 606 (4.6%) titles were excluded from full-text review, primarily due to lack of availability of the full-text article. The remaining 578 full-text articles reviewed were related to clinical excellence generally (3/578, 0.5%) or the specific domains of communication and interpersonal skills (380/578, 65.7%), diagnostic acumen (31/578, 5.4%), skillful negotiation of the health care system (4/578, 0.7%), scholarly approach to clinical practice (41/578, 7.1%), professionalism and humanism (2/578, 0.4%), knowledge (97/578, 16.8%), and passion for clinical medicine (20/578, 3.5%).

Conclusions: Results suggest that as familiarity and expertise are developed, clinicians are leveraging the EHR to provide clinically excellent care. Best practices identified included deliberate physical configuration of the clinical space to involve sharing the screen with patients and limiting EHR use during difficult and emotional topics. Promising horizons for the EHR include the ability to augment participation in pragmatic trials, identify adverse drug effects, correlate genomic data to clinical outcomes, and follow data-driven guidelines. Clinician and patient satisfaction with the EHR has generally improved with time, and hopefully continued clinician, and patient input will lead to a system that satisfies all.

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KEYWORDS

clinical excellence; electronic health record; electronic medical record; technology; communication skills; interpersonal skills; professionalism; humanism; patient care

Introduction

Use of the electronic health record (EHR) during clinical encounters is now a standard part of contemporary medical practice. The EHR—like other medical technologies—is designed to optimize the efficiency and quality of health care delivery, and ultimately—one hopes—improve patient outcomes. However, as anyone who has ever used or seen his/her health care provider use the EHR during a clinic visit knows that use of the EHR in a way that preserves or enhances clinical excellence is challenging. The Johns Hopkins Miller-Coulson Academy of Clinical Excellence (MCACE) has previously identified the following domains of clinical excellence: (1) communication and interpersonal skills, (2) diagnostic acumen, (3) skillful negotiation of the health care system, (4) scholarly approach to clinical practice, (5) professionalism and humanism, (6) knowledge, and (7) passion for clinical medicine [1]. To identify best practices around the clinically excellent use of the EHR, the authors conducted a literature review of the MCACE domains and the EHR.

Methods

The concepts of the clinical excellence domains and the EHR were defined using a combination of controlled vocabulary terms applicable to PubMed and keyword terms and phrases to

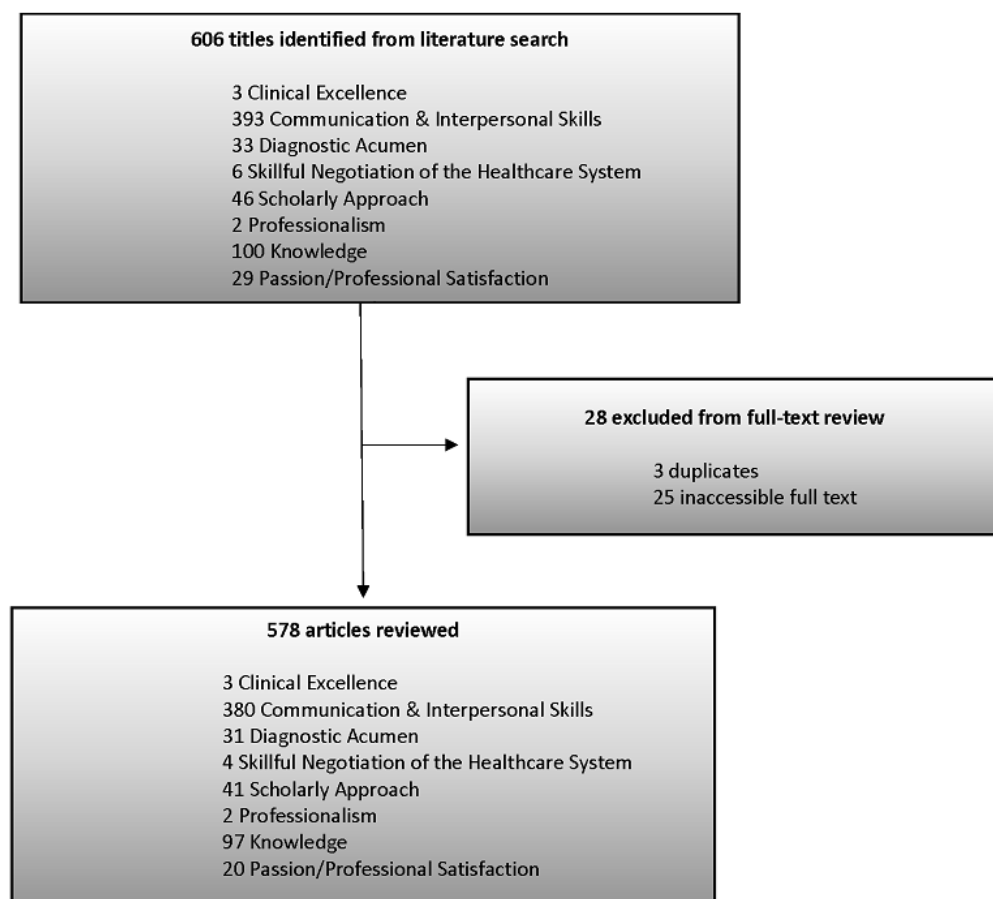
capture the English-language, peer-reviewed literature published between January 1, 2000, and August 2, 2016 ([Multimedia Appendix 1](#)). Citations were imported into a citation management system, and duplicates were removed. The authors ensured the search strategies captured a previously published review [2] on the topic. One author (LW, FB, or MSC) independently reviewed each article and extracted relevant data. The study was submitted to the institutional review board and deemed exempt from further review.

Results

Overview

The search identified 606 titles ([Figure 1](#)), the majority (393/606, 64.9%) were in the domain of communication and interpersonal skills. Twenty-eight of the 606 (4.6%) titles were excluded from full-text review, primarily due to lack of availability of the full-text article. The remaining 578 full-text articles reviewed were related to either clinical excellence generally (3/578, 0.5%) or to the specific domains of communication and interpersonal skills (380/578, 65.7%), diagnostic acumen (31/578, 5.4%), skillful negotiation of the health care system (4/578, 0.7%), scholarly approach to clinical practice (41/578, 7.1%), professionalism and humanism (2/578, 0.3%), knowledge (97/578, 16.8%), and passion for clinical medicine (20/578, 3.5%).

Figure 1. Flowchart for search strategy and review of English-language, peer-reviewed articles on clinical excellence and the electronic health record between January 1, 2000 and August 2, 2016.



Communication and Interpersonal Skills

Within the communication and interpersonal skills domain, the following practice-based themes emerged from the literature, yielding the following clinical “pearls.”

How Clinicians Practice

Clinicians’ baseline communication styles are the main determinants of how we communicate in the presence of EHR implying that continuing education on the basic skills of clinician-patient communication is essential as we implement the EHR [3-5]. Clinician attitudes toward the EHR can affect the attitudes of patients and the quality of clinician-patient communication in its presence [6]. It can be useful for clinicians to learn to touch type and consider the use of scribes to help optimize face-to-face communication [7-12]. Quieter keyboards can also be less disruptive to the flow of communication [2]. It is helpful for clinicians to be more transparent about their use of the EHR and to address its presence in appreciative tones [13-16].

Impact on Patients

Generational, cultural, and socioeconomic differences can affect patients’ attitudes toward and engagement with the EHR [17]. When working with patients who speak a different language, the EHR may be both an asset and a hindrance (translation capability within the EHR can potentially mitigate this, but can be tricky) [18,19]. For example, Ratanawongsa and colleagues [19] found that increased EHR use by clinicians was associated with more biomedical statements and less positive effect from patients with low English proficiency and low health literacy. This group advocated for further research on whether the increased use of technologies like the EHR are reducing or increasing the confusion of patients with language and health literacy barriers. Studies of patient attitudes toward the EHR generally show more favorable attitudes than clinicians or researchers anticipate [5,20-23].

How to Prepare for a Visit

It is helpful for clinicians to review the record ahead of time to identify interval events and data, and to review the patient’s social history so that communication during the patient visit is more valuable, personalized, and less superfluous [10,12,24,25]. Clinicians can use the EHR to remind them of current life events of patients, to help personalize the visit and couch discussion of health care issues in the context of their lives [26]. Clinician-patient communication through patient portals can enhance both inter-visit and in-visit communication [27-29].

How to Organize the Room

Screen sharing is a significant theme in the existing literature, for the promotion of patient engagement, facilitation of communication during the visit, transparency, and patient empowerment and education. It is helpful if clinicians ensure the screen is visible to both the clinician and patient so that they share a “joint focus of attention” [2,13,25,30-36]. It is imperative that the display be large enough for the patient to view. Optimally, the room should be organized to allow eye contact between the clinician and patient at all phases of the visit [24,32,33,37-39].

How to Engage Patients with the Electronic Health Record in the Room

Multiple strategies can be used to improve patient engagement in visits through conscientious use of the EHR. One of these is the use of “transition phrases” or “signposting” when moving from the patient to the EHR and back [2,12,16,30,31,40-42]. It is also wise to use a language of collaboration when discussing the EHR and to address openly any issues of confidentiality [23]. It can be helpful for both patient and clinician if clinicians repeat what they write in the EHR verbally while typing—to emphasize information and messages, and to maintain a shared focus on the topic [2,40,41]. Sharing the screen with patients can facilitate communication as well—through review and verification of content, as well as through visual display of information (eg, graphics) to educate and empower [2,4,13,16,31,41,43-47]. It can even be valuable to have patients input information [12,13,48].

Clinicians should limit the use of the EHR during difficult and emotional topics [4,12,49,50], and try to maximize eye contact to avoid missing nonverbal cues and to enhance the relationship [2,4,24,25,41,51-53]. Clinicians do not want to lose the narrative and patients must have time to express their concerns, and tell their story [42,53-57]. Several studies have highlighted ways in which EHR use can facilitate provider-patient dialogue and partnership strategies, even in the context of conversations around difficult topics [2,58,50].

How to Use the Electronic Health Record to Enhance Intervisit Communication

Patient portals for email communication are an opportunity to enhance the flow of information and to build relationships [26,27,39,59-62]. Multiple studies exist on the use of the EHR for patient self-management of chronic disease and health behaviors [39,61,63-65]. Tasks that took time during traditional office visits can be accomplished through intervisit use of the EHR, freeing up more time for meaningful communication in the office. Direct access to test results by patients can enhance the quality and safety of care [39,61,62,66,67]. It is important to remember, however, that not all patients will have access to or identify the means of bridging that gap. The EHR has significantly increased opportunities for interprovider communication and has demonstrated benefit in transitions of care, and in the coordination of care, especially for patients with complex health needs [68-71].

Diagnostic Acumen

Review of the literature revealed several ways in which the EHR can assist a clinician’s diagnostic acumen, such as instant access to historical records, and automation of risk score algorithms. The EHR makes access to past medical history automatic within the sphere in which the EHR operates. Retrieving outside data are the slowest area of progress, but is still improving with the EHR. The EHR’s ability to provide interconnected and immediate point-of-care access adds a new dynamic to the health care system, expanding the background of clinical knowledge and enhancing diagnostic acumen and speed of diagnosis [72].

The EHR also brings the potential to use calculated risk scores to the user's fingertips. Physicians admitting a patient with non-ST-elevation myocardial infarction can have immediate access to the thrombolysis in myocardial infarction score. An outpatient provider can have an automated atherosclerotic cardiovascular disease risk score calculated as soon as vital signs are measured. While debate exists around the utility of these scores [73,74], they have and will continue to be ever-present in our understanding of disease. The EHR gives clinicians the added functionality of automatically calculating and providing this data as an added input to the clinician, another tool in the toolbox.

Skillful Negotiation of the Health Care System

The EHR can help clinicians more deftly navigate the health care system to provide high-quality, cost-conscious care. One way the EHR helps clinicians improve care is by promoting adherence to guidelines. Despite knowing that guideline-directed care improves outcomes, chronic and acute-care patients receive guideline-directed care only about 50% of the time [75], and one-third of health care expenditure is wasteful [76]. Clinical decision support (CDS) is the set of prompts that highlight information that could change clinical care and is the answer to the gap in guideline-based care. CDS relies heavily on input from clinical staff who are up-to-date with guidelines. However, when done correctly, CDS has the potential to facilitate the delivery of high-quality care, improving the health of patients and avoiding unnecessary care [77,78].

Further, the Office of the National Coordinator for health care information technology is moving toward national knowledge-sharing for CDS prompts with the intent of eventually standardizing and classifying the importance of CDS. Together, these represent methods for ensuring that we are navigating our health care environment to provide succinct and concise care.

As the use of the EHR grows, data-sharing is being enhanced across networks in regional data exchange systems called health information exchanges (HIEs). With these, clinicians can share pertinent patient information, labs, and notes, as well as communicate directly about essential details. HIEs are the vehicle for creating seamless and secure data-sharing between networks.

Scholarly Approach to Clinical Practice

Use of the EHR facilitates the creation of patient databases and undertaking of pragmatic trials [79]. Through automation of the processes of patient screening, patients can be assessed for participation in pragmatic trials directly through diagnostic codes and demographic information, and messaged at home or asked in the office if they would consent to a study. For patients with the ability to access a computer, investigators have provided informed consent via online videos which can be viewed in the comfort of the patient's own home. Further, the addition of the computer to the clinical setting means that the networks for starting a pragmatic clinical trial are primed and ready. The data are already being collected in the system, and need only to be consented to appropriately and shared.

Professionalism and Humanism

The human price of the EHR is the distraction. CDS popups alert clinicians to a clinical need, an incorrect allergy warning may alarm while entering a prescription, and vital signs may flag a sepsis warning inappropriately. In the rapidly advancing world of the EHR with its increased distractions, it is imperative that clinicians maintain strong bonds with patients and stop the intrusion into clinician-patient relationships [25]. Best practices described in the Communication and interpersonal skills domain can support humanistic attitudes and professional behaviors in the face of the EHR.

The electronic interface of collection is transforming the field of Patient Reported Outcomes (PROs). Many patient portals are set up to ask and record PROs, which can seamlessly integrate into the patient's record. These PROs provide the ability to compare treatments and add patient-centered outcomes to the research. These data are being mobilized for use in decision making by groups like the Patient-Centered Outcomes Research Institute, the National Institutes of Health Collaboratory, and the American Society of Clinical Oncology.

Knowledge

The EHR brings a new way to interface with the knowledge that clinicians generate. Two of the most exciting changes to knowledge will be the discovery of new patterns and the incorporation of genetic data to patient records via "big data" methodology. In computing, big data refers to the use of extensive datasets that are analyzed computationally to reveal previously unknown trends and associations. With enough data points, data scientists suspect that computers will eventually be able to generate prediction models for individual cases based on repositories of old case data [80]. For example, a computerized model of hyponatremia correction in newborns has been created based on large numbers of observations by computers [81].

On the forefront, data scientists and geneticists hope to incorporate patient genomic information into the EHR to help identify patterns and uncover new genetic connections. Once genetic data has been added to a patient's profile, the EHR could theoretically learn what gene loci predispose a patient to angioedema, interstitial lung disease, or any number of previously poorly understood disease states [82,83].

In a similar vein, the EHR can automate the reporting of adverse drug reactions to newly prescribed drugs. By reporting early trends in side effects from a new agent, EHRs might accelerate the detection of untoward side effects—like myocardial infarction associated with cyclooxygenase enzyme inhibitors (ie, COX-2) [84].

Passion and Professional Satisfaction

The introduction of the EHR was fraught with underprepared EHR platforms and unrealistic expectations. Clinicians were initially confronted with decreased efficiency, increased burnout, and high turnover. Early on, physicians using computerized order entry and electronic documentation were 30% more likely to report burnout after controlling for other variables [85]. The only intervention that routinely improved satisfaction was

employing scribes, which suggests that the only positive experience associated with the EHR was minimizing its use [85]. Further analysis into trends of physician satisfaction reveals that a more robust platform is more correlated with satisfaction. Clinical notes, diagnosis function, and off-site capability were all associated with higher satisfaction. There was a trend that younger physicians were more likely to be satisfied than their elder peers [85]. Finally, and most promising of all, physicians who had access to their EHR for at least two years were 2.78 times more likely to be satisfied with their EHR compared to those with less than two years' experience [86].

Much of the literature in other domains touched on the EHR's potential to improve the interface with clinicians. Tools are being introduced to provide the clinician with medical references on demand for reading about developing medical data [87-89]. Finally, natural language processing is another advancing technology in which the computer attempts to interpret the clinician's intention when writing. As an example, when a clinician diagnoses a patient with pneumonia, the EHR could ask if it should open the pneumonia order set [34,90,91]. This technology is still in its infancy and will likely require years to be ready for implementation. That said, it is one of the exciting transformations of the EHR that would produce a more fluent interface between the clinician and computer, allowing clinicians to focus back on the priority—patients.

Discussion

Many articles published after our literature review cite the EHR as a significant factor in clinician burnout. For example, in their

2017 commentary, Shanafelt and colleagues [92] discuss clinician burnout in the era of the EHR and its attendant clerical, regulatory, and workload implications. They outline the potential broader impacts of clinician burnout for the quality of care and the health care system at large. They also emphasize the importance of measures to address the increasing documentation burden especially performance and documentation of components of care that are justifiable for billing purposes alone and do not contribute meaningfully to the episode of care. A recent systematic review by West and colleagues [93] highlights the evidence supporting both organizational and individual interventions to address burnout. Though beyond the scope of our review, clinician burnout is critical among factors that should be considered in the design, implementation, and use of the EHR going forward.

The EHR has completely transformed the clinical landscape. Its arrival and integration have been fraught with challenges, including having noticeably altered clinicians' communication with patients. That said, clinicians are gradually transforming their approach to, and interaction with, the EHR in a way that attempts to minimize distraction and enhance the quality of the clinician-patient connection again. Computerizing this work has effectively put clinicians "on the grid" and hopefully will continue to bring positive changes to the way that clinicians gather and interact with patient data to further enhance diagnostic acumen, scholarly approach to medicine, professionalism, knowledge, passion for clinical medicine, and the ability to negotiate the health care system to provide clinically excellent care for patients.

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Conflicts of Interest

None declared.

Multimedia Appendix 1

PubMed search terms and process for literature review for clinically excellent use of the electronic health record.

[PDF File (Adobe PDF File), 46KB - [humanfactors_v5i4e10426_app1.pdf](#)]

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Abbreviations

CDS: clinical decision support

EHR: electronic health record

HIE: health information exchange

MCACE: Johns Hopkins Miller-Coulson Academy of Clinical Excellence

PROs: patient reported outcomes

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Original Paper

Use of a Digital Medication Management System for Effective Assessment and Enhancement of Patient Adherence to Therapy (ReX): Feasibility Study

Ronit Shtrichman¹, MBA, PhD; Stefan Conrad¹, MBA; Kai Schimo¹, Dipl Inf (FH); Ran Shachar¹, BSc; Ehud Machluf¹, BSc; Enrique Mindal¹, BSc; Howard Epstein¹, MBA; Shirli Epstein¹, BSc; Alan Paz¹, BSc

DosentRx Ltd, Har Tuv, Israel

Corresponding Author:

Ronit Shtrichman, MBA, PhD

DosentRx Ltd

PO Box 9

Ganir Center 2 Hahar Street

Har Tuv, 9980101

Israel

Phone: 972 0526500938

Email: ronit.s@dosentrx.com

Abstract

Background: Medication nonadherence is a major problem in health care, imposing poor clinical outcomes and a heavy financial burden on all stakeholders. Current methods of medication adherence assessment are severely limited: they are applied only periodically, do not relate to actual pill intake, and suffer from patient bias due to errors, misunderstanding, or intentional nonadherence. ReX is an innovative medication management system designed to address poor patient adherence and enhance patient engagement with their therapy. ReX controls and tracks pills from the point of packaging right through to the patient's mouth. ReX generates robust, real-time adherence data. The system enables patients to report outcomes, complete surveys, and receive messages and instructions. ReX includes a reusable drug dispensing unit, disposable cassette containing pills, and a cloud-based data portal.

Objective: We aimed to evaluate ReX feasibility by human factor studies including evaluation of ReX safety; ReX acceptance and usability; and ReX efficacy of providing pills according to a preprogrammed dose regimen, managing reminders and adherence data, and enhancing the adherence rate compared with the standard of care.

Methods: The ReX system was evaluated in 2 human factor, nonclinical feasibility studies. Human subjects used ReX for the administration of pill-shaped Tic Tac sweets. The initial study evaluated ReX use and pill intake administration; second was a self-controlled, 4-day home-use study. All subjects took pills at home, according to a preprogrammed dose regimen, for 4 days each via the device (ReX test) or from standard packaging (control test). The adherence rate (percent of pills taken) was measured by the study subject's report, remaining pills count, and ReX records (in the ReX test). ReX safety and usability were evaluated by a questionnaire filled out by the subject.

Results: The initial feasibility study evaluated usability and acceptance of the ReX novel approach to pill dispensing. All subjects successfully managed 2 pill intakes. The ReX device was rated as easy to use by 81% (48/59) of subjects. The 4-day home-use study evaluated the safety, efficacy, and usability of the ReX system. No adverse event occurred; no pill overdose or pill malformation was reported. The overall adherence rate in the ReX test was 97.6% compared with 76.3% in the control test ($P<.001$). Real-time, personalized reminders provided in the event of a delay in pill intake contributed to 18.0% of doses taken during the ReX test. The ReX system was found easy to use by 87% (35/40) of subjects; 90% (36/40) felt comfortable using it for their medication.

Conclusions: ReX's novel "tracking to the mouth" technology was found usable and accepted by subjects. The assessment of adherence rates was reliable; adherence of subjects to the dose regimen was significantly enhanced when using ReX compared with the standard of care.

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KEYWORDS

medication adherence; medication nonadherence; personalized medicine; therapy management

Introduction

Medication nonadherence is defined as the extent to which patients fail to take medications or follow treatment recommendations as prescribed by their care providers. It is one of the most serious problems in health care, imposing a heavy financial burden on all stakeholders: insurers, employers, and patients [1].

The overall adherence for medication therapies was found to be almost 50% [2]. Forgetting to take medication and misunderstanding instructions are the most frequently reported reasons for nonadherence [3]. It is estimated that in the United States nonadherence leads to 125,000 deaths per annum and accounts for 33%-69% of all medication-related hospital admissions [4]. Between US \$100 and US \$300 billion of avoidable health care costs have been attributed to nonadherence in the United States annually, representing 3%-10% of total US health care costs [3]. A recent report estimated that nonadherence in 2016 cost the pharmaceutical industry up to \$637 billion in lost sales, of which \$250 billion were in the United States [5]. This estimate points to a far more significant problem than previously believed.

Adherence measurement is a considerable challenge. The current methods of measuring adherence may be classified as direct or indirect. Direct methods test the drug level or its metabolite in body fluids. Direct approaches are expensive, limited to periodic assessment, and subject to variations resulting from the patient's condition at the time of test. Indirect methods include patient questionnaires, self-reports, pill counts, rates of prescription refills, assessment of patient's clinical response, and patient diaries. Indirect methods are simple but inaccurate and biased [1].

Electronic medication packaging devices have been developed to remotely record, deliver, manage, and monitor drug intake information. The Medication Events Monitoring System can track and record the date and time of the medication removed from a container. The use of Medication Event Monitoring System was found to be reliable in several studies, at least compared with pill count and patients' reports [6]. Other novel technological solutions involving cell phone apps aim to enhance adherence by providing alerts for pill intake according to the dose regimen. However, these technologies cannot track each pill or eliminate medication overdose and abuse [7].

ReX is an innovative medication management system designed to provide a comprehensive solution to the nonadherence problem. ReX monitors the drug from its packaging in the pharmacy through to its administration into the patient's mouth. The pills are locked in the device and can be released only at the right time, at the specified dose, and only to the prescribed

patient's mouth. Pill intake data are recorded and transmitted in real time to caregivers. When a dose is missed, a personalized reminder is immediately provided to the patient. ReX can survey the patient's well-being and be used as a treatment diary. In this paper, we describe the evaluation of the ReX system in 2 human factor feasibility studies. The studies' goals were to demonstrate its safety, efficacy, and usability in adherence assessment and enhancement.

Methods

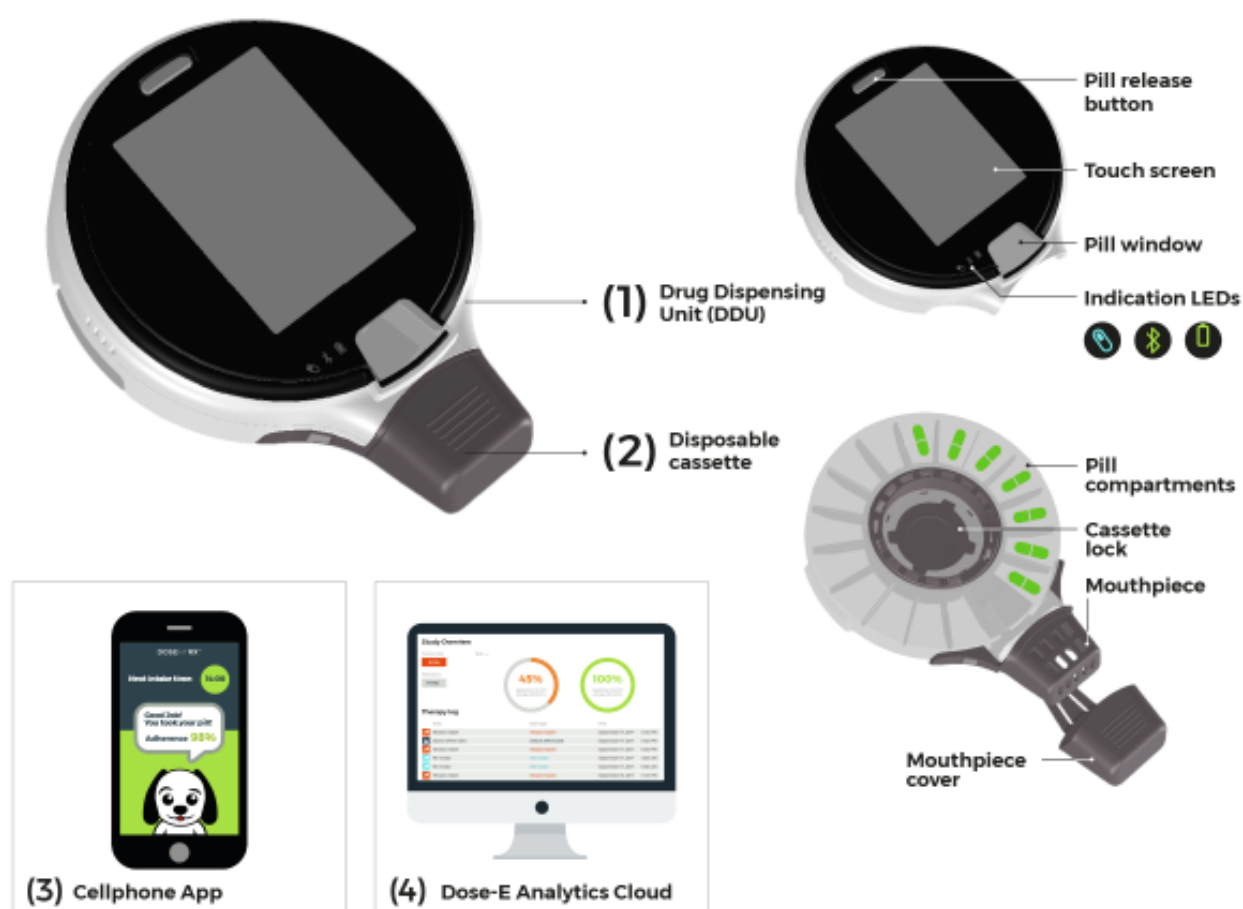
ReX System Design

ReX is a hand-held, mobile device intended to provide solid oral medication on patient demand according to a preprogrammed treatment protocol. ReX aims to address poor patient adherence by providing personalized medication therapy management.

The system comprises a reusable drug dispensing unit (DDU), a disposable cassette, a cellphone app, and a Dose-E Analytics cloud system. Figure 1 shows the ReX device, comprising reusable DDU (1), disposable cassette containing pills (2), cellphone app (3), and Dose-E Analytics cloud system (4). The DDU manages pill administration and includes a touch screen, which guides the user and presents patient-specific clinical surveys and therapy information. The DDU contains a chargeable battery and indicators demonstrating the device and the battery status, a pill window enabling pills to be viewed, operational sensors, and Bluetooth communication to an app on a cellphone. All therapy data are transferred to a patient-specific domain on a Web-based cloud. The DDU is also used to hold and lock the disposable cassette which contains the pills.

The disposable cassette is a locked, tamper-resistant container. It is supplied preloaded with bulk pills, located 1 in each of 16 separated pill compartments. The cassette is opened only on insertion in the DDU. The cassette includes an integral mouthpiece designed for pill ingestion. The mouthpiece incorporates an antichoke mechanism, which ensures that the pill falls directly onto the tongue. An integral protective cover keeps the mouthpiece clean and sealed. Once empty, the cassette is automatically released by the device. Cassette exchange is easily performed by the user.

The cellphone app transfers data between the DDU and the Dose-E Analytics cloud. The Dose-E Analytics cloud system is a proprietary browser-based app in which all therapies and patient information are collected and managed. The cloud allows caregivers to set up and track the therapy online and follow the patient's adherence. When a missed dose is recorded, the cloud sends alerts to a predefined contact person or to the call center.

Figure 1. ReX system components.

Principal Operation of ReX

Pill Intake Procedure

As seen in [Figure 2](#), the DDU prompts the patient to take a pill at the defined time by means of sound, light, and animations and via the cellphone app (1). The patient requests a pill by pressing on the pill release button (2). The patient applies a slight suction on the mouthpiece and the pill is released onto his tongue (3). If the patient presses the button within the predefined lockout period, the device will not release a pill. If a delay is recognized, a personalized phone call reminder is provided. The device offers clinical surveys (4), recording of an e-dairy, therapy information, and reinforcements (5).

Data Management

The device records all pill intake events. This information is transmitted through the cellphone app to the Dose-E Analytics cloud. Therapy data can be relayed in real time to payers, providers, and caregivers.

Reminders and Alerts

The time window in which the user can take a pill is termed the tolerance time. The tolerance time determines the reminders, including visual and acoustic alerts, on the DDU screen and cellphone app. As the tolerance time window progresses without a pill being taken, the reminders escalate in frequency and intensity. Toward the end of the tolerance time, if a pill has still

not been taken, an email is dispatched to the recognized contact person. The notified person contacts the patient by phone call to remind him to take his pill and to establish the cause of the delay. This process ensures that reminders are provided only when needed, eliminating diminished responsiveness to unsolicited alerts.

Surveys and Therapy Information

Real-time patient surveys and an e-dairy can be filled via the screen. The patient may use the screen to check his adherence rate, the course of treatment, and obtain treatment information ([Figure 2](#)).

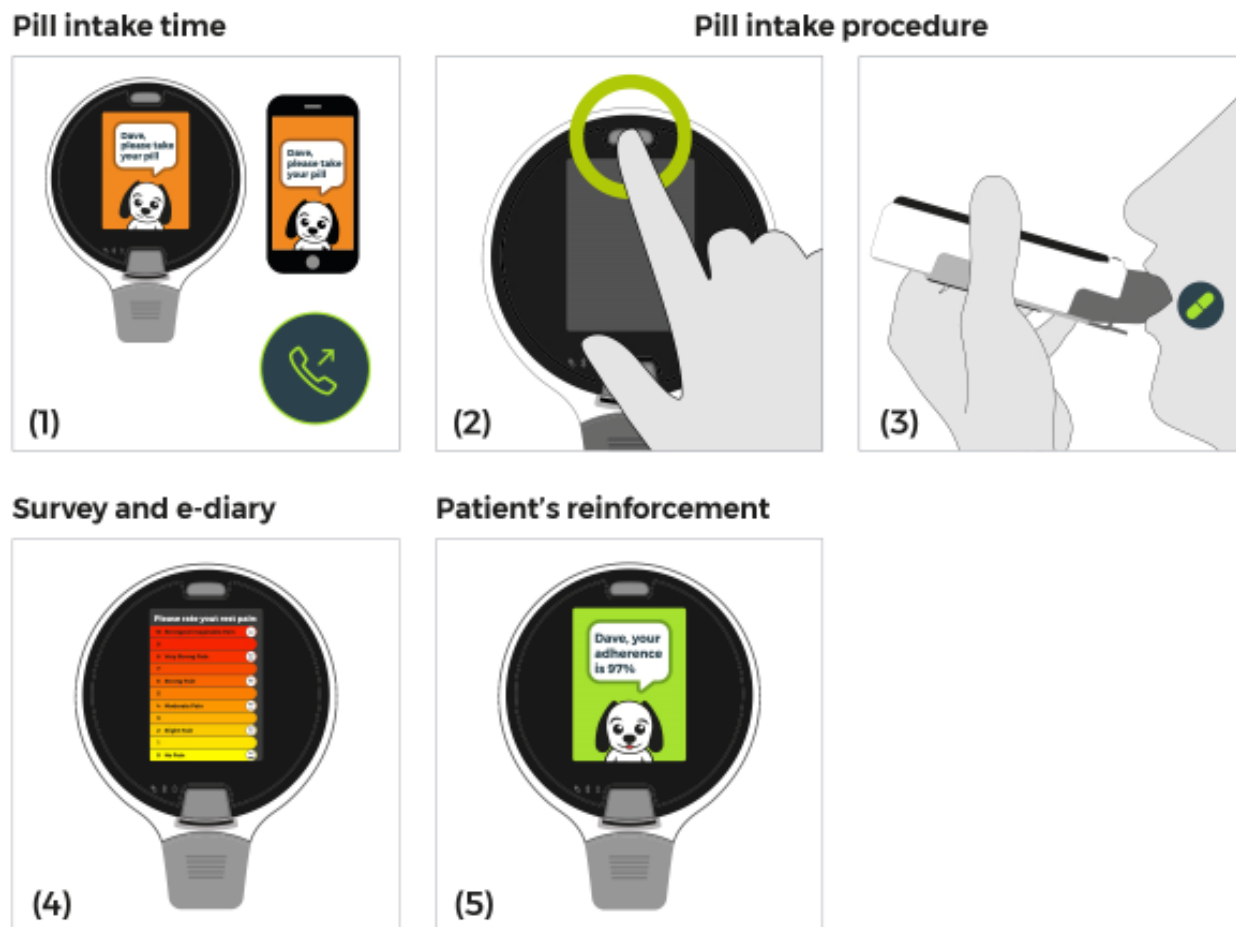
Initial Feasibility Study

Study Objectives

The initial feasibility study objectives were the evaluation of (1) ReX device functionality (inserting the cassette, pill extraction, screen menu) and (2) ease of extracting a pill and acceptance of the pill extraction concept. The study was nonclinical since the pills used were pill-shaped Tic Tac sweets.

Study Population

We enrolled 59 human subjects (29 males, 30 females), aged 18-92 years. The subjects were recruited following publication on social networks (LinkedIn, Facebook) and local advertisements. No compensation was provided to recruited subjects.

Figure 2. ReX operation and patient journey.

Study Design

All participated subjects were volunteers. All enrolled subjects signed an informed consent form. Each subject underwent a short one-on-one training session during which they were asked to insert a cassette and take 2 pills using the device. The subjects filled out a questionnaire about their experience with the ReX device.

Study Measures

The study evaluated the following parameters: subjects' ability to insert a cassette, success rate of pill extraction using the device, understanding of screen menus, understanding the concept of lockout and overdose prevention, and overall ease of use. Results were recorded on a questionnaire comprising Likert-scale responses. Subjective and unsolicited opinions were noted.

4-day Home-Use Feasibility Study

Study Objectives

The objectives of the 4-day home-use feasibility study included

- Evaluation of the safety, efficacy, and usability of the ReX system in 4-day home use.

- Assessment of ReX ability to enhance adherence rate compared with standard of care (taking pills from standard pill container). Pill-shaped Tic Tac sweets were used to mimic medication. The study is, therefore, defined as nonclinical.

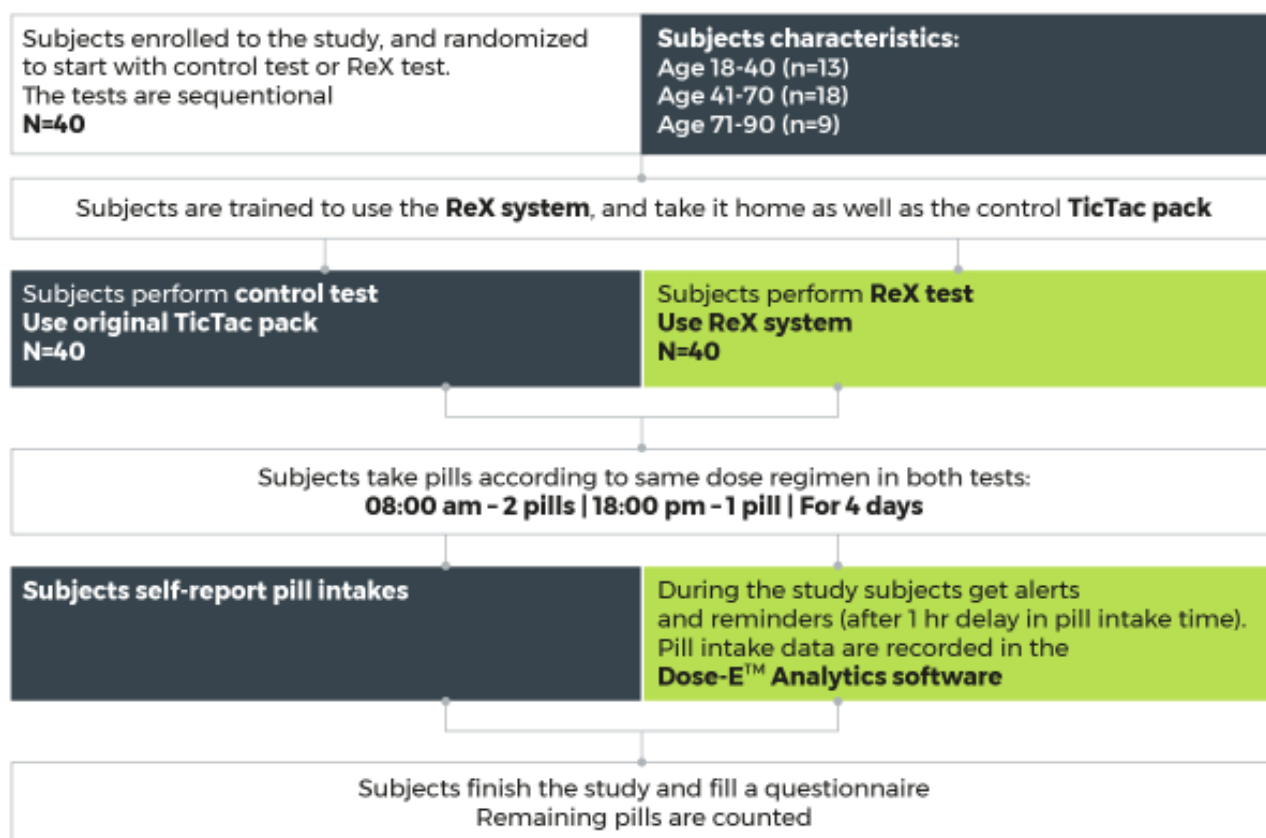
Study Population

We enrolled 40 human subjects, aged 18-90 years, and they all signed an informed consent form. The exclusion criteria were significant physical disability or mental disorder and failure to extract 2 pills after 3 attempts during ReX training. Subjects were recruited following publication on social networks (LinkedIn, Facebook) and local advertisements. No compensation was provided to the recruited subjects.

Study Design

In this self-controlled study each subject participated in the following sequential tests:

Control test: Subjects took pills from the original package and manually reported for each pill intake or missed dose. No reminders were performed during this test. At study end, the remaining pills were counted.

Figure 3. Flow diagram of ReX 4-day home-use feasibility study.

ReX test: Subjects took pills using the ReX device. Delays in pill intake lead to real-time personalized reminders. At study end, the remaining pills were counted and compared with the ReX records. Subjects were asked to report any safety or functionality problem encountered during the study and to fill out a questionnaire regarding their experience with ReX (Multimedia Appendix 1). The study design is shown in Figure 3.

Both tests had the same duration and dose regimen of 2 pills in the morning and 1 pill in the evening, for 4 days. The specific time of pill intake was programmed in the ReX device as 08:00 am and 18:00 pm. The tolerance time was set as ± 1 hour. In case of pill intake delay after the tolerance time, an email was dispatched prompting the principal investigator to contact the subject and remind him to take the missing pill.

Before the study start, each subject underwent a short, in-person training session in which he successfully completed 2 pill intakes using the ReX. During the ReX test, real-time adherence data were communicated to the Dose-E Analytics cloud and made available to the study's principal investigator.

Statistical Analysis

The adherence rate was calculated as percent of doses taken. In the ReX test, percent doses taken before and after the reminder were calculated and included in the adherence rate. Paired differences were calculated for adherence rate and percent of missed doses between the ReX test and control test for all subjects and by age categories. The paired *t* test and nonparametric signed-rank test for 2 means (paired observations) were applied to analyze the paired differences. All tests were

2-tailed, and a *P* value $\leq 5\%$ was considered statistically significant. The data were analyzed using SAS 9.3 (SAS Institute, Cary North Carolina).

Results

ReX Initial Feasibility Study

The initial feasibility study aimed to evaluate usability, acceptability, and ease of use of the ReX device for oral medication provision. There were 59 subjects, aged 18-92 years, in the study (Table 1).

Following a short tutorial, all subjects successfully inserted the cassette into the DDU and defined the process as easy. The usability of ReX for pill extraction was measured by the success rate of 2 pill intakes. All subjects managed 2 successful attempts at pill intake as required, and 81% (48/59) of subjects required only 1-2 attempts to extract a pill. A learning effect was evident in taking the pills: subjects were more successful in taking their second pill compared with the first.

All subjects easily grasped the concept and functionality of the screen displays. After 2 successful attempts at pill intake, 100% (59/59) of subjects understood the concept of lockout and overdose prevention, as confirmed by a third attempt at pill intake. The overall impression was very positive, with 97% (57/59) of subjects expressing confidence in using ReX by themselves and without assistance.

Figure 4 demonstrates subjects' response regarding overall ReX ease of use: 81% (48/59) of all subjects rated the ReX device as easy to use. This rating did not appear to be influenced by

years of formal education, as 100% of subjects with 6-10 and >20 years of formal education defined the ReX use as easy, while 4%-8% of subjects with 11-15 and 16-20 years of formal education, respectively, defined it as difficult.

However, analysis by age group demonstrated that ReX usability is influenced by age: 29% (2/7) of subjects >80 years old reported that ReX was difficult to use. Opinions as to ease of use slightly decreased with age. Still, 94% (16/17) of subjects aged 18-40 and 81% (42/52) of subjects aged up to 80 years defined the ReX as easy to use.

4-day Home-Use Feasibility Study

This study aimed to evaluate ReX's usability during home use and its capability to monitor and enhance patient adherence. The study was designed as self-controlled: pill intake using ReX was compared with intake from a standard pill container as the control. The same dose regimen was used for both methods. We enrolled 40 subjects with an age range of 18-90 years, as described at [Table 2](#).

Table 1. Demographic characteristics of 59 human subjects participating in the initial feasibility study.

Group	Ages (years), n (%)							
	All subjects	18-30 (n=10)	31-40 (n=7)	41-50 (n=11)	51-60 (n=8)	61-70 (n=10)	71-80 (n=6)	>81 (n=7)
Gender								
Male	29 (49)	4 (7)	6 (10)	7 (12)	3 (5)	4 (7)	2 (3)	3 (5)
Female	30 (51)	6 (10)	1 (2)	4 (7)	5 (8)	6 (10)	4 (7)	4 (7)
Years of formal education								
6-10	4 (7)	1 (2)	3 (5)	— ^a	—	—	—	—
11-15	24 (41)	7 (12)	—	3 (5)	2 (3)	4 (7)	3 (5)	5 (8)
16-20	26 (44)	1 (2)	3 (5)	7 (12)	4 (7)	6 (10)	3 (5)	2 (3)
>20	5 (8)	1 (2)	1 (2)	1 (2)	2 (3)	—	—	—
Take pills regularly	29 (49)	3 (5)	2 (3)	5 (8)	3 (5)	6 (10)	5 (8)	5 (8)

^aNot applicable.

Figure 4. Usability of ReX device.

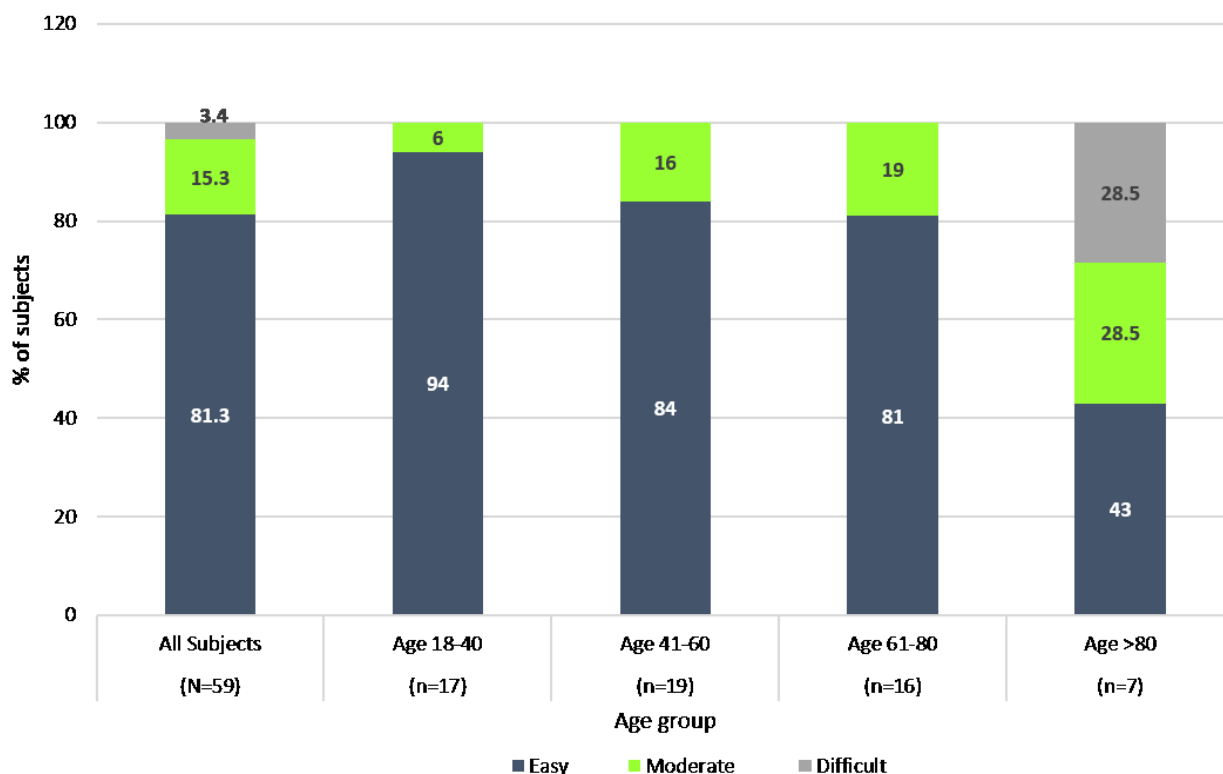


Table 2. Demographic characteristics of 40 human subjects participating in the 4-day home-use study.

Group	Ages (years), n (%)			
	All subjects	18-40 (n=13)	41-70 (n=18)	71-90 (n=9)
Age (years), mean (SD)	48.7 (20.2)	27.5 (6.6)	53.7 (8.5)	79.4 (5.3)
Gender				
Male	21 (53)	6 (15)	10 (25)	5 (13)
Female	19 (48)	7 (18)	8 (20)	4 (10)
Take pills regularly	17 (43)	1 (8)	10 (56)	9 (100)

Table 3. Adherence rate statistical analysis for all users and by age group.

Adherence Rate	N	Mean (SD)	Min	Median	Max	Lower 95% CI	Upper 95% CI	P value (paired <i>t</i> test)	P value (signed-rank test)
All subjects								<.001	<.001
ReX	40	97.6 (5.2)	83.3	100.0	100.0	95.9	99.3	— ^a	—
Control	40	76.3 (24.6)	0.0	83.2	100.0	68.6	84.0	—	—
Age, 18-40 years								.002	.004
ReX	13	98.1 (4.7)	87.5	100.0	100.0	95.2	100.9	—	—
Control	13	64.9 (27.8)	0.0	66.7	100.0	48.9	80.9	—	—
Age, 41-70 years								.02	.008
ReX	18	96.8 (5.4)	87.5	100.0	100.0	93.9	100.4	—	—
Control	18	79.4 (25.7)	8.3	85.4	100.0	65.7	93.1	—	—
Age, 71-90 years								.02	.03
ReX -C	9	98.6 (5.8)	83.3	100.0	100.0	93.9	101.2	—	—
Control	9	86.2 (13.4)	66.7	87.9	100.0	77.0	94.0	—	—

^aNot applicable.

ReX Device Safety

The safety of the ReX system was evaluated by a questionnaire filled out by the subjects and confirmed by data recorded in the Dose-E cloud. No incidence of pill overdose dispensed occurred, and no pill malformation was reported. Furthermore, no severe adverse events, such as pill inhalation, occurred.

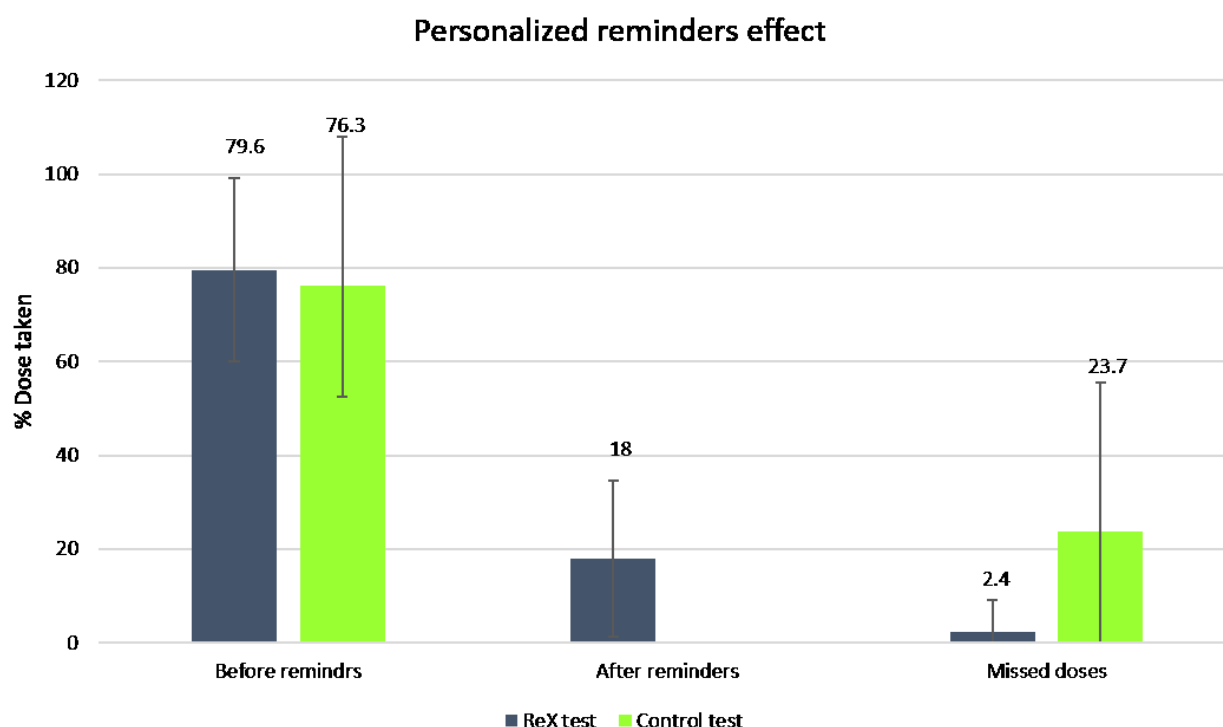
ReX Device Efficacy

The functionality of the ReX system was measured by the success rate of pill intakes. All subjects (40/40, 100%) successfully obtained pills by the ReX device according to their dose regimen. The principal investigators and 80% of subjects (32/40) did not encounter any technical difficulties during device use, such as problems involving the touch screen; pills extraction on time; and data transfer, monitoring, and management by the Dose-E Analytics cloud system.

The 2 processes of pill administration were compared: use of the ReX system (ReX test) or use of a standard pill container (control test). The subject's adherence rate was measured by the subject's report, remaining pill count, and ReX record (only for ReX test).

Table 3 lists the mean adherence rate obtained for all subjects and for the 3 different age groups. Results show that the adherence rate of all subjects in the control test was 76.3% while the adherence rate in the ReX test was 97.6% ($P<.001$). Analysis by age group also demonstrated significantly higher adherence rates in the ReX test compared with the control test. The adherence rate in ReX test was stable and reached 97%-98% for all age groups with very low variations (up to 5.2%). In contrast, adherence rates in the control test varied significantly between age groups and were subject to high SDs (up to 24.6%). Adherence rates in the control tests were 64.9%, 79.4%, and 86.2% for age groups of 18-40 ($P<.001$), 41-70 ($P=.02$), and 71-90 ($P=.02$) years, respectively.

Following a 1-hour delay in pill intake recorded by the ReX system (1-hour delay was defined as beyond the tolerance time), subjects doing the ReX test received a personalized reminder (phone call) from the principal investigator. This personalized communication aimed to prompt them to take their delayed dose and to understand the cause of the delay. It was found that 18% of doses were taken after personalized reminders. Only 2.4% of doses were completely missed in the ReX test, while 23.7% of doses were missed in the control test.

Figure 5. Effect of real-time, personalized reminders on percent dose taken.

Doses taken were recorded by pill count, self-report at study end, and by ReX record (only in ReX test). Figure 5 shows percent of dose taken before personalized reminders in both tests, after personalized reminders only in the ReX test (personalized reminders are not applicable in the control test), and percent of missed doses in both tests.

ReX Device Usability

The usability and ease of use of the ReX system were evaluated by questionnaires completed by the subjects (Multimedia Appendix 1), of whom 87% (35/40) found the ReX system easy to use, and 90% (36/40) mentioned that they felt comfortable using ReX for their medications. Moreover, when comparing between the ReX device and standard package, subjects responded that the ReX device was more effective in reminder provision (36/40, 90%) and in error prevention (38/40, 95%), and the ReX device was preferred to keep an e-diary during medication therapy (33/40, 82%).

Discussion

Principal Findings

ReX is an innovative system designed to manage oral medication therapy by directly monitoring pill intakes, allowing high confidence in the resulted adherence rate. ReX incorporates a “tracking to the mouth” approach. This is based on a patented technology for the safe ingestion of solid pills into the patient’s mouth and digitally tracking this action to provide accurate, reliable, and real-time adherence data to stakeholders. Electronic monitoring devices have been shown to provide good-quality information on adherence rate [8] and found to hold promise of improving adherence [9–11]. Methods that involve reinforcement interventions have been successful in improving patients’

cooperation and adherence behaviors. Clear and effective communication between caregivers and their patients has been found to be essential in improving patients’ adherence [12].

An initial feasibility study was conducted to evaluate the basic usability parameters of the ReX device and acceptability of the pill extraction concept. Results demonstrated that all subjects could successfully use the device for pill intake. The device was defined as easy to use, and 81% (48/59) of subjects required only 1–2 attempts for successful pill intake. Only mature users (aged >80 years) reported more difficulty, although they all could manage and extract pills using the device. These results demonstrate the feasibility of the ReX novel technology.

Following this, we designed a 4-day home-use study to evaluate ReX safety, efficacy, and usability. The adherence rate by ReX was compared with the standard of care. The adherence rate was tested by subjects’ reports, remaining pill count, and by ReX records (during the ReX test). Although patient self-report and remaining pills counts are common methods to assess patient adherence, there is extensive evidence that such methods greatly overestimate medication adherence when compared with plasma drug levels and electronic device measurements [8,13,14]. These methods may also suffer from intentional nonadherence, including removing and discarding pills from a blister card or bottle, to create false records while reporting good adherence [8]. In contrast, the ReX approach eliminates false measurements since each pill is tracked directly during ingestion. The adherence rate is obtained in an unbiased way, without patient involvement.

The 4-day home-use feasibility study demonstrated that ReX device is safe: no adverse events, overdoses, or pill malformations were encountered. The safety of pill ingestion by sucking was previously confirmed in a clinical study

evaluating the same technology for pain analgesic medication provision to postoperative patients in the hospital setting [15].

Functionality analysis revealed that all subjects could successfully use the ReX device for pill intake and that adherence data were available for the study's principal investigators in real time. Study results showed a statistically significant difference of 21.3% in adherence rate between the ReX test and the control test (97.6% and 76.3%, respectively). It is possible that low adherence rates in the control test occurred because subjects took Tic Tac sweets and not real medication, making it less important to them. However, the same subject group achieved 97.6% adherence rate in the ReX test. Such high adherence was due to stringent monitoring of each dose by the study's principal investigator and timely reminders to subjects in any case of delayed dose. This created effective communication and reinforcement to take the missed dose.

The adherence rate of the control test varied between the 3 different age groups of 18-40, 41-70, and 71-90 years. Only 8% (1/13) of the young subjects (age 18-40 years) took pills regularly and were, therefore, not used to taking pills. Their adherence in the control test was consequently relatively low (64.9%). However, use of ReX increased their adherence rate to 98.1%. Mature subjects (age 71-90 years) demonstrated higher adherence in the control test (86.2%). This may be because all subjects (9/9, 100%) of this age group take pills on a daily basis. However, using ReX enhanced adherence rate in all age groups. All differences in adherence rate between the ReX test and control test were statistically significant.

The ReX system also demonstrates benefits over technological solutions of adherence assessment and enhancement. An available approach is a memory chip embedded in bottle caps or blister packs that tracks medication adherence electronically. For example, the Medication Event Monitoring System cap [9] (AARADDEX Group, SA), which records the date and time of each opening. However, since this system does not track the intake of each pill, a false record of dosing can easily be created [8]. A vast pool of medication adherence cellphone apps is also available to help patients manage their medication regimen [16]. However, these apps add a burden on subjects to record and update each time they take a pill. This action may be missed at the real time of pill intake. Also, usual app alerts may be ignored and missed by subjects while in routine use.

During the 4-day home-use ReX study, personalized reminders were shown to add 18% of doses taken. This explains the major difference in adherence rate between the ReX test and the control test. Notably, adherence rates were almost similar between these tests before any personalized reminder. This highlights the effect of personal reminders provided in real time and only when needed. It also confirms the minimal impact of conventional visual and acoustics alerts that automatically appeared and are often ignored by the user.

The final percent of missed doses in the ReX test (2.4%) was almost 10-fold lower than in the control test (23.7%). This observation clearly demonstrates the benefit of using ReX system to monitor and enhance adherence.

The usability of ReX was evaluated by questionnaires filled out by the subjects participating in both the ReX and control tests. After 4 days of use and 12 pill intakes, 90% (36/40) of subjects reported that they felt comfortable taking their medication via ReX, and 87% (35/40) of subjects mentioned that it was easy to use. Moreover, most subjects believed that ReX provided effective reminders (90%), was highly effective in error prevention (94%), and was most suitable to be used as an e-diary to record symptoms during therapy (82%). These results are in agreement with the high usability and acceptance of the technology as demonstrated in a previous clinical study [15].

The feasibility studies described here demonstrate the potential of the ReX system for medication management. ReX may provide a considerable benefit in medication therapies such as: high risk drugs, to eliminate errors, overdose, and abuse (eg, opioid treatment [17], anticoagulants, or stimulants for attention-deficit/hyperactivity disorder treatment [18]); high cost drugs (eg, specialty drugs [19]); and clinical trials, in which adherence critically affects outcome reliability and study cost [20].

In summary, ReX is an innovative solution providing reliable, unbiased, and cost-effective adherence monitoring and enhancement, while safeguarding the patient by elimination of medication errors, overdose, and abuse.

Conclusions

Two feasibility studies confirmed the safety, efficacy, and usability of the ReX system. All objectives were achieved. Regarding ReX safety, the ReX system was safe under the study conditions; no adverse events, no pill provision during the lockout interval, no overdose, and no pill malformation were found. Evaluation of ReX efficacy demonstrated that all subjects successfully used ReX to take the pills according to their dose regimen. The data were available to the study's principal investigator in real time, and personalized reminders were provided in any case of a 1-hour delay in pill intake. The adherence rate in the ReX test was 97.6%, significantly higher compared with the control test (76.3%). The effectiveness of real-time personalized reminders was indicated by 18% of doses in the ReX test being taken after the reminders were received by the study subjects. As for ReX usability, ReX technology was well accepted by subjects participating in the studies. Over 80% of subjects described it as easy to use and mentioned that they felt comfortable to use it for their medications.

Study Limitations

The limitations of the study included the heterogeneous small group sizes and the use of candies and not real drugs. Also, Tic Tac sweets are chewable and are not swallowed with water like standard drugs. The adherence rate was based on self-reporting and remaining pill counts in the control test. These are known to be unreliable methods. ReX records are more reliable in the ReX test. The study design ensured that half of the subjects completed the control test before the ReX test and vice versa for the other half.

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Authors' Contributions

Design and development of the ReX system: SC, KS, RaS, EhM, EnM, HE, and AP. Design and performance of the feasibility studies: RoS, SE, and HE. Data analysis: RoS and HE. Manuscript writing and revision: RoS. Manuscript review and editing: HE.

Conflicts of Interest

RoS, SC, KS, RaS, EhM, EnM, and HE are DosentRx employees. DosentRx developed and owns the ReX system. AP is a cofounder and co-owner of DosentRx. SE is a nurse, experienced in clinical and human-factors studies.

Multimedia Appendix 1

ReX Use Questionnaire.

[PDF File (Adobe PDF File), 51KB - [humanfactors_v5i4e10128_app1.pdf](#)]

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Abbreviations

DDU: drug dispensing unit

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Original Paper

Collecting Health and Exposure Data in Australian Olympic Combat Sports: Feasibility Study Utilizing an Electronic System

Sally Bromley^{1,2}, MSc; Michael Drew^{1,2}, PhD; Scott Talpey^{2,3}, PhD; Andrew McIntosh², PhD; Caroline Finch^{2,4}, PhD

¹Physical Therapies Department, Australian Institute of Sport, Canberra, Australia

²Australian Centre for Research into Injury in Sport and its Prevention, Federation University Australia, Ballarat, Australia

³School of Health and Life Sciences, Federation University Australia, Ballarat, Australia

⁴School of Health and Medical Sciences, Edith Cowan University, Perth, Australia

Corresponding Author:

Sally Bromley, MSc

Physical Therapies Department

Australian Institute of Sport

Canberra,

Australia

Phone: 61 411802057

Email: sally.bromley@live.com.au

Abstract

Background: Electronic methods are increasingly being used to manage health-related data among sporting populations. Collection of such data permits the analysis of injury and illness trends, improves early detection of injuries and illnesses, collectively referred to as health problems, and provides evidence to inform prevention strategies. The Athlete Management System (AMS) has been employed across a range of sports to monitor health. Australian combat athletes train across the country without dedicated national medical or sports science teams to monitor and advocate for their health. Employing a Web-based system, such as the AMS, may provide an avenue to increase the visibility of health problems experienced by combat athletes and deliver key information to stakeholders detailing where prevention programs may be targeted.

Objective: The objectives of this paper are to (1) report on the feasibility of utilizing the AMS to collect longitudinal injury and illness data of combat sports athletes and (2) describe the type, location, severity, and recurrence of injuries and illnesses that the cohort of athletes experience across a 12-week period.

Methods: We invited 26 elite and developing athletes from 4 Olympic combat sports (boxing, judo, taekwondo, and wrestling) to participate in this study. Engagement with the AMS was measured, and collected health problems (injuries or illnesses) were coded using the Orchard Sports Injury Classification System (version 10.1) and International Classification of Primary Care (version 2).

Results: Despite >160 contacts, athlete engagement with online tools was poor, with only 13% compliance across the 12-week period. No taekwondo or wrestling athletes were compliant. Despite low overall engagement, a large number of injuries or illness were recorded across 11 athletes who entered data—22 unique injuries, 8 unique illnesses, 30 recurrent injuries, and 2 recurrent illnesses. The most frequent injuries were to the knee in boxing (n=41) and thigh in judo (n=9). In this cohort, judo players experienced more severe, but less frequent, injuries than boxers, yet judo players sustained more illnesses than boxers. In 97.0% (126/130) of cases, athletes in this cohort continued to train irrespective of their health problems.

Conclusions: Among athletes who reported injuries, many reported multiple conditions, indicating a need for health monitoring in Australian combat sports. A number of factors may have influenced engagement with the AMS, including access to the internet, the design of the system, coach views on the system, previous experiences with the system, and the existing culture within Australian combat sports. To increase engagement, there may be a requirement for sports staff to provide relevant feedback on data entered into the system. Until the barriers are addressed, it is not feasible to implement the system in its current form across a larger cohort of combat athletes.

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KEYWORDS

online; health; injury & prevention; athletic performance; internet; mobile phone

Introduction

Injury and illness can markedly impair an athlete's performance, both in training and competition [1]. Injury and illness monitoring is the foundation stage of accepted prevention frameworks and can be described as the routine collection and reporting of injury and illness data [2,3]. Results from a recent review have indicated that there is a lack of high-quality, prospective injury and illness data published across the Olympic combat sports of judo, boxing, taekwondo, and wrestling [4]. Only one high-quality study was identified in the review, which was in the sport of judo [5]. In this study on judo, a dedicated medical team worked alongside coaches to prospectively collect, analyze, and act upon health-related information on a daily basis [5], thereby potentially enhancing the capture of injuries and illnesses. In Australia, combat sports organizations are limited in their ability to hire medical personnel to collect and report on injury and illness data. Therefore, there is a need to utilize online data systems, which can be accessed from across the country. With many athletes owning or having access to personal electronic devices, online systems have the potential to be easily administered to collect health [6] and training data directly from athletes [7].

A large portion of the epidemiological literature on combat sports details injuries and illnesses, which were sustained by athletes at competitions [8-17]. Collecting data solely at competition introduces the survival bias, whereby athletes who are severely injured and ill would be unlikely to be present at the competition where the data are being collected. Therefore, the injury and illness patterns described in these studies may not be accurate in relation to the overall athlete health. Monitoring athletes both in and out of competitions can address the survival bias; moreover, it can enhance the capture of recurrent health problems. Work from the Oslo Sports Trauma Research Centre shows that the weekly administration of injury and illness questionnaires is superior to the monthly administration for the capture of reoccurring injuries or illnesses [6]. With the increasing evidence that modified training due to injury and illness can also lead to a loss in long-term performance [18,19], it is important to give athletes the tools to self-report on their health and well-being.

An online system termed the Athlete Management System (AMS; Smartabase, Fusion Sport, Brisbane, Australia) has been adopted by the Australian Institute of Sport (AIS) to collect and store the health-related data of Australian high-performance athletes. The AMS allows the capture of recurrent health problems by providing athletes with an avenue to self-report injuries, illnesses, and training information. While not being designed specifically for each sport, the AMS meets the needs of a range of sports stakeholders, including doctors, physiotherapists, and coaches who can access, add to, and act on athlete health and training data. Training status, injury, and illness have been linked to performance outcomes in track and field by utilizing data collected via the AMS [19]. The AMS has also been utilized to promote shared decision making in volleyball around the risks and benefits of athletes participating in camps and competitions [1]. The data collection tools within the AMS can be customized to some degree; however, a

limitation of the system is that the overall design remains the same regardless of the sport it is utilized for. In addition, the AMS does not assist with interpreting data once it is entered. To obtain information that can be fed back to coaches and athletes, a certain amount of work is required by sports personnel. In track and field, water polo, volleyball, and soccer, the sports staff who interpret and disseminate feedback based on the AMS data are physiotherapists and sports scientists based at the AIS. In a previously utilized cost-effective method, [5], team physiotherapists have collected data and provided feedback to coaches and athletes. In a recent study of 131 athletes across a range of sports, the provision of feedback was shown to enhance the uptake and engagement with an online self-report system [7]. Unlike Australian volleyball and track and field, there are no dedicated support staff, such as team physiotherapists, that drives monitoring and provides feedback for Australian combat sports programs. Due to a lack of support staff, it is unknown whether utilizing the AMS to monitor combat sports athletes and collect injury and illness data will be feasible.

The objectives of this paper are to (1) report on the feasibility of utilizing the AMS to collect longitudinal injury and illness data of combat sports athletes and (2) describe the type, location, severity, and recurrence of injuries and illnesses that an elite cohort of athletes experience across a 12-week period.

Methods

Participants

A feasibility study was implemented, and the source population was drawn from internationally competitive athletes in judo, boxing, taekwondo, and wrestling, who were affiliated with the AIS Combat Centre. Participants were recruited in April 2016, during an Olympic preparation camp. Of note, 5 eligible athletes were unable to attend the camp and were, therefore, contacted individually.

The inclusion criteria were elite and developing elite athletes who were affiliated with the AIS Combat Centre. Elite athletes were defined as those who had competed internationally for World Championship and Olympic qualification events in the previous 12 months. Developing elite athletes were defined as those who had competed internationally in Junior Grand Slams, Junior World Cups, and Junior World Championships in the previous 12 months. The exclusion criteria were athletes who only competed domestically and those who were not affiliated with the AIS Combat Centre. This project received ethical approval from an Australian Human Research Ethics Committee (approval number A16-023).

Electronic Data Collection

In this study, we utilized 2 tools within the AMS: (1) a tool designed to capture training load and injuries for each training session termed "session monitoring" and (2) the Health Problems Questionnaire (HPQ) [6]. The AMS is accessible from personal computers, tablets, and phones and can be utilized both online and offline to record a range of training and health-related data. The session monitoring and HPQ tools were displayed on the AMS home screen, which was visible to athletes after

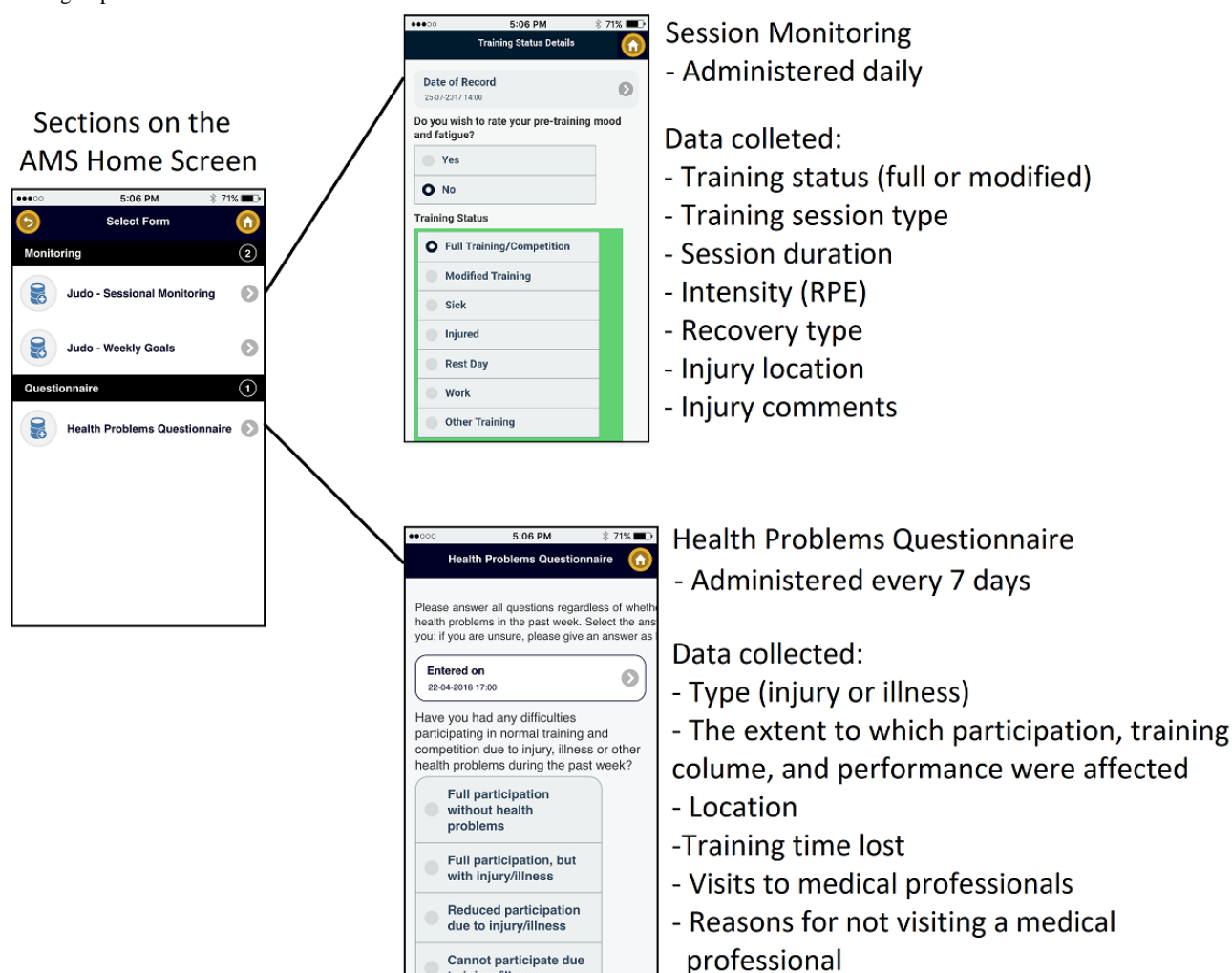
logging in with their unique identification and password. The session monitoring and HPQ tools were specifically selected because they collected data on the training status and the degree to which injury and illness affected the training quality, respectively. Together, the tools allow athletes to report injuries and illnesses and whether they trained without modification and the degree to which they needed to modify their training because of injury and illness.

The session monitoring tool recorded information about the type, duration, and intensity of training sessions and whether athletes experienced any injuries. If the athletes answered “yes” to sustaining an injury, they were prompted to further document the affected area on an electronic body map and were asked to provide additional written detail about the injury. The training load was computed as the rating of perceived exertion multiplied by the session duration for each training session. This is a cost-effective method, previously utilized in judo to quantify the training load [20-24]. Additionally, rapid shifts in training load have been associated with injury incidence and severity, and they represent a method of calculating the exposure [25].

The HPQ is a questionnaire designed to capture athlete self-reported injuries and illnesses, which may or may not result

in lost training time [6] and is embedded within the AMS. During the study, when an athlete clicked on the HPQ section within the AMS, 4 questions appeared related to the degree to which the athlete experienced a health problem that week. If they answered that a health problem had affected them, additional questions appeared that requested more detail about that health problem. The HPQ allows athletes to report on up to 10 health problems each week by asking “Have you experienced any other health problems this week?” as the final question. If the athletes answer yes, they are taken back to the start of the questionnaire. Previous literature utilizing this questionnaire found that a cohort of 142 Olympic athletes collectively documented 15 health problems per week; therefore, the option to report 10 health problems per athlete per week was determined to be sufficient [6]. The severity of combined health problems (injuries and illnesses) was calculated by scoring the responses to the 4 key questions from 0 (no problems) to 25 (maximum level), as has been published previously [26]. Where athletes reported the same injury and illness across both the session monitoring and HPQ tools, the HPQ data was omitted for that week to avoid duplication. Figure 1 displays the data captured across each tool and the frequency of administration.

Figure 1. Electronic data collection tools accessible from the Athlete Management System (AMS) home screen and the frequency of administration. RPE: rating of perceived exertion.



Upon enrollment, the principal researcher (SB) tested each athlete's access to the electronic system by accessing the AMS app on a smartphone and logging in as each athlete. Access to each tool was checked for each athlete; however, no data were saved. Study information was presented by SB as part of an introductory session of the Olympic preparation camp, where athletes performed administrative tasks and were briefed on the camp schedule. Upon enrollment in the study, written informed consent to contact the athlete's treating health professionals (medical practitioners, physiotherapists, etc) and their coaches was obtained in case there was a need to verify any entered data. In addition, consent was obtained for researchers to be able to contact the participant with reminders (eg, phone, email, face-to-face) to enter their data. After the camp, detailed instructions of how to access the AMS and enter data in both session monitoring and HPQ sections were emailed to enrolled athletes. Athletes were free to withdraw their consent at any time without penalty. Reminders and requests were sent to athletes when data were missing or incomplete. Sample communications are presented in [Multimedia Appendix 1](#). Coaches were not utilized as a means to increase the athlete engagement with the AMS; this decision was made so that a

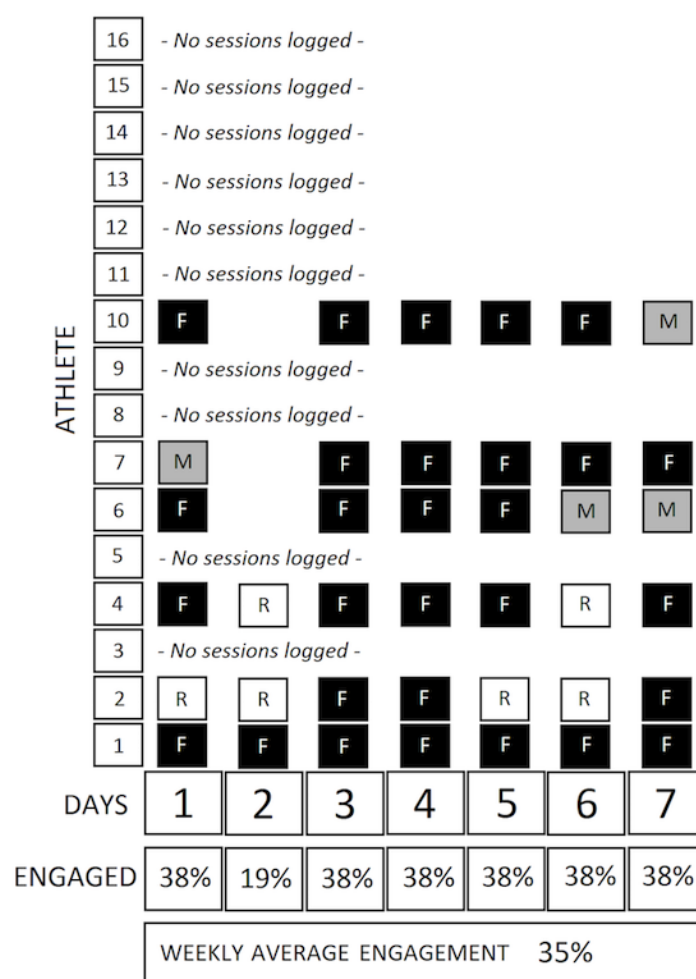
coach's previous experience with the system, if any, would not affect this study.

Data Analysis

Daily engagement with the session monitoring section of the electronic system was calculated and expressed as a weekly average. For each day of the study period, the number of athletes who made a session monitoring entry (which included an option for rest days) was divided by the total number of athletes enrolled in the study. This daily result was then averaged across 7 days to give a weekly cohort engagement score, expressed as a percentage ([Figure 2](#)). The weekly cohort engagement score indicates an athlete's autonomy to self-engage with the AMS.

Descriptive statistics were used to determine the level of uptake (percentage of athletes who were engaged within the first week of data collection) and engagement across the combat sports. In addition, injuries and illnesses were coded using the Orchard Sports Injury Classification System (OSICS) version 10.1 and the International Classification of Primary Care, version 2 (ICPC-2) [27,28]. Days lost to injury and illness were recorded, and the severity of injuries or illnesses were calculated using published methods [26]. Data were analyzed using Stata (13 IC, Stata Corp, College Station, TX, USA).

Figure 2. Method of calculation for weekly compliance rates. R: rest day; F: full training; M: modified training. Gaps indicate no data were entered for that day by that athlete.



Results

Uptake and Engagement With the Electronic System

In total, 21 athletes attended the Olympic preparation camp (boxing: 5 [3 females, 2 males], judo: 9 [4 females, 5 males], taekwondo: 3 [2 females, 1 male], wrestling: 4 [4 males]), and an additional 5 who did not attend the camp were contacted (boxing: 3 [1 female, 2 males], judo: 1 [1 male], taekwondo: 1 [1 male]), totaling 26 athletes (10 females, 16 males). Of the 26 athletes, 9 judo (4 females, 5 males) and 7 boxing (4 females, 3 males) athletes were enrolled in this study (response rate, 55%), with no taekwondo or wrestling athletes being enrolled.

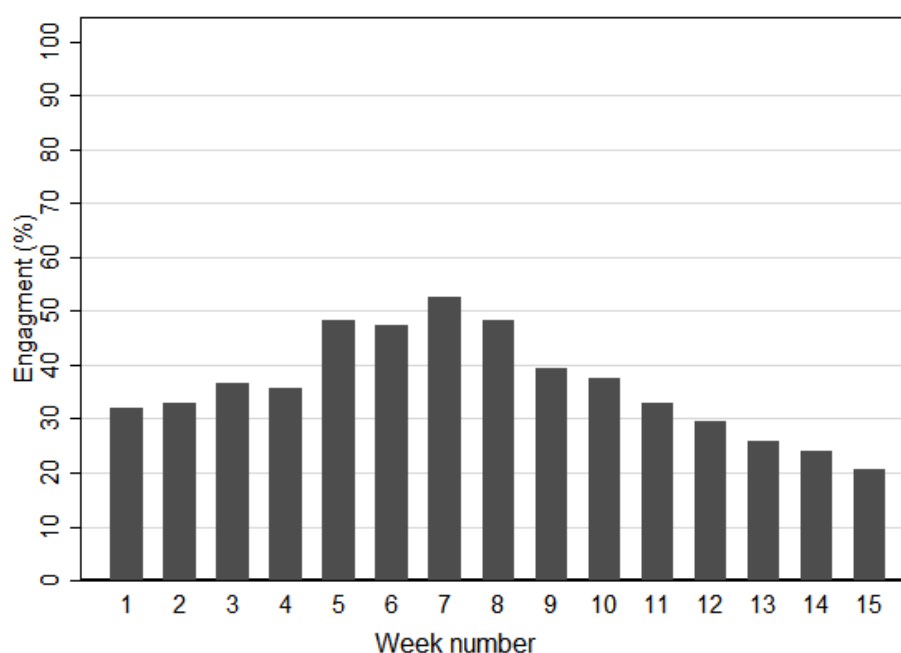
Of all the registered participants, 13% (2/16) participants entered data across the entire study period, 56% (9/16) entered data intermittently, and 31% (5/16) did not enter any data (boxing: 1 [1 male], judo: 4 [3 females, 1 male]). Data collection ranged from 84 to 109 days, equaling 12-15 weeks, depending on where the athletes were recruited within the recruitment period. Including the recruitment period, there was the potential to administer 224 weekly HPQs; however, only 27.2% (61/224) HPQs were completed. During the study, there was potential to collect 1744 days of data, yet only 34.6% (603/1744) days were logged into the online system. Table 1 summarizes the athlete characteristics and engagement rates across the monitoring period.

Table 1. Participant characteristics and engagement rates for the study period.

Sport	Competitive status	Engagement (days recorded), n (%)	Health Problems Questionnaire engagement (weeks recorded), n (%)
Judo	Developing elite	61 (75.3) ^a	8 (80) ^a
Judo	Developing elite	104 (95.4)	9 (64)
Judo	Elite	71 (65.1)	9 (64)
Judo	Elite	61 (56.5)	6 (43)
Judo	Elite	50 (45.9)	0 (0)
Boxing	Elite	82 (75.2)	13 (93)
Boxing	Developing elite	54 (50.0)	9 (64)
Boxing	Elite	32 (41.6) ^a	5 (50)
Boxing	Elite	12 (11.0)	3 (21)
Boxing	Elite	9 (8.3)	1 (7)
Boxing	Elite	69 (87.3) ^a	0 (0) ^a

^aFour weeks into the study, 3 athletes joined, 1 “developing elite” and 2 “elite”; therefore, engagement for these 3 athletes was measured on the basis of 81, 77, and 79 days, respectively, and 10 HPQs.

Figure 3. Average engagement rate across the cohort during each week of the study period.



The level of athlete engagement with the session monitoring section of the electronic system began at 32%, increased to 53% at week 7, and slowly declined to 21% at week 15. [Figure 3](#) depicts the level of engagement across the study period.

Over the study period, 161 separate communications were made by the principal researcher to the participating athletes via short message service (SMS) text messages (81/161, 50.3%), email (38/161, 23.6%), phone calls (2/161, 1.2%), face-to-face conversations (14/161, 8.6%), and a combination of methods (26/161, 16.1% SMS text messages plus email). The estimated time commitment for the principal researcher (SB) was 90 seconds per communication, equal to approximately 16 minutes per week of reminders and troubleshooting. In addition, SB had face-to-face conversations with 8 coaches of the enrolled athletes to reinforce the study benefits and made 17 communications to athletes who did not attend the camp to encourage them to engage with the tools ([Multimedia Appendix 1](#)).

Injuries and Illnesses

Over the study period, 23 unique injury codes and 7 unique illness codes were captured. There were 93 repeats of injury codes and 7 repeats of illness codes across both the tools, totaling 130 injury and illness incidents. [Table 2](#) outlines the

body area and prevalence of injuries and illnesses experienced by combat athletes across the study period.

Of note, 2 injuries affected one particular athlete for 8 weeks each, often being logged in the same session. In addition, 4 judo and 5 boxing (9/16, 56%) athletes completed HPQs throughout the monitoring period; however, their session monitoring entries were mostly inconsistent. [Figure 2](#) displays the severity of health problems experienced by these athletes for each week of the study period. A taller column for an athlete in a given week indicates that a health problem affected their training to a greater degree. Where there is no column for athletes, they either did not complete an HPQ or experienced no health problems that affected their training. In general, the combined severity of health problems (injuries and illnesses) captured suggests that, in this specific cohort, judo athletes tended to report more severe health problems than the boxers ([Figure 4](#)).

Time Lost to Injury and Illness

In this study, 2 injuries and 3 illnesses in 3 athletes (5/30, 16%, of unique injury and illness codes) resulted in lost training time. Time-loss for these events did not exceed 2 days. Generally, athletes trained through injury and illness for all remaining injuries and illnesses.

Table 2. Injuries and illnesses experienced by combat sports athletes (N=16) across the study period according to the sport and the complaint and area.

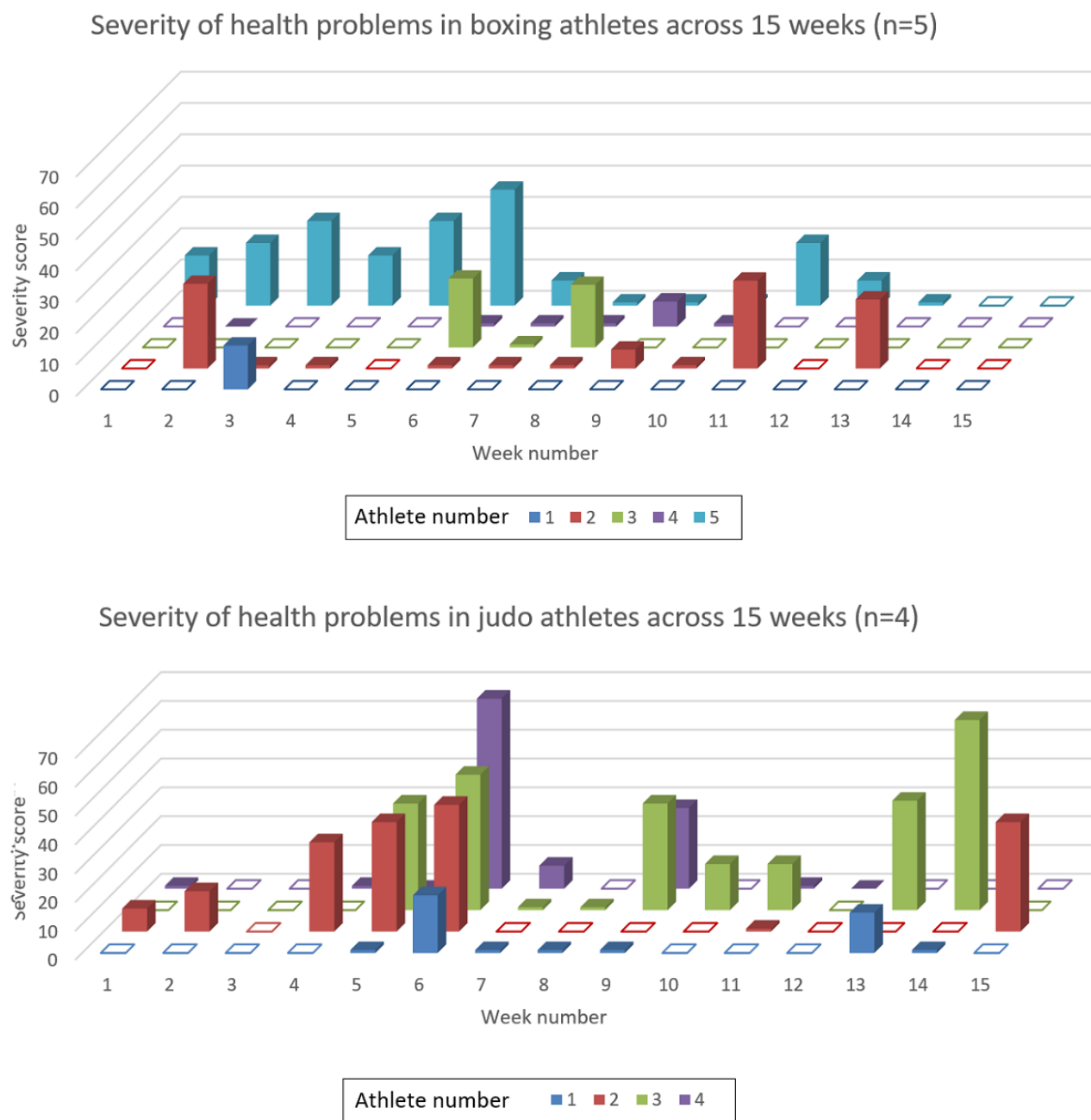
Complaint and area	Judo, n	Boxing, n	Total, n
Illness^a			
Abdominal pain or general cramps	1	N/A ^b	1
Chest infection	N/A	N/A	N/A
Chest symptom or complaint	2	1	3
Fever	1	N/A	1
General symptom or other complaint	4	1	5
Lymph gland(s) enlarged or painful	2	1	3
Injury^c			
Foot	6	N/A	6
Head	2	1	3
Hip and groin	2	1	3
Knee	2	41	43
Lower leg	N/A	3	3
Lumbar spine	3	2	5
Nerve issue, arm	N/A	N/A	N/A
Shoulder	2	7	9
Thigh	9	1	10
Trunk and abdomen	4	4	8
Wrist and hand	8	19	27

^aTotal illness: judo 10 (8%), boxing 3 (2%); percentages are calculated based on the total number of illnesses collected during the monitoring period.

^bN/A: not applicable.

^cTotal injury: judo 38 (29.2%), boxing 79 (60.8%); percentages are calculated based on the total number of injuries collected during the monitoring period.

Figure 4. Severity of health problems in boxing (n=5) and judo (n=4) athletes across the study period (unfilled squares: uncompliant; shaded squares: compliant but with no reported health problems).



Discussion

Principal Findings

This study reports the feasibility of utilizing the AMS to collect injury and illness data of combat sports athletes over a 12-week period and provides information on the injuries and illnesses sustained by the cohort during this time. A key finding is that engagement with the AMS was low; therefore, strategies to increase engagement will need to be specifically addressed if the AMS is to be fully implemented as a monitoring tool across the combat sports. However, data collected via the system illustrates a need for monitoring as the cohort experienced multiple health problems that tended to recur or progress toward chronicity.

Engagement With the Athlete Management System

Coach endorsement is one of the most important socioenvironmental factors for promoting the initial uptake of a monitoring system [7]. In an attempt to increase coach endorsement and subsequent athlete engagement, this project was launched at an Olympic preparation camp where coaches were directly informed about the study benefits. Despite launching at a high-profile camp, athlete engagement with the AMS was low across the study period, and at its peak, only half of the athletes were entering data; this aligns with a recently published work investigating the uptake of a similar self-report system in judo, swimming, and volleyball (50%, 61%, and 56%, respectively) [7]. A number of factors potentially influenced engagement with the AMS, including access to the internet, the design of the system, coach views on the system, previous

experiences with the system, and the existing culture within Australian combat sports.

Most athletes undertook competition travel during the monitoring period where a number of issues could have limited their intent to engage with the AMS. An offline mode is available at the log-in screen; however, once an athlete is logged in, the offline feature is less obvious. An athlete using the system in Australia may not log out when overseas; therefore, he or she may forget that this feature is available. Overall, the engagement rates indicate that the system is not intuitive and requires additional motivation and effort to use. Athletes who engaged with the system in the first week of the study were more likely to continue to engage thereafter. Internal motivation likely came from the study being launched at an Olympic preparation camp, where there may have been social desirability to use the system. Utilizing the preparation camp to increase internal motivation was the intent, as higher internal motivation has been linked to higher engagement with monitoring tools [7].

In contrast, those who did not engage early in the study did not change their behavior, even when contacted by the research team and encouraged to utilize the system. This could be attributed to a lack of additional encouragement from coaches to utilize the system as some had used the system before and were not convinced of its benefit. The AMS had been previously implemented in boxing across a small cohort, and monitoring and engagement was driven by a single staff member employed by Boxing Australia Limited. This staff member applied penalties for failing to engage with the system, rather than highlighting the benefits of such a system to athletes and coaches. It is possible that in this early trial, some coaches and athletes had good experiences (did not receive punishments) and some had bad experiences (received penalties) and that these previous experiences affected their intent to engage in the study. To avoid the influence of a coach's previous experience, athletes were contacted directly and coaches were not utilized to increase engagement. However, it is possible that some coaches may have expressed their opinion on the system to athletes at some point during the study.

As mentioned above, the outputs of the AMS require a level of interpretation, and therefore, feedback to athletes on their entered data is not immediate. This is a significant failing and is likely to contribute to the low engagement rates. The provision of immediate and relevant feedback to athletes has been cited as one of the key determinants as to whether an athlete will engage with a self-report tool [29]. In addition, feedback must be from a reputable and relevant source, such as a coach or sports staff member who works closely with athletes participating in monitoring programs [30]. Regular contact from the research team did not influence the rate of entry, whether used as a reminder or as positive reinforcement; therefore, it is possible that athletes did not view the source of feedback as relevant or reputable. Overall, approximately one-third of training days and one-quarter of HPQs were collected across the study period, indicating that it is not currently feasible to utilize this system to report injury and illness under the current combat sports structure. A primary difference between studies that have successfully collected high-quality data through the

AMS and this study is that support staff were employed by those other national sports organizations to interpret and provide relevant feedback on entered data to coaches and athletes. In combat sports, no staff are currently employed to provide such services. If the AMS is to be fully implemented, it will likely require dedicated staff to maximize engagement and subsequent data quality.

Injuries and Illnesses Within the Cohort

Despite low engagement with the monitoring system, a large number of health problems were reported through it, the majority of which did not affect training time. Of 603 recorded training and competition days, only 7 days were lost and 11 days modified due to injury and illness. There was double the number of repeated injury codes than unique injury codes, suggesting that athletes carried chronic injuries or injuries had a high recurrence. Data collected via online systems in Paralympic athletes showed that, on average, athletes sustained 0.31 new injuries per week (15 injuries recorded by 12 athletes over 4 weeks) [31]. The Paralympic study utilized similar injury and illness definitions to those in this study, which allowed the capture of injuries that did not result in lost training or competition time but affected the quality of training or competition. In this study, combat athletes reported more than double this amount—116 injuries over 12 weeks, equaling 0.88 injuries reported per week. Combat athletes were able to continue training irrespective of injury and illness events in 97% of cases. Together, these results suggest that this cohort of combat athletes maintained their training despite experiencing repeated health issues. In the cohort, the areas that had the highest injury frequency were the thigh in judo ($n=9$) and knee in boxing ($n=41$), with wrist and hand injuries being second highest in both sports ($n=8$ and $n=19$, respectively). This is in contrast with previous combat sports research, which indicates that the head or face is the most injured area in boxing training [32,33] and that the lower back is the most injured area in judo training [5]. This difference could be attributed to the injury and illness definitions utilized in previous studies, which have focused on injuries and illnesses that resulted in medical treatment and lost training time. This is a noted limitation in the combat sports literature [4] and does not account for injuries that may be self-managed by athletes, as discussed below.

Considerations for Monitoring Systems in Combat Sport

Self-report systems allow athletes to report self-managed health problems, which may not be apparent during training or require an urgent visit to a medical professional. In previous combat sports studies, data have been collected using paper-based systems and face-to-face consultations between medical staff, coaches, and athletes [5,32]; this leaves a gap in the collection of self-reported injuries and limits the ability to make comparisons between rates of self-managed health problems and those which require treatment by medical practitioners. A strength of this study is that the session monitoring tool within the AMS allowed athletes to reflect on a single training session; this likely increased the capture of these self-managed issues, which appear to have little impact on training time yet appear to impact performance during training. Additionally, in previous

judo and boxing research, all health problems have been treated in separation and, therefore, smaller problems may not have been recorded. Subsequently, the relationships between small and large injuries in combat sports could not be investigated as they have been in other sports [34]. Due to sample size limitations and low engagement, an analysis of the relationships between injuries is not possible; however, this study shows that using the HPQ and session monitoring tools within the AMS, these health problems can be documented.

In this study, athletes reported that they were able to train through the majority of their health problems; however, these problems led to reductions in performance, pain, or modified training and often lasted multiple weeks. This result may have been overlooked if the definition of injury had been restricted to lost training time, rather than relating to physical complaints. Only 4% of health problems would have been captured if a “time-loss” definition had been used in this cohort, meaning that 97 reports of health problems affecting athletes would not have been included in the final pool of injury and illness data. The majority of these (63 health problems) were repeats of previous OSICS or ICPC-2 codes, indicating that the issues were more recurrent than acute in nature. The phenomenon of training through injury may be unique to this particular cohort; however, due to combat sports being contact in nature with the goal to physically dominate an opponent, it is likely that training while carrying an injury is part of combat sports culture. Therefore, utilizing only missed training or competition time to define combat athlete injury and illness may not allow a full capture of injuries or illnesses in these athletes. To improve outcomes for athletes, health problems that affect both training time and the quality of health should be considered when identifying where prevention programs are targeted.

Limitations and Considerations for Future Research

Results from this study provide preliminary data detailing injuries or illnesses in this cohort of Australian judo and boxing athletes. Generalizing the injury and illness results of our study to the wider combat sports population is not appropriate due to the select cohort and the low engagement with the monitoring system. Furthermore, inconsistent engagement, both among athletes and across the monitoring period, likely affected the results. While these issues prevent application to the larger community of combat athletes, the study delivers important learnings around the utilization of the AMS as a monitoring system for combat sports. Reportedly, injury and illness monitoring allows the identification of injury and illness patterns and provides information for the development of intervention programs [2]. Despite the potential of AMS tools to collect high-quality data, a widespread implementation of the system in its current form is not feasible in Australian combat sports due to low engagement. Furthermore, issues with engagement could potentially be addressed by investing in the relevant medical or sports staff to assist with data interpretation and provision of timely feedback to athletes.

Conclusions

Australian combat athletes appear to experience repeated health problems, yet there are no permanent processes in place to monitor the health of these athletes. Results from this study indicate that engagement with data reporting systems such as the AMS is poor, possibly due to system designs that fail to provide immediate and relevant feedback on entered data. To address these barriers, relevant staff who can provide feedback to coaches and athletes and troubleshoot problems are required. Until the barriers are addressed, it is not feasible to implement the system across a larger cohort of combat athletes.

Acknowledgments

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Conflicts of Interest

None declared.

Multimedia Appendix 1

Communication channel and sample messages of contact to participants.

[PDF File (Adobe PDF File), 26KB - [humanfactors_v5i4e27_app1.pdf](#)]

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Abbreviations

AIS: Australian Institute of Sport
AMS: Athlete Management System
HPQ: Health Problems Questionnaire
ICPC-2: International Classification of Primary Care, version 2
OSICS: Orchard Sports Injury Classification System
SMS: short message service

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Original Paper

Alarm-Related Workload in Default and Modified Alarm Settings and the Relationship Between Alarm Workload, Alarm Response Rate, and Care Provider Experience: Quantification and Comparison Study

Manikantan Shanmugham¹, MS; Lesley Strawderman¹, PhD; Kari Babski-Reeves¹, PhD; Linkan Bian¹, PhD

Department of Industrial and Systems Engineering, Mississippi State University, Mississippi State, MS, United States

Corresponding Author:

Manikantan Shanmugham, MS
Department of Industrial and Systems Engineering
Mississippi State University
260 McCain Hall
479-2 Hardy Road
Box 9542
Mississippi State, MS, 39762
United States
Phone: 1 8016739973
Email: ms195@msstate.edu

Abstract

Background: Delayed or no response to impending patient safety-related calls, poor care provider experience, low job satisfaction, and adverse events are all unwanted outcomes of alarm fatigue. Nurses often cite increases in alarm-related workload as a reason for alarm fatigue, which is a major contributor to the aforementioned unwanted outcomes. Increased workload affects both the care provider and the patient. No studies to date have evaluated the workload while caring for patients and managing alarms simultaneously and related it to the primary measures of alarm fatigue—alarm response rate and care provider experience. Many studies have assessed the effect of modifying the default alarm setting; however, studies on the perceived workload under different alarm settings are limited.

Objective: This study aimed to assess nurses' or assistants' perceived workload index of providing care under different clinical alarm settings and establish the relationship between perceived workload, alarm response rate, and care provider experience.

Methods: In a clinical simulator, 30 participants responded to alarms that occurred on a physiological monitor under 2 conditions (default and modified) for a given clinical condition. Participants completed a National Aeronautics and Space Administration-Task Load Index questionnaire and rated the demand experienced on a 20-point visual analog scale with *low* and *high* ratings. A correlational analysis was performed to assess the relationships between the perceived workload score, alarm response rate, and care provider experience.

Results: Participants experienced lower workloads when the clinical alarm threshold limits were modified according to patients' clinical conditions. The workload index was higher for the default alarm setting (57.60 [SD 2.59]) than for the modified alarm setting (52.39 [SD 2.29]), with a statistically significant difference of 5.21 (95% CI 3.38-7.04), $t_{28}=5.838$, $P<.05$. Significant correlations were found between the workload index and alarm response rate. There was a strong negative correlation between alarm response rate and perceived workload, $\rho_{28}=-.54$, $P<.001$ with workload explaining 29% of the variation in alarm response rate. There was a moderate negative correlation between the experience reported during patient care and the perceived workload, $\rho_{28}=-.49$, $P<.05$.

Conclusions: The perceived workload index was comparatively lower with alarm settings modified for individual patient care than in an unmodified default clinical alarm setting. These findings demonstrate that the modification of clinical alarm limits positively affects the number of alarms accurately addressed, care providers' experience, and overall satisfaction. The findings support the removal of nonessential alarms based on patient conditions, which can help care providers address the remaining alarms accurately and provide better patient care.

KEYWORDS

clinical alarms; fatigue; physiologic monitoring; nursing; workload

Introduction

Background

Physiological monitor alarms and alerts specifically designed by medical device manufacturers are intended to alert clinicians to any deviation of physiological signals from the normal value. Although these devices ensure that doctors and nurses are always informed of physiological changes so as to respond to important deterioration events quickly, they generate very frequent alarms, of which a significant proportion are false [1-5]. Most of these alarms are not relevant to making clinical decisions, providing patient care, or ensuring patients' safety. About 70% of the alarms occurring in adult intensive care units do not add any value to the nurses' work process when monitoring patients [6].

Clinical alarms have received immense attention from clinicians, hospital administrators, and watchdog agencies, especially after the US Food and Drug Administration reported 566 alarm-related patient deaths [7,8]. The task of separating the true, actionable alarms from the false or nonactionable alarms lies with the clinicians responsible for responding to the alarms, who in most settings are nurses and their assistants. Alarm fatigue among health care workers, especially nurses, poses a risk to patient safety [9,10]. Upon deciding and initiating appropriate medical treatment, doctors hand off patients from their care to nurses and their assistants during recovery. Patients need to be continuously monitored during this recovery phase for any status changes [11]. When caring for multiple patients, nurses are exposed to numerous alarms per patient per shift and over time become fatigued due to an overwhelming number of alarms [12]. A frequently suggested solution to reduce fatigue is to adjust alarm parameters to suit patient conditions or a standard hospital protocol rather than using textbook normal values or default settings. However, the outcome of this suggestion was mixed [13,14].

Several types of devices—infusion pumps, physiological monitors, and therapy delivery devices—are used in typical patient care settings, and multiple alarms from these devices can cause information overload, leading to clinical errors and poor overall patient outcomes. During clinical alarm management, nurses perform many activities that require excessive cognitive processing, which may contribute to sensory overload, and therefore, their alertness may decrease and errors may occur [15]. Particularly, mental overload may decrease the functioning of working memory. Therefore, assessing the mental workload of attending nurses while they operate these medical devices and monitor patients using physiological monitors is important. Although fatigue and workload are conceptually different, they are closely related. Some researchers have described alarm fatigue as a multicausal, multidimensional, nonspecific, and subjective phenomenon resulting from prolonged activity and psychological, socioeconomic, and environmental factors that affect both the mind and the body [16]. Therefore, assessing mental workload during alarm

management will help understand alarm fatigue better. Nurses are an important resource who directly affect the health care system; therefore, ensuring optimal workload level is imperative [17].

Objective

Although several studies have reported that nurses' fatigue contributes to alarm mismanagement, no studies have quantified fatigue during alarm management and its effect on patient care quality and outcome. Little research has investigated workload and its correlation with alarm hazards and nurse response time. Given that clinical alarm management is a complex area in its infancy, cognitive workload cannot be described using 1 dimension or characteristic. A multidimensional scale is needed to quantify the mental workload. The National Aeronautics and Space Administration Task Load Index (NASA-TLX) provides a subjective measure of mental demand, physical demand, and temporal demand along with subjects' own performance, effort, and frustration [18]. Overall workload is measured by summing the scores on the 6 subscales. Although some studies have assessed mental workload in a clinical setting, the specific impact of increased workload on alarm management, response rate, and error rate has not been examined [19-21]. In subjective mental workload, the worker knows the amount of work needed to meet a particular demand. Subjective workload scales have been a familiar part of the human factors and ergonomics tool kit since the 1980s [22]. This study aimed to assess whether any changes in situational complexity, which is differentiated alarm settings, influence the subjective and physiological levels of mental workload and affect the care provider's experience while caring for patients.

Methods

Design, Sample, and Setting

The Mississippi State University's institutional review board approved this study, and participants' implied consent was obtained. This study was conducted in a clinical simulator. A total of 30 participants (23 females and 7 males) aged 24 to 60 years (mean 40.66 [SD 9.85]) were recruited. Participants were recruited from hospitals in the Pacific Northwest area of the western United States by word of mouth, phone calls, and flyer postings. Demographic data are presented in Table 1. Participants were randomly assigned to 1 of the 2 alarm threshold groups, default alarm setting and modified setting. Inclusion criteria for the study were medical alarm exposure and basic patient care experience. There were no exclusion criteria. The entire experiment was conducted in 2 waves over the course of 2 weeks. A week was allocated for each alarm setting—default alarm threshold and modified setting. The clinical simulator is equipped with modern physiological monitors and with intensive care equipment for life support, such as infusion and syringe pumps. The simulator setup for experiments was a progressive step-down care unit (patients in

this unit are typically low-risk and in the recovery phase of their clinical condition). The entire session was observed through a

one-way mirror in the simulator, and data were recorded.

Table 1. Demographic data.

Variables	Statistics
Age in years, mean (SD)	40.6 (9.9)
Gender, n (%)	
Female	23 (77)
Male	7 (23)
Nursing background, n (%)	
Registered nurse	10 (33)
Nurse assistants (CNAs ^a)	20 (67)
Years of experience in managing device alarms, n (%)	
None	0
Less than 1 year	1 (3)
1-3 years	3 (10)
3-5 years	9 (30)
More than 5 years	17 (57)
Trained on medical device alarms, n (%)	
Yes	10 (33)
No	20 (67)
Training provided by your institution is adequate, n (%)^b	
Yes	5 (17)
No	14 (47)
Did your assigned unit provide any training? n (%)^b	
Yes	7 (23)
No	8 (27)
Educational background, n (%)	
CNAs ^a or other	20 (67)
Associates	4 (13)
Bachelors	4 (13)
Graduate and more	2 (7)
Any other certifications? n (%)^b	
Yes	5 (17)
No	6 (20)

^aCNA: certified nursing assistant.

^bPercentage does not equal 100 due to missing responses.

Procedure, Instrumentation, and Data Collection

The patient condition to be monitored was kept constant to reduce variability. As previous studies have shown that a typical nurse in a progressive care unit does not spend their entire time solely on alarm management and performs other duties for up to 3 patients [23-25], a similar set up was reproduced in a clinical simulator for this experiment. In total, 3 male patient mannequins (SimMan), identified as M-1, M-2, and M-3, and

considered low risk based on the Goldman risk chart, were placed in supine positions. M-1 was instrumented with a ProSim SpotLight pulse oximeter simulator (Fluke Bio, Bothell, WA). A physiological monitor (Nellcor with software algorithm *Smart SatSec* feature for customization) connected to the pulse oximeter simulator presented the alarms shown in Table 2. The physiological monitor was set at default for the default setting portion of the experiment, and Smart SatSec was used for the modified setting. Alarms (shown in Table 2) were presented on

the screen at a programmed time interval using auto sequence mode. For both settings, the software algorithm was programmed to keep the alarm available for 75 seconds and automatically stop when the time lapsed. M-2 and M-3 did not require monitoring; they were simply recovering from minor outpatient surgical procedures. These mannequins were included to emulate a progressive care unit as closely as possible. Participants performed other assigned *dummy* patient-care tasks on these mannequins as part of the experiment. The additional tasks are described in the following section. Participants were strongly encouraged to complete all dummy tasks. These tasks were also set at the same difficulty level between different alarm conditions (normal alarm threshold and modified setting) to minimize variability. No experimental data other than completion rates were recorded on these tasks. The independent variables were the 2 alarm settings, and the dependent variables were alarm response rate, care provider experience, and overall satisfaction. After providing their background and demographic information, participants rated their care provider experience and overall satisfaction on a 5-point Likert scale survey. Furthermore, the percentage of incorrectly addressed alarms out of the total number of addressed alarms, defined as the error rate, was computed and used as dependent variable.

Various Alarms

All types of alarms allowed by the physiologic monitor manufacturer were considered in this study. They are defined as follows. An actionable alarm is an alarm that requires a clinician's intervention or warrants a clinician's input or interaction with other clinicians or patients. This alarm should lead to immediate intervention, but due to alarm fatigue could go unwitnessed or misinterpreted by the attending clinician. Actionable alarms require timely intervention to prevent an adverse event. A nonactionable alarm correctly identifies the underlying patient's physiologic condition, but does not require intervention. Its validity is based on waveform quality and accuracy, strength of signals from leads and detectors, and artifact conditions. Transient low-oxygen saturation and heart rate alarms are a few examples of nonactionable alarms. System messages are notifications about medical devices or monitor condition and do not require clinical intervention. A notification about upcoming preventive maintenance of a device is an example for this category. Advisory alarms are status indicators about the parameters monitored and are nonactionable. Elapsed therapy time and amount of remaining fluids left to be delivered are examples for advisory alarms.

Table 2. Alarm sequence.

Serial no.	Default setting of the alarm (as released to the hospital floor); total number of alarms=18		Modified to patient condition using <i>Smart SatSec</i> ; total number of alarms=11	
	Alarm type	Intervention type	Alarm type	Intervention type
1	Advisory	Nonactionable	Removed ^a	Removed ^a
2	Warning	Actionable	Warning	Actionable
3	System message	Nonactionable	Removed ^a	Removed ^a
4	Actionable	Actionable	Actionable	Actionable
5	Warning	Actionable	Warning	Actionable
6	System message	Nonactionable	Removed ^a	Removed ^a
7	Warning	Actionable	Warning	Actionable
8	Actionable	Actionable	Actionable	Actionable
9	Warning	Actionable	Warning	Actionable
10	System message	Nonactionable	System message	Nonactionable
11	System message	Nonactionable	Removed ^a	Removed ^a
12	Advisory	Nonactionable	Removed ^a	Removed ^a
13	Warning	Actionable	Warning	Actionable
14	Advisory	Nonactionable	Advisory	Nonactionable
15	Actionable	Actionable	Actionable	Actionable
16	System message	Nonactionable	System message	Nonactionable
17	Advisory	Nonactionable	Removed ^a	Removed ^a
18	Advisory	Nonactionable	Removed ^a	Removed ^a

^aThese alarms were not presented. Removed alarms: 5 premature ventricular contraction, 1 missed beat, and 1 noninvasive blood pressure.

Additional Task Details

The calls were made through an intercom system from outside the simulator, and participants were prompted using the simulator voice communication system at the appropriate time to make calls. Completion rates of tasks in this session were recorded but were not analyzed. Participants were reminded through the microphone when the task was due for completion. To minimize order and interference effects, a 15-min *warm-up* period before starting the session and a 2-min *cooling* period between tasks were provided to participants. During the warm-up period, we discussed alarms and scenarios and asked them to respond verbally. As interference effects between tasks may impact participants' alarm management, tasks 1 to 4 were presented with a 2-min cooling period before and after:

1. Task 1: call Pharmacy and check the status of ordered medicine for patient mannequin #2 (timing: 2 min into the experiment; call duration: 30 seconds)
2. Task 2: enter blood work result in Epic hospital system software for patient mannequin #3 (timing: 10 min into the experiment; task duration: 2 min)
3. Task 3: administer a bolus dose of pain medicine for patient mannequin #2 (timing: 14 min into the experiment; task duration: 1 min)
4. Task 4: take a call from another hospital unit to receive a patient into this unit (timing: 19 min into the experiment; task duration: 2 min).

Data Analysis

Participant characteristics, number of alarms addressed, errors made during management, care provider experience, and overall satisfaction were described using descriptive statistics. To determine any significant differences between the mean alarm response and error rates, 2 one-way analysis of variances (ANOVAs) were performed. As the normality assumptions of the ANOVA were violated according to the Ryan-Joiner method,

the Welch-ANOVA method was performed to test hypotheses. A Wilcoxon median rank within-subject test was used to identify any differences in care provider experience and participants' satisfaction levels when managing alarms in 2 different settings. Relationships between alarm workload and alarm response rate, error rate, care provider experience, and overall satisfaction were established using Spearman rank-order or Pearson product-correlation moment. $P < .05$ was considered statistically significant. IBM SPSS Version 25 for Windows was used for all statistical analyses.

Results

Participant Characteristics

Descriptive statistics for the dependent variables are shown in Table 3. A series of chi-square comparison tests were performed to examine whether the NASA-TLX subscale scores differed as a function of demographic characteristics (ie, age, gender, years of experience as a nurse, and alarm management experience). No differences were noted across all analyses ($P > .05$).

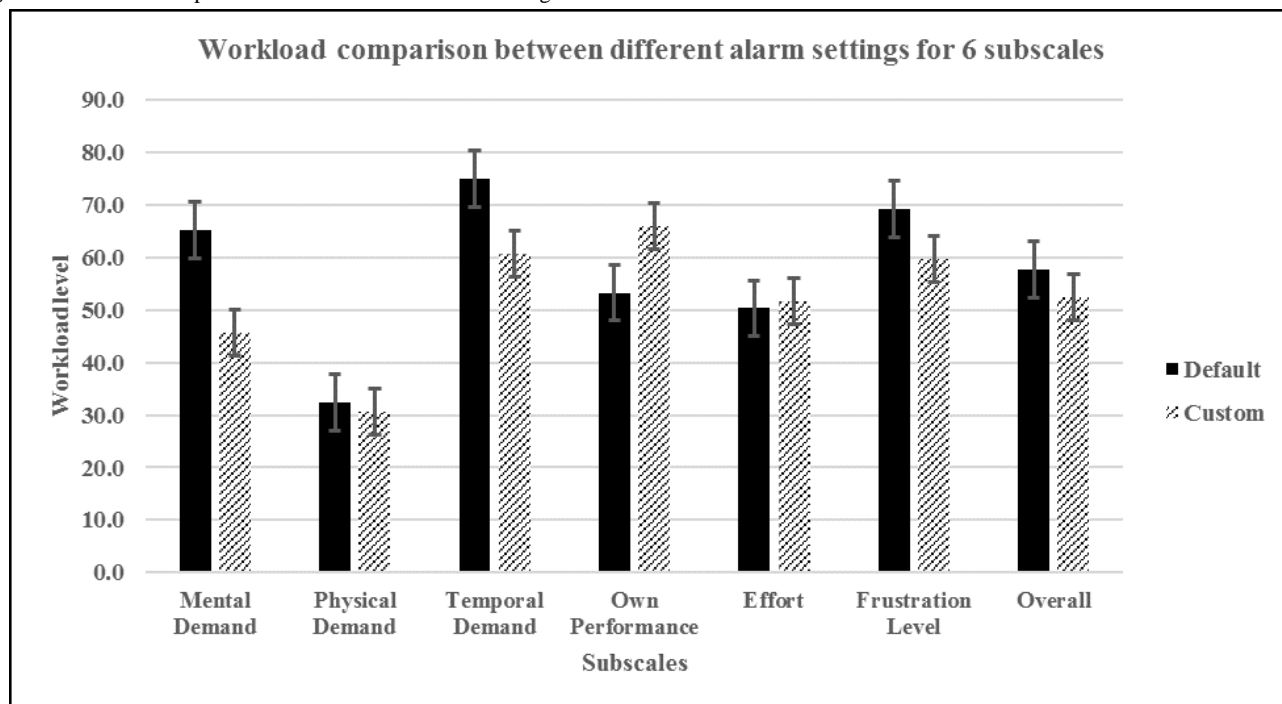
Workload Index

An independent samples *t* test was performed to determine any differences in participants' perceived workload between modified and default settings. An inspection of a boxplot indicated no outliers in the data. Workload index scores for each of the 6 subscales were normally distributed, as assessed by the Shapiro-Wilks test ($P > .05$), and there was homogeneity of variances, as assessed by Levene test for equality of variances ($P = .18$). The workload index was higher for the default alarm setting (57.60 [SD 2.59]) than for the modified alarm setting (52.39 [SD 2.29]), with a statistically significant difference of 5.21 (95% CI 3.38-7.04), $t_{28} = 5.838$, $P < .05$. Figure 1 shows participants' individual ratings on each subscale along with computed overall workload index.

Table 3. Descriptive statistics for dependent variables.

Alarm setting and variable	Mean (SD)	Total
Default		
Percentage of alarms addressed	68.9 (10.5)	30
Error rate	9.5 (6.0)	30
Care provider experience ^a	2.6 (1.3)	30
Overall satisfaction ^a	2.5 (0.9)	30
Modified		
Percentage of alarms addressed	86.7 (7.6)	30
Error rate	2.6 (4.5)	30
Care provider experience ^a	3.8 (0.8)	30
Overall satisfaction ^a	4.3 (0.6)	30

^aMeasured on 5-point Likert scale of 1-5 (1=very dissatisfied; 5=very satisfied).

Figure 1. Subscale comparison chart for different alarm settings.

Alarm Response Rate

A one-way Welch ANOVA was performed to determine whether the alarm response rate was different for the 2 alarm threshold settings. Participants were classified into 2 groups: default ($n=15$) setting and modified ($n=15$) setting. Alarm response rate significantly differed between different alarm settings: Welch $F_{1,25,44}=29.05$, $P<.05$. Alarm response rate (ie, number of alarms addressed) increased from the default setting to the modified setting due to fewer alarms when physiological monitoring was modified to patient conditions.

Relationship Between Alarm Workload and Alarm Response Rate

Pearson product-moment correlation analysis was performed to assess the relationship between workload and the number of alarms addressed (alarm response rate) while providing patient care. The relationship was linear with both variables normally distributed, according to Shapiro-Wilks test ($P>.05$), and there were no outliers. There was a strong negative correlation between alarm response rate and perceived workload, $\rho_{28}=-.54$, $P<.001$, with workload explaining 29% of the variation in alarm response rate. The negative correlation indicates that an increase in alarm workload is associated with a reduction in the number of addressed alarms; that is, modification of alarms according to patient conditions in patient-supporting medical devices help reduce care providers' workload and improve the alarm response rate.

Error Rate

A one-way Welch ANOVA was performed to determine whether the error rate was different for the default and modified settings. The error rate was significantly different between different alarm settings: Welch $F_{1,25,93}=12.46$, $P<.05$. The error rate significantly decreased from the default setting to the modified setting,

primarily due to fewer alarms when physiological monitoring was modified to patient conditions.

Relationship Between Alarm Workload and Error Rate

A Spearman rank-order correlation analysis was performed to assess the relationship between alarm error rate and perceived workload while providing patient care. A visual inspection of a scatterplot showed a monotonic relationship. There was a strong positive correlation between the number of errors committed (alarm error rate) and the perceived workload, $\rho_{28}=.60$, $P<.05$. The number of errors committed by nurses or assistants dropped simultaneously with the corresponding workload, which shows that they are associated with each other in a health care environment.

Care Provider Experience

A Mann-Whitney U test was performed to determine whether there were differences in care provider experience between default and modified alarm settings. Distributions of care provider ratings for default and modified settings were similar, as assessed by visual inspection. Care provider experience ratings (on a 5-point Likert scale) for the modified setting (mean rank=20.83) were significantly higher than those for the default setting (mean rank=10.17), $U=32.5$, $z=-3.422$, $P=.001$, using an exact sampling distribution for U .

Relationship Between Alarm Workload and Care Provider Experience

A Spearman rank-order correlation analysis was performed to assess the relationship between perceived workload and care provider experience while providing patient care in a progressive care setting. A visual inspection of a scatterplot showed a monotonic relationship. There was a moderate negative correlation between the experience reported during patient care and the perceived workload, $\rho_{28}=-.49$, $P<.05$. The care provider

experience, during or after caring for patients, was inversely proportional to the alarm-related workload. It is important to note that the participants were managing alarms along with several patient care tasks to mimic real-world situations. Therefore, any reduction in workload positively impacted care provider experience and well-being at the job.

Overall Satisfaction

To determine any differences in overall satisfaction between default and modified alarm settings, a Mann-Whitney U test was performed. Distributions of overall satisfaction ratings for default and modified settings were similar, as assessed by visual inspection. Overall satisfaction ratings (on a 5-point Likert scale) for the modified setting (mean rank=21.90) were significantly higher than those for the default setting (mean rank=9.10), $U=16.5$, $z=-4.146$, $P=.001$, using an exact sampling distribution for U .

Relationship Between Alarm Workload and Overall Satisfaction

A Spearman rank-order correlation analysis was performed to assess the relationship between perceived workload and overall satisfaction while providing patient care in a progressive care setting. A visual inspection of a scatterplot showed a monotonic relationship. There was a strong negative correlation between the overall reported satisfaction and perceived workload, $\rho_{28}=-.69$, $P<.05$. The negative correlation indicates that the workload increase is associated with overall satisfaction, which decreased significantly. Therefore, hospital administrators and risk managers should consider customizing alarms in patient-supporting medical products, as it is a key factor of care providers' satisfaction.

Discussion

Principal Findings

Delayed or no response to impending patient safety-related calls, poor care provider experience, low job satisfaction, and adverse events are all unwanted outcomes of alarm fatigue. In this study, alteration of alarm limits by customizing the experimental settings based on patients' conditions resulted in lower NASA-TLX scores than those obtained using the default manufacturer settings. That is, allowing the physiological monitoring device to operate under a default setting based on normal textbook values resulted in more alarms, thereby leading to a higher mental workload while managing these alarms. Higher NASA-TLX scores indicate that alarm management is a complex task and has the potential to induce fatigue. Higher mental workload impacts nurses' attentiveness, increases the risk of slow responses, and can result in poor task accuracy. The number of alarm signals has been reported to reach several hundred per day for some patients in 1 study, thus creating a high alarm burden for nurses [26]. Nurses will be desensitized by such a high alarm burden and may miss, ignore, or disable alarm signals, which might result in adverse events [27].

The scores on NASA-TLX show that temporal demand, mental demand (MD), and frustration level are the major contributors to alarm workload. This is not surprising, as responding to

alarms is secondary to primary care provider tasks such as medication administration, patient assessments, and note updates. In such dual-task systems, time spent on responding to alarms distracts from the primary tasks, and nurses feel pressed for time and frustrated. The higher MD score is attributable to the process involved in analyzing and isolating the source of the alarm, which often requires higher cognitive amplitude.

Participants' self-reported performance was higher in the modified setting than in the default setting. The higher alarm response rate in the modified setting supports this score. Better alarm response rate is also manifested across 2 other subscales, lower frustration and overall workload index, as shown in Figure 1. Not surprisingly, the subscale scores for physical demand and effort in the modified and default settings were statistically similar and lower compared with other subscales in their respective groups. Although only 4 of the 30 (13%, 4/30) participants provided narrative data, making it difficult to generalize for the entire group, the common theme for the default setting was the excessive number of alarms and tasks. The most important finding is that the number of alarms addressed was inversely proportional to the workload encountered during patient care. Participants were able to address almost all presented alarms when the alarm settings were modified according to patient conditions. This finding is consistent with those of similar alarm setting modification studies, which showed that a 43% reduction in alarms is possible through alarm setting customization [26,27]. Participants also expressed positive views of alarm customization. Some researchers have reported reducing the total number of alarms from 180 per patient per day to 40 through a unit-level standardization project, which included a daily individualization of alarm parameters [28]. More than a 50% reduction in the total rate of alarms per bed per day and a significant decrease in noise are possible by eliminating 3 types of ventricular contraction alarms [29].

Another unique finding of this study is that the alarm workload was directly proportional to the number of errors committed. The decrease in the number of errors is associated with the number of alarms that needed to be addressed during patient care. This suggests that the removal of certain nonessential alarms enabled the nurses to address the remaining important alarms accurately without any or with only minimal errors. The overwhelming number of alarms in the default setting put time pressure on nurses, and thus, they attempted to address more alarms within the limited time and made errors along the way. This can also be seen in a different way—if the number of opportunities (alarms) to make an error is limited, the number of errors committed will likely reduce.

Care provider experience and overall satisfaction were inversely correlated to alarm-related workload. As the alarm-related workload increases—which is typical when the alarms are set at the manufacturer's default setting—the quality of the experience of care providers caring for patients decreases. When the number of alarms to be assessed and addressed is low or lower they have more time to focus on patient care tasks and carry out other critical administrative tasks. The lesser the job stress and feeling of *burn out*, the higher the job satisfaction

and general well-being in a typical health care setting [30]. It is likely that the lesser number of alarms in the modified setting allowed participants to complete all tasks with less time pressure and to be engaged with the system, which was reflected in higher satisfaction scores. The only difference between the default and modified experimental set-up(s) was the total number of alarms. Therefore, changes observed in care provider experience and overall satisfaction were most likely associated with modifications in alarm-related workload. A larger sample population and other types of monitoring devices are needed to determine whether alarm workload is the causal factor.

Limitations

The entire experiment was executed in a simulator lab setting, which is controlled and supported; therefore, the applicability of the findings should be examined further and may need to be repeated before being implemented into policies and procedures. Future studies should also include additional populations such as physicians, medical assistants, and other therapists who are also part of the patient care team. The sample population was entirely based out of 3 local hospitals in the Pacific Northwest

region of the United States. It is well known that the health care field has regional cultures. Future studies should recruit participants across the country and investigate whether the effect of alarm modifications will bring similar benefits under other patient care settings such as intensive care, coronary care, emergency wards, and medical-surgical units.

Conclusions

The findings of this study show that removal of certain nonessential alarms based on patient condition can result in better care provider experience, reduced mental workload, and higher overall satisfaction. The number of managed alarms is directly proportional to workload and the number of errors (error rate) committed and inversely proportional to alarm response rate and care provider experience. Evidence for optimal alarm settings for physiological monitors and cardiac devices is abundant. Hospital administrators should make efforts to develop appropriate threshold levels for various physiological measures that clinicians monitor for typical patient conditions. This will help reduce the alarm burden for nurses and their aides significantly.

Conflicts of Interest

None declared.

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Abbreviations

ANOVA: analysis of variance

MD: mental demand

NASA-TLX: National Aeronautics and Space Administration-Task Load Index

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