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Contents

Original Papers

Original Paper

Development and Usability of REACH: A Tailored Theory-Based Text Messaging Intervention for Disadvantaged Adults With Type 2 Diabetes

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Abstract

Background: Among adults with type 2 diabetes mellitus (T2DM), adherence to recommended self-care activities is suboptimal, especially among racial and ethnic minorities with low income. Self-care nonadherence is associated with having worse glycemic control and diabetes complications. Text messaging interventions are improving the self-care of adults with T2DM, but few have been tested with disadvantaged populations.

Objective: To develop Rapid Education/Encouragement And Communications for Health (REACH), a tailored, text messaging intervention to support the self-care adherence of disadvantaged patients with T2DM, based on the Information-Motivation-Behavioral skills model. We then tested REACH's usability to make improvements before evaluating its effects.

Methods: We developed REACH's content and functionality using an empirical and theory-based approach, findings from a previously pilot-tested intervention, and the expertise of our interdisciplinary research team. We recruited 36 adults with T2DM from Federally Qualified Health Centers to participate in 1 of 3 rounds of usability testing. For 2 weeks, participants received daily text messages assessing and promoting self-care, including tailored messages addressing users' unique barriers to adherence, and weekly text messages with adherence feedback. We analyzed quantitative and qualitative user feedback and system-collected data to improve REACH.

Results: Participants were, on average, 52.4 (SD 9.5) years old, 56% (20/36) female, 63% (22/35) were a racial or ethnic minority, and 67% (22/33) had an income less than US $35,000. About half were taking insulin, and average hemoglobin A_{1c} level was 8.2% (SD 2.2%). We identified issues (eg, user concerns with message phrasing, technical restrictions with responding to assessment messages) and made improvements between testing rounds. Overall, participants favorably rated the ease of understanding (mean 9.6, SD 0.7) and helpfulness (mean 9.3, SD 1.4) of self-care promoting text messages on a scale of 1-10, responded to 96% of assessment text messages, and rated the helpfulness of feedback text messages 8.5 (SD 2.7) on a scale of 1-10. User feedback led to refining our study enrollment process so that users understood the flexibility in message timing and

that computers, not people, send the messages. Furthermore, research assistants' feedback on the enrollment process helped improve participants' engagement with study procedures.

Conclusions: Testing technology-delivered interventions with disadvantaged adults revealed preferences and concerns unique to this population. Through iterative testing and multiple data sources, we identified and responded to users' intervention preferences, technical issues, and shortcomings in our research procedures.

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KEYWORDS

mobile health; patient adherence; type 2 diabetes mellitus; text messaging; health status disparities

Introduction

Overview

Currently, at least one in three people will develop type 2 diabetes mellitus (T2DM) in his or her lifetime [1]. People with diabetes are at higher risk of critical health complications including kidney failure, heart disease, and stroke [1]. More than 20% of health care spending in the United States goes toward people with a diagnosis of diabetes [1]. Racial and ethnic minorities are more likely than non-Hispanic whites to have a diagnosis of T2DM [1] and, once diagnosed, have more diabetes-related complications [2], hospitalizations [3], and premature death [4].

People with T2DM can take medication, eat healthily, exercise, and test blood glucose levels to achieve optimal glycemic control [5] and, in turn, prevent diabetes complications [6] and premature mortality [7]. However, the initiation and maintenance of these self-care activities is challenging [8], and rates of self-care adherence are low among adults with T2DM [8,9]. Adherence rates are even lower among racial and ethnic minorities [10-12] and persons of low socioeconomic status (SES) [13] owing in part to financial difficulties and misconceptions about diabetes and self-care (eg, believing they do not have control over their diabetes, believing medication is not important) [8,14-16].

Mobile phone–based interventions using text messaging are a practical approach for improving medication adherence among low-SES, racial and ethnic minorities with T2DM. More than 90% of US adults own a mobile phone [17]. Although smartphones are used less among individuals with diabetes [18], lower income [19], and lower education [19], text messaging does not require a smartphone and is the most common activity among all mobile phone users, used equally across SES, race, and ethnicity strata [20,21].

Text messaging interventions are improving the self-care and glycemic control of adults with diabetes [22-24], but few have been tested with disadvantaged populations in the United States [25]. Two prior text messaging interventions [26,27] improved glycemic control in low-SES samples but not relative to a control group. A third text messaging intervention [28] improved glycemic control among a racially diverse sample but this sample had relatively high SES. Each of these interventions use text messages to address barriers to self-care, but none identifies and addresses each user's unique barriers. Such barriers vary from person to person with T2DM [29-32], requiring a tailored user experience.

Tailoring text messages to a user's unique adherence barriers can address issues most applicable to him or her, such as limited diabetes knowledge, negative beliefs about medication (eg, fear of side effects), or limited financial resources [16]. Although interventions cannot easily target a person's SES, they can enhance one's problem-solving ability to address financial barriers and other modifiable barriers [14,16]. We developed the MEssaging for Diabetes (MED) intervention that sends tailored text messages addressing user-specific barriers to adherence and text messages assessing adherence [33]. After 3 months of MED among disadvantaged adults with T2DM, users' barriers were reduced and barrier reduction was associated with improved glycemic control [34]. Furthermore, MED users were highly engaged, responding to 84% of daily assessment messages, and engagement did not differ by sex, race, income, health literacy, or duration of diagnosed diabetes [35]. MED's findings are consistent with reviews suggesting text messaging interventions with personally relevant, tailored content are more engaging [36] and effective [37] than those without tailored content.

Additionally, there is mixed evidence as to whether theory-based interventions are more effective than atheoretical interventions [38,39]; this is in part due to interventions not extensively applying theory and using theories that are inappropriate for behavior change [38]. The Information-Motivation-Behavioral skills (IMB) model suggests that adherence to a behavior depends on behavior-specific knowledge, personal and social motivation, and behavioral skills [40]. The IMB model is empirically validated among a wide range of diverse samples of adults with T2DM, including samples with low SES [41-43], and explains more than 40% of the variance in their medication adherence [43]. Text messaging interventions for T2DM self-care are rarely based on health behavior theory [24,44,45]. Of the few text messaging interventions tested among disadvantaged populations with T2DM, only 2 mention using a theory-driven approach [27,28]; however, the extent to which theory was applied in these interventions is unclear.

Objective

We developed Rapid Education/Encouragement And Communications for Health (REACH), a tailored, IMB model–based text messaging intervention. We performed 3 rounds of usability testing with adults with T2DM receiving care from Federally Qualified Health Centers (FQHCs) to identify and address any content and functionality issues before evaluating REACH's effects on self-care and glycemic control.

Methods

REACH Intervention Development

REACH was developed with MEMOTEXT, an algorithmic communications and data management platform supporting personalized user outputs and inputs via short message service (SMS); interventions using this platform have been tested with diverse patient populations with different health conditions who found them acceptable, engaging, and whose adherence improved >30% [46,47]. We worked with MEMOTEXT to develop REACH based on our experience developing and testing MED [33-35].

REACH Content Development

Similar to MED, we created tailored text messages addressing barriers to medication adherence common in our target population; however, REACH addresses more barriers to adherence than MED and barriers map onto the IMB model. To develop REACH content, we first conducted a thorough review of published studies reporting medication adherence barriers among adults with T2DM. In October 2014, we searched for studies in PubMed using terms from each of 3 categories: (1) medication adherence (ie, diabetes medication, medication adherence, medication nonadherence, medication compliance), (2) barriers (ie, barriers, challenges, problems), and (3) diabetes or type 2 diabetes. Terms were intralinked with "OR" and "AND." There were no restrictions on year of publication. We then searched references cited in eligible articles and articles citing relevant articles by hand. Experts in diabetes medication adherence on our team (authors SK and CYO) ensured our search captured meaningful articles. We reviewed all studies identifying barriers to diabetes medication adherence among adults diagnosed with T2DM and documented the reported barriers and race and ethnicity of the sample. Across 30 studies, we identified 68 barriers to taking medications and 7 barriers to taking insulin. We then sorted and collapsed similar barriers, resulting in 31 medication-related and 5 insulin-specific barriers. Finally, we tagged each of the 36 barriers to the IMB model's information, motivation, or behavioral skills constructs [40], and content experts drew on identified studies to develop text messages addressing each barrier (Table 1).

Users of MED wanted text messages providing information specific to their prescribed medications. Therefore, the REACH team's clinical pharmacist and nurse practitioner identified and classified available oral hypoglycemic agents, insulin, and noninsulin injectable drugs (glucagon-like peptide-1 receptor agonists). They then developed regimen-specific text messages on how to handle missed doses, manage medication side effects, administer medication, and store and discard medication for each class of medication.

MED users also recommended adding messages promoting other self-care behaviors (in addition to medication adherence) and inspirational messages [67]. In response, the REACH team's dietitian/diabetes educator developed text messages with tips promoting adherence to healthful eating, physical activity, and self-monitoring of blood glucose (SMBG). These messages were developed with the goal of providing general diabetes nutrition, exercise, and SMBG statements that are applicable to people with diabetes (vs specific instructions or information that should be determined in a one-on-one consult). Therefore, guidelines for development of these messages were to generate content providing concrete and practical diabetes information applicable to most adults with T2DM. We also developed inspirational text messages to encourage the initiation and maintenance of self-care efforts (eg, "Remember that you have the power every day to make progress toward improving your health!") and ensured all messages were contextually appropriate (eg, referenced local resources, avoided mention of things such as gym memberships).

After developing all content, the REACH team's health communication experts reviewed and edited text messages to be readable and understandable (ie, written at the sixth-grade reading level, avoided complex terms and jargon, and health literacy appropriate). Finally, a digital content developer shortened messages (≤160 characters) and ensured consistent tone across messages and appropriateness for digital delivery.

REACH Functionality Development

With the help of MEMOTEXT, we developed functionality to optimize the REACH user experience, making it more personalized and interactive than MED. MED users received a daily text message assessing whether they took their medication that day. Users responded to this message frequently [35] and said it served as a reminder to take their medication [67]. We retained this feature in REACH but made the experience more interactive. For example, if users respond "no," they receive a follow-up message asking why they did not take their medication with response options to encourage reflection on reasons for nonadherence (Figure 1).

MED users received feedback on their adherence (ie, aggregated responses to daily adherence assessment messages) via an interactive voice response (IVR) call. Although users enjoyed receiving adherence feedback, most said the IVR call was a nuisance [67]. They were also less likely to answer calls than respond to text messages [35]. Therefore, REACH delivers adherence feedback via a weekly text message instead of a weekly IVR call. Feedback reflects participants' adherence for the past week and for the prior week and delivers an encouraging message tailored to whether adherence improved, declined, or stayed the same.

Finally, MED users wanted to change the times they received text messages, so REACH allows for flexibility in text message timing. Users determine a preferred window of time to receive self-care promoting text messages and indicate their bedtime for receiving adherence assessment text messages. Participants are able to adjust message timing throughout the intervention by contacting the REACH Helpline (described below).

Table 1. Information, Motivation, and Behavioral skills (IMB) barriers to medication adherence for patients with type 2 diabetes mellitus identified through a literature review.

Identified barriers to diabetes medication adherence	Sample	No. of text messages addressing barrier
Information		
Not understanding what medication is for	AA[a] and NHW[b] [48]	20
Not understanding why medication regimens change	NHW [49]	22
Not taking medication when feeling well	AA [50,51]	16
Seeing no immediate benefit from taking medication	Racially Diverse [52]	16
Believing generic medication is not as good as proprietary drugs	AA and NHW [53]	16
Believing medication is not important	AA [50]	14
Believing it is acceptable to skip doses or stop medication	Racially Diverse [54]	16
Believing that regularly taking medication will not help control blood glucose levels or prevent complications	Racially Diverse [52,55]	15
Personal motivation		
Believing medication is harmful	AA and NHW [53]	23
Taking medication is unpleasant	AA and NHW [48]	17
Fear of side effects	AA and NHW [48]	20
Worried about consequences of long-term use	Racially Diverse [55]	19
Worried about medication causing weight gain	Racially Diverse [56]	15
Believing that consequences of diabetes are predetermined and therefore inevitable	Racially Diverse [57]	15
Burnout (ie, tired of taking medication)	Racially Diverse [55,56]	15
Fear of side effects related to insulin injection[c]	Racially Diverse [58]	21
Social motivation		
Not being supported by family or friends to take medications	AA [59], Racially Diverse [60,61]	16
Help with adherence from family or friends leads to conflict.	Racially Diverse [60]	16
Family or friends give annoying reminders to take medication	Racially Diverse [62]	17
Feeling judged by others because you take medication	Racially Diverse [63,64]	16
Close others are disapproving of or do not value taking medications	Racially Diverse [58]	14
Feeling embarrassed when taking medication	Racially Diverse [58]	22
Family priorities make it difficult to take medication regularly	AA [65], Racially Diverse [32,55]	18
Family or friends give inaccurate information about medication	AA [65], Racially Diverse [62]	20
Feeling judged by others because you take insulin[c]	Racially Diverse [63]	22
Embarrassed to take insulin in public[c]	Racially Diverse [58]	13
Behavioral skills		
Regimen is too complex	NHW [49], Racially Diverse [56], AA and NHW [48]	17
Taking medication disrupts routine/life	Racially Diverse [55,57]	15
Hard to read medication labels	Racially Diverse [31]	17
Difficulty asking provider about medication-related problems	AA and NHW [48]	18
Forgetting to take doses	AA [50,66], Racially Diverse [31,52,54,55,57], NHW [49], AA and NHW [48]	14

Identified barriers to diabetes medication adherence	Sample	No. of text messages addressing barrier
Cost of medication	AA [50], NHW [49], Racially Diverse [31,52], AA and NHW [53]	16
Forgetting to get refills.	AA [50]	14
Difficulty getting refills (eg, transportation, finding a pharmacy that carries prescription and/or offers affordable options)	Racially Diverse [31,52]	19
Not taking insulin because it interferes with daily activities[c]	Racially Diverse [58]	22
Not knowing how to manage pain when injecting insulin[c]	Racially Diverse [58]	15

[a]AA: African American.

[b]NHW: non-Hispanic white.

[c]Only assessed among participants who were prescribed insulin.

MEMOTEXT tailors, schedules, and sends text messages using participant data received through an application programming interface (API). At enrollment, research assistants enter participants' survey responses and electronic health record (EHR) data into REDCap, a secure, Web-based application designed to support data capture for multisite studies [68,69]. REDCap data are then transferred to MEMOTEXT via the API. MEMOTEXT tailors the messages addressing medication adherence barriers by ranking participants' self-reported barrier scores (see Measures section) and sending messages addressing each user's 4 highest-ranked barriers. In instances of a tie, the system randomly selects among the tied barriers. MEMOTEXT also tailors regimen-specific messages based on each user's prescribed diabetes medication taken from the EHR.

We describe each REACH component in Table 2. REACH users receive 2 daily text messages: (1) a text promoting self-care—either tailored to user-identified barriers to medication adherence or nontailored to promote another self-care behavior—and (2) a text assessing medication adherence for that day. Users also receive a weekly text message with medication adherence feedback based on responses to daily assessment texts. Furthermore, after users have their hemoglobin A_{1c} (HbA_{1c}) level tested during study enrollment, they receive a text message providing directions on how to access their HbA_{1c} test result; users can either log on to a Health Insurance Portability and Accountability Act (HIPAA)–compliant webpage hosted by MEMOTEXT or, if they do not have access to Internet, call the REACH Helpline. Finally, users have access to the REACH Helpline for research-, technical-, and medication-related questions. When users leave a voicemail on the Helpline, a REACH team member returns their call within one business day. Figure 2 illustrates the REACH user experience with example text messages.

Table 2. Rapid Education/Encouragement And Communications for Health intervention components (REACH).

Component	Description
Daily text message promoting self-care	Every day, users receive a text message promoting self-care at a random time within their prespecified window of time. Each week, REACH[a] sends 7 of these messages, consisting of 3 tailored messages addressing 1 of their 4 identified barriers to medication adherence, 1 tailored regimen-specific message, and 3 nontailored messages providing tips for diet, exercise, or SMBG[b] (Figure 2).
Daily text message assessing adherence	Every day, users receive a text message at their prespecified bedtime asking if they took all of their diabetes medication that day (requesting a "yes" or "no" response). Users responses may trigger follow-up messages (Figure 1).
Weekly text message delivering adherence feedback	At the end of each week, users receive a feedback text message based on the number of "yes" responses to the assessment text message for that week. The feedback is accompanied by an encouraging statement tailored to the number of days the participant adhered to their medication and whether the participant's adherence improved, stayed the same, or declined relative to the prior week (Figure 2).
HbA_{1c}[c] text message	Participants have their HbA_{1c} level tested upon study enrollment and receive an HbA_{1c} text message when their result is ready. The HbA_{1c} text message provides directions on how to access the result, either by logging on to a HIPAA[d]-compliant webpage hosted by MEMOTEXT or calling the REACH Helpline (Figure 2).
REACH Helpline	Participants have access to the REACH Helpline, an inbound answering service hosted by MEMOTEXT. Participants call the Helpline to leave a voicemail regarding a research-related question (eg, compensation, changed phone number, accessing HbA_{1c} test result), technical question (eg, problems receiving or sending text messages), or medication-related question (eg, how to handle side effects and/or a missed dose).

[a]REACH: Rapid Education/Encouragement And Communications for Health.

[b]SMBG: self-monitoring of blood glucose.

[c]HbA_{1c}: hemoglobin A_{1c}.

[d]HIPAA: Health Insurance Portability and Accountability Act.

Figure 1. Functionality for adherence assessment text message.

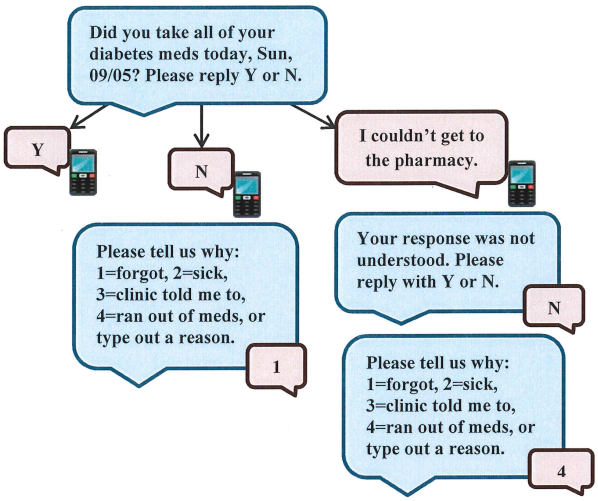

Figure 2. Rapid Education/Encouragement And Communications for Health (REACH) experience for a hypothetical user. Each medication adherence (blue circle) text message (3 per week) addresses one of the user's top 4 barriers to medication adherence. IMB: information-Motivation-Behavioral skills; SMBG: self-monitoring of blood glucose; A1c: hemoglobin A1c.

User Information:
Name: Sarah; Prescribed diabetes medication: metformin; Four highest ranked IMB model-based barriers: Believing meds are not important (Information), Believing meds are harmful (Personal motivation), Feeling embarrassed when taking meds (Social motivation), Forgetting to take meds (Behavioral skills); Preferred time window to receive daily text promoting self-care: 7:00am-8:00pm; Bedtime for receiving daily text assessing adherence: 9:30pm

Overview of REACH text messages with example content

Type of Text Message	Frequency	Individual Tailoring			Message Content
		Name	Content	Time of Day	
Welcome text	Once	X			Hello, Sarah. It's your first day in the REACH program! You will get texts with tips and support for your diabetes starting today! Welcome to REACH.
Daily text promoting self-care:					
either *Tailored content:* Medication adherence	3/week		X	X	Taking your diabetes medicine will help you stay healthy for all the things that are important to you in life.
Medication regimen-specific	1/week		X	X	Take metformin (Glucophage) immediate release with food.
or *Non-tailored content:* Exercise	1/week			X	It can be hard to add exercise time to your already busy schedule. Try setting small goals and build on your success.
Diet	1/week			X	Try to bake, broil or grill your foods. Use small portions of good oils like canola or olive oil instead of other fats.
SMBG	1/week			X	Testing your blood sugar at different times can give you an idea of the different things that affect your glucose levels.
Daily text assessing adherence	1/day			X	Did you take all of your diabetes meds today, Sun, 01/22? Please reply Y or N.
Weekly text providing feedback	1/week		X	X	You took your diabetes meds 5 days last week. Terrific progress! Try to take your meds every day next week!
A1c text	After A1c test			X	Hello, your A1c test result is ready and can be viewed online at www.reacha1c.com using this code: [generated by MEMOTEXT]. Or you can call [REACH Helpline number] to get your results.

Two-week REACH User Experience

	Sun (1/18)	Mon (1/19)	Tues (1/20)	Wed (1/21)	Thurs (1/22)	Fri (1/23)	Sat (1/24)
7:00am	(7:30am)	(12pm)	(9am)	(5:30pm)	(1pm)	(7pm)	(10am)
9:30pm							
	Sun (1/25)	**Mon (1/26)**	**Tues (1/27)**	**Wed (1/28)**	**Thurs (1/29)**	**Fri (1/30)**	**Sat (1/31)**
7:00am	(1:30pm)	(8pm)	(2pm)	(8:30am)	(3pm)	(11am)	(4:30pm)
9:30pm							

Usability Testing

Sample and Recruitment

Using flyers, interest cards, and referrals from clinic staff, we recruited participants from FQHCs in Nashville, Tennessee. Eligible participants had a T2DM diagnosis, were currently prescribed at least one daily diabetes medication, were responsible for taking their diabetes medication (ie, a caregiver did not administer medication), had a mobile phone with text messaging, were at least 18 years of age, could speak and read English, and provided a social security number (necessary to process compensation). Exclusion criteria included an existing diagnosis of dementia, auditory limitations, an inability to communicate orally, and an inability to receive, read, or send a text message as determined by trained research assistants.

Data and Procedures

The Vanderbilt University Institutional Review Board approved all study procedures before enrollment. Research assistants met with interested patients to describe the study and verify eligibility. In a private room at the patient's clinic, research assistants administered a brief cognitive screening instrument [70] and sent a test text message to each patient to assess whether he or she could see, read, and successfully respond to the message. If a patient passed this screener, research assistants obtained informed consent before verbally administering survey measures. A clinic phlebotomist performed a blood-drawn HbA_{1c} test. Research assistants accessed participants' EHRs to confirm a T2DM diagnosis, collect the type and quantity of prescribed diabetes medication, and the study HbA_{1c} test result.

During each testing round, participants experienced REACH for 2 weeks and then completed a semistructured phone interview that qualitatively assessed their user experience. Following each round, research assistants collected user feedback, the REACH team resolved content- and research-related issues, and MEMOTEXT resolved technical issues before the next round. Participants received up to US $54 for completing the enrollment survey (US $20), replying to assessment messages (US $1/day), and completing the phone interview (US $20).

Measures

Sample Characteristics

We collected self-reported age, sex, race, ethnicity, income, education (ie, years in school), insulin status, and diabetes duration (ie, years since a diabetes diagnosis). We also asked about comfort with mobile phones and text messaging and used validated survey instruments to capture additional information.

Barriers to Medication Adherence

Respondents rated how much each barrier in Table 1 (written as statements, eg, "I'm not sure what my diabetes medicine is supposed to do") gets in the way of taking their diabetes medication from 1="not at all" to 10="a lot." Each item maps onto a single IMB model–based barrier.

REACH Engagement

We measured engagement with system-collected responses to daily adherence assessment texts, the frequency of REACH Helpline calls, and the frequency of accessing HbA_{1c} test results via the website. We calculated engagement with assessment text messages by dividing each participant's number of responses by the total number of messages sent to him or her. MEMOTEXT tracked Helpline calls and HbA_{1c} website use.

User Feedback

Likert-type items assessed ease of understanding and helpfulness of the REACH intervention elements. Open-ended items assessed what users did and/or did not like, asked how and why an element was or was not helpful, and elicited suggestions for improving the REACH user experience. Table 3 presents items used to elicit user feedback.

Analyses

We calculated descriptive statistics with SPSS Statistics version 23 (IBM Corp). Interviews were audio-recorded and transcribed verbatim by an external transcription service. Questions and responses were pasted into REDCap under each interview question, organized by testing round, and then exported to Excel. We undertook a pragmatic approach to analyze participant feedback quickly between rounds to support changes to the intervention in a timely fashion. Between rounds, a member of the research team (LAN) read interview transcripts to manually categorize participants' feedback by intervention component. We then looked across participants' comments for each intervention component to identify areas for improvement and to ascertain the overall tone and message of the users' feedback for each component.

Table 3. User feedback interview items by intervention element.

Element	Item format	Item content	Mean (SD)
Daily self-care text message	Likert scale	On a scale from 1-10, where 1 is not easy and 10 is 1 very easy, how easy was it for you to understand the messages that gave tips?	9.6 (0.7)
		On a scale from 1-10, where 1 is not helpful and 10 is very helpful, how helpful were those messages to you?	9.3 (1.4)
	Open-ended	Can you tell me why you chose that number? (Follow-up to question above.)	N/A[a]
		Tell me about some of the messages you received that were very helpful. Why were those messages helpful?	N/A
		Tell me about some messages that did not help you or did not apply to you. Why did the messages not help or apply to you?	N/A
Daily assessment text message	Likert scale	On scale from 1-10, where 1 is not helpful and 10 is very helpful, how helpful were those messages to you?	9.1 (2.1)
	Open-ended	Can you tell me why you chose that number? (Follow-up to question above.)	N/A
		Is there anything else you can tell me about your experience with the text messages that asked if you took your meds?	N/A
Weekly adherence feedback text message	Likert scale	On a scale from 1 to 10, where 1 is not at all 1 and 10 is very much, how much did the messages at the end of the week help you take care of your diabetes?	8.5 (2.7)
	Open-ended	Can you tell me why you chose that number? (Follow-up to question above.)	N/A
		Is there anything else you can tell me about your experience with the text messages that asked if you took your meds?	N/A
Hemoglobin A_{1c} text message	Open-ended	Why did you/did you not access your A1c[b] result using information in the text message?	N/A
		What are your thoughts about receiving your A1c test result online or by calling our research team?	N/A
REACH[c] helpline	Open-ended	Why did you/did you not use the Helpline?	N/A

[a]N/A: not applicable.

[b]A1c: hemoglobin A_{1c}.

[c]REACH: Rapid Education/Encouragement And Communications for Health.

Results

Participant characteristics

An average of 12 participants experienced REACH each testing round, totaling 36 participants (Table 4). The average age of the participants was 52.4 (SD 9.5) years, 63% (22/35) were a racial or ethnic minority, 39% (14/36) had less than a high school degree or equivalent, and 67% (22/33) had an income less than US $35,000. The average HbA_{1c} level was 8.2% (SD 2.2%); 64% (23/36) of the participants had suboptimal glycemic control (HbA_{1c}≥7.0%). Across rounds, the most frequently reported barriers to medication adherence were forgetting to take doses (56%, 20/36 users reported this barrier with an average score of 5.2, SD 3.0, of 10), the high cost of medication (44%, 16/36 users; mean score 6.2, SD 2.7, of 10), and believing that taking medication is unpleasant (42%, 15/36 users; mean score 5.2, SD 2.6, of 10). The most commonly reported insulin-specific barrier was feeling embarrassed to take insulin in public (35%, 6/17 users who were prescribed insulin; mean score 4.5, SD 2.4, of 10).

Table 4. Participant characteristics.

Characteristics	Total (N=36)	Iterative testing round		
		1 (n=10)	2 (n=13)	3 (n=13)
Age in years, mean (SD)	52.4 (9.5)	51.6 (9.1)	52.4 (11.7)	52.8 (7.8)
Sex, n (%)				
Male	16 (44.4)	6 (60.0)	4 (30.8)	6 (46.2)
Female	20 (55.6)	4 (40.0)	9 (69.2)	7 (53.8)
Race [a], n (%)				
White	13 (37.1)	3 (30.0)	5 (38.5)	5 (41.7)
Nonwhite[b]	22 (62.8)	7 (70.0)	8 (61.5)	7 (58.3)
Education, years, mean (SD)	13.7 (2.5)	14.0 (3.0)	13.8 (2.3)	13.3 (2.4)
Annual household income [c], US$, n (%)				
<10,000	7 (21.2)	1 (12.5)	4 (30.8)	2 (16.7)
10,000-34,999	15 (45.4)	3 (37.5)	6 (46.2)	6 (50.0)
≥35,000	11 (33.3)	4 (50.0)	3 (23.1)	4 (33.3)
Comfortable with using mobile phone, n (%)	36 (100.0)	10 (100.0)	13 (100.0)	13 (100.0)
Text message with mobile phone, n (%)	36 (100.0)	10 (100.0)	13 (100.0)	13 (100.0)
Diabetes duration, years, mean (SD)	7.3 (6.0)	7.4 (6.5)	9.4 (6.4)	5.0 (4.5)
Number of prescribed diabetes medications, mean (SD)	1.7 (0.8)	1.9 (0.7)	1.8 (1.0)	1.4 (0.8)
Insulin status, taking insulin, n (%)	17 (47.2)	4 (40.0)	7 (53.8)	6 (46.2)
Health literacy (BHLS [d]), mean (SD)	11.4 (2.7)	10.9 (3.1)	11.6 (2.2)	11.6 (2.9)
Limited (≤9), n (%)	10 (27.8)	3 (30)	3 (23.1)	4 (30.8)
Adequate (>9), n (%)	26 (72.2)	7 (70)	10 (76.9)	9 (69.2)
Medication adherence (ARMS-D[e]), mean (SD)	25.4 (2.9)	25.2 (2.6)	25.5 (2.0)	25.4 (4.0)
General diet (SDSCA[f]), mean (SD)	3.8 (1.9)	4.4 (2.0)	3.8 (1.4)	3.4 (2.3)
Specific diet (SDSCA), mean (SD)	3.6 (1.4)	3.7 (1.9)	3.5 (1.0)	3.7 (1.4)
Exercise (SDSCA), mean (SD)	2.6 (2.5)	4.4 (2.3)	2.2 (2.4)	1.7 (2.1)
SMBG[g] (SDSCA), mean (SD)	3.0 (2.8)	3.4 (2.9)	3.3 (2.6)	2.4 (2.9)
Glycemic control (HbA_{1c}[h], %), mean (SD)	8.2 (2.2)	9.3 (2.8)	8.1 (1.9)	7.5 (1.9)

[a]One participant did not report race.

[b]Nonwhite participants were majority (77.3% (17/22)) African American.

[c]A total of 3 participants did not report annual household income.

[d]BHLS: Brief Health Literacy Screen.

[e]ARMS-D: Adherence to Refills and Medications Scale for Diabetes (possible range 7-28).

[f]SDSCA: Summary of Diabetes Self-Care Activities (number of days with medication adherence in the past week).

[g]SMBG: self-monitoring of blood glucose.

[h]HbA_{1c}: hemoglobin A_{1c}.

All 36 participants completed an exit interview. Overall, participants said REACH was helpful and gave favorable feedback on each intervention element. Participants reported preferences and technical issues requiring iterative improvements between testing rounds. Below, we describe this feedback, our iterative changes by intervention element, followed by changes in our research processes.

Daily Text Message Promoting Self-Care

Across rounds, participants rated the ease of understanding and helpfulness of the daily self-care text message, on average, 9.6 (SD 0.7) and 9.3 (SD 1.4) on a scale of 1-10, respectively.

Participants appreciated that these messages were simple and without medical jargon. Participants said inspirational messages made them feel supported and not alone in living with diabetes and motivated them to take more initiative with self-care. Messages with self-care tips and information were helpful because they either provided a useful reminder or communicated something new.

Interviewer: *Why did you read those messages? What made you want to?*

Participant: *They was [sic] helpful. Some things I didn't know [sic]. They helped me understand a lot of stuff because I didn't understand. [37-year-old, African American male]*

Many participants valued reminders to care for their diabetes when they otherwise might not think about it:

I thought these messages were very helpful. I get so busy in the day that I don't [even] take time to eat. And then when I get a text, [I realize] oh, wow, I need to do something. That really helps a lot. I wish I had somebody who did that for me all the time. [59-year-old, white male]

Despite the overall positive feedback about self-care messages, some participants had concerns. For example, a round 2 participant said a message provided a suggestion for remembering to take medications, without providing the steps for carrying out the suggestion. A few participants said some messages implied a problem when they did not have one (eg, "Struggling to take your diabetes medications every day? Talk to a loved one about what is getting in your way."). To address such concerns, we revised all problematic text messages between rounds 2 and 3 to provide additional context and be less presumptuous (see Table 5 for examples of problematic and revised text messages).

Daily Text Message Assessing Adherence

Across rounds, participants responded to 96% of adherence assessment text messages and, on average, rated the helpfulness of these messages 9.1 (SD 2.1) out of 10. Assessment messages helped remind participants to take their medications and maintain their routine. One participant commented on these messages' emotional and social support:

[The texts] keep you on task about what you should do...especially if someone doesn't have anybody around. You know it's kind of like having a family member around to remind you, "Hey, you should take your meds." These [texts] make you feel like someone cares or is concerned about your health and makes sure you're taking care of yourself. So I think that's very helpful. [48-year-old, African American male]

Several participants with optimal glycemic control (HbA_{1c} <7%) said these messages were not particularly helpful because they routinely took their medication and rarely missed doses. Nonetheless, these participants endorsed the value of these messages for others recently diagnosed with diabetes and/or newly prescribed medication who do not have an established routine.

Round 1 participants complained about needing to respond to assessment messages several times before the system would accept their response. Upon viewing system-collected data, we learned that participants used different variations of "Yes" to respond (eg, "Yup" or "Yeah"). Therefore, we expanded the acceptable response options representing "Yes" and "No" between rounds (see Table 5).

Weekly Text Message Providing Feedback

Across rounds, participants rated the helpfulness of the weekly feedback messages, on average, 8.5 (SD 2.7) out of 10. Round 1 participants had two concerns with the weekly adherence feedback text message. First, many participants felt these messages were wordy and confusing. Because the message provided numerical information about the number of days a participant took his or her medication in both the past and the prior week, the content was difficult to read and interpret. We simplified feedback messages by including only the number of adherent days from the past week, but we indicated whether adherence had improved, stayed the same, or declined with an encouraging statement (Table 5).

Second, some round 1 participants complained their feedback underreported their adherence. This was due, in part, to the limited number of accepted responses to the assessment message (described above). However, we also learned the system was not counting responses received after midnight on the day it sent this message, so we extended the response time window (Table 5). In round 1, participants rated the helpfulness of feedback messages 8.2 (SD 3.0) out of 10. After revising feedback text messages and resolving functionality issues, participants in subsequent rounds rated the helpfulness of these messages 8.8 (SD 2.2) out of 10.

Hemoglobin A1c Text Message

Across rounds, very few participants accessed their HbA_{1c} test result. One participant logged into the HbA_{1c} website and 2 participants called the REACH Helpline to get the result over the phone. Participants' most common reason for not using either option was that they learned their HbA_{1c} test result from their clinic before receiving the HbA_{1c} text message. When asked their opinion about accessing their result with the HbA_{1c} text message, some participants appreciated this convenience, whereas others preferred their health care provider contact them with the result. On the basis of this feedback and the feedback from providers who preferred delivering and individually interpreting HbA_{1c} test results, we reduced our interpretation of the HbA_{1c} test result on the website (Table 5) and over the phone.

Table 5. Changes made to the Rapid Education/Encouragement And Communications for Health intervention during usability testing (REACH).

Type of change	Example or description
Content	
Revising daily text messages promoting self-care	Rounds 1 and 2: "Sometimes you can see stress coming. When this happens, make a plan for how to keep up your diabetes med routine during the storm." "Ask any pharmacist for help coming up with a daily plan. Together, you may be able to group your meds into a few set times each day." Round 3: "If you look at your calendar and can see a busy, stressful week ahead, make a plan now for how to keep up with your med routine during the chaos." "If you're struggling to come up with a daily plan for your meds, ask your pharmacist for help. He or she can help you group them into a few set times each day."
Revising weekly adherence feedback text messages	Round 1: "Congrats! You took all of your diabetes meds on 3 day(s) last week, which is better than 2 day(s) the prior week. Keep up the good work!" Rounds 2 and 3: "You took your diabetes meds 3 days last week. You're making progress, but keep working to take your meds every day!"
Revising HbA_{1c}[a] test result interpretation provided on HbA_{1c} webpage and over phone	Round 1: 6%-7%: This is within the normal range for a person with diabetes. Great job. Keep up the good work! 7.1%-8.9%: This is a little above the goal range. It is often recommended patients be as close to 7 as their nurse or doctor recommends. You may want to discuss this with someone at your next clinic appointment. 9% and above: This number is above where we want our patients to typically be. You may want to discuss this with someone at your next clinic appointment. Rounds 2 and 3: 7% or lower: at goal 7.1% to 8.9%: high 9% or higher: very high If you have any questions, please contact your doctor.
Functional	
Expanding acceptable responses for assessment text message	Round 1 response options: "Y," "Yes," "N," "No." Rounds 2 and 3 response options: "Yes," "Y," "Yea," "Yeah," "Ya," "Yep," "Yup," "No," "N," "Nope," "Na," and if any of these responses are included at the beginning of a response (eg, "yes, ma'am"; "no, ma'am").
Extending window for assessment text message responses	Round 1: system would only accept responses to assessment messages sent by midnight of the night an assessment message was received. Rounds 2 and 3: system accepts responses to assessment messages until a message promoting self-care is received the following day.
Research processes	
Creating a two-stage process for barrier assessment	Round 1: participants rated how much each barrier got in the way of taking their diabetes medication on a scale from 1 = "not at all" to 10 = "a lot." Rounds 2 and 3: First, participants sort cards with each barrier printed on them into piles labeled "Never" or "Sometimes" based on whether the barrier applies to them. Next, participants rate the degree to which each barrier placed in the "Sometimes" pile applies to them from 1 = "a little" to 10 = "a lot."
Modifying instructions provided during enrollment process	Round 1: Many participants were unaware that they could change the timing of their messages and that text messages were automated. Rounds 2 and 3: Research assistants provided explicit instruction during enrollment process of the flexibility in message timing and how to change timing at any point. Additionally, we included language in the informed consent document that indicated a computer system was sending text messages and responses were not being monitored.

[a]HbA_{1c}: hemoglobin A_{1c}.

REACH Helpline

We received 22 voice mails on the REACH Helpline (12 research-related, 8 technical-related, and 2 medication-related voice mails) from 11 participants (8 of whom called more than once). When we asked the other 25 participants about the Helpline, most said they simply did not need it but thought they might use it if the program lasted longer.

Research Processes

On the basis of participant feedback and lessons learned by research staff, we made several changes to our research process.

One change involved modifying how we administered the barrier assessment. Initially, research assistants asked participants to rate how much each of the barrier items gets in the way of taking their medication by reading each item aloud sequentially and asking for a rating. After round 1, research assistants reported some participants became disinterested/disengaged when completing this assessment and 20% reported no barriers despite having suboptimal HbA_{1c} levels. Therefore, after round 1, we changed the barrier assessment to a two-stage process. The first stage is a card-sorting task in which participants sort cards with barrier statements printed on them (see Measures section) into piles labeled "Sometimes" or "Never" based on whether or not the barrier applies to them. Next, research assistants ask participants to rate the degree to which each barrier placed in the "Sometimes" pile applies to them from 1="a little" to 10="a lot." Before the two-stage process, round 1 participants reported a total of 62 barriers. After implementing the two-stage process, round 2 and round 3 participants reported 87 and 92 barriers, respectively. According to research assistants, participants in rounds 2 and 3 were more engaged during the barrier assessment process than participants in round 1.

We also modified the instructions provided during enrollment. Round 1 participants did not know they could change the timing of their text messages, so, in subsequent rounds, we clarified that participants could call the REACH Helpline at any point to request a time change. Also, during round 1, many participants sent unprompted responses (eg, "Thanks" or "OK, I will") to the text messages promoting self-care, suggesting they thought a person sent these messages. Therefore, we revised our informed consent to make clear that a computer was sending text messages and not a person. For additional safeguarding, MEMOTEXT monitors all text message responses and notifies the REACH team if any text message requires follow-up.

Discussion

Principal Findings

Text messaging interventions provide an opportune platform for extending the delivery of tailored diabetes education and support; however, few have been designed for and tested among disadvantaged persons with T2DM [27,28]. We developed REACH—a tailored text messaging intervention designed to overcome user-specific medication adherence barriers and support other self-care behaviors—and tested its usability among patients with T2DM who were representative of the population REACH is designed for (ie, racially diverse, low SES, more than 25% limited health literacy). Participants who experienced REACH for 2 weeks had favorable opinions and responded frequently to daily text messages. We learned participants' concerns/preferences, technical issues, and problems with our research process that we then fixed between each testing round, improving REACH in preparation for an evaluative trial.

Overall, participants were satisfied with REACH and provided favorable ratings for each of its elements. Text messages provided emotional/social support, reminded participants to engage in self-care activities, and helped them keep their self-care routine on track. In a similar 4-week study, Dick et al [71] assessed the usability of a text messaging program (SMS-DMCare) for improving T2DM self-care among African Americans. Participants provided ratings comparable to REACH regarding SMS-DMCare's ease of use and provided similar interview feedback (eg, messages were helpful by reminding participants to take medication amid the demands of their daily lives) [71]. REACH's text message engagement was higher than SMS-DMCare's engagement [71], which may be due to REACH's tailored content and/or personalized adherence feedback.

Usability studies often rely on survey- or questionnaire-based feedback [72], which may overlook much of what participants like or do not like about a system and how to improve it. Georgsson and Staggers [73] endorse using multiple data sources to identify and address usability issues. We collected both quantitative and qualitative feedback and system-collected data to fully understand users' experience, improve our programmatic content and functionality, and resolve technical problems. REACH users who were adults from racially diverse and low-SES groups expressed concerns with the phrasing and wordiness of some messages, so we improved them. Furthermore, unanticipated feedback from research assistants and clinic staff was instrumental in refining our research process.

Through this multiple data source approach to usability testing, we made several improvements to REACH and enriched the user experience. We revised text messages to be more comprehensive, clear, and consistent with participants' preferences. We limited our interpretation of HbA_{1c} test results to be more respectful of provider-patient relationships. We also improved REACH's functionality to ensure the system recognizes and records participants' attempts to interact with the intervention. Finally, we improved our assessment for capturing participants' adherence barriers and modified our informed consent to ensure participants know how to use each intervention component and that a computer, not a person, sends all text messages.

There are several limitations to this study. First, participants experienced REACH for 2 weeks. Therefore, feedback and engagement may not be representative of participants experiencing REACH for longer periods. Furthermore, we compensated participants US $54 for their participation in the 2-week usability testing and feedback interview. By providing this incentive, we sought to adequately compensate participants for time and travel to the enrollment appointment and to offset mobile phone costs associated with text messages and the phone interview. This compensation may have inflated engagement with the intervention, but it was important for usability testing that participants actually use the intervention to be able to provide meaningful feedback. Despite this compensation, few participants accessed the REACH Helpline and HbA_{1c} website, making it difficult to gain insight on how participants felt about these elements and their functionality. Furthermore, participants may have been reluctant to provide critical feedback owing to study compensation, social desirability, or associating the study with their clinic. Additionally, because we were interested in specific questions concerning each intervention element, we composed our own feedback interview items and do not have validity and reliability information to report. Finally, although

our sample size far exceeded the targeted enrollment for qualitative (at least 5) and quantitative (at least 20) usability testing [74,75], our sample was still too small to examine differences in opinions by participant characteristics.

Conclusions

Usability testing is imperative for ensuring that effects identified during efficacy trials are due to the intervention as intended and not due to errors in understanding or using the intervention [72]. Moreover, involving disadvantaged adults in usability testing may reveal preferences and concerns unique to this population. Iterative usability testing of the REACH intervention using multiple data sources revealed shortcomings in content, functionality, and research processes that we addressed before evaluating its effects on adherence and glycemic control in a randomized controlled trial. The REACH randomized controlled trial will assess the intervention's effectiveness by recruiting patients from FQHCs and comparing outcomes between patients who did and did not experience REACH. To gain knowledge about REACH's potential for implementation in clinic settings as a supplement to usual care, we will compensate participants for completing study assessments but will not provide them mobile phones or mobile phone plans. Although users experienced and commented on REACH specifically, our usability testing process and findings are applicable to other technology-delivered health interventions for disadvantaged populations. Specifically, informed consent should affirm that participants understand an intervention's functionality, capabilities, and automation. Additionally, intervention content should provide enough information to be useful and avoid implying that a user is experiencing a specific issue; this is challenging while maintaining brevity necessary for digital content. Finally, our findings emphasize the importance of using multiple methods and sources of data to identify and resolve usability issues.

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Authors' Contributions

LAN codesigned the study, analyzed and coded data, and wrote the manuscript. LSM codesigned the study, oversaw data collection and analyses, and cowrote and edited the manuscript. KW codesigned the study and edited the manuscript. SK codesigned the study and edited the manuscript. EMB oversaw data collection and edited the manuscript. CYO codesigned the study, oversaw data collection and analyses, and cowrote and edited the manuscript.

Conflicts of Interest

SK is a consultant to SAI Interactive and Bioscape Digital. KW is an advisor to EdLogics, Inc.

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Abbreviations

EHR: electronic health record
FQHC: Federally Qualified Health Center
HbA_{1c}: hemoglobin A1c
HIPAA: Health Insurance Portability and Accountability Act
IMB: information-motivation-behavioral skills
IVR: interactive voice response
MED: MEssaging for Diabetes
REACH: Rapid Education/Encouragement And Communications for Health
SES: socioeconomic status
SMBG: self-monitoring of blood glucose
SMS: short message service
T2DM: type 2 diabetes mellitus

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Original Paper

Exploration of Deaf People's Health Information Sources and Techniques for Information Delivery in Cape Town: A Qualitative Study for the Design and Development of a Mobile Health App

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Abstract

Background: Many cultural and linguistic Deaf people in South Africa face disparity when accessing health information because of social and language barriers. The number of certified South African Sign Language interpreters (SASLIs) is also insufficient to meet the demand of the Deaf population in the country. Our research team, in collaboration with the Deaf communities in Cape Town, devised a mobile health app called SignSupport to bridge the communication gaps in health care contexts. We consequently plan to extend our work with a Health Knowledge Transfer System (HKTS) to provide Deaf people with accessible, understandable, and accurate health information. We conducted an explorative study to prepare the groundwork for the design and development of the system.

Objectives: To investigate the current modes of health information distributed to Deaf people in Cape Town, identify the health information sources Deaf people prefer and their reasons, and define effective techniques for delivering understandable information to generate the groundwork for the mobile health app development with and for Deaf people.

Methods: A qualitative methodology using semistructured interviews with sensitizing tools was used in a community-based codesign setting. A total of 23 Deaf people and 10 health professionals participated in this study. Inductive and deductive coding was used for the analysis.

Results: Deaf people currently have access to 4 modes of health information distribution through: Deaf and other relevant organizations, hearing health professionals, personal interactions, and the mass media. Their preferred and accessible sources are those delivering information in signed language and with communication techniques that match Deaf people's communication needs. Accessible and accurate health information can be delivered to Deaf people by 3 effective techniques: using signed language including its dialects, through health drama with its combined techniques, and accompanying the information with pictures in combination with simple text descriptions.

Conclusions: We can apply the knowledge gained from this exploration to build the groundwork of the mobile health information system. We see an opportunity to design an HKTS to assist the information delivery during the patient-health professional interactions in primary health care settings. Deaf people want to understand the information relevant to their diagnosed disease and its self-management. The 3 identified effective techniques will be applied to deliver health information through the mobile health app.

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KEYWORDS

Deafness; sign language; South Africa; mHealth; health; qualitative research; co-creation; community-based co-design

Introduction

Background

Deaf spelled with a capital "D" denotes membership of a cultural, linguistic minority group who choose signed language as their preferred language. This is as opposed to deaf with a small "d" that denotes someone with a hearing loss. Deaf people who mainly use signed language for communication experience disparity in information access in the majority hearing society [1]. Particularly in South Africa, Deaf individuals express the need to access understandable health information and communication to improve their well-being [2,3]. We have received similar messages from all the Deaf communities with whom we have been collaborating. Consequently, we took the initiative to design and develop a mobile health app called SignSupport and now wish to extend it with a Health Knowledge Transfer System (HKTS) [2,4]. This mobile app can support Deaf people's communication at health facilities and can improve understanding of the diagnosed disease including self-management. Via a process of cocreation with Deaf communities and health professionals in Cape Town, we have gained an understanding to build the groundwork for the proposed HKTS. The app is meant to provide equitable information access as well as bridge communication gaps that are manifested by social barriers. An extended literature review led us to a number of social barriers that many Deaf people have faced since childhood.

Social Barriers to Deaf People's Access to Health Information

The Lack of Sign Language Within the Education of Deaf Learners

Signed languages cannot be translated word-for-word due to their structure distinct from spoken languages [5,6]. Driven by communication difficulties, social barriers are intrinsically formed. A standardized South African Sign Language (SASL) curriculum was not approved for teaching at schools for Deaf learners until 2012 [7]. As a result, many Deaf children in the past learned signed language from their peers [8]; which is how dialects developed and were passed through the generations across different regions of South Africa. Only 14% of their educators at schools for Deaf learners could use sign fluently which left many subjects untaught in SASL [9,10]. These educational barriers have resulted in average reading and writing skills of a Grade-4 level equivalent among Deaf school leavers [11]. Consequently, 75% of South African Deaf adults are functionally illiterate, and 70% of the Deaf population remains unemployed [12].

Disconnection From Hearing Family Members

Ninety percent of Deaf children are born to hearing families where many parents do not use signed language [13]. A Deaf child's incidental learning of health information within the household usually fails due to language barriers. Health information, such as risks and dangers, from direct instructions by the parents or from "overhearing" conversations among family members cannot be understood by the Deaf child. Missing this kind of learning may have an impact on the physical and mental health, including the academic achievement of the Deaf person [14].

Noninclusive Health Information Through the Mass Media

Deaf people have very limited access to understandable health information available through the mass media, for example, newspapers, television, and the Internet. The majority of Deaf adults cannot understand jargon and technical terminology [15]. To a large extent, health information in the mass media is not presented in SASL, although some interpreting does appear on the news bulletins of South African TV channels. In addition, many Deaf people cannot afford Internet access to explore information, which is possibly available there in a signed language.

The Shortage of SASL Interpreters in the Health Care Context

There are no professional SASL interpreters (SASLIs) readily available at any health facility. Eighty-four SASLIs are currently registered at the Deaf Federation of South Africa to officially serve the Deaf population of around 600,000 [16,17]. The number of SASLIs who can interpret medical jargon is in even more critical shortage. In addition, the scarce SASLIs are too expensive for most Deaf people to hire for each health consultation [18]. The charge is between 250 and 350 South African Rand per hour excluding Value Added Tax; this may take up a 28% of the monthly Disability allowance of 1270 ZAR for a Deaf patient [19].

The Necessity of Providing Access to Health Information

Human Rights on Understandable Health Information

Everyone has the right to receive information with regard to a medical condition and in a language that she or he understands. The South African Health Act (61 of 2003) and Convention on the Rights of Persons with Disabilities 2006 both support the necessity of providing understandable health information to Deaf people. The first enforces, "*The health care provider concerned must, where possible, inform the user in a language that the user understands and in a manner which takes into account the user's level of literacy* [20], " and the latter states, "*The purpose of the present Convention is to promote, protect and ensure the full and equal enjoyment of all human rights and fundamental freedoms by all persons with disabilities, and to promote respect for their inherent dignity* [21]." Therefore, Deaf people are entitled to have access to health information in SASL, their own language, like all other patients.

To Induce Better Health

Many Deaf patients do not adhere to the suggested treatment or the prescribed medicines due to their limited health literacy as a consequence of poor access to understandable and accurate information. Some simply dispose of their prescribed

medications if they do not understand the diagnosis or the importance of medication intake [3,22]. Others with chronic diseases purposely miss the follow-up visits by sending a hearing family member or a friend to get the repeat medication in order to avoid the confusing communication and inferior care [22,23]. Medical adherence would improve if the Deaf patients could understand their diagnosed condition and participate in the decision-making process for their treatment [24,25].

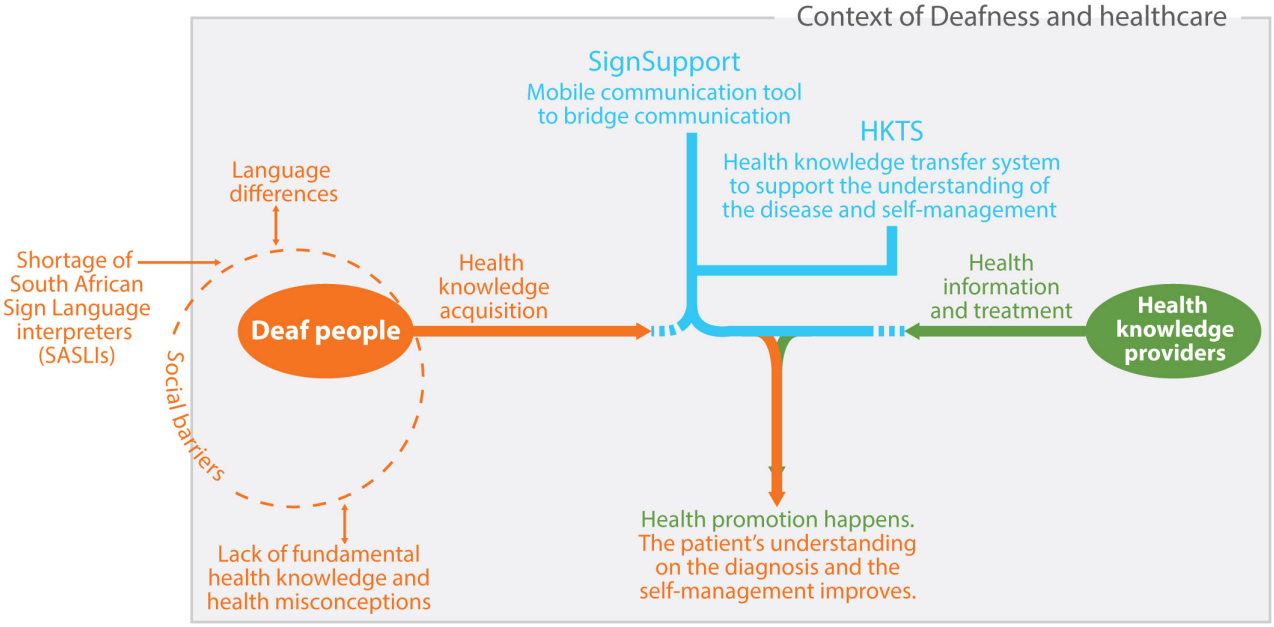
Therefore, together with our collaborators, we seek the opportunity to improve Deaf people's access to health information and consequently their health through a mobile health app, SignSupport together with HKTS.

Background About SignSupport and the HKTS

We initially started along this trajectory with a Deaf community in Cape Town. The theme "communication in a health care context" was prioritized to start the design and development of the mobile health app, SignSupport [2]. The research team later narrowed down the scope to focus on the medication dispensing process. This resulted in a SignSupport prototype which prompts a pharmacist to explain the prescribed medication instructions to a Deaf patient. The process of the explanation consists of making selections from provided options and taking photos of the medicine(s). The selections made by the pharmacist are matched with prerecorded SASL videos on the mobile device, which are then orchestrated as a set of medication instructions for the patient to view in SASL. From the usability test, Deaf participants reported their satisfaction with the use of SignSupport. Deaf participants could understand the medication instructions: medicine photo, dosage, medication intake time, recommendations, and warnings [26]. However, some of the Deaf participants revealed nonadherence to medication instructions. This was caused by health misconceptions shared within their community [27]. This is the point where the HKTS was conceived to provide Deaf users with understandable and accurate information of diseases and appropriate self-management (Figure 1), to provide more information to Deaf users beyond SignSupport, bridging the communication gap between the patient and the pharmacist.

Before writing this paper, the Deaf in Cape Town had confirmed mobile phones as their preferred tool for receiving and viewing health information. Within the same research session, many participants also suggested using diabetes as a case study for the design and development of the HKTS [4]. Our journey in building the groundwork for the HKTS was then given a specific context in which our mobile health app can be of use and the suitable techniques for delivering understandable health information to Deaf people. This paper therefore describes an exploration of which modes of health information delivery should be incorporated by the HKTS, and which effective presentation techniques can be applied.

Figure 1. Overview of the design and development of SignSupport and Health Knowledge Transfer System (HKTS).



Related Work

Exploring the Information Sources Which People Use or May Use

Delivering health information at the right place and time can also increase the potential that the patient can improve their self-management [28,29]. Other projects that aim to develop accessible information sources for people with specific needs investigated on the information sources that people use and may use in the future. A consortium that was setting up an information center for the Deaf in Europe collected all the information sources Deaf people used. They learned the problems which Deaf people faced while using each information source in order to come up with possible solutions. Special needs retrieved from Deaf people were taken into consideration. Deaf people's wishes on the future information center were also included in the study. All participants in the investigation wished for a pan-Europe information system with uniform standard for Deaf people in Europe [30]. Besides, understanding problems which the users of the information sources are facing, the trust issue should be as well investigated. Trust is an important

component for one to take an action on the received health information [31,32].

Attempts to Distribute Health Information to Deaf People

There are a limited number of health information sources that provide health information in sign language. However, there are some websites that present health information in signed language, mainly in British Sign Language (BSL) or American Sign Language (ASL) for educational purposes. The following are examples of health information available via the Internet for Deaf people. Sign Health, developed by the Deaf Health Charity, supports BSL users with access to a large collection of videos related to health conditions and diseases. The information about each disease is signed by a BSL interpreter (BSLI), but no figures are used to accompany the explanations [33]. This information portal was originated after the report "Sick of It"—the report that shows the British Deaf people's poorer health in comparison with their hearing counterparts [22]. The British Heart Foundation provides health information primarily for hearing people and some for Deaf people. The health information for Deaf people is explained using mixed techniques: combining motion graphics, narration by a BSLI, and sometimes subtitles [34]. Deaf Diabetes United Kingdom is a Deaf-led organization that provides support to Deaf people with diabetes. The informational materials on this website refer to the videos from the British Heart Foundation [35]. Deaf Health was developed to give clear and concise health information in ASL to the Deaf and Hard-of-Hearing community. The information available from this website is only narrated by ASL interpreters (ASLIs) [36]. Deaf Health by the University of California, San Diego (UCSD) provides information especially about different types of cancer. The information is presented by different combinations of techniques, for example, animation with simple and short text or subtitles and voice, and drama in signed language with subtitles and voice [37]. Noticeably, this accessible health information is mostly available for Deaf people in the rich economies, whereas it can hardly be found in other parts of the world. There is still no Web-based health information or mobile health information available for SASL users. As signed language is nonuniversal, this is an opportunity to explore the Deafness and health care context in South Africa for the design and development of the HKTS.

Methods

Approach

Through a community-based codesign (CBCD) approach, we involved both Deaf communities and health professionals in all phases of the action research (context exploration, planning, design and development, as well as testing and evaluation) in order to define suitable solutions toward the provision of equitable health information access to and for Deaf people [38,39]. We applied this qualitative research approach during the context exploration phase to answer the following research questions (RQs):

RQ1. What are the current modes of health information distribution available to Deaf people in Cape Town?

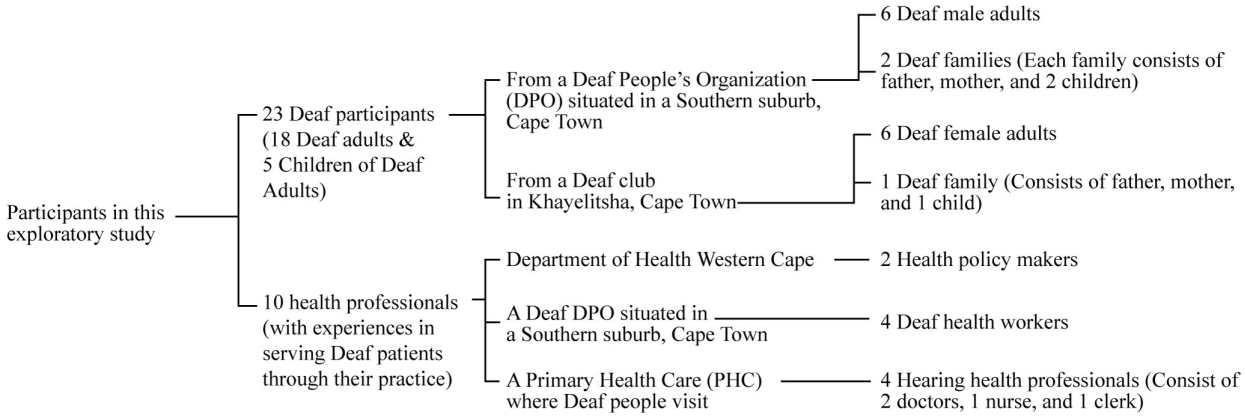
RQ2. What are the health information sources which Deaf people prefer and what are their reasons for this choice?

RQ3. What are the effective techniques to deliver understandable health information to Deaf people?

Research Site and Participants

The exploration took place in Cape Town during the period of January to May, 2014. A total of 23 Deaf participants and 10 health professionals were approached and invited to join interview sessions (Figure 2). It is important to note that these 10 health professionals were chosen because of their experience serving Deaf patients through their practice. In fact, these health professionals were specifically recommended by the Deaf communities with whom we worked.

Figure 2. Participants in the exploratory study. DPO: Deaf People's Organization.



Procedure

A qualitative approach with a design-oriented methodology was applied for this exploratory study [40]. Two separate sets of semistructured questions were used for the interviews with groups of Deaf participants as the "information acquirers" and all health professional participants as the "health professionals." Sensitizing tools were also used for retrieving extra insight information from the Deaf participants (Table 1). All Deaf participants were interviewed in groups. Based on our prior experience, Deaf participants tend to be more comfortable when they are among their peers; the discussion of nonprivate issues also becomes more dynamic. At the beginning of the interview, the participants agreed to allow each other an equal chance to

give answers or share stories in response to the questions. The health professionals were interviewed either in a group or individually depending on their availability.

Table 1. Techniques used for data collection.

Participants	Techniques	Procedure run by a session facilitator
Information acquirers		
Male group (Participants were not married nor had a child who could interpret for them) Female group (Participants were not married nor had a child who could interpret for them) Deaf families consisted of Deaf parents and hearing children (the so-called CODA[a])	Group interview: Semistructured questions with assistance from SASLI[c] Sensitizing tools: - Sticky notes with Deaf participants' mentioned health information sources - Evaluation map of the accessibility of the mentioned information sources (5 areas on the map indicate the degrees of accessibility, from the highest to the lowest)	Step 1a: The research facilitator asked open-ended questions to explore the current health information sources that are available to Deaf participants. Then she wrote down each source that was mentioned on a sticky note. Step 2a: The research facilitator asked the Deaf participants to share their experiences and techniques used during receiving or acquiring health information from the abovementioned sources. Step 3a: (Only with the Deaf families groups) The research facilitator asked the participants to explain if their hearing CODAs are considered as their health information source and if they have any informational influence on them as parents. Step 4a: The research facilitator showed the evaluation map and gave the written sticky notes to the participants. Then she asked the participants to discuss within the group the accessibility of each mentioned information source with reference to their access to this source, the techniques used for information delivery, and the comprehensibility of the retrieved information. The sticky notes are then placed in the areas of degrees of accessibility they agree on, and they reflect on their reasons. At this step, we derived *"the list of the current health information sources"* that Deaf people can access. Step 5a: The research facilitator asked the participants to discuss within the group the information sources they wish to have available to them. Then they wrote down each source they wish to have available on a sticky note. This resulted in *"the wished-for sources."* Step 6a: The research facilitator asked the participants to discuss and adjust the positions of all sticky notes (with the current health information sources and the wished-for health information sources) on the evaluation map of accessibility. Then she asked them to reflect on the reasons for these decisions. From this step, we derived *"the extended list with the wished-for sources"* added.
Health professionals		
Health policy makers Deaf health workers Hearing health professionals at the PHC[b] facility	Group interview: Semistructured questions with assistance from SASLI Group interview or individual interview: Semistructured questions	Step 1b: The research facilitator asked open-ended questions to understand the responsibilities in terms of health information distribution to all the patients. Step 2b: The research facilitator asked the participants to share their experiences and the techniques used in delivering health information to Deaf patients.

[a]CODA: child of Deaf adult.

[b]PHC: primary health care.

[c]SASLI: South African Sign Language interpreter

Data Analysis

All interviews were recorded on video and audio formats. Both inductive and deductive coding was applied to the analysis. The indepth information retrieved from different groups of Deaf participants was combined in order to define the modes of health information distribution to Deaf people and their preferred health information sources. The information retrieved from Deaf participants and health professional participants was later used to verify the health information delivery techniques that were found to be effective or ineffective.

Ethical Considerations

We received ethics approval from the Health Research Ethic Committee of Delft University of Technology and from the Institutional Research Board of the University of the Western Cape for this research. The research purpose, risks, and benefits of the design and development of the HKTS, rights of

participants, and identity protection were communicated to all participants in advance of any interview. Certified SASLIs, who are also accepted by the participating Deaf communities, assisted to relay the communication with all Deaf participants. The informed consent from the Deaf participants was recorded via raised hands in front of a video camera. We addressed many, if not all, of the ethical concerns that arise when dealing with Deaf participants [41].

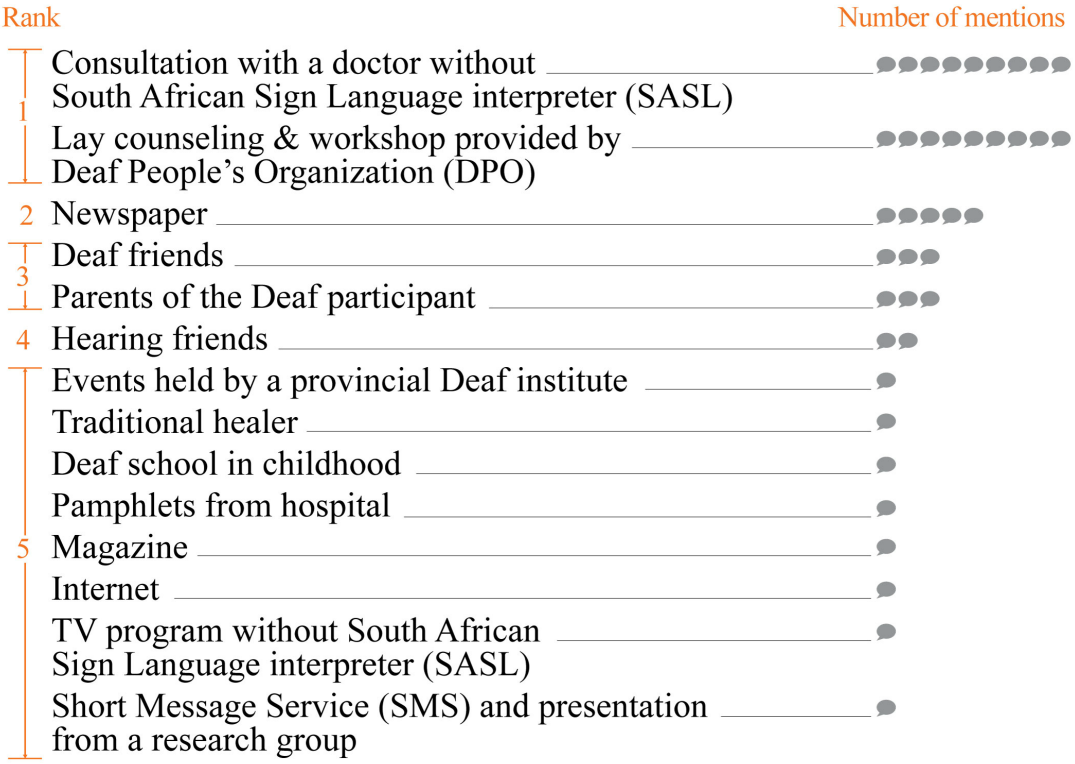
Results

Current Modes of Health Information Distribution

The exploration shows that under the limitation, Deaf people approach some sources to get health information from. The Department of Health (DoH) in the Western Cape sets a health calendar for national and international health days each year. The DoH distributes the mandated health information to the Deaf population through Deaf and other relevant organizations. Deaf people also have the opportunity to receive health information from consultations with health professionals or from the mass media despite the aforementioned limitations. In addition, they randomly receive information through personal interactions with their Deaf peers and a few hearing friends or family members. Figure 3 illustrates 14 information sources, which the information-acquirers mentioned as being available to them. The ranking was composed according to the amount of times each source was mentioned.

The 14 sources were then coded into themes and clustered into 4 modes of health information distribution for answering RQ1. The details including feedback from participants on each of the 4 modes are as follows:

Figure 3. The current health information sources available to Deaf people.



Health Workshops and Counseling Offered by Deaf and Other Relevant Organizations

Workshops and Lay Counseling Offered by Deaf People's Organizations

In 2014, there were 5 health workers, who are also Deaf, across Cape Town. All of them were located at one Deaf People's Organization (DPO). The Deaf health workers were mainly trained for HIV/AIDS lay counseling [42]. They currently collaborate with other relevant organizations to promote health information to Deaf members according to the DoH's health calendar. The health workers and the auxiliary members presented information using 2 communication strategies: (1) private and confidential counseling for individual clients with HIV/AIDS and (2) workshops and dramas in SASL for a mass signing audience. The lay counseling aims to identify HIV/AIDS-infected members for timely assistance in self-management and treatment-adherence education. The health workers performed social and health dramas in SASL for Deaf members during their monthly gatherings and also with outreach programs around the Western Cape to smaller Deaf communities. The dramas cover common and relevant health misconceptions gathered through their casework. A short presentation with pictures is subsequently presented to the audience. The session ends with an open platform for questions and answers.

Deaf participants like the health dramas because they are in SASL. As a result, the story and the arguments are easy to follow:

> *When there is drama, you get to understand something you never understood, so it's very good.*

In addition, a few Deaf participants wished to review the dramas at their own time and place of convenience due to their limited budget for traveling from home to the DPO.

The Deaf health workers also find the combined techniques effective in delivering and simplifying health information. They compose the drama to imitate the daily lives of Deaf people, so it helps Deaf people let go of common misconceptions. The short presentation is used to further explain the topic; and pictures are used to enhance the audience's understanding during the presentation. At the end of the session, the open platform for questions and answers provides opportunities for the audience to clarify their doubts based on the characters in the drama without revealing their personal problems.

Events Held by a Provincial Deaf Institute

The information is also presented to the Deaf audience in SASL through the assistance of the certified SASLIs.

Health Education From School

Health education given during one's schooling is considered by a Deaf participant as the information source that lays down some fundamental health knowledge for the person.

Health Texting and Presentations From a Research Group in Cape Town

A text message (Short Message Service, SMS) is written in simple English, isiXhosa, or Afrikaans, which Deaf people can understand. Although some participants from our Deaf-female group mentioned that only a few of them understood the SMS text messages, they all agreed that it was still better than receiving nothing. In addition, since 2008, this research group has been offering the first free-of-charge SASL interpreting to Deaf outpatients with advance booking prior to a health facility visit [43].

Consultations With Hearing Health Professionals

As with all health professionals, the ones participating in this study have their own roles to play in their aims and responsibilities to maintain wellness, prevent illness, and promote health during face-to-face interaction with all patients. Group communication forums for chronic diseases, small support groups for HIV, and health education in the waiting areas at the health facilities are additional communication strategies that PHC system uses for optimizing health promotion to specific groups of patients. Given the situation that most if not all health professionals are hearing, and in this case, dealing with Deaf patients, the health professionals must also address the need for assistance from SASLIs at health facilities.

All Deaf participants emphasized the communication problems they experienced at the health facilities in the absence of an SASLI. Deaf patients who had no SASLI as an escort had to communicate via writing or lip-reading, which is not preferred. This led to confusion and frustration for the patient when one could not understand his or her diagnosis. Several Deaf participants admitted that their nodding during the consultation was to rush the consultation to an end; it did not refer to their understanding:

> *When it comes to writing back and forth with the doctor, it's difficult to deal with. You will say (nod) yes, yes, yes to everything. And then when you go outside, you will ask people what it means because when you stop them (doctors), they get furious.*

Deaf participants from Deaf family groups who sometimes had an SASLI or a CODA escorted them to a repeat appointment for a chronic disease, in contrary, had better experiences during the consultations. They understood the test results, the treatment planning, and medication adjustment:

> *When the interpreter is there, she will communicate with the doctor and then will sign to me. I understand everything perfectly. The same applies when I go to the pharmacy, when the interpreter is there, it's easy to explain how to use medication, and if your blood pressure is high or your diabetes is high. So it is easy when the interpreter is there. But when the interpreter is not there, there can be some misunderstanding on medication and others things, so I always go with a sign interpreter when going to a public hospital.*

Many health professionals routinely wrote or merely shouted while communicating with their Deaf patients since they did not understand Deaf people's backgrounds and their specific communication needs. Some health professionals who understand a little SASL would avoid signing as it could cause miscommunications. Drawing may be used to explain the time for medication intake. A doctor from the interviews demonstrated his explanation of a disease progression to the Deaf patient in analogy, whereas another doctor would rather explain only the important actions that the patient must take to avoid further confusion. Therefore, a Deaf patient usually does not receive complete information about the diagnosed disease, treatment planning and its options, self-management, and schedules for follow-up appointments. Due to the communication gaps, the health professionals could not check-back their patient's understanding of the explained subject.

The health policy makers are aware of these communication problems among Deaf patients and health professionals and the shortage of SASLIs in the health care context. They additionally understand that the support groups provided for hearing patients are not suitable for Deaf patients. Therefore, they are still looking for solutions that optimize the use of existing information and communication technologies to distribute inclusive health information for all.

Information Shared Through Personal Interactions

Deaf Friends

Deaf friends who can read become the immediate information source to others. These friends can give simple advice, read and explain medication instructions, or suggest one to a health facility with Deaf-friendly staff. On other hand, several health misconceptions are commonly shared through the close-knit relationships in the Deaf communities [15].

Hearing Friends

A participant mentioned partial health information received from hearing friends; however, another participant additionally revealed a miscommunication received from his hearing friend about smoking and health. Both participants showed a similar pattern of language barriers as a problem while communicating with their hearing friends.

Parents of the Deaf Person

Three participants received some advice from their mothers concerning their own or their partner's pregnancy. On the opposite side, none of the Deaf participants considered their CODAs as their health information source, although the children occasionally shared some information with them, for example, lifestyle modification for better health.

Mass Media

Printed Media

Five participants read the newspaper and found some interesting health information although they did not always understand the terminology used in the articles. One participant who experienced problems while communicating with a support group prefers self-study via pamphlets with pictures distributed at the health facility . One other participant likes reading information concerning her chronic disease from her favorite magazine. These participants construct their understanding from the wording they understand in combination with the accompanying pictures, although they could not understand all the terminology used in the content.

TV Programs

A participant followed her favorite program that presented health-related information. She used her lip-reading skills in combination with the visual graphics that appeared on screen to construct her understanding. She might also ask her CODA to relay the information.

Internet Browsing

A participant frequently browsed the Internet to acquire further information about the terminology found elsewhere. However, most of our Deaf participants do not have access to the Internet or adequate computer literacy skills.

Preferences of Deaf People on the Health Information Sources

The participants were asked to discuss health information sources that they wish to be available for Deaf people (Table 1: Step 5a). The wished-for sources were added to the list of current information sources. The participants subsequently evaluated the extended list of health information sources on comprehensibility with a focus on language and communication techniques used. This list contained the preferred health information sources which comprises the answers to RQ2. This evaluation resulted in a new ranking which reflects the preferences among Deaf people for accessible health information sources. By comparing the 2 lists (Figure 4), we noticed that Deaf participants wished to have SASLIs for most services available publicly. Having an SASLI available at health facilities is the most desired situation in this context because they need to understand their health conditions at the time of seeing the health professional. Having the counseling and workshop provided by the DPO and SASL interpreting on TV for health information also increases the opportunities during which Deaf people can learn to take care of their health.

Techniques of Delivering Health Information

From all the participant's feedback, 3 effective techniques for delivering understandable health information to Deaf people were defined. These are the answers to RQ3. In addition, 2 ineffective techniques are additionally described for acknowledgment. These techniques are presented in no particular order.

Effective Techniques

Information Delivery in SASL

The responses from Deaf participants, Deaf health workers, hearing health professionals, and policy makers confirmed that delivering health information in SASL is the most important element for Deaf patients. Efficient methods of delivering information in different dialects should also be considered.

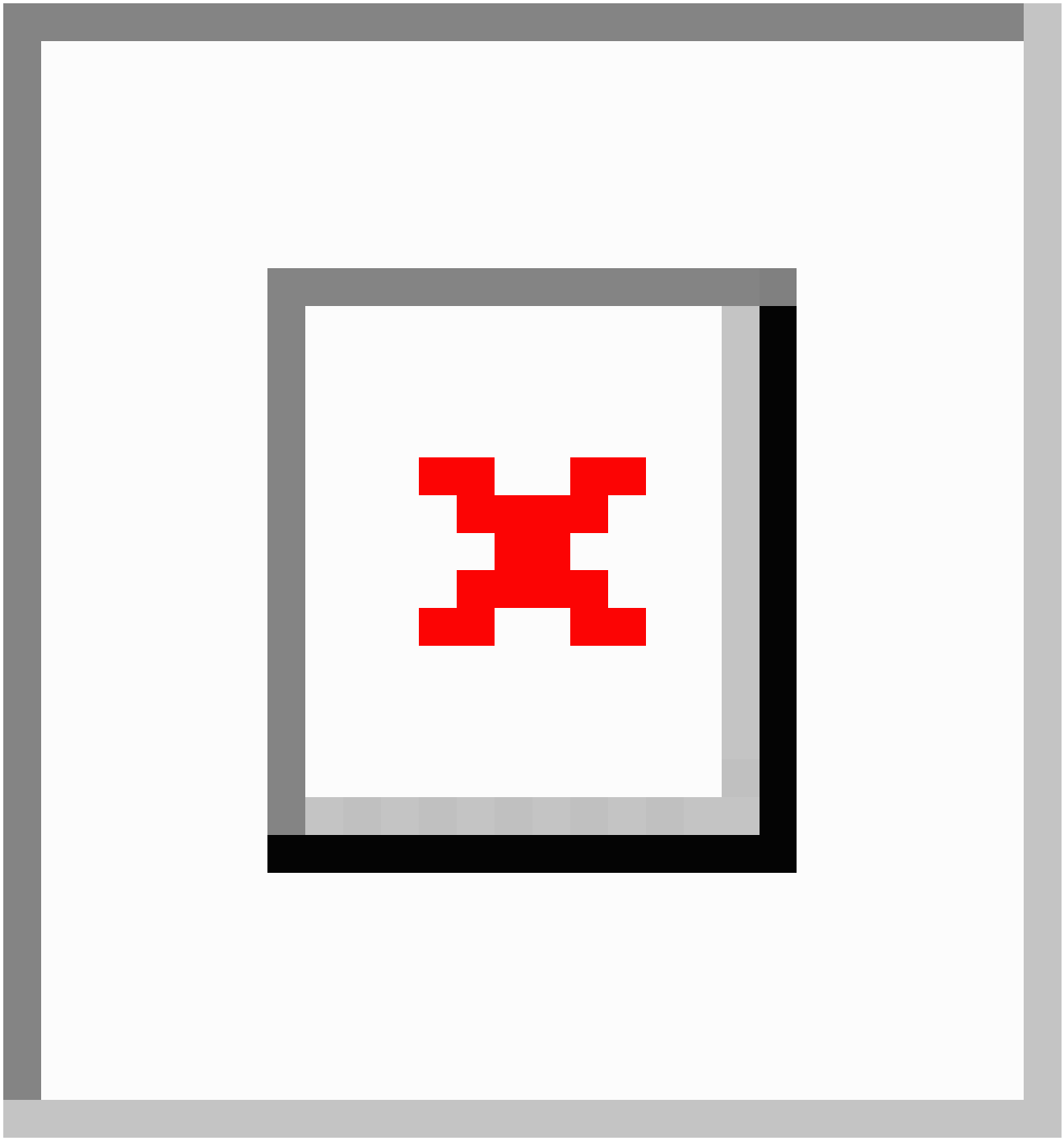
Health Dramas With Combined Techniques

Complicated subjects or topics can be simplified and made memorable through SASL drama for a Deaf audience. The Deaf health workers usually combine this effective technique with a short presentation and an open platform for questions and answers. These combined techniques helped Deaf people to confront the facts and undo the health misconceptions, which they had held for a long time.

Pictures in Combination With Simple Text Descriptions

We learned that pictures in combination with simple text descriptions can help Deaf patients construct and enhance their understanding about the information. The descriptions could be in English or any other written language which the Deaf patients are familiar with. This finding corresponds to the findings that the scientific principles or processes must be made visual for Deaf learners in order to be understood [44]. As we noted in the introduction, many Deaf people are functionally illiterate with written language, in this case English, Afrikaans, or isiXhosa. However, evidence has shown that even with limited textual capabilities, Deaf people regardless frequently use text to communicate with each other via SMS [45] and undoubtedly now with apps like WhatsApp, Facebook, and email; and further, Deaf people do wish to learn textual literacy as evidenced by the long-running English literacy project at the Deaf Community of Cape Town, the use of the text at tertiary level at the National Institute of the Deaf, for example, and others. Having both SASL video and text side-by-side in an app could potentially offer benefits in this regard. In addition, it must be noted that for the sake of the developers, having textual "bread crumbs" in the human computer interface greatly assists with keeping track of content (although it must be matched up rigorously with SASL video content) [26].

Figure 4. Comparison of the list of the current health information sources and the extended list.



Ineffective Techniques

Functional Literacy Requiring Information

Writing is an ineffectual technique to deliver health information to Deaf patients because many Deaf people are less skilled in reading and writing. Heavy text content with jargon and complicated terminology will lose their attention. Similar findings were made by other studies related to health information delivery to Deaf people in different countries [46-48].

Lip-Reading Skills Requiring Information

Lip-reading is not preferred by Deaf people. The accuracy of English lip-reading is only 30-35% [49]. In addition, no patient could read the doctors' lips while they are wearing a mask. Unfortunately, many health professionals do not realize this issue because they have limited understanding of Deaf people's communication requirements [2].

Discussion

Principal Findings

From this exploratory study, we found 4 modes of health information distribution that are currently available for Deaf people in Cape Town. Based on these modes, we also gained an understanding of Deaf people's preferred health information sources. The Deaf people based their preferences of the information accessibility on the language and the communication techniques used by each information source. The effective

techniques for delivering the understandable health information to the Deaf users will be applied to the design and development of the HKTS. Delivering health information in SASL will significantly provide increased accessibility to Deaf people, especially on a low-cost mobile device. The video drama, combined with other techniques, is seen as a particularly innovative way to present and simplify health information to a Deaf audience. The use of pictures in combination with simple text descriptions can provide opportunities for Deaf people with low functional literacy to construct an understanding of the explained subject, recalling that Deaf people with much stronger sign language literacy yet are still interested to acquire textual literacy as it is by necessity needed to integrate into the greater hearing world.

While building the groundwork for the design and development of the HKTS, we learned that the mobile phone is the preferred communication tool for Deaf people to receive and view the health information. The Deaf communities also suggested diabetes care as a subject for the HKTS. From this exploratory study, we have defined 3 effective techniques for delivering understandable and accurate health information which Deaf people need. In addition, we see the opportunity for the HKTS to assist the health professionals in delivering understandable information to a Deaf patient, especially when an SASLI is absent. Deaf people consider that timely understanding of their health condition during consultation is very important. We will focus on the communication between a Deaf patient and health care staff at PHCs as the problem in delivering health information prominently occurred in that specific setting. The next phase of the research will be to cocreate the HKTS among the Deaf people, health professionals, and the research team. The content-specific health information within the HKTS will be determined to meet both parties' requirements. Inputs from all participants are valuable to help us verify the attributes of the systems.

Limitations

The Deaf participants who we invited from 2 Deaf communities appear to have connection and access to similar health information sources. It is possible that Deaf members of other Deaf communities in Cape Town, who we did not invite to participate in the focus groups, may have access to different health information sources. This may also result in different preferences on the sources. Their responses that were not collected may also lead to different effective techniques in delivering understandable and accurate health information. In addition, we need to take into account the different needs among Deaf communities when applying our findings to other Deaf communities outside Cape Town.

We realize the probable but unavoidable (inter)subjectivity and therefore the bias which influences the analysis of the results from this purely qualitative study. Of course our results might not be replicable as they target specific communities with low sample sizes. However, it is also accepted that qualitative methods such as ethnographic action research [50] and community-based codesign [51] can yield results that are transferable, for example, from one community to another. Furthermore, we also designed the responses in this study redundantly to assist in triangulating toward transferable results: the participants give their answers (Table 1: Step 1a and 1b), reflect their reasons (Table 1: Step 2a, 3a, and 2b), and affirm their answers (Table 1: Step 4a, 5a, and 6a). This is to extract the "real" meaning of the answers given by the participants as valid as possible, and likewise reducing the bias by the researcher during the data analysis. For the purpose of this study we can accept these limitations, as we toil in the action research space, in our case with various small Deaf communities. In other words, we aim for transferability over generalizability [52], and claim that our results and recommendations are as valid as quantitative methods; only that in our case, qualitative methods are better able to address the chosen research problems
.

Conclusions

With regard to RQ1 (What are the current modes of health information distribution available to Deaf people in Cape Town?), Deaf participants mentioned 14 health information sources that they can access. The sources can be clustered into 4 modes of health information distributed to Deaf people in Cape Town, viz, (1) health workshops and counseling offered by Deaf and other relevant organizations, (2) consultations with hearing health professionals, (3) information shared through personal interactions, and (4) the mass media.

With regard to RQ2 (What are the health information sources which Deaf people prefer and what are their reasons for this choice?), Deaf people base their preferences, whether an information source is accessible, on 2 factors viz, (1) that it delivers information in signed language; and (2) that it uses techniques to simplify the topic and to help Deaf people construct their understanding. These factors make the consultation with a doctor in the presence of an SASLI, lay counseling and workshops provided by a DPO, and TV programs with SASLI rank as the top 3 of the extended list in Figure 4.

At the end of the analysis, with regard to RQ3 (what are the effective techniques to deliver understandable health information to Deaf people?), we found that there are 3 effective techniques to deliver understandable health information to Deaf people. The information delivery in SASL including its dialects is the most important element of the accessible information because it is the language that Deaf people mainly use for communication in Cape Town, South Africa. The health drama with combined techniques, as optimized by a DPO, helps in simplifying complicated topics; followed by a short presentation and an open platform for questions and answers helps Deaf people to debunk the health misconceptions they may have. Pictures in combination with simple text descriptions accompanying the health information helps the Deaf information-acquirers construct and enhance their understanding on the explained subject. These effective techniques will be applied for the future design and development of the HKTS.

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Conflicts of Interest

None declared.

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Abbreviations

SASL: South African Sign Language
SASLI: South African Sign Language interpreter
BSL: British Sign Language
BSLI: British Sign Language interpreter
ASL: American Sign Language
ASLI: American Sign Language interpreter
UCSD: University of California, San Diego
HKTS: Health Knowledge Transfer System
CBCD: Community-based codesign
RQ: Research question
PHC: Primary Health Care
DoH: Department of Health
DPO: Deaf People's Organization
SMS: Short Message Service

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Original Paper

Role of Large Clinical Datasets From Physiologic Monitors in Improving the Safety of Clinical Alarm Systems and Methodological Considerations: A Case From Philips Monitors

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Abstract

Background: Large datasets of the audit log of modern physiologic monitoring devices have rarely been used for predictive modeling, capturing unsafe practices, or guiding initiatives on alarm systems safety.

Objective: This paper (1) describes a large clinical dataset using the audit log of the physiologic monitors, (2) discusses benefits and challenges of using the audit log in identifying the most important alarm signals and improving the safety of clinical alarm systems, and (3) provides suggestions for presenting alarm data and improving the audit log of the physiologic monitors.

Methods: At a 20-bed transplant cardiac intensive care unit, alarm data recorded via the audit log of bedside monitors were retrieved from the server of the central station monitor.

Results: Benefits of the audit log are many. They include easily retrievable data at no cost, complete alarm records, easy capture of inconsistent and unsafe practices, and easy identification of bedside monitors missed from a unit change of alarm settings adjustments. Challenges in analyzing the audit log are related to the time-consuming processes of data cleaning and analysis, and limited storage and retrieval capabilities of the monitors.

Conclusions: The audit log is a function of current capabilities of the physiologic monitoring systems, monitor's configuration, and alarm management practices by clinicians. Despite current challenges in data retrieval and analysis, large digitalized clinical datasets hold great promise in performance, safety, and quality improvement. Vendors, clinicians, researchers, and professional organizations should work closely to identify the most useful format and type of clinical data to expand medical devices' log capacity.

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KEYWORDS

large clinical data; audit log; physiologic monitors; clinical alarms; alarm fatigue; intensive care unit; nursing

Introduction

Clinical alarm systems safety is a national concern in the United States [1-7]. The US Joint Commission issued a National Patient Safety Goal, NPSG.06.01.01, titled, “Improve the Safety of Clinical Alarm Systems,” which requires health care facilities to establish alarm systems safety as a hospital priority and to identify the most important alarm signals to manage [8].

Of all devices, physiologic monitors (also referred to as bedside or patient monitors) were associated with the highest number of alarms and deaths in the US Food and Drug Administration’s MAUDE (Manufacturer and User Facility Device Experience) database where a total of 566 alarm-related deaths were reported [9]. Past research identifies the high rate of alarms produced by physiologic monitors [6,10-17], and alarm-related issues continue despite device design improvements. This poses a particular challenge for meeting the Joint Commission safety goal. Current methods to track alarm issues and outcomes of practice changes are time-consuming and challenging. This paper offers an in-depth discussion of a more novel technique for analyzing alarm data, managing alarms, and evaluating results of alarm practice changes. This paper (1) describes a large clinical dataset using the audit log from the physiologic monitors, (2) discusses the benefits and challenges of using an audit log in identifying the most important alarm signals and improving the safety of clinical alarm systems, and (3) provides suggestions for presenting alarm data and improving the audit log in physiologic monitors.

Patient monitors are an essential component in critical care treatment processes. In recent years, improvements were incorporated into these monitors to facilitate the monitoring process, including (1) connection to smaller portable monitors; (2) larger monitoring displays; (3) multimeasurement modules to capture different variables such as cardiac output and mixed venous oxygen saturation; (4) histograms and tabular views for trended data; (5) wireless transmission of bedside monitor data to central station monitors, other bedside monitors, hospital servers, and communication devices such as phones and pagers; (6) integration of smart alarms such as delay in alarm announcement; (7) integration of clinical protocols, such as detection and treatment of sepsis; and (8) a variety of alarm tone sounds and displays of color-coded messages based on alarm priority.

Most important, modern physiologic monitors now have the capability to log triggered alarms with associated data. On the basis of available technical features, some can log hundreds of thousands of data points and send them to large clinical datasets. Unfortunately, these datasets are rarely used for predictive modeling, personalized treatment, capturing unsafe practices, or guiding quality initiatives, yet a growing recognition exists among health care organizations, federal agencies, and health care policies on the importance of large clinical datasets [18,19].

A significant body of research exists on clinical alarm safety. The majority of studies used structured observations or field notes to quantify the volume and types of alarms in intensive care units (ICUs) [10,15-17,20,21], cardiac telemetry units [22], adult medical surgical units [23], pediatric medical units [24], and emergency departments [4,25]. Although a commonly used approach, these techniques can be problematic. The validity of observations depends highly on observers' knowledge and skills including the knowledge of the phenomenon, the intensity (volume and priority level) of the alarms triggered by different devices, ability of the observer to manage that intensity, and the number of variables under observation. Variables can go well beyond simple quantification to include identifying all alarming devices with the associated numbers and types of alarms, clinician response to alarms, sequence of alarms, patient condition during the alarms, and the duration of the alarm or clinician response time. The shortcomings of the observation technique also include cases where too many alarms or simultaneous or overlapped alarms affect the precision of the observation. This is specifically true for observations taking place on day shifts when patient procedures and alarms are greater in volume. The use of non–health care professionals as observers, not uncommon in these types of studies, can also limit the type and scope of data being collected [24]. Additionally, some alarm events cannot be captured by human observations because alarms are displayed based on priority chains, as described in the following sections of this paper. Thus, a need exists for more objective, complete, and comprehensive data to quantify alarms generated by monitoring devices. The use of alarm audit data could fulfill that need.

A few studies on alarm systems safety were found to use the available data from physiologic monitors to measure the actual number of clinical alarms. Two of these studies retrieved and used the audit log [14,17]. Other studies transferred these data from the monitors to a different database using software [11,12]. Nevertheless, none of these studies (1) addressed techniques about using the large set of clinical data generated from monitoring devices to quantify alarms; (2) described elements of the logged data, benefits of using such data, and challenges faced on data storage, retrieval, and analysis; or (3) provided suggestions for improvement of the logged data in order to be a useful source for clinicians, researches, vendors, and policy makers. This paper addresses these gaps.

Methods

Use of an Audit Log in an Alarm Safety Project

In our previous projects on alarm systems safety we utilized data logged from physiologic monitors to quantify alarm rates in a 20-bed transplant cardiac ICU [15-17]. Our previous projects examined the effect of a change in physiologic monitors’ alarm parameters on decreasing the number of false and nonactionable alarms as well as improving nurses' perceptions and attitudes toward clinical alarms. The audit log data file was retrieved from the server of the central station monitor of the transplant cardiac ICU for alarm rates 10 weeks before and 10 weeks after the change in monitor parameters. The results of these projects, as previously published [15-17], showed a significant reduction in alarm rate. On the basis of our experience in data retrieval and analysis using the audit log of alarm data from our previous projects in the transplant cardiac ICU and from our current projects in other adult ICUs (surgical trauma, neuro, and medical ICUs), the focus of this paper is to

discuss important methodological considerations in the use of audit data for future health and informatics projects.

Description of the Setting and Physiologic Monitors

Our 4 adult ICUs have a total of 230 nurses and 155 beds and are equipped with Philips IntelliVue MX800 (Koninklijke Philips N.V, Amsterdam, the Netherlands) bedside monitors. The central station monitor is Philips IntelliVue Information Center iX, an information hub that allows patient information management at the bedside, unit, and hospital levels through information transferred from the networked bedside cardiac monitors. Both bedside and central monitors are capable of capturing, displaying, and storing real-time waveforms, parameters, and alarms and are wirelessly connected to the institution's electronic health record (Sunrise, Allscripts® Chicago, IL, USA).

Bedside monitors are hardwired to a switch, which automatically transfers the monitors' data to the central station monitor (Information Center). The data are then routed to a Health Level Seven (HL7) interface that converts the device data into HL7 format and sends them to the electronic health record. Wi-Fi connectivity is only available when a transport or portable monitor or multimeasurement module (MMS X2) is used and is disconnected from the bedside monitor (host monitor).

The monitors generate (1) patient-related (physiologic) alarms and (2) inoperative or technical (INOP) alarms. Technical alarms indicate the monitor's inability to appropriately measure physiologic parameters. Alarms are announced in 2 different areas in the bedside monitor, one for physiologic alarms and the other for technical alarms. When triggered, alarms flash on both the bedside and central station monitors. Monitors display the level of an alarm by (1) sound, (2) number of asterisks (*) for physiologic alarms or exclamation marks (!) for technical alarms, and (3) color of the message. Physiologic alarms have 3 levels of priority from advisory (*) to high (***), and technical alarms have 3 levels ranging from soft (with no exclamation mark assigned next to the alarm) to moderate (!!) to high (!!!). Severe physiologic alarms are displayed in red, whereas yellow reflects moderate-level physiologic alarms.

Data Storage and Retrieval of the Audit Log of the Physiologic Monitors

The audit log is a chronological record of the alarms and clinicians' interaction with the monitors. It is stored by and retrieved from the Information Center database. Storage period is only 90 days, and then the Information Center begins to overwrite the oldest data. Retrospective (oldest) data beyond 90 days will be lost or no longer accessible. The maximum data retrieval period at one time is 50 days and the minimum is 15 minutes. Therefore, at least 2 retrievals are necessary for 90 days' retrospective logged data (ie, 50 days and 40 days).

There are 2 types of audit logs. The patient audit log is patient specific and can be searched using the patient's first or last name, medical record number (MRN), or bed label. The unit audit log contains unit-specific data. Search categories are Alerts (alarms) and Actions (represent clinician navigation and interaction with the monitor). Alerts search criteria include Red Alarm, Yellow Alarm, Logged INOP, and Alert Sounds. Clinician actions include 21 types of actions or search criteria. Examples include Silence, Pause/Resume, Measurement On/Off, Alarm On/Off, Alarm Limit Change, Stand By On/Off, Admission/Discharge/Transfer, and Paced Status Changed. After selecting the desired type of audit log, unit, and search duration and criteria, the resulting file can be exported into Excel (Microsoft) format for analysis.

Description of Audit Log Data

Clinicians and researchers select variables of interest to download from the audit log. Table 1 displays an example of selected cases of data extracted at the unit level (unit audit log). In our transplant cardiac ICU project, we categorized alarms as categorical and numerical. Categorical alarms do not have upper or lower limits and are displayed in the log data as generated or ended. Examples of categorical alarms include types of premature ventricular contractions (PVCs) such as multiform PVCs and Pair PVCs, Run PVCs High, AFIB (atrial fibrillation), and Irregular Heart Rate. All technical INOP alarms are also categorical, such as Check Patient ID, Check Equipment, Batt (battery) Empty, and Leads Off. Numerical alarms are signaled if the parameter value was above or below the current programmed limits. Examples of these alarms include RR (respiratory rate), HR (heart rate), Apnea, PVCs/min, ABP (arterial blood pressure), NBP (noninvasive blood pressure), PAP (pulmonary artery pressure), SpO_2 (peripheral capillary oxygen saturation), and Desat (desaturation). Some alarms fall under both categories. For example, Apnea alarms can be displayed in three different messages: (1) "***Apnea generated," indicates cessation of respiration for longer than the programmed apnea time, (2) "***Apnea X:YY" where X:YY represents the apnea duration in minutes and seconds, and (3) "***Apnea > 20 sec," which means respiration has stopped for more than 20 seconds.

The alarm messages in the "Alarm and Action" column (Table 1) includes (1) the priority of the alarm based on the number of "*" or "!" signs next to the alarm, (2) name of the alarming parameter, (3) value of the parameter when the alarm was generated for parameters with numerical limits, (4) default or programmed settings of the numerical parameter, and (5) status of whether the alarm was generated or ended. Table 1 also presents examples of "Actions" that indicate clinician interaction with the monitor (eg, Silence, Resume All Alarms, Patient transferred, Patient category set to Adult).

Table 1. An example of a unit audit log.

Date	Bed label	MRN[a]	Alarm and Action	Device name[b]
4/20/14 0:00:00	9115-S1	0000000	**PAPd[c] 18 >16 Ended.[d]	PIIC iX: ixsurv006
4/20/14 0:00:00	9115-S1	0000000	**PAPd 18 >16 Generated.[d]	PIIC iX: ixsurv006
4/20/14 0:00:00	9115-S1	0000000	Yellow alarm sound played.[e]	PIIC iX: ixsurv006
4/20/14 0:00:02	9115-S1	0000000	**ABPs[f] 170 >160 Generated.[d]	PIIC iX: ixsurv006
4/20/14 0:01:05	9123-S1	0000000	***Desat[g] 70 < 78 Generated.[h]	PIIC iX: ixsurv005
4/20/14 0:01:05	9123-S1	0000000	Red alarm sound played.[e]	PIIC iX: ixsurv005
4/20/14 0:01:12	9123-S1	0000000	***Desat 73 < 78 ended.[h]	PIIC iX: ixsurv005
4/20/14 0:01:16	9115-S1	0000000	**ABPs 168 >160 Ended.[d]	PIIC iX: ixsurv006
4/20/14 0:01:20	9123-S1	0000000	Silence.[i]	PIIC iX: ixsurv005
4/20/14 0:01:40	9115-S1	0000000	*Multiform PVCs[j] Generated.[d]	PIIC iX: ixsurv006
4/20/14 0:01:40	9115-S1	0000000	Resume All Alarms.[i]	PIIC iX: ixsurv006
4/20/14 0:01:40	9117-S1	0000000	**RR[k] 37 >30 Ended.[d]	PIIC iX: ixsurv006
4/20/14 0:01:40	9111-S1	0000000	Patient transferred to 9035-S1.[i]	PIIC iX: ixsurv006
4/20/14 0:01:42	9095-S1	0000000	Patient category set to Adult.[i]	PIIC iX: ixsurv006
4/20/14 0:01:43	9090-S1	0000000	Pacer algorithm set to Pacer Algorithm On.[i]	PIIC iX: ixsurv006
4/20/14 0:01:44	9123-S1	0000000	ECG[l] Leads Off Generated.[m]	PIIC iX: ixsurv006
4/20/14 0:01:44	9123-S1	0000000	INOP[n] sound played.[e]	PIIC iX: ixsurv006
4/20/14 0:01:59	9123-S1	0000000	ECG Leads Off Ended.[m]	PIIC iX: ixsurv006
4/20/14 0:02:00	9093-S1	0000000	Equipment Offline.[i]	PIIC iX: ixsurv006
4/20/14 0:02:00	9115-S1	0000000	**PAPd 18 >16 Generated.[d]	PIIC iX: ixsurv006
4/20/14 0:02:00	9093-S1	0000000	Equipment Online.[i]	PIIC iX: ixsurv006
4/20/14 0:02:00	9085-S1	0000000	ST: Al. Limits ST-V2[o] High: 1.6 ST-V2 Low: −1.6.[p]	PIIC iX: ixsurv006
4/20/14 0:02:00	9117-S1	0000000	Arrhythmia Off.[q]	PIIC iX: ixsurv006
4/20/14 0:02:02	9115-S1	0000000	Pause All Alarms.[i]	PIIC iX: ixsurv006
4/20/14 0:02:02	9075-S1	0000000	Arrhy: Missed Beat Off.[r]	PIIC iX: ixsurv006
4/20/14 0:03:00	9085-S1	0000000	SpO_2[s]: Desat Limit 78.[p]	PIIC iX: ixsurv006

[a]MRN is the medical record number and was presented as zeros for confidentiality purposes.

[b]Device name refers to the Information Center host name (eg, PIIC iX: ixsurv006).

[c]PAPd: pulmonary artery pressure diastolic.

[d]These are examples of yellow physiologic alarms.

[e]These messages appear if “Alert Sound” was selected as a search criterion from the Alerts category.

[f]ABPs: arterial blood pressure systolic.

[g]Desat: desaturation.

[h]An example of a red physiologic alarm.

[i]These are examples of clinicians’ actions. They depend on the “actions” selected from the search boxes.

[j]PVC: premature ventricular contraction.

[k]RR: respiratory rate.

[l]ECG: electrocardiographic.

[m]An example of INOP alarm.

[n]INOP: inoperative.

[o]ST-V2: a segment in the electrocardiogram.

[p]Examples of User Action–Alarm Limit Change.

[q]An example of User Action–Measurement Off.

[r]An example of User Action–Alarm Off; Arrhy: arrhythmia.

[s]SpO_2: peripheral capillary oxygen saturation.

Results

Benefits of the Audit Log

Benefits of the audit log are many and are as follows:

Easily Retrievable Data at No Cost

The audit log dataset is easily retrievable at no cost. Persons with legitimate access to the data, such as researchers, clinicians, biomedical engineers, and device representatives, can perform the search and obtain the data within a few minutes without having to coordinate with the information technology department.

Tracking of Clinicians' Interaction With the Monitor

Clinicians' interaction with the monitor can be tracked using time stamps. Examples of clinicians' actions include enabling or disabling alarms and/or measurements, silencing and pausing alarms, and changing alarms' limits.

Complete Records of Data

All types of configured or programmed alarms are automatically recorded by the Information Center in the audit log and have no missing data. Furthermore, more complete records are available than with observational data, as the audit log can capture and display different values of the same parameter from different sources, such as ABPs (systolic) or ABPm (mean), if programmed by clinicians. These additional values provide an objective record of the number of alarms and likely better reflect sources of alarm fatigue. Duplicative alarms are easy identified. Overuse of alarms can be identified and targeted for elimination. Additionally, the Information Center can store different types of electrocardiographic (ECG) and non-ECG waves in graphic and tabular formats. This can be extremely valuable information for alarm annotation.

Evaluation of Quality Initiatives

Quality initiatives can be evaluated using audit data. The audit log can be used to evaluate the effectiveness of different interventions by comparing pre- and postintervention data [16,17]. For example, evaluations could occur after best practice education sessions on frequency and methods of changing electrodes and the difference in "leads off" alarms. Nurse adherence to different targeted interventions can be evaluated [16,17].

Identifications of Monitors Missing Required Parameter Changes

Managers can easily identify monitors missing any required parameter changes, as the audit log can identify specific bedside monitors missing the required adjustments. For example, in one of our previous projects [16], we found alarms on our audit log that we thought were disabled, such as Paired PVCs or Bigeminy PVCs. The audit log included the bed number of the monitor lacking the required changes.

Detection of Unsafe Limits and Inconsistent Practice

Any parameters changed to unsafe limits and inconsistencies in practice can be identified. Setting limits for each parameter across monitors can be easily tracked using audit data. Unit managers can then monitor whether alarm limits were adjusted safely for the patient's condition. Table 2 shows selected cases with variations in the lower limit setting for the Desat parameter ranging from 50% to 90%. Clearly, 50% is an unsafe lower limit for that parameter. This information can also be easily obtained from User Action–Alarm Limit Change search criterion.

Similarly, the audit log data may indicate inconsistencies in the priorities assigned to some parameters. For example, we found that a low priority was assigned to the HR (1 asterisk) and Batt Empty (1 exclamation mark) alarms in some cases, whereas these were a higher priority elsewhere (2 asterisks and 2 exclamation marks). This was despite the similarity in the value of the triggered alarm in the 2 priority cases in the HR limits (eg, "*HR 153>150 Generated" and "**HR 153 >150 Generated").

Easier Comparisons Across Studies

Finally, comparisons across alarm studies may be easier, as alarms can be analyzed per patient days, bed, hours, or minutes, alarm parameter, and parameter priority. With the lack of published standards on reporting alarm rates, the audit log could allow easier comparison across studies on clinical alarm safety, specifically because different previous studies reported alarm rates using different units of analysis.

Benefits are obvious. In comparison with the observation technique, the use of the audit log allows cost-effective collection of alarm data, eliminates missing alarm data, safeguards the objectivity of the data, and, most important, allows unique discoveries from the collected information for analyses.

Table 2. An example of variations in setting the lower limit of the Desat (desaturation) parameter.

Date	Bed label	Alarm and Action	Device name[a]
7/16/14 4:57	9101-S1	*** Desat 89 < 90 Generated.[b]	PIIC iX: ixsurv007
7/28/14 21:44	9115-S1	*** Desat 87 < 88 Generated.	PIIC iX: ixsurv006
7/30/14 1:24	9109-S1	*** Desat 8 < 80 Generated.	PIIC iX: ixsurv006
8/11/14 11:59	9097-S1	*** Desat 44 < 50 Generated.	PIIC iX: ixsurv007
8/12/14 10:43	9113-S1	*** Desat 80 < 83 Generated.	PIIC iX: ixsurv006
9/5/14 21:38	9123-S1	*** Desat 0 < 78 Generated.	PIIC iX: ixsurv005

[a]Device name refers to the Information Center host name (eg, PIIC iX: ixsurv006).

[b]The three starts (***) indicate that Desat (desaturation) is a red or high priority alarm.

Challenges in Analyzing the Audit Log Data

Challenges exist in analyzing the audit log retrieved from the Philips Information Center. One challenge is that data cleaning and analyses are time-consuming processes. For physiological (yellow and red alarms) and INOP technical alarms, the "alarms and action" cell (Table 1) includes 3 (for categorical alarms) to 6 (for numerical alarms) different variables about the alarm. These include alarm priority, name of the alarming parameter, value of the alarming parameter that initiated the alarm, the upper limit of the programmed setting, the lower limit of the programmed setting, and the status of the alarm (generated vs ended). Some technical alarms are displayed with no priority assigned to them (eg, ECG Leads Off). To export the Excel audit log file into IBM SPSS (IBM Corporation) for analysis, for example, numerical and categorical alarms need to be first separated into 2 files. Then, technical alarms without priorities need to be filtered out from the categorical data and entered after importing all other categorical data into SPSS. Likewise, numerical alarms with distinctive displays (without ">" or "<" signs, such as Apnea X:YY) also need to be filtered out from the numerical alarm Excel file and then entered after importing the data into SPSS. The latter 2 cases require rearranging the date column to provide trended, date-based alarm data.

Additionally, the generation and end times of an alarm event are logged as separate, unconnected events. Analyzing the duration of each alarm requires sorting the data per the MRN, bed, date, and device name, separating the generation from the end alarm times and then pasting correlated events together. Data sorting is necessary, specifically because the audit log records the end time of an alarm before the generation time for alarms that signaled for less than a second (see Table 1, rows 1 and 2). Tracking alarm duration is a critical factor indicating clinician response time to an alarm and also contributes to alarm fatigue, specifically for long alarms that keep beeping with no immediate attention. Clearly, attention to detail is required in data cleaning as missteps can result in data interpretation errors.

Finally, the available Information Center stores data only for 90 days and allows the retrieval of 50 days of data at a time. This limited storage and retrieval increases the required time for data downloads, data cleaning, and analyses if separate downloads are needed for retrospective studies. For example, we had to retrieve alarm data 3 times, 2 for 50 days and 1 for 40 days, in order to capture all data over the 20-week project period. According to the vendor, an option exists for a longer storage period with an additional purchase, but many sites may choose the more economical version.

Discussion

Considerations for Presenting Alarm Data

Previous research presented the number and types of alarms, limits of parameters, and changes in parameters' limits [10-13,15-17,20-23,25-27]. This information is insufficient to inform contemporary quality initiatives on alarm safety. Alarms are announced based on monitor features and configuration as discussed below. The features below, which are usually absent from clinical alarm safety studies, must be explicitly discussed to understand alarm behaviors and for comparisons across studies.

Loss of Connectivity

Researchers and clinicians need to understand the data storage mechanism on servers from different vendors of cardiac monitors to estimate the number of alarms missed (if any) during any losses in connectivity. Data connection to the server can be lost in cases of hardware failure or system upgrade and maintenance. In our system, when connection to the server is lost, the data are saved in the bedside monitor and rerouted back to the server when the connection is restored. However, if a patient is disconnected from the bedside monitor and connected to the wireless transport monitor and the wireless device was out of range, data will be lost. Cases of connectivity loss are captured and recorded by our audit log. This allows the analysis and reporting of reliable data.

Indication of Latching Versus Nonlatching Alarms

When presenting alarm rates, duration, and corresponding alarm fatigue, researchers need to identify latching and nonlatching parameters. Some critical alarms are configured as "latching," which are high-priority red alarms (***) that signal nonstop continuous audible sound even after the condition is no longer present, requiring a clinician to silence them (eg, asystole and ventricular fibrillation). For both latching and nonlatching alarms (where alarm indicators reset after the condition ends) when they are acknowledged and the condition is still present, the audible alarm will turn off as well as the alarm lamp but the flashing numeric will keep on as well as the audible reminder (if configured to do so). The audible reminder is recorded as a

separate alarm event. Latching versus nonlatching alarms affect both the number of alarms and alarm duration.

Indication of Basic Versus Enhanced Alarms

It is equally important to identify whether alarms are set as basic (standard) versus enhanced. For example, in the arrhythmia analysis using our monitors, "Basic" capability allows the analysis and recording of 10 different arrhythmia alarms, for example, asystole, ventricular fibrillation, and ventricular tachycardia. The "Enhanced" arrhythmia analysis provides 13 additional alarms, for example, nonsustained ventricular tachycardia, supraventricular tachycardia, and run PVCs. Therefore, identifying the monitor configuration as basic or enhanced arrhythmia analysis would reflect the number of expected alarms.

Identification of Automatic Detection

Parameters set to automatic measurement or detection mode should be reported in alarm rates. This feature allows the monitor to detect measurements from different sources and decreases the number of false alarms. For example, automatic detection of respiration allows the monitor to adjust the detection of the respiration automatically, and the use of "Enhanced Asystole Detection" eliminates false asystole alarms.

Alarm Delays

Another factor to list is the use of "Smart Alarm Delay" and the mode of the delay, which delays an alarm based on the amount and duration over the set limit. This will eliminate the number of alarms for patients recovering from an alarm condition and appropriately decrease the total number of alarms.

Identification of automatic detection and alarm delay are very important to be reported given that some alarms may last for less than a second as shown in Table 1, which indicates lack of clinical significance.

Pausing and Silencing Alarms

Pausing and silencing alarms affect the duration of alarms. For example, some monitors allow "Pausing" alarms for 1 or 2 minutes or infinity (disabling the alarm). This also affects the number of false alarms. Another notable feature is that some systems allow "All Alarms Off for Yellow Alarms Only" and not for red alarms, whereas others allow this function for all types of alarms.

Priority Chain for Alarm Display

The priority chain of the alarm display affects the number of the announced alarms. The Information Center displays alarms based on 3 criteria: alarm sound, number of asterisks or exclamation marks in the message, and color of the message. Some situations inhibit the audible and visual indication of the alarm even when it is detected by the system and recorded in the audit log. These include cases of concurrent alarms where the system displays the most serious life-threatening event with highest priority based on a default priority algorithm using 3 chains (PVC alarms, beat detection, and rate alarm). All other alarms go to a display accessible by a drop-down list. Only the highest-priority alarm condition in each chain is announced. In cases of active high-priority alarm, the lower-priority alarms will not be announced. For example, when a Paired PVCs alarm is active and announced and another Pause alarm is detected, the Pause alarm will not be displayed because it is a lower priority. If another condition from another priority chain with equal severity is detected, the monitor will announce the more recent alarm. If the alarm is silenced by the nurse but the condition persists, the alarm message will still be displayed but without sound. The system first announces any unacknowledged red alarms, then any unacknowledged long yellow in the presence of any other yellow or INOP alarms, then short yellow alarms, then hard INOP technical alarms, followed by the soft INOP technical alarms (alarms with no priority assigned to them).

In cases of more than 1 alarm, an arrow to the right of the message on the central station monitor must be clicked to display a list of all active alarms with their times. A maximum of 10 alarms are displayed. In observation methods these alarms may be missed.

Alarms Not Amenable to the Changes (Hard Stops)

Monitors include default settings not amenable to changes by the clinician and only a monitor representative can change them. Examples of these settings are TachyClamp, BradyClamp, TachyExtract, and BradyExtract. Changing the default settings of all other alarms affects the alarm rate; therefore, researchers will want to indicate the types of alarms not amenable to clinician changes.

Audible Versus Inaudible Alarms

Studies need to identify and present the types of audible versus inaudible alarms [13]. For example, in our system there is no sound for soft INOP or technical alarms such as Noisy ECG. Although the audit log records the 2 types of alarms, audible alarms contribute more toward alarm fatigue.

Connecting Alarms to the Appropriate Settings and Reliable Monitoring Conditions

Different conditions may affect the number of alarms, specifically in cases of inappropriate settings made by the clinician or conditions affecting the reliability of the monitoring process. For example, clinicians must select the appropriate primary and secondary leads for the monitor to compute heart rate and to detect arrhythmias. The arrhythmia system automatically classifies patients' beats. To decrease the chance of false alarms, nurses need to modify the ECG analysis and relabel any arrhythmia beats if they do not agree with the way the monitor is classifying beats. For patients with a pacer, nurses should make sure that the system is not counting pacer spikes as QRS complexes.

When ST and STE (ST-segment elevation) are both in use, redundant ST Elevation alarms will occur. Additionally, different values will be obtained because of the different measurement points (isotonic point and ST point are used for ST measurement and isotonic point and the J point are used for STE measurement). Thus, nurses need to adjust the ST measurement points for appropriate ST detection. Because STE alarms are patient specific, nurses need to set the 12 leads

appropriately for each individual patient. Each ST lead has its own alarm limits.

In some conditions, monitoring some parameters is unreliable and may cause false nonactionable alarms. For example, ST monitoring is not recommended in cases when arrhythmias such as atrial flutter and fibrillation are present.

In the future and for the most accurate data, researchers will want to correlate alarm data to these conditions. None of the past studies on alarm safety correlated alarm data to whether appropriate monitor settings or reliable monitoring conditions existed.

Suggestions for Improvement and Future Directions

The audit log is a combination of the current capabilities of the monitoring systems, the specific monitor configuration, and alarm management practices and clinician-monitor interaction. The recommendations below can improve monitoring systems practices and optimize audit log data for performance improvement and research.

First, improvement in capabilities of the monitors for data recording, storage, and presentation is recommended. Vendors need to enhance the standard recording, retrieval, and storage capabilities of monitors. Longer recording and storage periods are recommended. Adding the list of parameters (eg, HR, RR, PVC) to the Alerts search criteria would be very helpful for researchers and clinicians. Each alarm event (from generation to end) should be displayed as 1 event versus 2 events to more easily identify duration of the event. This would also help assessments on alarms lasting for more than a specific time period (eg, 1 minute). Additionally, the use of common nomenclature for alarm reporting between vendors is highly recommended to facilitate comparison across studies. This includes visual and audible alarm indicators, alarm behaviors, and meaning of parameters and alarms (eg, TachyClamp, basic vs enhanced).

Second, expand the tracking of user interaction with the monitor. Although monitors have some capabilities to track user actions, such as disabling or enabling alarms and measurement, they do not track screens visited. Tracking user interactions with the monitor via the visited screens could capture unsafe practices, common approaches in addressing alarms, best practices, work-arounds, and indicate clinician knowledge of the monitors' capabilities. Previous studies used direct observation technique or surveillance cameras to capture clinician response to alarms [11,12], but few studies are available about how nursing practice and monitor configuration affect the number of alarms. For example, the use of the "Extending Alarm Pause Time Function" can extend the alarm pause time in cases of long procedures and decrease the number of false alarms.

Third, there is a need for expanding the audit log. Incorporating clinical data such as medications or laboratory values into the audit log could be extremely useful for more accurate alarm annotation. Monitoring devices and the audit log are currently based on univariate alarm algorithms where alarms are triggered based on the limits of one parameter. However, modern monitors allow detection of trended data (changes in a parameter over time). The use of trended data and interconnection among parameters and variables (multivariate), such as medications and laboratory data, is more clinically meaningful than a given observation in a specific time period. These have not yet been extensively examined [26,27].

Additionally, the Information Center has capabilities of storing different types of ECG and non-ECG waves in graphic and tabular formats, but this valuable information is stored separately from the audit log. The waveform file can be only printed and not stored or exported in e-format. Storing the waveforms information along with each alarm, especially for lethal alarms, would be valuable for classifying false versus actionable alarms.

Limitations

Our analysis and audit log description represents the offering of one vendor. Although this particular vendor is one of the largest physiologic monitor vendors, the capabilities of other cardiac monitoring devices from other vendors may be different.

Conclusions

The majority of modern medical devices such as cardiac monitors, smart infusion pumps, and ventilators are capable of automatically logging data. The audit log provides an objective, detailed data source of recorded alarms' events and types and user's actions. Unfortunately, this capability is not well utilized in research and quality initiatives. The information presented in this paper may encourage providers, clinicians, and researchers to use audit logs more frequently in research and performance improvement studies.

Despite current challenges in data storage, retrieval, and analysis, large digitalized clinical datasets hold great promise for safety and quality of care. Vendors, clinicians, researchers, and professional organizations should work closely to identify the most useful format and type of clinical data to expand medical devices' log capacity.

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Conflicts of Interest

None declared.

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Abbreviations

ABP: arterial blood pressure
AFIB: atrial fibrillation
Desat: desaturation
ECG: electrocardiographic
HL7: Health Level Seven
HR: heart rate
ICU: intensive care unit
INOP: inoperative
MAUDE: Manufacturer and User Facility Device Experience
MRN: medical record number
NBP: noninvasive blood pressure
NPSG: National Patient Safety Goal
PAP: pulmonary artery pressure
PVC: premature ventricular contraction
RR: respiratory rate
SpO2: peripheral capillary oxygen saturation
STE: ST-segment elevation

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Original Paper

An Evaluation of Understandability of Patient Journey Models in Mental Health

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Abstract

Background: There is a significant trend toward implementing health information technology to reduce administrative costs and improve patient care. Unfortunately, little awareness exists of the challenges of integrating information systems with existing clinical practice. The systematic integration of clinical processes with information system and health information technology can benefit the patients, staff, and the delivery of care.

Objectives: This paper presents a comparison of the degree of understandability of patient journey models. In particular, the authors demonstrate the value of a relatively new patient journey modeling technique called the Patient Journey Modeling Architecture (PaJMa) when compared with traditional manufacturing based process modeling tools. The paper also presents results from a small pilot case study that compared the usability of 5 modeling approaches in a mental health care environment.

Method: Five business process modeling techniques were used to represent a selected patient journey. A mix of both qualitative and quantitative methods was used to evaluate these models. Techniques included a focus group and survey to measure usability of the various models.

Results: The preliminary evaluation of the usability of the 5 modeling techniques has shown increased staff understanding of the representation of their processes and activities when presented with the models. Improved individual role identification throughout the models was also observed. The extended version of the PaJMa methodology provided the most clarity of information flows for clinicians.

Conclusions: The extended version of PaJMa provided a significant improvement in the ease of interpretation for clinicians and increased the engagement with the modeling process. The use of color and its effectiveness in distinguishing the representation of roles was a key feature of the framework not present in other modeling approaches. Future research should focus on extending the pilot case study to a more diversified group of clinicians and health care support workers.

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KEYWORDS

patient-journey modeling; process modeling; technology integration; health information technology

Introduction

Health Information Technology Prospects

Health information technology (HIT) is expected to improve patient care through increased accessibility to high-quality information, reduction in documentation efforts, and general overall time savings for clinicians [1]. For these reasons, there have been numerous initiatives to spur investment in HIT including computerized order entry systems, electronic medical records (EMRs), and more complex clinical decision support systems [2-4]. Governments, hospitals, clinics, and individual physicians have been investing millions of dollars into HIT. This is a large investment for both the government and

physicians, especially given the lack of confidence that the implementation of EMR will result in a positive return expressed by many physicians [2]. Various studies [5-9] have proven that the advances in health care, especially HIT, are not being incorporated by practitioners into clinical best practices. Recent studies have also focused on identifying the unintended consequences of HIT implementations [10-17], and in particular, the importance of the effects of organizational constraints on HIT remains an understudied domain [18]. The implementations of HIT have been predicated not only by monetary and fiscal constraints but also by other organizational factors as well such as access to innovative technologies, the applicability of the HIT to clinical practice, and the attitudes of the clinicians themselves [19,20].

Although technical barriers and system design flaws do exist, these are too often the source for blame when HIT implementation failures or undesirable consequences arise [21,22]. Many of the undesirable consequences are a result of human and sociotechnical interactions (the interactions between new HIT and the organization's culture), including in particular their workflows, team dynamics, communications structures, and existing information systems [17,23]. Due to the increased demand for demonstrating meaningful use and integration of HIT into clinical practice, changing the current methods for evaluating the integrated potential of HIT is critical for all health care organizations [24,25]. Kaplan [26] found that one of the primary barriers in the managing of HIT design and implementation projects was communication and understanding of the workflow-related issues stemming from the broad spectrum of stakeholders involved in the projects: "Participants described the difficulty in fully understanding workflow, as evidenced by the workflow changes resulting in endless workarounds." We propose the use of patient journey models to provide a clear visual representation of the workflows, technology, and communication interactions. Using visual models to depict health care situations enables all stakeholders to audit current practices and subsequently strategically plan process improvement initiatives focused on patient safety, quality of care, and efficiency [27].

Many studies on HIT evaluation methods support the need for improved modeling techniques to meet the specific complexities and social contexts of health care [28,29]. The modeling of information flows and integration into practice in HIT evaluation studies continues to be an issue requiring additional research. Process modeling has traditionally been used to improve information flows within organizations [27,30]. These techniques use basic flow charts [31], lean process mapping, or other methods derived from the manufacturing sector [9,32-34]. Recently, work has focused on modeling processes through the lens of the patient using various patient journey modeling (PJM) techniques [27,35]. These models can help both administrators and clinicians understand potential consequences of changes in processes and information flows due to HIT implementations. Using these models as a component of existing HIT evaluation methods, it will be possible to determine a set of unique clinical care processes based on the organization's culture that integrate EMR systems for the benefit of improved patient care.

Although various modeling techniques are being used in support of quality improvement and technology adoption, there remains an issue of whether those affected by the organizational change are able to assess the potential impact based on how the information is represented. In our earlier research [36], we have demonstrated the difference when 2 modeling techniques are used to represent the same patient journey from a functional matrix perspective. This paper presents a comparison of 5 process modeling techniques with a focus on supporting HIT integration into clinical practice. The results of an initial pilot study of user perceptions of the understandability of the representation of a patient journey model within which they actively participate across 5 process mapping techniques is also presented to provide support for the theoretical constructs. This research was part of a larger EMR technology adoption change management initiative at Providence Mental Health Care, Kingston, Ontario.

Background

Given the current era of technology development, there are a number of research findings that support the utilization of advancing HIT in clinical practice [2,9,37]. Although the benefits of using HIT in the health care setting have been proven to improve patient care, "adapting new information systems to health care has proven difficult, and rates of use have been limited" [38]. There are many HIT resources available, such as EMR, computerized physician order entry systems, and clinical decision support systems that enable improved patient care through timely delivery of secured patient information. However, a number of studies have identified unintended consequence to workflows as a major issue in HIT implementations [10-13,15,16]. We refer the reader to Greenhalgh's systematic review summarizing the tensions and paradoxes in EMR research results for a synopsis of this work [39].

A number of studies have examined nurses' perceptions of EMR, and more generally HIT, to understand the barriers to technology integration in health care [40-43]. These studies have found that although nurses are open to the possible benefits of EMR and HIT, they continue to have concerns about how these technologies will integrate into bedside care. Results from studies on physicians using EMR have supported similar concerns [11,39,44,45]. Many technology adoption–led change management initiatives failed to enable people in various health care roles to fully understand their future work practice behaviors. In their systematic review of HIT implementations, Cresswell and Sheikh [18] found that the implementation of HIT has been noted to have significant challenges in integrating a range of interrelated technical, social, and organizational factors necessary to fully integrate the technology with clinical practice. These challenges present opportunities for the utilization of a process modeling architecture that integrates technical, social, and organizational factors into the process modeling to convey information effectively and enabling both HIT designers and clinicians to clearly understand the proposed future work practices.

To improve patient safety and quality under increasing budget constraints, researchers in health management began to modify

business process modeling techniques from traditional manufacturing applications [9,32]. Recently, a number of studies have looked at lean approaches for process re-engineering and cost reductions [46-50]. A significant amount of research has focused on a patient-focused model to analyze problems occurring in health care [6,7,51]. Identification of such "system of care" improvements is the primary objective of PJM initiatives through a patient-centric activity that details a patient's progress through a health care system for a given service [52]. PJM aims to improve patient safety and overall health care quality by highlighting patient information flow issues and thereby aiding in the reduction of variability in the care process. The results of the analysis, combined with the provider goals, are used to derive target processes and justify change management proposals [53,54]. Creating clinical care pathway models that focus on the patient's perspective aid in the identification of potential unintended consequences of HIT implementations, as well as potential innovations related to the use of HIT at all levels of the organization. Clearly, presented models aid in identifying gaps or inefficiencies in information flow, workflows that integrate EMR, and providing visual representations of clinical practice for improved consistency in quality of care. Improving the understanding of the sociotechnical issues will facilitate communication between stakeholders. It will also increase the level of understanding of the potential consequences to workflow and communication patterns due to the HIT implementation [12,13]. Unfortunately, gaining this insight continues to become more challenging as the technological and institutional changes in health care increase the complexity of the workflows and related social interactions. These social interactions continue to be difficult to integrate within many modeling techniques [43].

Modeling of the multiple dimensions that contribute to the entire journey experienced by a patient within and across hospitals, clinics, and community health organization(s) must include the inherent complexity of their inter-relationship that influence the structure, processes, and outcomes of the service system [55,56]. Therefore, from a high-level perspective, the process of PJM is to optimize improvement of services and innovation across structural changes, process improvements, and outcome improvements simultaneously. At a more specific level, PJM provides direct opportunities for improvements and process innovation in areas such as improved information flows among all members of the health care team including the patient and their family, streamlined handovers between and across health care organizations, elimination of duplicated work and data collection, and increased compliance to organizational policies. The use of PJM also increases the level of engagement and empowerment of employees and patients through their involvement in the modeling process. The results of the analysis of the patient journey models, combined with the provider goals, are used to derive future desired processes and justify change management proposals [55,56]. By analyzing the models (both those representing the current state and those predicting the future, post-HIT implementation state), designers of HIT systems as well as practitioners can better understand the sociotechnical limitations of the organization. This is important, as it will help identify potential consequences to the clinical and administrative processes mediated by the HIT implementation. Given the complexity of the collaborative work and multiple information flows among people, information systems, documents, and organizational processes [57,58], these models provide a comprehensive view of how changes in HIT will affect existing paradigms. However, if the PJM created does not correctly reflect the current state and this is not detected by staff due to issues of model understandability, then those unrepresented activities are not included within the quality improvement or technology adoption initiative. This has great potential to lead to issues with future state implementation.

There are also a number of limitations to existing patient journey and process modeling techniques [59]. Existing models have limitations on the details that can be represented in them. There is also concern about the usability of developed models [60]. Most modeling methodologies have specific languages developed from information systems and have not been developed with novice modelers or involvement of the general public in mind [61]. The modeling methodologies each have a unique notation, which does not leverage aspects of perceptual discriminability and semantic transparency [62]. These languages are difficult for most people in an organization to understand and therefore limit the number of employees who can easily be engaged in the modeling process as well as the clarity of the developed models. To develop and easily maintain process models, it is important to engage employees at all levels, as this will significantly increase the organization's ability to identify possible innovation opportunities and improve the efficient and effectiveness of patient care.

Recently, there has been a growing interest in using visual process models for communication and as a tool to support change management initiatives in organizations [63]. Process models are also being considered for use in staff training, customer or patient information, or as teaching tools in higher education [64]. These applications require a model that is intuitive, clear, and easily understood. The models must also be comprehensive to ensure a high degree of knowledge transfer. To achieve these outcomes, the process modeling notation must exhibit a high degree of cognitive effectiveness [62]. It is the involvement of the stakeholders that supports change management and the development of lasting process innovations as they become aware of inefficiencies through the visual analysis of the process models as they are developed and refined [65].

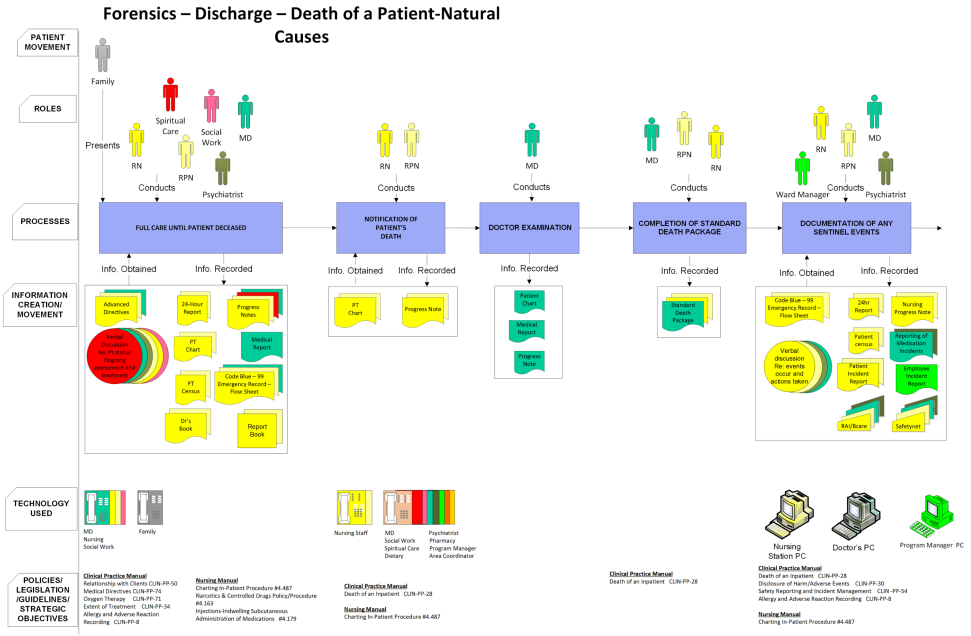
The health care environment is also quite different from manufacturing or even many other services. In particular, unlike most lean initiatives where duplication should always be eliminated, in health care, some duplication is essential for patient safety and specified in clinical protocols (eg, medication reconciliation at all handovers) [65]. Health care also tends to have a greater number of decision points due to the complexity of comorbidities. These result in data being recombined in a number of ways to support decision making throughout the patient journey. The decision-making process typically integrates a coordinated team approach making many process modeling approaches unable to adequately capture the team dynamics and role differentiation [66]. Health care also has a high level of required documentation. This increases the need to represent in the process models how information is recorded and the

standardization of this data collection [67]. Finally, it is critical that health care process models include policies and guidelines that support each process step. Capturing these data sources is critical for identifying potential process improvements and areas where HIT could be leveraged for compliance with best practice approaches [65].

The Patient Journey Modeling Architecture (PaJMa) is a patient journey modeling methodology that enables a visual representation of the interaction of processes, technologies, and people used to support a patient's experience in the health care system [9,36]. This modeling technique represents the following layers: staff roles, processes, information creation/movement, HIT, IT infrastructure, patient needs/practice guidelines/policies, and metrics [51] (refer to Figure 1 for an example). This ensures the visual integration of all the major elements in Sittig and Singh's [68] sociotechnical model for studying HIT in complex health care environments. The updated architecture also uses color coding to aid in the identification of which role is the primary user of the information source and those that are also subusers of information recorded in the information source. Color is a powerful visualization means allowing for the identification of different or similar roles and processes [69]. The use of color supports redundant coding and has been shown to reduce noise and protect the transfer of information from interpretation errors [62]. This color coding helps in the requirements gathering process by clearly identifying the roles that require access to the various set of information and at what stage in the patient journey this information is recorded, updated, or simply accessed to support decision making. Similarly, to aid in the identification of the number and types of technology resources (both input and output devices) that are required, as well as infrastructure needs, these too are color coded to indicate the individuals who use the devices. The networks that are used, whether internal to the hospital, links to external care providers, or patient homes are also color coded to aid in the specification of any security and/or infrastructure needs that would have to be considered if the process were to be altered. This is particularly important when considering many of the new eHealth initiatives to support home-based care or self-monitoring of chronic conditions.

The use of the PaJMa approach aids in visually depicting the current care processes within a particular health care unit or facility as well as the potential future state after HIT implementations. PaJMa is an effective method for pointing out inefficiencies and allowing health care professionals to work with and alter the model to benefit their practices [36]. The PaJMa model is the only model that integrates IT into the representation while enabling the explicit representation of the guidelines and/or protocols that relate to tasks within the process model and the only approach that supports patient needs.

Figure 1. PaJMa Model of Forensic Unit Discharge Process.



Methods

Comparing the PJM Methods

In Table 1, we present a comparison of key aspects of process definition required for PJM. This comparison is not meant to provide a complete functional comparison from a business process perspective, but rather to highlight some key requirements within the domain of health care.

Table 1. Comparison of patient journey modeling techniques.

Description	Data flow diagram	Flow chart	IDEF-0	Lean VSM	PaJMa
Process definition					
Definition of tasks	Yes	Yes	Yes	Yes	Yes
Decompose tasks to subtasks	Yes	Yes	Yes	Yes	Yes
Construct process model	Yes	Yes	Yes	Yes	Yes
Conditional paths	Implicit	Explicit	Implicit	Explicit	Explicit
Expected task times	No	No	No	Yes	Yes
Expected queue times	No	No	No	No	Yes
Roles					
Definition of roles	Yes	Sometimes	Yes	Yes	Yes
Roles to process definition	Yes	Sometimes	Yes	Yes	Yes
Roles to information	Explicit	No	Implicit	Implicit	Explicit
Information					
Information storage name	Yes	No	Yes	Yes	Yes
Information storage medium	No	No	No	Yes	Yes
Information access technology	No	No	No	No	*Yes*
Information network access	No	No	No	No	*Yes*
Information creation	Implicit	Implicit	Implicit	Implicit	Explicit
Information retrieval	Implicit	Implicit	Explicit	Implicit	Explicit
Guidelines and protocols					
Guideline associated with task	No	Sometimes	No	No	Yes
Patient needs					
Cultural needs associated with tasks, eg, interpreter	No	No	No	No	Yes
Religious needs associated with tasks, eg, female patient not left alone with a male health care practitioner	No	No	No	No	Yes
Metrics					
Expected task times	No	No	No	Yes	Yes
Expected queue times	No	No	No	Yes	Yes
Task cost	No	No	No	Yes	Yes
Task targets	No	No	No	Yes	Yes

The comparison is grouped based on process definition, roles, information, guidelines and protocols, patient needs, and metrics. This comparison supports the recent trend for the use of Lean Value Stream Mapping [70,71] as it shows the functional quality of the approach. However, the PaJMa model is the only model that enables the explicit representation of the guidelines and/or protocols that relate to tasks within the process model and the only approach that supports patient needs [72]. It is also the only model that integrates the technical aspects of the information systems infrastructure along with the data requirements.

Understanding the benefits that EMR can bring to the patient, health care team, and to the delivery of care is an important part of systems implementation planning. The use of patient journey models has been shown to be very beneficial in the systems requirement gathering process as it combines the perspectives and needs of all members of the health care team into a cohesive vision [36]. These diagrams are also extremely valuable to the systems development team for identifying the upgrade possibilities with the highest impact on patient care, in supporting change management initiatives, and improving user support for the EMR system [73]. Once the benefits of EMR implementation have been analyzed, the developers and health care providers must then integrate the use of EMR to clinical practice and minimize the potential for unintended consequences.

Case Study

To explore and validate the understandability of the PJM frameworks, we used a qualitative/quantitative mixed methods approach with 17 health care practitioners from the Forensics

Ward and Adult Rehabilitation Ward at Providence Mental Health Care in Kingston, Ontario. The participants consisted of the entire clinical team working on the electronic patient record initiative for the design of the organization's EMR system. The study was approved by the University of Ontario Institute of Technology research ethics board and was run at the host site as the first project under a memorandum of understanding to support the University in its teaching and research with undergraduate and graduate students in health sciences and health informatics. This is a small pilot study to support the conceptual model developed, and all results should be viewed with an understanding of this limitation.

A brief introduction to process modeling was presented to participants to give them a little background with regard to the purpose of the research and the survey instrument. The survey instrument explores 3 key aspects of the model architectures: (1) personal factors and model factors which affect the reader`s understandability of the model; (2) whether these models are sufficient for clinician understanding; and (3) the comparison between various modalities of models. The survey instrument is available from the authors on request.

A process used on the participants' unit was modeled, and models using 5 different modeling techniques were presented; data flow diagram, IDEF-0, traditional flowchart, lean, and PaJMa model. Once all 5 models were presented, the models remained visible to the participants and a survey was then conducted to collect feedback on preferences. These different models were presented to compare and contrast the differing PJM frameworks in terms of ease of understanding the process, ease of identifying their own role within the model, and overall visual aspects of the models. None of the participants had used the PaJMa or other frameworks before in their work processes, although many were familiar with flow charts.

Figures 1-4 present a matching segment of the larger process used as part of the study due to space restrictions. The standard flow chart example was not included in the paper but is available from the authors on request. Although only showing a segment, it still illustrates the functionality of each modeling technique for the purposes of reporting our research findings. The IDEF-0 (refer to Figure 2) and data flow diagram (refer to Figure 3) are techniques derived from information systems research. These techniques focus on supporting systems development but are not intuitive for novice patient journey modelers. The techniques were found to be difficult for care providers to understand, and they were found to have limited ability to incorporate key elements in understanding the patient journey such as policies, guidelines, and caregiver roles.

The participants were also asked to explain how the use of color affected their overall ranking on the models. They were then asked to focus on the PaJMa model and were provided with the same model in color and black and white to explore how color affected the perceptions on the usability of this modeling method. Participants were given the opportunity to express their rationale for selection of preferred modeling methods as well as asked to provide specific aspects of the modeling framework that contributed to ease of understanding and improved organization of the data regarding information flow in the patient journey. Figure 3 represents an example of the PaJMa model presented and the same process is mapped as a Lean Value Stream Map in Figure 4.

Figure 2. IDEF-0 Model of Forensic Unit Discharge Process.

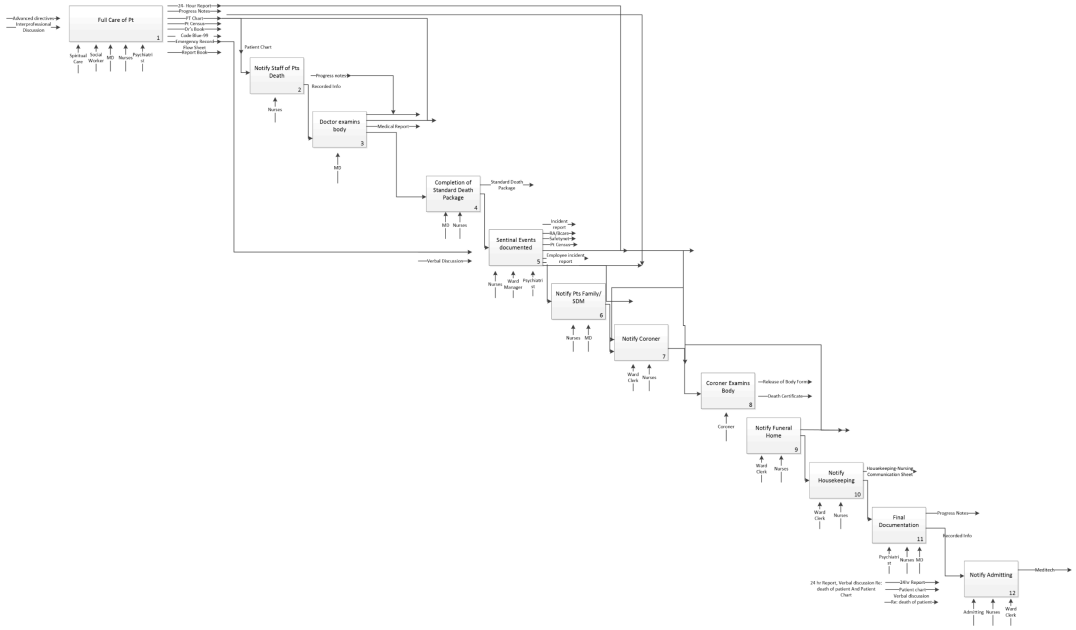


Figure 3. Data Flow Diagram of Forensic Unit Discharge Process.

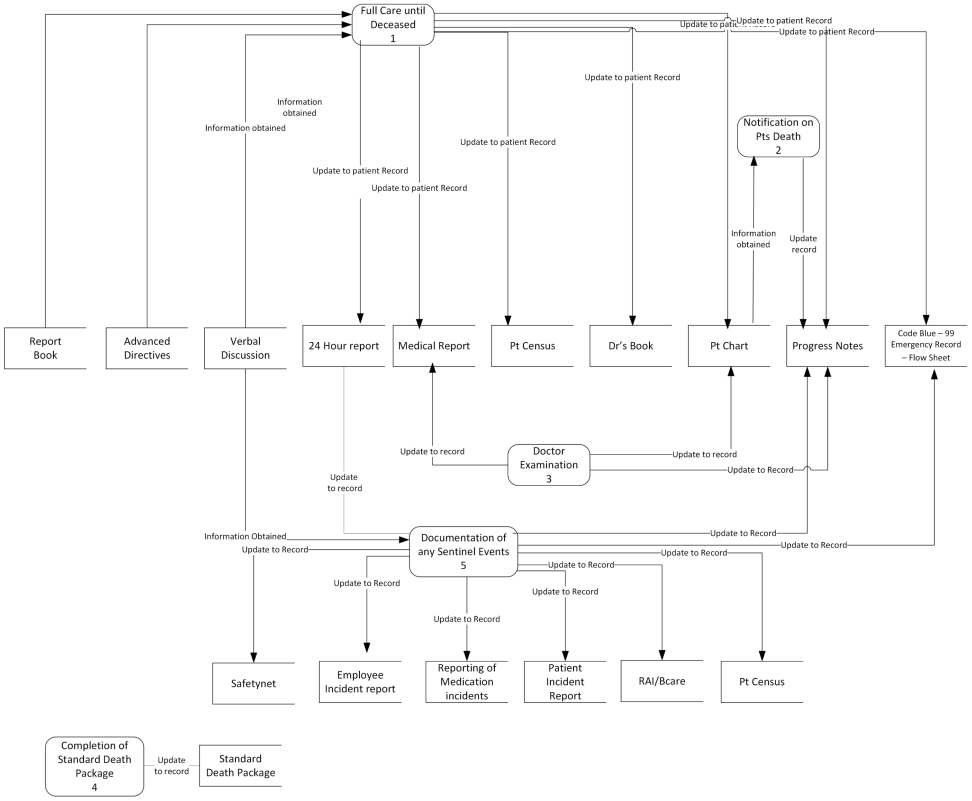
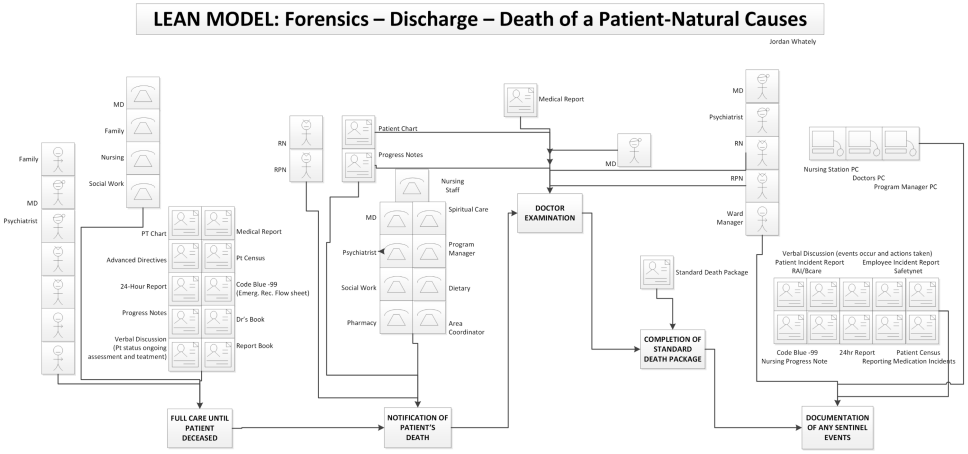


Figure 4. Lean Value Stream Map of Forensic Unit Discharge Process.



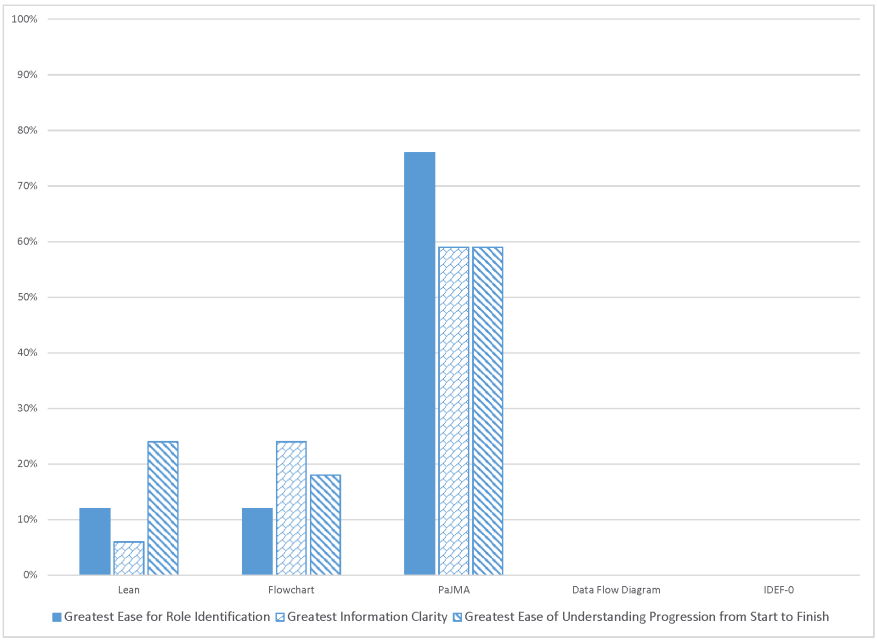
Results

The results from the survey suggest that the health care professionals understood the PaJMa model more easily than the Lean Value Stream Map that was presented. From the data, 7 (41%) of participants found the PaJMa model to be the most visually pleasing when compared with the other models with a basic flow chart next at 4 (24%) and a Lean Value Stream Map next at only 3 (18%). When we focused the analysis on role identification, information clarity, and general ease of flow progressing through the model, respondents found the PaJMa model to outperform the other options (Figure 5).

When asked about what would be important factors for using the models, 13 (76%) of participants considered the length of time working on the ward, the amount of experience with models, or both factors together as key characteristics for determining how a staff member may interpret the models being used on the wards. In addition to this, when participants were asked about factors of the model that they noticed contributed to the enhancement of the model's usability, 13 (76%) of participants mentioned the use of color in their answers. It was found that 14 (82%) of the participants favored the PaJMa model with its use of color compared with the same black and white version of the PaJMa model. Statements made included: "the colour, pictorial diagrams, layers, and explanations linked (shape and color) contributed to the usability of the model. The presentation/explanation on how to read the model and inclusion of staff was great" and "size, color, role representation, and shapes of various items used on the models contribute to the ease of interpretation." This demonstrates that color is an important, and easily implemented, element that should be

leveraged in all modeling methodologies. The results support the conclusion that the PaJMa approach has increased clarity and overall cognitive effectiveness than the other models.

Figure 5. Comparison of Ease of Use of Patient Journey Models.



Discussion

Principal Findings

Although workflow models must encompass accurate details of the processes it illustrates, it must be able to do so in a way that allows each piece of the puzzle to be distinct and discernible from one another. We found that those who participated in the survey favored the characteristics of the PaJMa model such as color, size, and the structured approach of the layout. The PaJMa model allows for current processes to be laid out as they presently are, and feedback from the stakeholders will be used to update these models to reflect the thoughts of all the stakeholders. While these models provide valuable insight into potential consequences of HIT implementations, these insights are limited by the accuracy of the models. Models that detail the current and future HIT-enabled processes, taking into account the opinions and feedback of a variety of stakeholders, are valuable tools in the design and implementation of HIT systems and eHealth services. The high level of usability and access by front-line practitioners will ensure increased adoption of the model and will support the minimization of errors, ultimately improving the understanding of all stakeholders and improving the quality of patient care.

The use of the PaJMa framework will enable health care organizations to clearly visualize how EMR, and HIT in general, can be beneficial for themselves and their patients. By developing their own unique sets of models, each organization will gain greater depth of understanding on their sociotechnical constraints including the requirements that their organizational culture and practices have for an EMR implementation. The use of this type of modeling will also support a more effective and easier implementation of HIT, as health care professionals can visualize the benefits and challenges before implementing the new technology. This will allow new practices to be developed and training of all staff to take place before the new system is implemented. The models can also serve as a process measurement tool enabling improved analysis of the benefits obtained once the implementation is complete.

Conclusions

This paper has presented preliminary assessment of the understandability of the PaJMa framework to aid in effectively integrating HIT into clinical practice through visualization of current and future patient journeys. The incorporation of EMR into clinical practices is essential to the future of health care. Not only will it increase accessibility to patient information but also will increase patient safety, support patient confidentiality, and decrease time spent reviewing and asking about a patient's health history thereby improving patient care and the sustainability of the health care system. These models help improve practitioner and HIT designer's understanding of the network of information flows and cultural relationships that shape the organization's workflow patterns. Understanding these elements has been linked [20,74] to mitigating unintended consequences of such HIT implementations.

This research demonstrated increased staff understandability of the representation of their processes and activities within the PaJMa models and higher degrees of engagement in the change process [75]. The results indicated that the modeling approach was valuable to the host organization and was of interest to the consulting company working on the development of the electronic patient record project. The PaJMa methodology is also currently being utilized as part of a HIT capacity audit across Canadian Neonatal Intensive Care Units (NICUs). Future research will look into how to adequately transform an organization to use new practice guidelines that integrate HIT and how to leverage patient journey models to support improved EMR design.

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Conflicts of Interest

None declared.

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Abbreviations

EMR: electronic medical record
HIT: health information technology
NICU: Neonatal Intensive Care Unit
PaJMa: Patient Journey Modeling Architecture

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Original Paper

Medication Management: The Macrocognitive Workflow of Older Adults With Heart Failure

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Abstract

Background: Older adults with chronic disease struggle to manage complex medication regimens. Health information technology has the potential to improve medication management, but only if it is based on a thorough understanding of the complexity of medication management workflow as it occurs in natural settings. Prior research reveals that patient work related to medication management is complex, cognitive, and collaborative. Macrocognitive processes are theorized as how people individually and collaboratively think in complex, adaptive, and messy nonlaboratory settings supported by artifacts.

Objective: The objective of this research was to describe and analyze the work of medication management by older adults with heart failure, using a macrocognitive workflow framework.

Methods: We interviewed and observed 61 older patients along with 30 informal caregivers about self-care practices including medication management. Descriptive qualitative content analysis methods were used to develop categories, subcategories, and themes about macrocognitive processes used in medication management workflow.

Results: We identified 5 high-level macrocognitive processes affecting medication management—sensemaking, planning, coordination, monitoring, and decision making—and 15 subprocesses. Data revealed workflow as occurring in a highly collaborative, fragile system of interacting people, artifacts, time, and space. Process breakdowns were common and patients had little support for macrocognitive workflow from current tools.

Conclusions: Macrocognitive processes affected medication management performance. Describing and analyzing this performance produced recommendations for technology supporting collaboration and sensemaking, decision making and problem detection, and planning and implementation.

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KEYWORDS

aged; medication therapy management; medication adherence; workflow; cognition

Introduction

For older adults with one or more chronic diseases, maintaining health typically requires continual management of complex medication regimens [1,2]. These regimens involve taking multiple drugs, each with complicated names, directions, and purposes, several times a day on differing schedules [3]. Often constrained by age, disease-related cognitive and physical decline, and having to navigate a complex health care system, it is no surprise that many do not take their medications as prescribed [4,5]. Lack of medication adherence is associated with poor outcomes, including increased rates of institutionalization, disability, and death [6-8].

Heart failure is one chronic disease with especially complex medication and lifestyle management components. Heart failure affects 5.7 million US adults and 12% of older adults; it is the leading and fastest-growing cause of death in the United States [9]. Heart failure is characterized by impairment in the heart's ability to pump and expel body fluid. Treatment involves consistent medication administration to control fluid accumulation and prevent complications [10,11]. Surprisingly, nonadherence to medications has been reported in 40% to 60% of heart failure patients [12]. Emergency room visits, hospitalizations, and the likelihood of survival are related to failing to take heart failure medications as prescribed [13-15].

Interventions to improve medication adherence have primarily involved educating and motivating the patient, with only moderate effects on short-term and little effect on long-term medication adherence [16,17]. Innovative solutions are needed, and there is interest in the potential of consumer-facing health information technology to improve heart failure medication adherence [18-20]. Health information technology (IT) developed for older adults, however, has inconsistently supported their health management needs [21-26]. Older adults using technology for health management report a lack of perceived benefit, a lack of fit to their lifestyle, and that currently available technology is cumbersome and confusing, adding to rather than reducing the effort required to manage their health [27]. According to the principles and international standards for user-centered design, the above problems can be proactively addressed by basing health IT design on an explicit understanding of users, their activities, and their contexts [28-32]. Understanding the actual work health IT is intended to support is the starting point for designing effective technology [33]. Therefore, design of health IT to effectively promote medication adherence in older adults requires a deep understanding of the work activities and work context of medication management [34,35]. We define the concepts of patient work and medication management in Textbox 1.

Textbox 1. Definitions of concepts of patient work and medication management.

- Medication management is the process of related activities enabling the optimal use of medicines to achieve maximum health benefits with minimal harm for a specific patient [36]. We avoid the term "self-management," which implies the patient acts alone.
- Patient work is the "exertion of effort and investment of time on the part of patients or family members to produce or accomplish something" [37]. Health-related patient work bears some similarity to paid professional work (eg, assessing symptoms, wound care) but includes unique tasks such as coping with disease progression, scheduling appointments, managing health finances, and preparing diet-appropriate meals [35,38]. Patients also engage in collaborative work, in which either the patient or family member and at least one health care professional are active participants (eg, in-visit communication and shared decision making) [39].

Prior research reveals that the patient work process related to medication management is complex, cognitive, and collaborative, rather than the linear execution of simple, standard tasks. Sensemaking, defined as the deliberate, continuous effort to understand relationships between people, places, and events in order to anticipate their path on which to base actions, is a foundational medication management activity [37] and is essential to chronic disease management [40]. Other medication management processes identified in prior research include tracking, collaborating, ordering, and organizing [38]. In the case of heart failure, some define patients' self-care (including medication management) as a process of naturalistic decision-making involving situation awareness, mental simulation, and outcome evaluation in the face of uncertainty, ambiguity, and time pressure [39]. Research on health IT functionality has described medication management activities as seeking information, maintaining autonomy, reconciling medications across multiple clinicians [1,41], planning, and creating reminders [42-44]. Nevertheless, these cognitive processes of medication management have not been studied simultaneously in a single group of patients. This has precluded an integrated, systematic categorization and modeling of cognition in medication management in its full complexity. Furthermore, to design effective tools and technologies for older adults with heart failure, it is necessary to understand the unique cognitive workflow of heart failure medication management as it occurs in actual practice.

Our objective is to describe and analyze the work process of medication management by older adults with heart failure, using a macrocognitive workflow framework to adequately capture the complexity of medication management work. Our research framework extends the Workflow Elements Model [45], which portrays workflow as a set of continually evolving and changing processes. Workflow can be planned, routine, and sequential but often emerges based on situational factors and interaction between workflow elements. Those elements are *actions*, performed by *actors* using *artifacts*, producing *outcomes*, supported or constrained by the secondary elements of *context* (ie, physical, social, cultural environments), *timing* (ie, scheduling and coordination), and *aggregation* (ie, interactions, combinations). Our study expanded the model to better operationalize the actions component of the model as a set of macrocognitive processes, such as sensemaking, replanning, coordinating, problem detecting, and deciding [46,47]. Macrocognitive processes are "the collection of cognitive

processes that characterize how people think in natural settings" [48]. Macrocognition is explicitly theorized as the type of cognition occurring in complex, adaptive, and messy nonlaboratory settings and can be accomplished by multiple people and supporting artifacts [46]. Thus, combining the Workflow Elements Model with macrocognitive processes facilitates the study of "workflow in the wild" rather than "workflow in a textbook."

Methods

During 2012-2014, we performed a study on the self-care of older adults with heart failure. A sample of 61 patients was enrolled in the study and 31 informal caregivers consented to participate in patient interviews, at times multiple per patient. Caregivers often answered questions or added to patients' answers. Patients and, if present, caregivers were observed during clinic visits and at home and participated in either an extended interview lasting 90-120 minutes or in a short 30-minute interview followed by a longer 90-minute interview. Data from electronic medical records and self-administered standardized patient surveys with a 97% response rate provided additional data. Interviews were semistructured and probed about the actors, artifacts, actions, outcomes, and context of heart failure self-care in general, and of medication management in particular. Interviews were structured on a model parallel to the Workflow Elements Model, namely the Systems Engineering Initiative for Patient Safety (SEIPS) 2.0 model [39], which includes: people; tasks; tools/technologies; social, physical, and organizational context; physical, cognitive, and social processes; and outcomes. A separate subset of questions was asked of each participant, including questions about the perceived efficacy and side effects of medications, medication errors, and medication management tasks such as refills.

Patient participants were aged 65 years or older and lived in a 200-mile radius of Nashville, Tennessee, USA. Half of them were recruited from an outpatient cardiology clinic specializing in heart failure, while the rest comprised discharged patients diagnosed with acute heart failure. Participants (caregivers and patients) provided informed consent and only patients received up to US $65 for participation, to use or split as they wished. The study was approved by the Vanderbilt University Institutional Review Board and Human Research Protection Program. Detailed descriptions of sampling plans and data collection methods are reported elsewhere [38].

Analysis organized findings and major themes into the core elements of the Workflow Elements Model, focusing primarily on the actions (process) element. Within the actions element, data were analyzed according to 5 macrocognitive processes: sensemaking, planning, monitoring, decision making, and coordinating [47,49]. The specific data analysis method was descriptive qualitative content analysis with iterative category development [50]. This method systematically derives trends, patterns, and themes from large amounts of textual data, revealing the underlying meaning [51]. During first-pass structural coding [52], researchers RSM and RJH identified broad passages of data mentioning the management of medications as defined previously. In the second-pass analysis, author RSM assigned initial thematic codes related to broader categories of macrocognitive processes. Definitions of macrocognitive process were based on those established by Patterson and Hoffman [47] and Crandall et al [49]. Next, macrocognitive subprocess categories were iteratively identified using constant comparison [53], after which they were compared to definitions from an extensive review of the macrocognition literature (Table 2), with the final categories adapted to fit macrocognitive processes found in the data. Analysis memos documenting category development decisions were kept throughout this process [50]. Themes within and across categories were noted, for example, describing how macrocognitive processes were related or how a subprocess could break down. Authors RSM, RJH, and KMU met approximately every 2 weeks for a 10-month period to discuss coding and category development; coding exemplars in the form of quotation tables for categories and subcategories was one of the things discussed. Such coding discussions are a proven technique for facilitating analytic convergence among multiple coders [54,55] but in our single-coder arrangement contributed to conceptual clarity and corrections of coding errors.

Results

Participants

Table 1 describes patient participant demographic characteristics, caregiver support, and living arrangements.

Overview

Medication management involved far more than administering pills on time, opening bottles, or binary decision making on whether to take a medication. Behind individual tasks were a host of interacting cognitive processes, promoting a holistic understanding of what patients and caregivers need to do to manage medications in real world situations. Managing medications and the outcomes thereof involved a complex, interacting, and interdependent flow of actors performing actions enabled by artifacts (Figure 1).

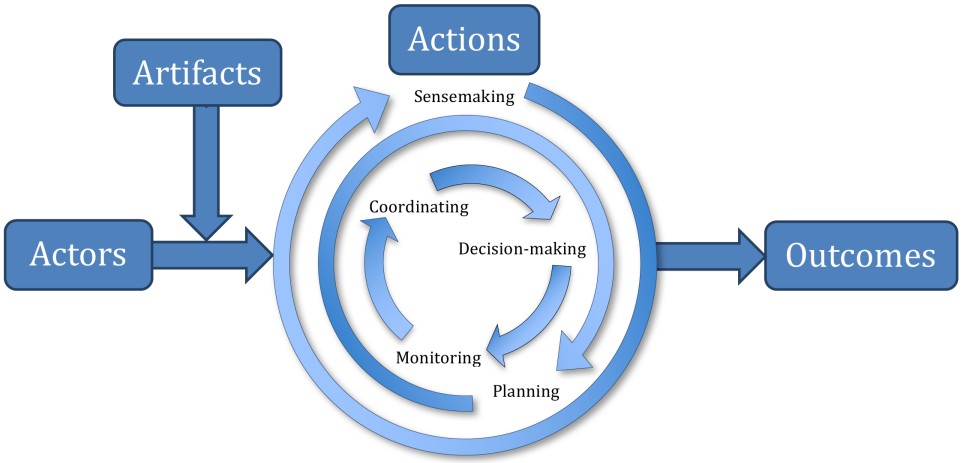
Our focus, the actions element of the Workflow Elements Model, and other elements are briefly described in the following sections.

Table 1. Patient demographics (N=61).

Demographic variables	% or mean (SD)
Age 65-86 years, mean (SD)	73.31 (6.73)
Male gender, n (%)	31 (51)
White race, n (%)	45 (74)
Annual income in US $, (n=56), n (%)	
<25,000	19 (34)
25,000-49,000	18 (32)
50,000-99.999	14 (25)
≥100,000	5 (9)
Reported years since heart failure diagnosis (n=52), n (%)	
<1	14 (27)
2-9	24 (46)
≥10	14 (27)
No. of medications 3-34, mean (SD)	16.9 (5.53)
Comorbidities[a]	
Hyperlipidemia	50 (82)
Hypertension	55 (90)
Diabetes Mellitus	37 (60)
Caregiver support, n (%)	
None	32 (52)
Spouse	18 (30)
Adult child or children	11 (18)
Living arrangements, n (%)	
Alone	19 (31)
With spouse	33 (54)
With sibling	7 (11)
With adult child or children	1 (2)
With grandchild	1 (2)
Other assistance, n (%)	
Assisted living	5 (8)
Home health	7 (11)
Retired, n (%)	55 (90)

[a]Commonly associated with congestive heart failure, not intended to be a list of all comorbidities of patients in our sample.

Figure 1. The macrocognitive workflow of medication management (adapted from the Workflow Elements model [45]).

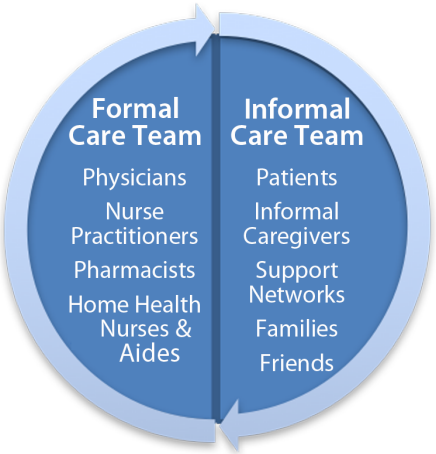


Actors

A variety of laypersons and health care professionals participated alongside the patient in medication management activities (Figure 2). Informal caregivers, if present, included spouses, adult children, friends, and grandchildren. Their help was dynamic, far-reaching, and varied based on their availability and the needs and desires of the patient. The son of an 85-year-old woman explained how the family administered his mother's medications: "It started out my sister did it primarily. Then she showed me, and then mom just wanted to do it herself sometimes, but we check." Assistance sometimes included sharing medications. An 85-year-old man expressed comfort knowing "my sister has some of the same medicine that I take...I can borrow some from there." Informal team members varied widely in skills, abilities, knowledge, and motivation.

The number of health care professionals comprising the formal team varied with the patient's condition, comorbidities, and need for home health services. These individuals assisted the patient in a variety of clinical and nonclinical settings. Clinicians who prescribed medications included nurse practitioners specializing in heart failure and physicians with specialties in primary care, cardiology, endocrinology, nephrology, neurology, and pulmonology. Some patients received medication-related assistance in their homes or assisted-living facility from nurses and aides. A 65-year-old patient described not having to leave her home for a blood test to determine the dose of a medication: "It helps me a lot when the home health nurse can come and do my INR (coagulation test) ...and then, she calls that into the Coumadin clinic." Pharmacists also assisted patients. An 81-year-old patient consulted his pharmacist when his blood pressure was high: "He (pharmacist) said, well now it should've gone down, but he says Norvasc is a tricky medicine, it may take it 3 hours to go down, but it will finally go down."

Figure 2. The actors constituting the formal and informal care teams.



Textbox 2. Artifacts used by older adults with heart failure.

(1) Patients and informal caregivers used tools for monitoring and measurement (eg, blood pressure cuffs, scales), tracking and communication (eg, vital sign logs, medication lists, online patient portals), organizing administration (eg, pill organizers, baskets), and gathering information (eg, Internet, books, brochures). Many patients (37/61, 61%) used pill organizers to decrease the effort of managing multiple medications and reduce the possibility of error. Some patients and informal caregivers used an online patient portal (20/61,33%) provided by their medical center and found the portal useful for communicating with health care professionals about refills and other needs.

(2) These tools did not always adequately support medication management activities. For example, some patients adapted medication lists received from the clinic. The son of an 84-year-old patient explained why his mother used an old medication list:

And sometimes there's been a print out from them (clinic) around, but somehow or another this is just the one we have been using. Particularly because it will also help by telling me what it's for (referring to hand-written annotations on purpose of each medication).

(3) Personal devices including blood pressure cuffs used by some patients were originally designed for clinical use and patients and informal caregivers did not always understand the meaning of the raw numerical output. For example, a 68-year-old patient described his blood pressure reading to his nurse practitioner: "Well, let's see, the other night I was sitting there resting and it was good. I believe it checked it, I checked it, it was, uh, 198 over 136."

(4) Multiple medication representations (eg, medications, prescription labels, numerous medication lists, electronic health record lists) were difficult to reconcile across care settings. For example, a 65-year-old patient could not remember the name of a prescribed medication, but knew its timing and appearance: "I have to take it twice a day, it's supposed to be three times, I take it twice a day. It's orange and kind of brown."

Artifacts

Artifacts—tools and technologies—facilitated patients' medication management. We have previously described the artifacts used by heart failure patients in this study [56]. Textbox 2 summarizes these findings [56].

Actions

For ease of presentation, we describe medication management actions in categories of discrete macrocognitive processes in Table 2. However, these processes interacted, overlapped, and were alternatively concurrent and sequential. For instance, when a patient gathered information about a medication (a subprocess of sensemaking), decision-making and planning were likely also taking place. Table 2 defines the macrocognitive processes and subprocesses reported in this study.

Sensemaking

Sensemaking actions described by participants were retrospective, deliberate processes that integrated new information into existing understanding to guide future action. Sensemaking processes were foundational, contributing to all macrocognitive processes.

Due to the continuous flux in patients' health and medication regimens, punctuated by various health-related events (eg, hospitalization, new prescription), participants perpetually searched for meaning and causal explanations by gathering information, adapting mental models, and storybuilding.

Information gathering occurred across actors, locations, and time. During clinical visits, most of the questions from observed participants were about verifying or executing an existing medication plan. They asked questions such as: "How many do I take? " [65-year-old male], "You sent her refill in, didn't you?" [daughter of 74-year-old female], and "Can I have a dental exam (while on an anticoagulant)?" [65-year-old male]. These questions implied a concern for "what do I do" more than "why do I do it." Many patients (46/61, 75%) also gathered medication information from sources outside the clinical setting (Table 3). Reasons for gathering additional information included (1) a new diagnosis requiring medications, (2) an upcoming procedure, (3) a change in the medication regimen, (4) questioning the validity of medication choices made by clinicians, and (5) uncertainty or anxiety. Participants commonly gathered information from laypersons such as family, friends, or support groups. They sometimes shared this social network-sourced information with clinicians. A 65-year-old patient suggested to his physician: "So, one of my friends said well maybe you just need a, a pap, what do you call it? Pa-, Paxil, is it?" Participants who mentioned Internet or television information viewed it as valid and authoritative but had difficulty filtering and prioritizing it.

Table 2. Medication management process and subprocess definitions.

Process	Subprocess	Definition
Sensemaking		Deliberate, retrospective efforts to understand and explain events typically triggered by a change [57].
	Information gathering	Exploratory activities to "gather, differentiate, interpret, evaluate, and aggregate" information from sources [58].
	Adapting mental models	Reframing internal representations (how things work, mechanisms) on which to base future actions and expectations [59,60].
	Storybuilding	The process of constructing narratives (stories, scripts, schema) to infer how a current situation might have evolved from an earlier state [61].
Planning		Generating and adapting methods for action to transform current state into desired future state [49].
	Generating plans of action	Generating options for methods by balancing available resources and existing constraints to achieve a specific goal [62].
	Adapting plans	Responding to changes in goals from a variety of sources such as peers, constraints, opportunities, events, or changes in anticipated plan trajectories [47].
	Anticipatory thinking	Preparing to respond to constraints, contingencies, and opportunities that could be encountered while implementing a plan [62,63].
Monitoring		Maintaining awareness of system state; to observe and check the progress or quality of (something) over a period of time; keep under systematic review [64].
	Problem detection	Noticing when events may be taking an unexpected direction [47].
	Tracking	A control process that follows the course or progress of something to keep the system within safe and acceptable levels of performance [65].
Decision making		Commitment to one or more options or actions [47,66].
	Applying rules	Using a prescribed, explicit, and understood regulation as a guide for conduct or action [64].
	Pattern matching	Matching the circumstances of the present situation to similar events and clusters of cues from the past [63].
	Mental simulation	Imagining how a decision will play out [67].
	Making trade-offs	Losing one quality or aspect of something in return for gaining another quality or aspect [68].
Coordinating		Managing interdependencies across members of a team with overlapping, common, and interacting activities, roles, and possible conflicting goals [47,69].
	Reconciling information	The process of bringing information or understanding into agreement (ie, maintaining common ground) [69].
	Managing interdependencies	Managing the mutual reliance and dependencies between elements of a system [69].
	Negotiating	Coordinating competing roles, goals and plans in the "give and take" process by which team members agree on a common issue or solution [70].

Table 3. Information sources outside of the clinical setting (n=61).

Information source	%	Information type
Medical Center Portal (n=20)	33	laboratory tests, diagnostic tests, clinical summaries, lists of current medication regimen
Internet (n=25)	41	websites with health, disease, and medication information
Television (n=5)	17	commercials, TV shows (eg, Dr. Oz)
Educational print materials (n=14)	23	medical books, medical brochures, information booklets
Educational classes (n=2)	3	organized diabetes, heart failure instruction
Prescription inserts (n=6)	10	medication indications, dosing, side effects, special instructions
Family, friends, support groups (n=27)	44	shared personal advice, experience, knowledge

Participants synthesized gathered information with previous experiences and current knowledge by adapting mental models or their personal understanding of "how things work." To illustrate, a 75-year-old patient revealed not taking her medications because she perceived they had no effects on her health, and did not like taking "so many" medications. She explained that after a hospitalization and conversation with her physician, she revised her mental model to view medications as similar to vitamins: "Medication is a form of preparation, you know, and builds your system up to fight off what may come in the future." After this mental model revision and a reduction in the number of daily medications prescribed by her physician, she subsequently began to take her medications regularly.

At times, participants developed inaccurate mental models, especially regarding functional or causal relationships between body systems, medications, and health events. A 75-year-old female patient contended, "I don't have no heart failure medicine. I only have blood pressure medicine." Several participants had difficulty connecting fluid retention to heart functioning. An 85-year-old female patient elaborated, "I don't think it's (fluid) in the ankles or the hands or anything like that. I think it's the fluid in the heart area that would make the heart beat less."

Table 4 gives examples of participants' descriptions of causal factors contributing to past health events.

Table 4. Example causes of health events described by patients and informal caregivers.

Cause	Quotes
Prescribing decisions	The rejection (heart transplant) and it was due to their neglecting, negligence of not resuming my appropriate therapeutic level of Procrit, my medication. [68-year-old male patient]
	They gave him an overdose of it (Lasix). [wife of 72-year-old patient on why her husband experienced kidney failure]
	My hair has fell out because they took me off my medicine. [65-year-old female patient]
Medications	Yeah, that's (medication) what made me mean. I kicked a t-, a tray out of the nurse's hands and stuff like that when I was in the, in the rehab. [78-year-old male patient]
	Well, all the other times, you know, I'd never had it (diabetes)... Some of the medication that they put me on would cause high sugar. [68-year-old male patient]
Procedures	Okay. Yeah, um, I think most of my health problems came after an open-heart operation, mitral valve repair in late 2001. [81-year-old male patient]
	Some of his memory problems...but he was put to sleep four times in two months and that really isn't very good. [wife of 81-year-old male patient]
Genetics	It's certain things and this is a genetical (sic) thing with a black man's diet and a white man's diet. See, uh, we grew up on pork that's the worst meat you can eat. Pork, half dog, half rat, half, and they eat anything, you understand? [67-year-old male patient explaining the cause of his high blood pressure]
Comorbidities	I think it (stroke) take a toll on my heart... That is why I have a pacemaker. [79-year-old male patient]
Symptoms	So I think all that pain and all may have caused heart trouble. I don't know. [74-year-old male patient]
Environment	That portion of when I look back now was a lot of just losing my breath, shortness of breath and all, came from the room fresheners. [68-year-old male patient]

Storybuilding was a subprocess that enabled the creating and updating of mental models as well as organizing information and communicating one's mental model to others. A 69-year-old patient retold the story behind her pacemaker insertion:

> *I was seeing a doctor and he had increased my medicine, Coreg, and the more he increased it the less my heart functioned so that's when they decided they had to...so I came back, I moved my mother, came back down here and, um, uh a doctor put in my pacemaker.*

In summary, patient and informal caregiver sensemaking (1) combined information gathered from multiple sources including sources outside health care settings and past experience, (2) developed causal models for health events, and (3) produced new or revised mental models often expressed in personal stories.

Planning

Planning was the practical, prospective translation of instructions into implementable actions under known constraints, with the goal of achieving a desired future state. Generating plans of action provided the "how" of performing generic instructions such as "take Lasix three times a day" in practice.

Participants expressed planning as an ambiguous process not well supported by their formal care team. A 74-year-old male patient described the lack of guidance for planning: "There's, there's not a, you know there's not a magic list of instructions that they lay out." A recently discharged 65-year-old patient similarly conveyed the lack of guidance after her hospitalization: "When you go home, you're kinda on your own. You're kinda flyin by the seat of your britches."

As participants recognized changes in symptoms, medication regimen, available resources, and existing constraints, they were continually adapting plans. To exemplify, a 66-year-old patient explained how mixing up 2 look-a-like medications resulted in an adverse drug reaction; consequently, he planned to break a newly prescribed medication in half to distinguish it from other pills. As in this case, action plans often arose from new awareness of constraints (look-a-like medications) based on

feedback from implementing a prior plan (adverse drug event). After experiencing severe shortness of breath that led to a hospitalization, an 84-year-old patient decided weight was not a sensitive indicator in detecting fluid retention. He instead planned to use a pulse oximeter to dose his conditional diuretic. He observed nurses using the device in the hospital and saw other patients with the device in the clinic waiting room. Although not directed by his clinicians to use the device, he explained his rationale:

> *No, no one told me, but I know what happens when you don't have enough oxygen... I don't take any chances. When my oxygen gets down and doesn't come above 96, 95 or 96, I, I consider that a, uh, uh, a push a go button to do something.*

This plan, however, was potentially unsafe and may have resulted in the diuretic overuse and resultant kidney damage.

Planning and replanning often created new routines and leveraged known resources such as pillboxes [56] or a patient's "self-care workspace" [71].

> *You can put the daily dose in each (pillbox compartment) in advance so you don't overlook it. Because trying to open half a dozen containers twice a day, is impossible* [81-year-old male patient]
>
> *So it's all right there when he sits at the table where he can get to everything and that makes a difference too. You know that reminds him to do it.* [Daughter of 80-year-old patient]

Anticipatory thinking aided planning; projecting into the future possible consequences, constraints, and opportunities that might be encountered when implementing a plan. A 70-year-old patient explained a strategy he created in anticipation of forgetting whether he took his insulin:

> *I've le- got a system for that now too anyway... I keep all, it takes ten syringes out of the little bag and I put them in, with the rest of my in-, with my insulin and stuff and if, if I've got an even amount that means I haven't taken the morning one, but if I s-, if later on if I've got an odd amount it means I didn't take that evening medicine.*

Participants placed high value on planning as a method to cope with uncertainty and anxiety. A 67-year- old patient emphasized the importance of filling pillboxes weekly to assure she did not forget to take her medications: "I don't, I don't forget that. That's my lifeline. How do you forget your lifeline?" This and other observations illustrate planning as a method of control over complex medication management requirements.

Monitoring

Monitoring involved what participants called "listening" or "watching" for changes. Endsley [72] and other researchers have previously described this concept as maintaining situation awareness, defined as perceiving the current state, interpreting its meaning, and projecting the future. Problem detection occurred when a participant noticed something wrong with the current state whereas tracking occurred as people followed data over time to identify patterns and trends indicating a potential future problem. To illustrate the distinction, noticing that a medication bottle was empty involved problem detection, while documenting medication refill dates involved tracking.

Problem detection required "noticing" an anomaly, yet many participants described difficulty in distinguishing between symptoms and the effects of medications. A 68-year-old patient recounted an instance of this confusion when she forgot to take a morning medication: "I really didn't feel you know that bad. Um, of course it could have been one of those days I was feeling not that good anyway." Not understanding the expected effects of medications compounded ambiguity, as did the lack of perceivable problem cues. Patients developed their own cues based on experience. Many patients (26/61, 43%) created a personal "sign" of fluid retention. A 68-year-old woman described hers: "I knew the signs of my congestive heart failure, and which mine is, I might get a little smother some and my irregular heartbeat and a little bit of discomfort in my chest." An 83-year-old retired physician shared his: "(It is) how much trouble I have getting in my pickup truck. If I'm short of breath after I do that, then, I know that I'm in failure."

Detecting medication administration problems such as forgetting or mixing up medications was important but unlike symptom detection, did not benefit from personal warning signs. Some participants recalled instances when they forgot or took the wrong medication and were not aware until the next administration time. A 68-year-old male patient recounted: "I opened up the little box for my morning pills, the (bedtime) pills were still in there." Some participants questioned the appropriateness of medication prescriptions and went to the Internet to "follow behind" and "check if it's right" or validated with other clinicians to verify if the right medication was prescribed.

Compared with problem detection, tracking was a longer-term, forward-looking function. Some information that participants tracked was very specific. One patient kept a list of medications he could not tolerate to assure an unknowing clinician did not prescribe them in the future. Another patient tracked refill information (eg, prescription number, ordering clinician, refill date) in a self-made chart. Two patients documented when they administered an as-needed diuretic on their vital sign logs to prevent over-administering the medication. One patient tracked the cost of her medications at various pharmacies and switched pharmacies to avoid going into the "doughnut hole," a maximum yearly limit imposed by the Medicare insurance plan. Patients and caregivers also tracked information in a less purposeful manner or "just in case" it was needed. Some stored all the documents they received from their clinicians or hospital discharges. Information was also tracked as stories, adding to either an individual or shared narrative, as illustrated by the following piecing together of a medication misadventure by a 74-year-old patient, her husband, and a nurse practitioner (NP):

> *Husband: Well now, they give her, I can't even think. He give her one, one time, but that put her back in the hospital... It, it was just a little pill, but...*
>
> *Patient: I lost my arms and legs, the use of 'em. I don't know how many times he's had to get up and pick me up. I, it was once a week.*

NP: I think I remember that.

Patient: What doctor was it? Do you remember?

Husband: That one that shocked her heart... It was just four milligram. We took it once a week, but man, it put her down.

Some participants assumed the electronic health record tracked their medical information and therefore they did not need to track this information themselves. A 65-year-old patient did not bring a copy of her medication list or the medications themselves to her cardiology appointment and dismissed the need: "They always just get it off there (electronic health record). Nothing has changed." However, during the appointment several medication discrepancies were discovered.

Decision Making

Decision-making processes resulted in a variety of decisions, including calling a clinician, taking or skipping a medication, or modifying behavior (eg, diet). Table 5 provides examples of how participants made decisions involving potential fluid retention, indicated by swelling or sudden weight gain. Some medication management problems had solutions prespecified by a clinician and could be solved by applying rules for the appropriate situation. Some patients (12/61, 20%) had a clinician-provided rule to take an as-needed diuretic when their weight exceeded a threshold value. These rules were helpful but not all patients received rules and some had rules they did not follow. Participants also often established their own rules and decision-making criteria based on their own or others' experiences. For example, a patient did not begin taking a medication his primary care physician prescribed until he spoke to his cardiologist; this rule stemmed from a negative experience with a nonspecialist prescribing cardiac medications in the past.

Table 5. Medication decision making for fluid retention.

Process	Decision	Quote
Applying rules	Call clinician	I mean I have instructions from (clinician) if your weight goes up this much in two or three days call me. [74-year-old male patient]
Gathering information	Delay	And it was, it (blood pressure) was an hour earlier, the difference in a hour uh so I take it again if it was, seemed to be off. [80-year-old male patient]
Pattern matching	Seek assistance	So, I monitor that (weight) fairly carefully. If it goes up, I usually call and say, "What do I do now, daddy?" [80-year-old male patient]
	Use familiar action	I just take an aspirin (for shortness of breath), or I take some Tylenol. [83-year-old female patient]
	Do only as instructed	They said to check it (blood oxygenation) and if it's a certain level then it's okay. But then when it's not, you know they said let, you know write it down. [wife of 70-year-old patient]
	Use a familiar action for a similar symptom	I used to have childhood asthma, occasionally I'll wake up at night with a slightly asthmatic tight feeling and sort of I'll walk it off. [81-year-old male patient, describing his response to heart failure symptoms]
Making trade-offs	Prioritize medication goals	I just stayed home, you know. There was no (bladder) control at all. [80-year-old male patient]
	Prioritize personal goals	So I didn't take it (medication) then for several days in a week or two-week time... I didn't want to be, uh, be stopping on the road every fifteen minutes. [67-year-old male patient]

Participants sometimes utilized pattern matching. The husband of a 65-year-old patient explained how his wife (wrongly) matched her usual solution for coughing to her shortness of breath from fluid retention: "I'll tell you what she does when she had, is having a problem breathing... She's got on these menthol cough drops... and sometimes she'll take up to ten or eleven of them." Participants also used mental simulation in making decisions. An 83-year-old man responsible for the care of his debilitated wife did not contact a clinician when he experienced shortness of breath because he imagined it would result in hospitalization and consequently leave his wife unattended.

Making trade-offs was a decision making subprocess that occurred when participants confronted conflicting goals and unclear solutions.

I ended up having blood in the urine and this, this, well this creates a problem so, you know, you talk to them and they say drink lots of water, a lot of liquids, you know. Well I drink lots of water, a lot of liquids and what happened is it didn't stop bleeding right away but it sure filled me up with water. I couldn't breathe and I mean I had a heck of a time. [74-year-old patient]

Participant trade-offs sometimes involved going against medical advice. A compromised kidney function required the physician to discontinue a 74-year-old patient's gout medication. During an acute gout attack, however, she took the discontinued medication, "They (physicians) took my gout medicine away from me and I told (husband), I said you just get that right back... I said if you don't want to give it to me, I'll take it from myself and so, so I did."

Coordinating

Due to the distributed nature of the patient care team, coordinating information and activities across locations, actors, artifacts, and time required continual effort. Coordinating enabled and constrained other macrocognitive processes. Reconciling information brought actors and artifacts into agreement by updating one another and identifying

discrepancies. For example, an 85-year-old patient described reconciling new medication information with his informal caregiver and a medication artifact: "(when) I know they've changed my prescription, I make a note and call her (daughter) and tell her so she put it on her list and I write on my top (of pill bottle)." During clinic visits, medical assistants reconciled the electronic health record medication list with the patient's paper list, prescription bottles, or memory. Discrepancies were common and not all information was reconciled or shared. An 81-year-old patient stopped taking medications when he traveled but "never discussed it" with his physician. Coordination breakdowns at times stemmed from not reconciling clinician provided information with a patient's understanding. A good illustration was a 65-year-old man being unaware he recently suffered a heart attack based on information he received at the hospital: "It (heart attack diagnosis) was a surprise cause it, they (just) told me, they told me my enzymes was elevated."

Coordination was also accomplished by managing interdependencies (actions and information) between care team members across time and space. Timing of clinical appointments often depended on the availability of a family member to drive. A pending surgical procedure required an 81-year-old patient to inquire with his cardiologist about when to discontinue an anticoagulant: "They (surgeon) want to know what I need to do about getting the okay to stop the Coumadin." Participants did not always manage interdependencies effectively. There were many examples of communication breakdowns between care team members. In one example, a 72-year-old woman received the wrong medication from the pharmacy after a hospital discharge. Her frustrated daughter explained, "She (pharmacist) said well they faxed it in, but you still got some on the other one so they ain't never filled that new prescription that he (physician) called."

Coordination also required negotiating roles, treatment plans, and medication goals. A simple example of role negotiation was the wife of a 74-year-old patient informing the cardiologist she did not need him to refill prescriptions: "I'll just get him (primary care physician) to do all of his prescriptions." Roles were also dynamically negotiated between patients and family members. When asked who was responsible for administering her medications, an 85-year-old patient stated, "Well everybody is really. If sometimes, you know I usually get it (medications) myself, but sometimes I'm just so tired I'll ask (for help)." Patients negotiated medication regimens with their clinicians. A patient who did not like swallowing pills negotiated with her cardiologist to decrease the number of daily pills from 8 to 4. In contrast, some participants omitted, decreased, or increased medication doses without coordinating or communicating with health care professionals. The son of a 79-year-old patient described the medication "tinkering" practice of his father: "He likes to play doctor for himself you know."

Outcomes

The interactions between macrocognitive processes and other elements of the medication management system produced successful and unsuccessful outcomes. Textbox 3 and Figure 3 present a patient scenario illustrating macrocognitive processes and their relationships to outcomes based on one participant narrative.

Textbox 3. Scenario of medication management outcomes.

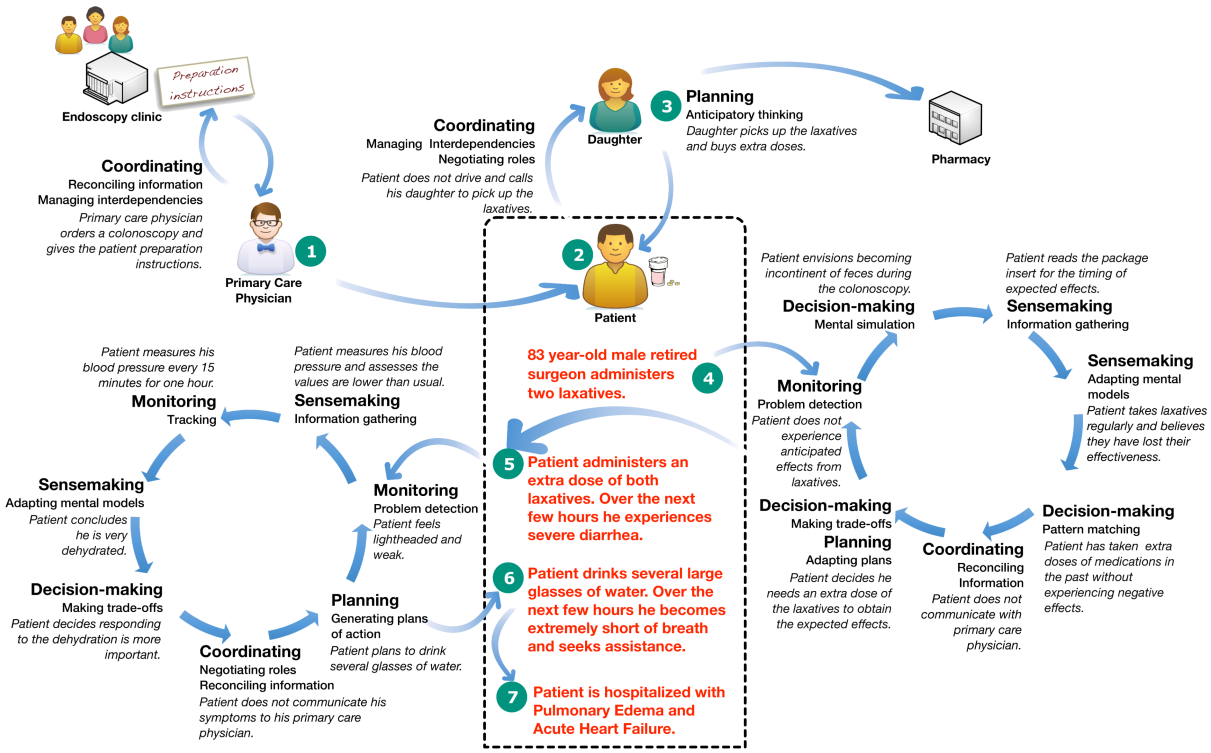
An 83-year-old retired surgeon is scheduled for a routine colonoscopy. Written instructions from the endoscopy clinic are given to him by his primary care physician and instruct him to administer a combination of laxatives the day before the procedure.

The patient self-administered the laxatives in the morning the day before the procedure. He was anxious about the colonoscopy because he occasionally was incontinent of feces. He did not want to have an accident during the procedure.

Hours after the administration of the laxative, he perceived no effect. He decided to administer an extra dose of the laxatives. Later he experienced a large amount of diarrhea and became lightheaded. He perceived himself to be dehydrated and drank several large glasses of water.

Several hours after drinking the water, he became extremely short of breath. He called for assistance from the assisted-living facility he lived in. When she saw the patient, the medical assistant immediately called an ambulance. The patient was admitted to the hospital for pulmonary edema and acute heart failure.

Figure 3. Patient macrocognitive workflow scenario.



Discussion

Expanded Framework

Expanding the scope and frame of patient medication management uncovered insights into previously unexplored cognitive processes underlying performance. Broadening this lens confirmed the complex, cognitive, and collaborative nature of medication management workflow suggested by previous research. This analysis also provided new insights and implications for design of medication management tools and technologies, summarized in Table 6.

Examining processes at a level above individual microcognition allowed for a theoretical expansion of the actions element of Workflow Elements Model (Figure 1). A limitation of that and other workflow and work system models [45,73,74] has been their vague depiction of process (eg, care vs noncare; cognitive, physical, or social-behavioral). Here, actions generically called "cognitive processes" in the past were systematically broken down into distinct functional processes and subprocesses.

Applying the expanded framework to heart failure medication management, we found that these cognitive processes were collaborative, with patients, informal caregivers, and clinicians all serving key roles in care [1,75,76]. Such findings further blur the lines between what is considered patient work versus the work of health professionals, especially as new technologies support patients in carrying out health work previously performed only by health professionals. Researchers now insist that patients and professionals are coproducers of care [77] and perform collaborative patient-professional work [39]. However, we found here and elsewhere [56] that patients and informal caregivers lacked the tools to support collaborative workflow around medication management both within households and across other settings (patient's home, caregiver's home, clinic). In addition, patients were not always willing to collaborate with formal caregivers and withheld information or made critical decisions without conferring with them. Openness to enhanced collaboration and communication will require a paradigm shift in the minds of formal and informal team members [77].

Based on the present analysis and prior research, we discuss 3 areas in dire need of well-designed technology: collaboration enables sensemaking, problem detection precedes decision-making, and planning requires implementation. Table 6 summarizes specific recommendations for technology supporting effective macrocognitive workflow during medication management, based on our findings.

Table 6. Summary of findings and recommendations for design.

Findings	Recommendations for design
Collaboration and Sensemaking	
Patients or informal caregivers lacked the tools to support the collaborative workflow of medication management.	Design technology with shared access to all members of the care team to promote information sharing and reconciliation. Design technology to support mediated synchronous and asynchronous opportunities for interactions (eg, telehealth technologies, text messaging, email, patient portals). Use structured, automated detection and record keeping of events (eg, prescriptions) to facilitate reconciliation across care settings.
Patient or informal caregiver mental models were inconsistently shared with health care professionals.	Design structured tools to elicit patient/informal caregiver sensemaking of information and events during formal or informal team interactions. Support for the joint creation of explicit representations of "how things work" to support accurate team sensemaking.
Patients or informal caregivers struggled to synthesize large amounts of information and translate into actions.	Technology that supports the retrieval and visualization of information from multiple sources into meaningful displays of information. Personalized shared information dashboards editable by all team members.
Decision Making and Problem Detection	
Patients or informal caregivers struggled with decision-making	Design decision-support tools for use by patients and informal caregivers in the home setting (eg, clinical decision rules).
Patients or informal caregivers value the experiences and behavior of others for decision-making.	Support access through social media to heart failure support groups that include formal and informal team members for sharing stories, information, tips and tricks (eg. PatientsLikeMe). Support access to individuals who can serve as model exemplars, for example, through discussion forums or lay coaching.
Patients or informal caregivers struggled to detect symptom and medication effect cues.	Collect or use available data (eg, from cardiovascular implantable electronic devices, wearables, smartphone sensing, motion sensors) to automate cue detection or inform patients of the need to be vigilant for cues.
Patients or informal caregivers relied on electronic health records (EHR) for medical and medication history tracking.	Automate tracking to the extent possible, to counteract cumulative difficulty of tracking. Provide easy access to EHR information or a shared historical health record. Encourage EHR screen sharing during clinic visits.
Planning and implementation	
Patient or informal caregivers lack support for planning and implementation of medication regimens into the context of their own lives.	Support for structured tools to facilitate collaborative medication planning (eg, MedTable [78]) and strategy development. Use projection and simulation to help compare and validate plans. Offer planning tools for a variety of crises and other eventualities (eg, Plan Your Lifespan [79]).

Support for Collaboration and Sensemaking

Coordination is the core of successful team performance [80] and "wraps" around other macrocognitive processes [47]. Sharing information towards the goal of establishing mutual understandings is a characteristic of high-performing teams [70,81,82]. Multiple comorbidities add to complexity and increase coordination requirements and the data to consider for sensemaking. With growing access to digital information, we found that patients gathered a large amount of data from multiple sources but struggled to synthesize them and translate data to actions. We also identified unidirectional information flow, with patients gathering but not always sharing information, or not sharing it clearly. This led to incongruous mental models between patients and others, with minimal opportunity for making corrections. Our analysis demonstrates that the emerging role of the patient as actor can create silos of information and few guidelines for information sharing. IT can support collaborative information management towards the development of shared understanding and better coordination.

Support for Decision-Making and Problem Detection

While the majority of work related to clinical decision-support has focused on clinicians in professional settings, our study provided clear evidence that decision-support tools for patients and informal caregivers to use in home contexts are needed. Our results demonstrate that laypeople often make decisions based on their previous experiences and not by comparing options in a risk or benefit type analysis, in agreement with research in other domains [49,83]. Mental simulation, situation awareness, and problem detection were crucial processes enabling decision-making about responding to symptoms. However, as with prior work, it was not clear whether these processes were effectively performed by everyone or only by a subset of patient "experts" [84,85]. Participants also made decisions by modeling the behavior of others, suggesting that technology could help connect patients to individuals who can serve as model exemplars, for example, through discussion forums or lay coaching. Participants also indicated a clear desire for support in judging the appropriateness of decisions made by clinicians.

Support for Planning and Implementation

Implementing the medication regimen in a patient's specific life context is challenging. Others have reported that heart failure patients knew "what" to do but struggled with "how" to implement the medication regimen into their daily lives [86]. Having identified the patterns of patients' planning and execution of medication management in their natural context, we note several implications for technology design in Table 6. In particular, we stress on technology to help patients with 3 key areas of work: develop and strengthen daily routines, plan specific behaviors (eg, using goal setting methods), and compare different implementations of the same general plan (eg, taking medications upon waking vs with breakfast).

Limitations

The analyzed research interviews had a broad scope of heart failure self-care, including specific questions about medication management. This breadth made it difficult to thoroughly examine medication management for an individual participant but patterns emerged when examining data across participants. The sample was limited to individuals in one region, with many receiving care at the same US academic medical center. This study did not collect data structured enough to develop quantitative workflow models capable of producing state transition probabilities, that is, the flow from one action to another. Finally, observation data were limited compared with interview data. A recent publication suggests the various methods that can be used to more rigorously study patient work phenomena such as medication management workflow [87], and how future work could incorporate additional methodologies. A single coder assumed primary responsibility for codebook development and application, due to resource limitations and institutional expectations of dissertation research projects. All the authors extensively discussed codebook development and used throughout the research, with the lead author presenting multiple examples of how codes were developed, underlying data, and rationale behind coding decisions to coauthors. Although every effort was made to address potential concerns about internal validity of the codebook through extensive and repeated discussions, the primary single coder approach remains a potential limitation of the analysis process. Involving multiple coders in the analysis process could strengthen future analyses.

Areas for New Research

This study highlighted important new areas of inquiry previously unexplored in patient medication adherence and management research. The collaborative, distributed nature of medication management calls for the application of team models and theories to the understanding of health management behavior. Improving knowledge building, knowledge transfer, and mental models sharing is a promising focus for interventions and technology design. More research is also needed in the area of patient expertise, how expertise is expressed in patient work, and how tacit knowledge develops in individuals and communities through information sharing and experience. Additional research is warranted into assessing the workload associated with cognitive work such as medication management, including better measures of cognitive demands, cognitive resources, and the balance of the two. Of great interest is the notion of articulation work, or the work needed to ensure processes such as medication management can be effectively performed. Articulation work such as managing one's health insurance and finances to maintain a supply of medication is often "invisible" and under investigated, but a necessary component from a macrocognitive perspective. More research is needed on how to integrate new technology with existing well-functioning artifacts and practices. There is a need for further research using ethnographic methods, cognitive task analysis, and other techniques adaptable to study the work of patients. Methods such as experience sampling methodology or day reconstruction method are needed to understand cognitive work contemporaneously without disrupting patients' lives, but these methods have their challenges as well, including variability in the depth and accuracy of collected data.

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Conflicts of Interest

None declared.

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Abbreviations

IT: information technology
NP: nurse practitioner
SEIPS: Systems Engineering Initiative for Patient Safety

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Original Paper

Impact of Structured Rounding Tools on Time Allocation During Multidisciplinary Rounds: An Observational Study

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Abstract

Background: Recent research has shown evidence of disproportionate time allocation for patient communication during multidisciplinary rounds (MDRs). Studies have shown that patients discussed later during rounds receive lesser time.

Objective: The aim of our study was to investigate whether disproportionate time allocation effects persist with the use of structured rounding tools.

Methods: Using audio recordings of rounds (N=82 patients), we compared time allocation and communication breakdowns between a problem-based Subjective, Objective, Assessment, and Plan (SOAP) and a system-based Handoff Intervention Tool (HAND-IT) rounding tools.

Results: We found no significant linear dependence of the order of patient presentation on the time spent or on communication breakdowns for both structured tools. However, for the problem-based tool, there was a significant linear relationship between the time spent on discussing a patient and the number of communication breakdowns (P<.05)—with an average of 1.04 additional breakdowns with every 120 seconds in discussion.

Conclusions: The use of structured rounding tools potentially mitigates disproportionate time allocation and communication breakdowns during rounds, with the more structured HAND-IT, almost completely eliminating such effects. These results have potential implications for planning, prioritization, and training for time management during MDRs.

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KEYWORDS

teaching rounds; communication; intensive care units

Introduction

Multidisciplinary rounds (MDRs) serve as a common venue for formulating shared patient care goals and plans of care by care providers from different clinical specialties [1,2]. Due to its multidisciplinary and collaborative format, MDRs support a patient-centered model of care [3,4]. Studies on MDRs have demonstrated positive clinical outcomes through improvements on patient care quality and safety [5], minimization of hospital length of stay (LOS) [6], and reduction in patient mortality rates [7]. In addition to their prominent role in care coordination [8,9], MDRs provide a forum for discussing diagnoses and treatment trajectories and practicing communication and professional

skills. In critical care units, MDRs are often the only forum for the transfer of patient care responsibilities [10].

Notwithstanding these patient care benefits, researchers have pointed out several divergent perspectives regarding MDRs [11-14]. Much of the prior research has reported on the frequency and duration of rounds [15-17]. For example, Plantinga et al [17] reported that patients who had more frequent sit-down MDRs had better health outcomes, often achieving their clinical performance targets. Similar studies on MDRs in trauma settings have shown an increase in the efficiency of patient flow, reduction in length of stay, and unnecessary revisits [16]. Although there is evidence that planned and structured MDRs, especially in critical care settings, can improve patient and clinician outcomes [15], a major concern regarding MDRs is the time taken away from patient care activities [1].

One of the underexplored areas of research on MDRs is related to the time allocation and distribution during patient discussions. Recent research has illustrated that verbal discussions during rounds were vulnerable to unequal time allocation—a phenomenon that has been described as a "portfolio problem" or "end of round time compression" [18-20]. For example, Cohen et al [18] examined video-recordings of 23 end-of-week handoff sessions in a 21-bed intensive care unit (ICU) and found that patients discussed earlier received about 50% more time than the patients discussed later in the same session, regardless of their severity or complexity of illness. Similarly, Kannampallil et al, [20] reported an average decrease of 54 seconds for every additional patient discussion during morning rounds in a Cardiothoracic ICU. As a part of a larger clinical trial, Sung et al [21] analyzed 759 patient discussions from 2 clinical teams and found similar decrease in the time spent for patients discussed later during the rounds, after adjusting for illness severity.

The presence of such a disproportionate allocation of time can lead to potential decision-making and communication failures, with a consequent detrimental impact on care coordination and safety outcomes [22,23]. The causal underpinnings of such a temporal phenomenon have been debated, but require further exploration [19,24]. To support effective and efficient decision-making and communication during MDRs, hospitals have relied on a wide range of rounding tools [1,25,26]. These include patient-centric tools, which help clinicians to gather information on the clinical condition of a patient; process-oriented tools, which help clinicians to organize information to support verbal communication during rounds; and decision-support tools, which help clinicians to make decisions related to clinical diagnosis and treatment.

In this exploratory study, we evaluate the effect of 2 structured rounding tools on time allocation for patient case presentation and communication during daily rounds. As a secondary research question, we also examine whether the distribution of time allocation has an impact on the effectiveness of round communication.

Methods

The data used for this study were collected as part of a larger study that compared the communication practices in a medical ICU (MICU) [27,28].

Study Setting

This study was conducted in a 16-bed MICU at a tertiary medical center with approximately 55,000 emergency department visits per year. This MICU follows a "closed" model of care, where patient care decisions are internally managed by the MICU multidisciplinary team comprising an attending physician (ie, intensivist), a fellow, residents and interns, critical care nurses, a pharmacist, a respiratory therapist, and a nutritionist. The MICU residents' and interns' shifts lasted for approximately 24 hours, with additional 4 hours for participating in care transition activities during rounds (from ~8:00 am, day 1 to ~12:00 pm, day 2).

The unit has an average of 1200 patient admissions per year (Case Mix Index=4.72; average patient LOS=3.8 days; average number of vent days=3.1; and top 2 diagnosis-related group codes were sepsis and respiratory failure).

Rounding Process

The formal morning MDRs were led by an attending physician, and focused on transferring information, responsibility, and control from the outgoing team (postcall resident and intern) to the incoming team (on-call resident and intern). At this setting, there were no formal protocols and practices on the selection of the order of patient case presentations during rounds.

Rounding Tools

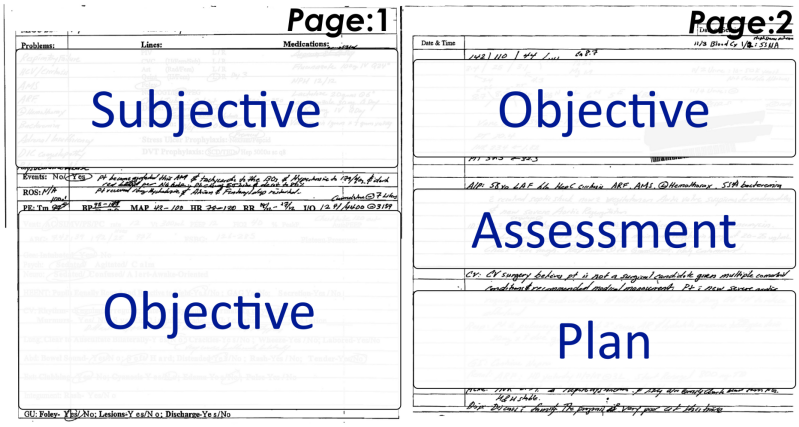
Two paper-based rounding tools were used: a patient problem-oriented, Subjective, Objective, Assessment, and Plan (SOAP) note, and locally developed, body systems-oriented, Handoff Intervention Tool (HAND-IT) [27]. The rounding tools (SOAP or HAND-IT) were used for gathering patient care information in preparation for rounds, and for supporting presentation and communication during MDRs.

SOAP is based on the problem-oriented medical record format [29]. The SOAP tool aids physicians to focus on the primary complaints of the patient, and other care-related information categorized under 4 headers (Figure 1). Subjective information regarding the patient includes patient's chief complaint and history of patient illness including past and pertinent medical, family, and social history. The objective component comprises information gathered through observations of patient actions and behaviors including physical exam, and results from laboratory and radiology tests pertinent to the current episode of care. The assessment comprises the clinical impression regarding the patient case summarized for the newest or most acute problem including a statement of patient problem, differential diagnosis, and reasoning regarding the problem. Assessment is often based on the subjective and objective data, and indicates progression of change or no change in patient condition. Finally, plan comprises 4 separate information categories such as diagnostic testing, treatment plan, patient

education, and planned follow-up, listed for all patient problems [30].

HAND-IT was developed based on a previous evaluation study that showed that structuring information in a checklist-based, body-systems format improves filtering, retrieval, and documentation of information in preparation for rounds [28]. The information on HAND-IT is organized by body systems including pulmonary, neurology, endocrine, hematology, cardiovascular, infectious disease, and renal and genitourinary organ systems. The information within each body system is organized in a medical knowledge hierarchical format [31]. Such an organization helps physicians in developing a bottom-up understanding of a patient case: in other words, this format supports inductive reasoning helping physicians in translating clinical data to clinical hypothesis, leading to effective treatment or management decisions [31,32]. HAND-IT also follows the Society of Critical Care Medicine's guidelines including identification of delirium, sedation practices, prophylaxis, and feeding information [33] (Figure 2).

Figure 1. Subjective, Objective, Assessment, and Plan (SOAP)-based tool that was used for the rounds.



Participants

There were 16 participants during the 2-month study period, divided into 2 independent teams. Each team was in the MICU for a 1-month period and consisted of 8 core participants for the entire month (1 attending physician, 1 fellow, 3 residents [PGY2/3], and 3 interns [PGY1]). In addition to this, there were 6 critical care nurses, 1 pharmacist, 1 respiratory therapist, and 3 medical students who participated in the rounds each month. The institutional review board of the University and Hospital approved this study and written consents were obtained from all participants.

Study Design and Data Collection

Morning rounds on 8 randomly selected days over the course of 2 months with 2 independent MICU care teams were audio recorded. The recordings consisted of round discussion of 82 patient cases (n_{SOAP}=41, $n_{HAND-IT}$=41). Follow-up informal interviews with physicians confirmed that the order of patient presentation and discussion varied depending on the attending physician's priority and patient acuity.

During the first month of data collection, team 1 trained with SOAP for 4 days, followed by 2 days of testing; then trained with HAND-IT for 4 days, followed by 2 days of testing. During the second month, a new team followed the same process of training and testing with the reverse order of tool usage (ie, HAND-IT followed by SOAP). This was done to counterbalance the effects of tool use. The training period involved introductory training on the structure and various content fields of each tool. During the training period, residents used their assigned tool during rounding to gain familiarity.

The testing period involved collection of verbal communication data through audio recording of the rounds. The total audio recorded time was approximately 40 hours. In addition, a researcher (the first author, JA) observed these sessions, made field notes, and conducted informal interviews after the rounds. An illustrative representation of the study design is shown in Figure 3.

Given the exploratory nature of this study, and limited previous research results, our purpose was to compare our results with the results reported in other published research articles [18]. There was no control condition (ie, a "no tool" condition), and the comparisons were made only between the 2 considered rounding tools.

Data Coding

Audio-recorded verbal communication during rounds was used to compute the length of time spent presenting each patient. The verbal transcripts were used to evaluate the quality of communication during rounds.

Figure 2. Body systems-oriented Handoff Intervention Tool (HAND-IT) with the various body system elements highlighted.

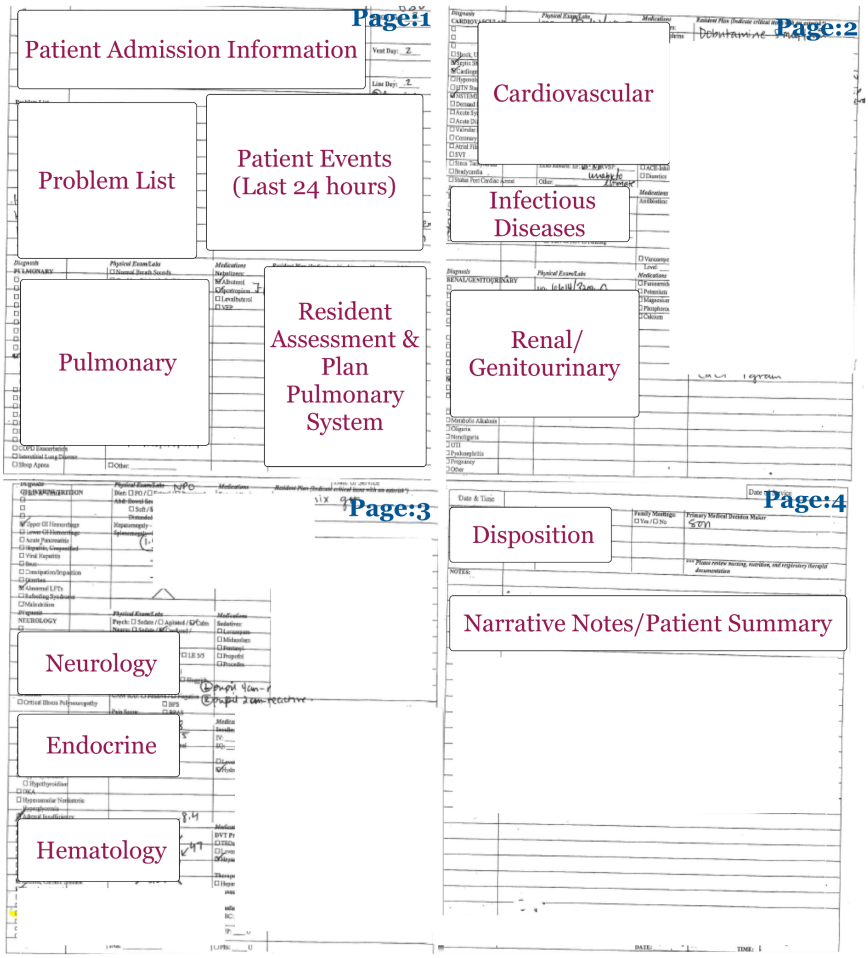
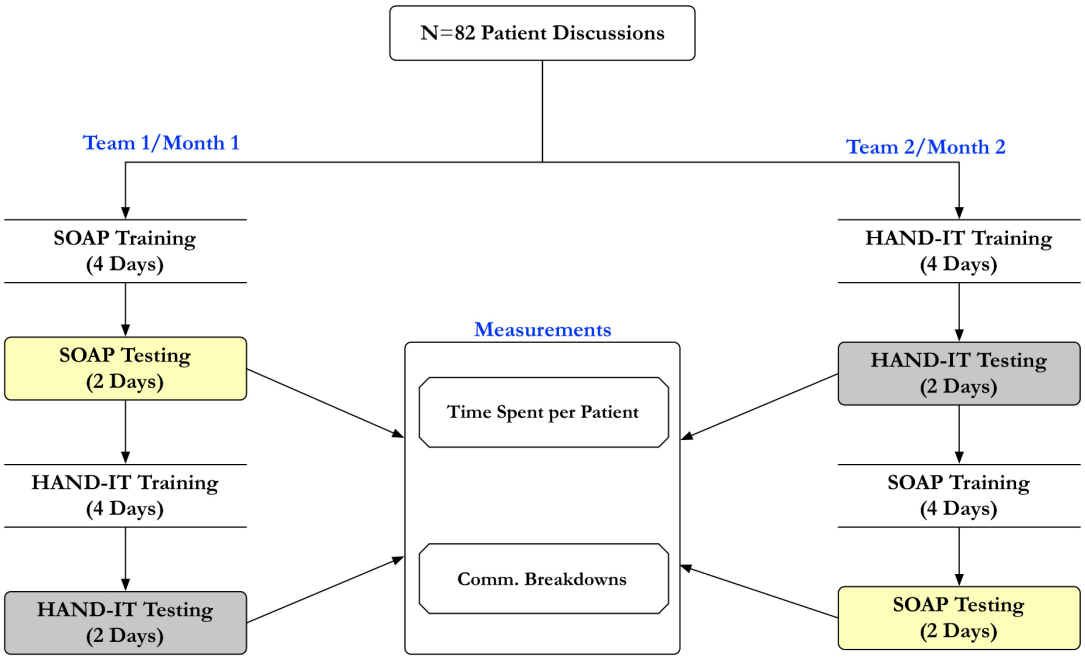


Figure 3. The study design showing the organization of training and testing using both tools is shown. The measurements (time spent and communication breakdowns, shown in the center) were compared with the order of patient case presentation. SOAP: Subjective, Objective, Assessment, and Plan; HAND-IT: Handoff Intervention Tool.



Round Communication Duration

Two researchers (the first author, JA, and a research assistant) listened to audio recordings to note the time spent on discussing each patient. The start time of each handoff was identified as the moment when the resident or intern started a patient presentation. The end time of each handoff was identified as the moment when the attending physician signed-off on his or her progress note for a patient case. This denoted the end of patient discussion. The audio recordings were also marked-up for interruptions, and other distractions unrelated to the patient case being presented. The total time was calculated by combining the duration of patient presentation and discussion, and excluding the time periods of interruptions, similar to the time coding performed by Cardarelli and colleagues [34].

There was a significantly high inter-rater agreement between the 2 coders (Cohen κ=.975). The discrepancies in the time identification were resolved through discussion and relistening to the audio recordings.

Round Communication Breakdowns

Breakdowns were defined as any failure in information flow and transfer from the outgoing postcall team to the on-call team (ie, receiving team consisting of the attending physician, fellow, resident, intern). The breakdowns in communication were evaluated using a validated communication framework [8,27] and classified into one of the following 3 categories: missing or incomplete information, incorrect or conflicting information, and irrelevant or ambiguous information.

Two authors (JA, TK) coded the breakdowns in communication with a high degree of inter-rater agreement (Cohen κ=0.96). Any disagreement in the coding of breakdowns was resolved through discussion. Description of each of these types of breakdowns is shown in Table 1. Although we categorized breakdowns into 3 categories for coding purposes, we did not perform separate analyses for each type of breakdowns.

Table 1. Different types of communication breakdowns that were coded for each of the transcripts.

Type of communication breakdowns	Description
Incomplete information	Lack of complete patient information provided by the postcall team to the oncall team during rounds
Inaccurate and conflicting information	Erroneous patient information provided by the postcall team to the on-call team during rounds
Irrelevant information	Inappropriate care plan provided by the postcall team to the oncall team during rounds (that does not follow the clinical reasoning logic nor suitable for the patient at that moment in time)

Statistical Analysis

To determine whether there was a significant relationship between the order of presentation of patient cases and the time spent on the discussion for each of the tools, we computed the Kendall τ rank order coefficient for each session. Kendall τ rank order coefficient is a nonparametric test statistic that is used to determine the measure of association between 2 variables. The test statistic provides a measure of the rank correlation between the ordering of data ranked by each of the variables. As the predictor variable is ordinal, Kendall τ provides an appropriate test regarding the hypothesized relation with values varying between −1.0 and +1.0. A negative Kendall τ between the order of presentation and time spent shows lesser time for patients presented later, zero correlation shows that relatively equal time was spent across all patients, and a positive correlation shows more time spent for patients presented later. Given that the data were collected across 8 sessions (4 sessions per tool), similar to Cohen et al [18], we computed the Kendall τ per session and averaged across all sessions per tool.

Similar rank order coefficients were also computed for evaluating whether the order of presentation had any effect on communication breakdowns for each of the tools. Linear regression analysis was also used to investigate the relationship between the time spent on patient discussion and communication breakdowns. A significance level of $P<.05$ was used.

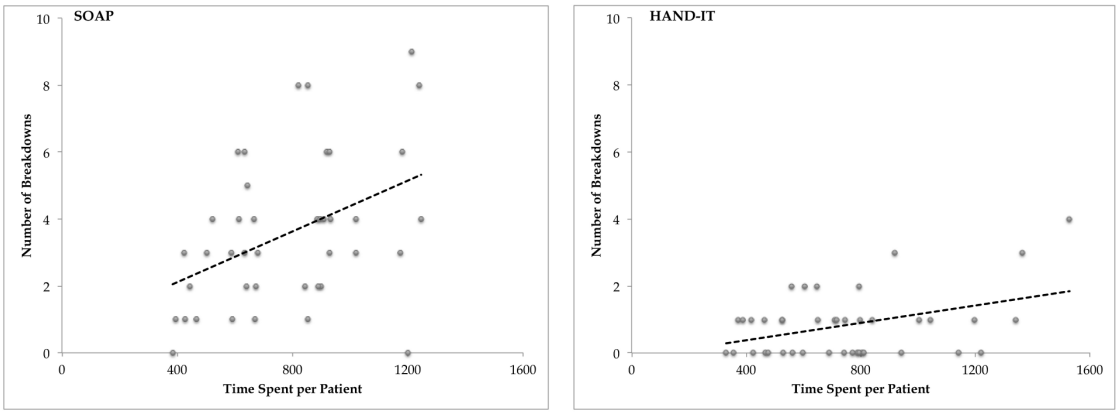
Results

There were no differences in the number of patients discussed per day between the 2 rounding tools ($t=0$, $P>.05$; $Mean_{SOAP}=10.3$, SD=3.3; $Mean_{HAND\text{-}IT}=10.3$, SD=2.2). In addition, there were no differences in the time spent on discussion of each patient between the 2 rounding tools ($t=0.56$, $P>.05$; $Mean_{SOAP}=770.9$, SD=55.6; $Mean_{HAND\text{-}IT}=753.4$, SD=110.3).

In terms of the time spent per patient with respect to the order of presentation, the mean (SD) Kendall τ correlations were marginally negative for SOAP (−0.11 [0.38]), and HAND-IT (−0.01 [0.30]). In terms of the communication breakdowns with respect to the order of presentation, the mean (SD) Kendall τ correlations were negative for SOAP (−0.25 [0.41]), and marginally positive for HAND-IT (0.05 [0.17]). In other words, the time spent on discussing a patient or the number of breakdowns did not change significantly over the course of a session for either rounding tool, potentially showing no disproportionate time allocation or communication breakdown effects.

However, based on regression analysis, there was a significant linear dependence between time spent discussing patients and breakdowns ($P<.05$): for SOAP, there was an average increase of 1.04 breakdowns with every additional 120 seconds spent on discussing a patient. For HAND-IT, the increase in breakdowns was about 0.018 for a similar 120 seconds additional time spent on discussing a patient. In other words, the increased length of conversation per patient is more likely to lead to communication breakdowns in SOAP than in HAND-IT. The summary of the linear dependence between communication breakdowns and time spent on discussing the patients is shown in Figure 4.

Figure 4. The number of breakdowns as a function of the time spent per patient for Subjective, Objective, Assessment, and Plan (SOAP) and Handoff Intervention Tool (HAND-IT) tools. For SOAP, the number of breakdowns increases (n=41 patient discussions)—the trend line for the estimated linear regression is b=.0038t+.59 (P<.05, 95% CI of t: 0.00118, 0.0064). For HAND-IT, the increase is marginal—the trend line for the linear regression is b=.0013t−.138 (P<.05, 95% CI of t: (0.00031, 0.0022). Both estimates were statistically significant at P<.05.



Discussion

Principal Findings

Our results suggest that structured tools are likely to mitigate the effect of disproportionate time allocation during rounds. Although correlations of the order of presentation in relation to both time spent and breakdowns in communication were marginal for both HAND-IT and SOAP, the relative effect was lesser for HAND-IT: with almost no correlation; Kendall τ being .01 and .05 for time spent and breakdowns in communication, respectively. We also found that additional time spent in discussing a patient during MDRs may lead to more breakdowns in communication in SOAP than that in HAND-IT.

Although further research is required to ascertain how structured tools mitigate the disproportional time allocation across patients, we acknowledge that there would be instances where structured tools may not be strictly followed due to patient-, clinician-, and environmental-related factors in critical care settings, in which cases, disproportionality in time allocation may be preferred (eg, differences in patient complexity and acuity, number of days the patients has been in the unit, and recent changes in the patients' condition).

We discuss 3 implications of our results within the context of the MDR process: supporting communication, planning for distribution of time, and prioritization of patient order. Research on rounds has focused primarily on developing tools for supporting information presentation by outgoing clinicians using an information transmission perspective [35], with limited functionalities to foster the tasks of information gathering and organization by incoming clinicians. Structured tools such as HAND-IT can serve as cognitive support for promoting effective communication, as it allows the incoming clinician to know what to expect during the presentation and to quickly identify any discrepancies or gaps in the ongoing communication and instantaneously repair them. In addition, our informal discussions with residents provided evidence that although HAND-IT required more effort and time to gather and document information, it reduced the time spent and additional effort during rounds to address the information gaps. .

Research in psychology and cognitive sciences has shown human limitations regarding planning for tasks—both in terms of biases in time allocation, and overconfidence in the precision of outcomes [36]. In other words, human planning for time is predicated on optimistic expectations of timely task completion, even with prior evidence to the contrary. During MDRs, uncertainties of time requirements are amplified by factors such as patient uncertainty, unexpected complications, varying clinician task load, multiple consult service coordination of care decisions, and possible new admissions (eg, transfers from emergency room or floor units). In addition to these contextual factors, there are organizational aspects that put a significant constraint on time availability for MDRs. For example, Accreditation Council for Graduate Medical Education (ACGME) guidelines on resident hours restrict maximum duty limit to 28 hours—24+4 hours for transitional and education activities—requiring rounds to be completed by a certain time. Such requirements add to the planning challenges. Structured tools can potentially help in streamlining conversations, smoothing the time spent across multiple patients in a session thereby helping in time planning and removing the element of "subjectivity" that is often attributed to personal physician preferences, style, and priorities [9].

Another closely related aspect of rounding is prioritization. Physicians often select and prioritize patients for discussion during MDRs. These selections are based on patient criticality (eg, the sickest patient first), time of admission (ie, LOS in the unit), bed order, or costeffectiveness ratio [37]. For example, Cohen et al [18] suggested that the sickest, newest, or patient's requiring further discussions should be seen first during rounds. However, there are other external constraints that play into the decisions regarding the priority order of patient presentation that can accelerate the disposition of patients in a unit. Tools supporting such global strategies and assisting in patient prioritization have been described to improve efficiency in critical care settings [38]. In an another study, Iapichino et al [39], suggested stratification of patients in intensive care settings should be based on their illness severity at patient admission to achieve cost effectiveness in the care delivery process.

Limitations

We acknowledge that this exploratory study has several limitations.

First, the study was conducted at a single academic MICU setting using a nonrandomized design with only 2 clinical teams. However, we evaluated a large number of handoffs (N=82 patients) providing validity for our preliminary results.

Second, we did not control for any patient-related, unit-related, or other external variables in our analysis. Our assumption was that, given the unpredictability of patient arrivals or discharges and similar resource availability for all patients, the order of patient discussion was effectively randomized, making any of the patient, unit, or external variables unrelated to the discussion order (a similar claim was made by Cohen et al [18] regarding randomization and discussion order).

Third, the increased number of breakdowns for longer communications may have been an effect of length-biased sampling: the greater the length of the conversation, the greater the likelihood of communication breakdowns.

Fourth, in this study, we did not have a true "control" condition; that is, a condition where we showed the existence of disproportionate time allocation during rounds. Instead, drawing on a prior study—by one of the coauthors [20] —and on recently reported research literature that showed the evidence for disproportionate time allocation, we evaluated whether structured tools had any effect on moderating the effects of disproportionate time allocation.

Finally, although our exploratory findings demonstrate the moderating effects of structured rounding tools on time allocation, we would like to acknowledge that at times, disproportionate time allocation maybe unavoidable. Such situations arise due to complexity of patient cases, LOS of patient, prior knowledge of the patient, limited changes in therapeutic regimen, or other time constraints.

Conclusions

Time constraints impose challenges to critical care practice, often adding additional cognitive load on the physician's already complex work activities. One of the unintended effects of time constraints is their disproportionate time allocation to similar tasks. Although there is no evidence on whether disproportionate time allocation can have any detrimental outcomes, it increases the possibility for errors and inefficient patient care delivery and management. We found preliminary evidence that structured rounding tools may mitigate such disproportionate time allocation effects during MDRs. In addition, increased structure within the tools can also mitigate the communication breakdowns during MDR discussions. Although our results provide preliminary evidence of the time allocation and quality of communication using structured tools, further research is required to establish the causal underpinnings of time allocations during rounds.

Acknowledgments

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Conflicts of Interest

None declared.

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Abbreviations

HAND-IT: Handoff Intervention Tool
ICU: intensive care unit
LOS: length of stay
MDRs: multidisciplinary rounds
MICU: Medical ICU
SOAP: Subjective, Objective, Assessment, and Plan

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Original Paper

Usability Testing of a National Substance Use Screening Tool Embedded in Electronic Health Records

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Abstract

Background: Screening, brief intervention, and referral to treatment (SBIRT) is currently being implemented into health systems nationally via paper and electronic methods.

Objective: The purpose of this study was to evaluate the integration of an electronic SBIRT tool into an existing paper-based SBIRT clinical workflow in a patient-centered medical home.

Methods: Usability testing was conducted in an academic ambulatory clinic. Two rounds of usability testing were done with medical office assistants (MOAs) using a paper and electronic version of the SBIRT tool, with two and four participants, respectively. Qualitative and quantitative data was analyzed to determine the impact of both tools on clinical workflow. A second round of usability testing was done with the revised electronic version and compared with the first version.

Results: Personal workflow barriers cited in the first round of testing were that the electronic health record (EHR) tool was disruptive to patient's visits. In Round 2 of testing, MOAs reported favoring the electronic version due to improved layout and the inclusion of an alert system embedded in the EHR. For example, using the system usability scale (SUS), MOAs reported a grade "1" for the statement, "I would like to use this system frequently" during the first round of testing but a "5" during the second round of analysis.

Conclusions: The importance of testing usability of various mediums of tools used in health care screening is highlighted by the findings of this study. In the first round of testing, the electronic tool was reported as less user friendly, being difficult to navigate, and time consuming. Many issues faced in the first generation of the tool were improved in the second generation after usability was evaluated. This study demonstrates how usability testing of an electronic SBRIT tool can help to identify challenges that can impact clinical workflow. However, a limitation of this study was the small sample size of MOAs that participated. The results may have been biased to Northwell Health workers' perceptions of the SBIRT tool and their specific clinical workflow.

(JMIR Hum Factors 2016;3(2):e18) doi:10.2196/humanfactors.5820

KEYWORDS

clinical decision support; adoption; primary care; usability; SBIRT

Introduction

Screening, Brief Intervention, and Referral to Treatment: National Program that Works

Screening, brief intervention, and referral to treatment (SBIRT) is a nationally and federally sponsored program that provides a structured approach to better aid health care providers in identifying risky substance use and delivering early intervention and treatment services for persons at risk of, or with substance use disorders. SBIRT is an evidence-based protocol to identify patients who use substances in ways that increase their risk of health (physical or emotional), work, family, or social problems.

It is used in a variety of settings including primary care practices, emergency departments, colleges, employee assistance programs, and mental health agencies. New York (NY)SBIRT-II is a project funded by the Substance Abuse and Mental Health Services Administration and coordinated by the NY State Office of Alcohol and Substance Abuse Services. Its goal is the implementation of a sustainable model for administering the SBIRT within New York State. Northwell Health and The National Center on Addiction and Substance Abuse at Columbia University are partners in the implementation of this project in three major Northwell Health departments; Emergency Medicine, Medicine, and Psychiatry/Behavioral Health.

With collaborative efforts between the Northwell Health Office of the Chief Information Officer and multiple teams within the Northwell Health Information Technology infrastructure, NYSBIRT-II has been successful in embedding SBIRT services within four major electronic health record (EHR) systems (AllScripts Electronic Health Record; AllScripts Emergency Department Information System; Sunrise Emergency Care). These EHR systems are used in both emergency medicine and primary care settings. These efforts have benefited the overall project by allowing the tool to integrate well within clinical workflows (which are heavily dependent on EHR usage).

Electronic Screening, Brief Intervention, and Referral to Treatment: Success and Pitfalls

Since 2008, there has been an increase in the adoption of EHR technology to meet objectives set forth by the Health Information Technology (IT) for Economic and Clinical Health Act of 2009. The expansion of tools being developed in the EHR is allowing researchers and clinicians to find creative solutions for streamlining screening guidelines and standardizing care management plans [1].

While the SBIRT screen has traditionally been conducted through paper-based surveys administered by clinical staff, there is a growing emphasis on finding health IT strategies to integrate the screen into health technology platforms, such as the EHR.

Formative Assessment and Usability Testing

There is an over arching goal among health systems to increase the use of the EHR in order to decrease medical errors and in turn, increase the quality of patient care. However, if the user is not taken into regard in the design of the tool, this may lead to failure of successful integration into the health care providers' workflow. Ultimately, this can lead to EHR tools being neglected [2-4].

Researchers have now employed usability testing methods from the commercial industry and are applying them to health IT and EHR products with success [5-9]. Usability testing has shown to be successful in increasing a clinical decision support (CDS) tool's use and impacting providers' behavior. This is a result of formative assessment and usability testing addressing all components of the clinical environment and how the CDS tools address the micro (clinicians' workflow) and macro (system) levels factors. These factors will impact the design and workflow of an EHR tool [10,11]. An example of factors to consider are the organizational policies around using pop-up alerts in the EHR (system), nurse's versus clinician's culture, and communication style during a clinical visit (clinical). On a personal level, each level of provider interacts with the EHR during a different decision making process and having the tool to execute during that specific point could determine acceptance or dismissal of the tool [12]. All of these challenges are addressed during the early stages of usability testing. Usability testing stresses iterative designs with the goal of creating tools that streamline care and improve compliance, while making the clinical visit more efficient [2].

Therefore, in designing a health IT solution for SBIRT, we sought out a formative assessment process and conducted several rounds of usability testing to determine the best design. We also sought to document the methods, strategies, and lesson learned from usability testing that could be shared nationally and guide others on their implementation strategy. This study evaluated the integration of an electronic SBIRT tool into clinical workflow. We hypothesized the electronic version would enhance the clinician workflow.

Methods

Study Design

An observational study was conducted in an academic primary care practice (patient-centered medical home) within Northwell Health. The SBIRT screening tool had been originally implemented on paper and later implemented within the EHR system, which calculates the screening tool (Figure 1). The SBIRT tool is a screening tool that enables health coaches to identify those patients at risk for addiction in order to allow for early intervention and referral. Eligibility criteria for participation in this study included: employed as a medical office assistant (MOA) at the primary care clinic, past clinical experience, familiarity with the paper and electronic SBIRT screening tool, previous experience working with AllScripts EHR, and over the age of 18 years. A summary of participant demographics is summarized in Table 1.

Table 1. Medical office assistant demographics.

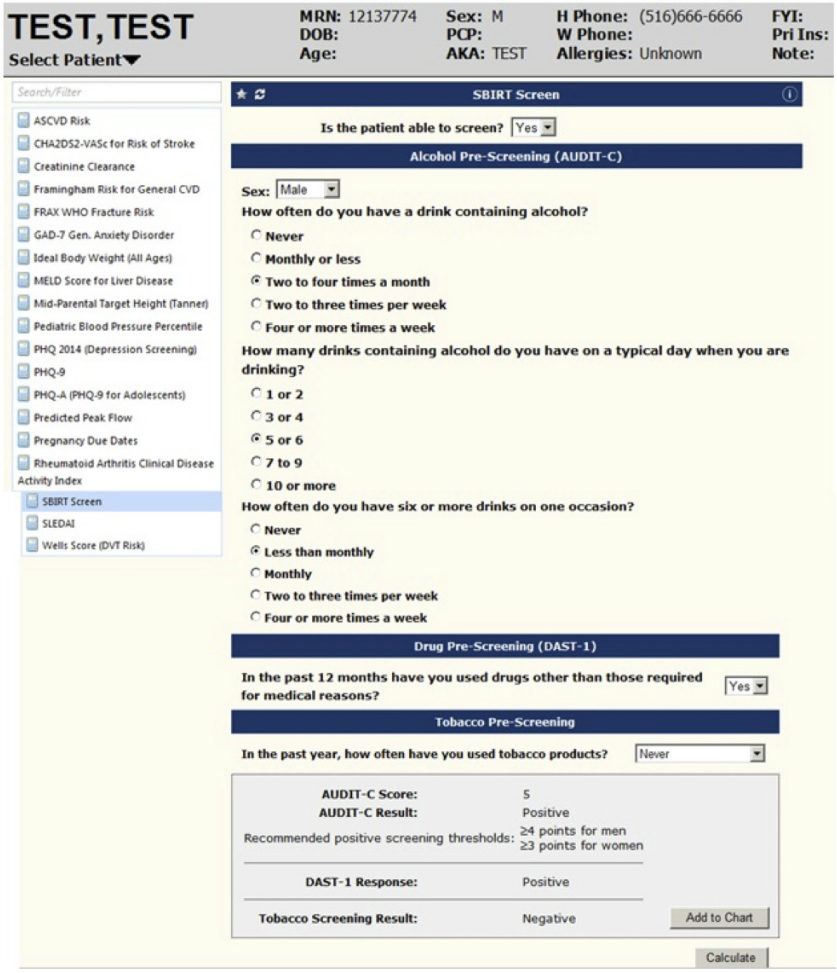
Participant	1 (Round 1)	2 (Round 1)	3 (Round 2)	4 (Round 2)	5 (Round 2)	6 (Round 2)	Average
Years worked as above title	2 years	14 years	5 years	2 years	3 years	3 years	4.8 years
Age	25 years	46 years	39 years	23 years	27 years	46 years	34.3 years
Years of medical experience	5 years	16 years	11 years	3 years	5 years	10 years	8.3 years
If yes to above, were you trained on computer and/or paper	Computer and paper	Computer and paper	Computer and paper	Computer and paper	Computer and paper	Computer and paper	6/6 (100%) computer and paper
Which SBIRT[a] do you use regularly	Paper	Paper	Computer	Computer and paper	Computer	Computer and paper	2/6 (33%) paper 2/6 (33%) computer 2/6 (33%) computer and paper
How comfortable are you with SBIRT (1 to 5, with 5 people more comfortable)	5	5	5	5	5	5	5
Have you had experience in the past with computer decision support tools	No	Yes	No	No	Yes	Yes	3/6 (50%) yes 3/6 (50%) no
Have you had experience in the past with substance abuse screening tools	No	No	No	No	No	No	6/6 (100%) no
How long have you been using the above EMR[b]	2 years	4 years	4 years	2 years	3 years	3 years	3 years
How comfortable are you with the EMR you use? (1 to 5, 5 being most comfortable)	5	5	5	5	5	5	5

[a]screening, brief intervention, and referral to treatment.

[b]electronic medical record.

MOAs were given a description of this study and were given the opportunity to volunteer. All MOAs who volunteered had experience with SBIRT within Northwell Health. Two rounds of observations were conducted over a 1-year period. This research study has approval from the Northwell Health institutional review board.

Figure 1. EHR SBIRT tool.



Description of the Tool

The SBIRT screening tool was built into the outpatient EHR system. In the first version, the tool was separated into two separate sections to be completed: alcohol and drugs was on one screen and tobacco was on a separate screen. In order to access the screens, you would have to click on each individually. Once each of the screens was completed, the user would have to make sure to click the "calculate" button. Once this was clicked, the user would then click the "add to chart" button. This had to be done on both the alcohol and drug screen and the tobacco screen. There was no alert system for the health coach once a screen had been added to the chart.

In the second generation of the tool, the questions were sectioned by category of alcohol, drugs, and tobacco; however, unlike the first version, they were all on the same page (Figure 1). The tool included the The Alcohol Use Disorders Identification Test (AUDIT-C) Drug Abuse Screening Test (DAST-1), and Alcohol Smoking and Substance Involvement Screening Test (ASSIST) screening questionnaires that screen for alcohol, drugs, and tobacco use, respectively (Multimedia Appendix 1). The tool incorporated branching logic, wherein if the answer to the first question of the AUDIT-C is "Never," then the two remaining AUDIT-C questions will not come into view. Similarly, if the answer to the first question of the AUDIT-C is monthly or more, than the two remaining AUDIT-C questions will appear. Once calculate is pressed, the patient's age, gender, and given answers are used to determine if the patient's prescreen is negative or positive. Once the prescreen is complete it is saved under Order Viewer, CLINICAL Calculators, and summarizes the patient's status (prescreen negative or positive), questions, and responses (Multimedia Appendix 2). If a screen were calculated as positive by the electronic SBIRT tool it would go into the user's task list within the EHR. The user then forwarded the task to the health coach in order to alert the health coach of a positive screen.

First Round of Testing

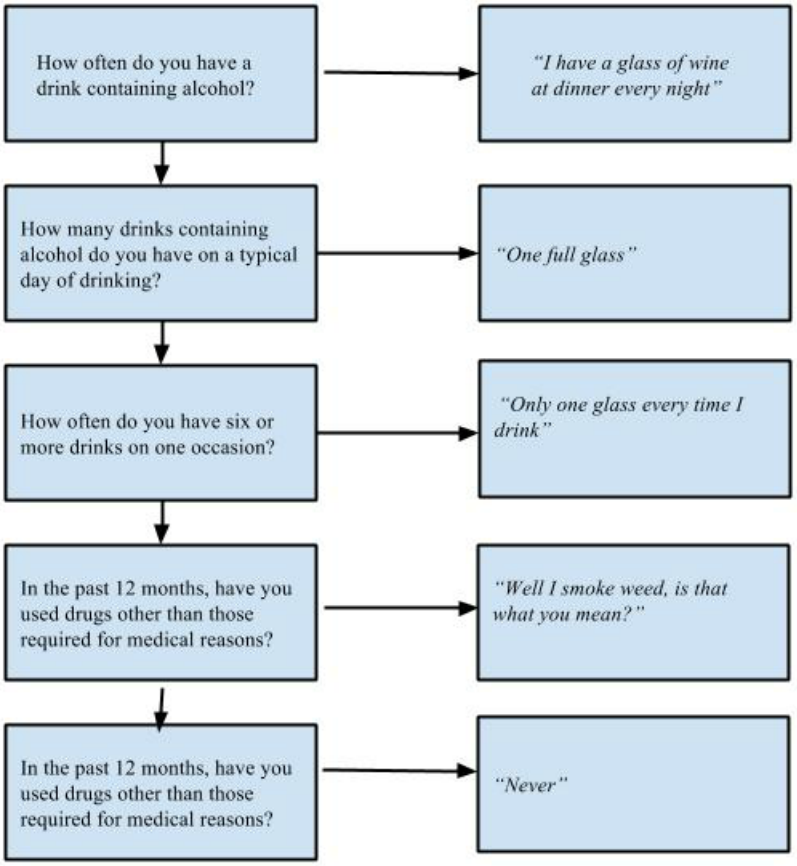
The first round of usability testing was conducted directly after an electronic-based screen was introduced into the EHR to frontline clinical staff who were using a paper-based workflow. During the first round, two participants volunteered for this study. The MOAs had received trainings on both the paper and electronic versions of the SBIRT screen and had approximately 1 week of familiarity with both mediums. Testing was done within the clinical setting in which the MOAs regularly work and a standardized patient was used for the clinical scenarios. One MOA interacted with a patient at a time and the patient presented the same case in both interactions. For the first interaction, the MOA completed the paper SBIRT screen and for the second interaction the MOA completed the electronic SBIRT screen. Each electronic screen consisted of two parts: part one for alcohol and drug use and part two for tobacco use.

After completion of the interactions, the MOA submitted the screen depending on the existing workflow and the medium used – into the completion box for paper screens, and pressing the "add to chart" button for the electronic screening tool.

During the first round of testing, the MOAs were audio and video recorded and had a research staff member present for the interactions. Following the standardized patient visit, the MOAs participated in informant interviews regarding their experiences with the SBIRT screening tool, conducted by study staff. The interviews included qualitative questions and annotative feedback regarding the screening mediums.

Recordings of the mock clinical sessions and annotations of the interviews were analyzed by two raters for thematic similarities. The analysis included both qualitative and quantitative measures based on the recordings of the clinical scenarios and the answers to the informant interviews. The quantitative measures analyzed were time and accuracy during the clinical scenarios, while the qualitative measures that were analyzed were the observations of the clinical scenario and MOA responses during the interviews. An example of patient interaction is seen in Figure 2.

Figure 2. Mock patient scenario.



Second Round of Testing

The second round of testing took place 12 months later when version two of the electronic tool was integrated into the EHR. The second generation was created based on feedback from the first round of testing and MOA feedback. While awaiting the revision of the first generation of the electronic screen, paper screening continued to be used.

During the second round of testing, four MOAs volunteered to participate. The MOAs had 2 weeks of familiarity with version two of the electronic screen. The testing scenario was kept the same as it was in the first round. Important differences were as follows: (1) version two of the electronic screen was used, therefore there was only one part to the screen, as opposed to the two seen in the first round, and (2) there was no audio or visual recording in the second round. This was due to two research staff members being present for the interactions.

As in the first round of testing, following the standardized patient visit, the MOAs participated in informant interviews regarding their experiences with the SBIRT screening tool, conducted by study staff. The interviews included qualitative questions and annotative feedback regarding the screening mediums made by the MOAs. Annotations of the interviews were analyzed by two raters for thematic similarities. The analysis included qualitative measures based on the answers to the informant interviews. The qualitative measures that were analyzed were the observations of the clinical scenario and MOA responses during the interviews.

Results

First Round

Cases were analyzed using both quantitative and qualitative analyses. As part of the quantitative analysis, the two screen mediums were timed to compare efficiency of both SBIRT

mediums. Timing was done using the time stamp on the recording device. The SBIRT screening took an average of 45 seconds when used as a paper screen and 94 seconds when the electronic version was employed. This results in a 48.5 second difference between the two mediums, with the paper screen being almost two times faster to complete than the electronic version.

The ability to complete the tool was evaluated as well. Each paper screen was completed correctly and submitted to the correct location (health coach completion box). The electronic screens were completed correctly, however, in both cases there was a failure to submit part one, the drug and alcohol section, to the correct location; clicking add to chart within the EHR was not done.

As additional quantitative analysis, the MOAs completed the system usability scale (SUS) survey [13] after the mock patient scenario was completed. Answers were totaled by percentages for each question (Figure 3). The results of the quantitative analysis are summarized in Table 2.

Table 2. Round 1: observations from qualitative analysis.

SBIRT[a]tool	Usability constructs (workflow integration, efficiency; effective; learnability; satisfaction)	Example rater comments
Paper Screen MOA[b] #1	Good patient/provider interaction Strong workflow integration	Smooth flow between questions Eye contact A lot of patient interaction Very few interruptions with workflow
Paper Screen MOA #2	Good patient/provider interaction Strong workflow integration	A lot of patient eye contact, interaction, and engagement
Electronic screen MOA #1	Poor workflow integration Inefficient tool Poor patient/provider interaction	Slow transition between questions Slow to initialize EHR[c]tool after introducing the SBIRT tool to the patient Not a lot of eye contact Few direct patient interactions Struggled to find boxes to fill out the tool Difficulty calculating the score
Electronic screen MOA #2	Poor workflow integration Inefficient tool Poor patient/provider interaction	Not a lot of eye contact with the patient Not a lot of patient interactions Great difficultly flowing through the questions Needed guidance with regards to where to click

[a]screening, brief intervention, and referral to treatment.

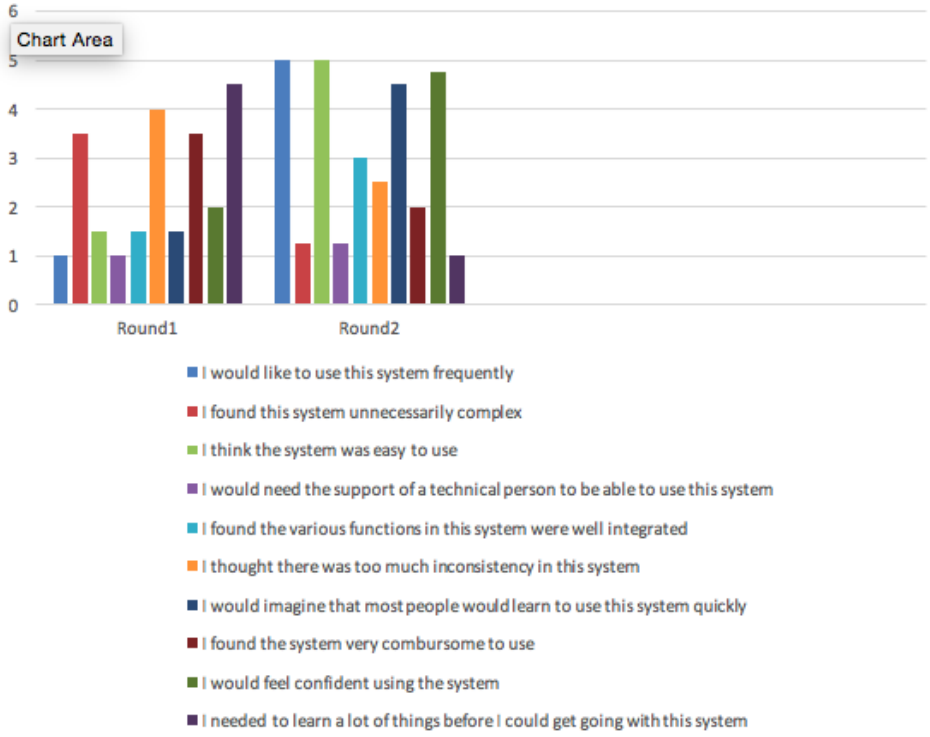
[b]medical office assistant.

[c]electronic health record.

Areas for improvement of the SBIRT tool were suggested and included increasing spacing of the question and answers to avoid wrong clicking, one button to identify all answers as negative, keeping the order of questions the same as the paper version, faster loading process, and a change in the alerting system that ensures addition of the form to the chart.

After Round 1 of testing, conversations with the study team (clinical leaders, project directors, health coaches) and clinic staff deemed that the electronic screen tool was slower and less efficient that the paper version. This resulted in the immediate cessation of the EHR-based tool, and full paper-based workflow.

Figure 3. Comparison of the system usability scale between Round 1 versus Round 2 of the EMR SBIRT tool.



Second Round

Cases were analyzed using both quantitative and qualitative analyses. As part of the quantitative analysis, MOAs completed the SUS survey after the mock patient scenario was completed. Answers were totaled by percentages for each question. Results show the highest rated answers were that the MOAs would use the system frequently, the system was easy to use, and the MOAs did not need to learn a lot to use the system. These questions all received a 100% rating. The lowest rated answers were that there is too much inconsistency within the system and all functions are not well integrated.

The ability to complete the tool was evaluated, as it was in the first round. All screens were completely correctly and submitted to the correct location (clicking add to chart within the EHR and alerting the health coach via EHR). The results of the qualitative questioning are summarized in Table 3.

Table 3. Qualitative data on usability constructs: paper versus electronic SBIRT tool.

Question	Round 1		Round 2	
	Paper version	Electronic version	Paper version	Electronic version
Did you make a lot of mistakes while you were working with the programs?	No	Yes	No	Yes-hit the wrong button especially when in a rush
How do the versions work in the daily workflow?	Convenient; easy to incorporate	Too much to navigate; scrolling and clicking takes a long time; gets in the way of normal workflow	More effective interaction with patient	Enter it into the EMR[a] after patient seen; lag time in loading slows down efficiency; easier to not have the computer with you; difficult to do when there are multiple patients
What are some of the pros and cons/obstacles, etc that you have faced while working the tool?	More patient eye contact; easy and fast	Would prefer this version if it were easier to use; inconvenient; slow; interferes with patient interaction; less patient eye contact and interaction	Easy and fast; have hard copy in case something goes wrong with EMR; can talk to health coach about complex patients before entering; takes time to look up patient information to be added to sheet; have to remember to bring to health coach; waste of paper	Accuracy in EMR; easy to work with; goes right to patient chart and right to the health coach; everything automatically documented; easier to write on paper and transfer; slows down work flow; Interferes with patient interaction; lags when opening; order of questions is not the same as the paper was; can forget to click to calculate, add to the patient chart, or to alert the health coach.
Suggestions and improvements	If the electronic were easier to use, would prefer that; set up (in the EHR[b]) should be more like the paper; too many clicks with the electronic version		Improve layout/spacing of the question answers to avoid clicking wrong option; if patient is negative for everything – there should be one button to press so as not to waste time going through all questions; keep the order of the questions the same as when the original implementation was done (electronic version should have been the same as the paper version)	
Which method do you prefer?	2/2 (100%) paper		2/4 (50%) electronic 2/4 (50%) undecided	

[a]electronic medical record.

[b]electronic health record.

Discussion

Round 1

During Round 1 of usability testing, we observed more cons in the electronic version than originally hypothesized, with our hypothesis being that the electronic version would improve workflow and have high user satisfaction/usability. Participants' negative feedback on the electronic SBIRT tool was: a lack of interaction between the MOA and the patient, a lack of certainty in the hand-off of the tool to the health coach, and a decrease in general usability of the screening tool. An additional problem noted during Round 1 was the time to complete the electronic screen and improper completion of the tool. From the screen capture analysis, there were many mistakes captured in the electronic screening tool. The MOAs had difficulty navigating through the EHR and often wrong buttons were pressed or the "submit to chart" button was not pressed, as it was not readily visible after completion. It was noted however, that if the items mentioned were adjusted, the electronic screen had the potential to impact the patient visit in a positive manner. One participant noted "having all the clinical information for each patient in one place would make for a more efficient patient visit."

Based on feedback and analysis of results from usability testing, many changes were made to the electronic SBIRT screen within the EHR. After the first round of testing, the problem of uncertainty of the hand off to the health coach was alleviated by alerts being set up within the electronic SBIRT tool. Once the screen was completed, calculated, and added to the chart, a positive screen was automatically sent to the patient's chart and the users task list. The user then forwarded an alert to the health coach.

Round 2

As a result of the usability testing, identifying barriers to adoption in the tool, and addressing them in the new design, during Round 2 of testing (1 year later), the MOAs felt the electronic SBIRT tool had improved and had high levels of user satisfaction. Specifically, participants noted that the delivery of the screen to the health coach and the patient's EHR was more accurate than even the paper version. However, during Round 2, the workflow with the EHR screening tool had changed.

Instead of entering the information from the screening directly into the computer during a patient interaction, answers were added only after the MOA was finished in the room with the patient. As noted by the MOAs in the qualitative interview, although the functionality of electronic SBIRT tool had improved due to adjustments based on Round 1, the issue with the length of time loading the tool on the computer created a situation that deterred the MOA from entering the screen into electronic SBIRT tool in real time during the patient visit. This slowed down workflow considerably. Therefore, discussions after Round 2 were focused on improving lag times so that MOAs could enter information in real time in order to enhance workflow and decrease timing of patient visits.

This study demonstrates the importance of usability testing during initial design. We were able to refine an electronic SBIRT tool to address usability barriers and create a user-friendly version of the electronic tool. This study also demonstrates how clinical practice is dynamic, and therefore tools should also be flexible and easily edited. Usability testing a year later was able to identify new barriers and direct a new iteration of the tool. Using the SBIRT screening tool as a clinical case to constant usability testing highlights how other clinical decision support tools and electronic screening tools should consider periodic usability testing.

The SBIRT tool integration into the EHR also demonstrates that electronic tools may not always improve workflow if not tested thoroughly before implementation; electronic tools need a user-centered design before launching. The final electronic SBIRT tool sets precedence for other SBIRT sites to develop, test, and implement an electronic SBIRT tool in their EHR and clinical workflow.

Limitations

One limitation of this study was the small sample size of MOAs that participated. The results may have been biased to Northwell Health workers' perceptions of the SBIRT tool and their specific clinical workflow. Therefore, usability testing is recommended before the introduction of CDS and screening tools into each new environment, so tools can be customized to site specific and staff specific workflows.

Conclusion

With the advances of health IT, progression of meaningful use, and implementation of EHR health systems, health systems are eager to implement IT solutions. The SBIRT screening tool is one example of this trend. Our study used a specific usability testing methodology to implement the SBIRT screening tool into the EHR in a way that was streamlined to the existing clinical workflow. Analysis of film, quantitative, and qualitative questions identified setbacks, areas for improvement, and highlights of both the first and second versions of the electronic SBIRT tool. By doing so we were able to identify ways to improve the tool, which resulted in an increase in user satisfaction and an increase in the accuracy of the tool. This study demonstrates the importance of usability testing in designing EHR tools. Future studies must focus on a more robust sample size in standardized usability testing laboratory to allow for more thorough investigations into the optimization of the SBIRT into its electronic form. An example of a study design would be talk aloud methodology combined with near-live simulation testing. This would allow for more individualized feedback and investigation into real-life workflow limitations and would allow for further optimization of the tool. This would also allow for revisiting fidelity, barriers/facilitators, and process mapping of clinical workflows at multiple time points.

Conflicts of Interest

None declared.

Multimedia Appendix 1

AUDIT-C and DAST-1 questionnaire forms.

[PDF File (Adobe PDF File), 551KB - humanfactors_v3i2e18_app1.pdf]

Multimedia Appendix 2

SBIRT screening tool workflow.

[PDF File (Adobe PDF File), 206KB - humanfactors_v3i2e18_app2.pdf]

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Abbreviations

ASSIST: alcohol smoking and substance involvement screening test
AUDIT-C: the alcohol use disorders identification test
CDS: clinical decision support
DAST-1: drug abuse screening test
EHR: electronic health record
EMR: electronic medical record
IT: information technology
MOAs: medical office assistants
NYSBIRT: New York screening, brief intervention, and referral to treatment
SBIRT: screening, brief intervention, and referral to treatment
SUS: system usability scale

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Original Paper

User Experiences of the McMaster Optimal Aging Portal's Evidence Summaries and Blog Posts: Usability Study

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Abstract

Background: Evidence summaries and blogs can support evidence-informed healthy aging, by presenting high-quality health research evidence in plain language for a nonprofessional (citizen) audience.

Objective: Our objective was to explore citizens' perceptions about the usability of evidence summaries and blog posts on the Web-based McMaster Optimal Aging Portal.

Methods: Twenty-two citizens (aged 50 years and older) and informal caregivers participated in a qualitative study using a think-aloud method and semistructured interviews. Eleven interviews were conducted in person, 7 over the telephone, and 4 by Skype.

Results: We identified themes that fell under 4 user-experience categories: (1) desirability: personal relevance, (2) understandability: language comprehension, grasping the message, dealing with uncertainty, (3) usability: volume of information, use of numbers, and (4) usefulness: intention to use, facility for sharing.

Conclusions: Participants recognized that high-quality evidence on aging was valuable. Their intended use of the information was influenced by how much it applied to their own health circumstances or those of a loved one. Some specific formatting features that were preferred included consistent layout, content organized by subheadings, catchy titles, numerical information summarized in a table, and inclusion of a glossary.

(JMIR Hum Factors 2016;3(2):e22) doi:10.2196/humanfactors.6208

KEYWORDS

Web-based health information; consumer health information; usability testing; knowledge translation; aging

Introduction

Background

At a time when patients have become more active participants in health care decision making [1], the Internet can be used as a healthy-aging information "tool" [2,3]. Increasingly, people turn to the Internet as a source of information, motivation, and support for healthy living and management of common health conditions [4]. Accessing Web-based health information helps older people to take better care of their own and loved ones' health, either by attending to an existing health condition or

improving health behaviors [5]. Seniors can also use the information to prepare for and follow-up after a health care–related appointment [5]. For patients who want to ask questions that they perceive as embarrassing or private, the Internet provides anonymity and convenience [6]. Many older adults are also supported by family and informal caregivers who seek out Web-based health information on their behalf [2,7]. However, much of the health information available on the Internet has not been informed by good-quality evidence [8,9], and therefore is unlikely to produce beneficial results on health.

McMaster Optimal Aging Portal

A full description of the Web-based McMaster Optimal Aging Portal [10] and its components is available elsewhere [11]. In this paper, we focus on 2 types of Portal content that provide citizen-friendly research evidence about aging: "lay" evidence summaries and blog posts about the best available research. 'Citizens' include members of the general public and health care consumers such as patients and caregivers. The term is used to distinguish them from health care professionals (clinicians, public health workers, policymakers) who are the typical target audiences for research evidence.

A scoping review found a scarcity of knowledge translation research focused on the care of older adults [12]. Evidence summaries and blogs can support evidence-informed healthy aging. Within the knowledge-to-action cycle framework, these resources fall into the third milestone of adapting knowledge to the local context [13], by explaining and translating health research evidence into plain or lay language for citizens. While we know older adults and caregivers are going to the Internet to find health information [14-16], we need to know about the optimal ways to package that information to be most useful [17].

As part of the overall formative evaluation of the Portal [11], we conducted individual interviews with citizens to identify prominent perceptions about the usability of the evidence summaries and blog posts.

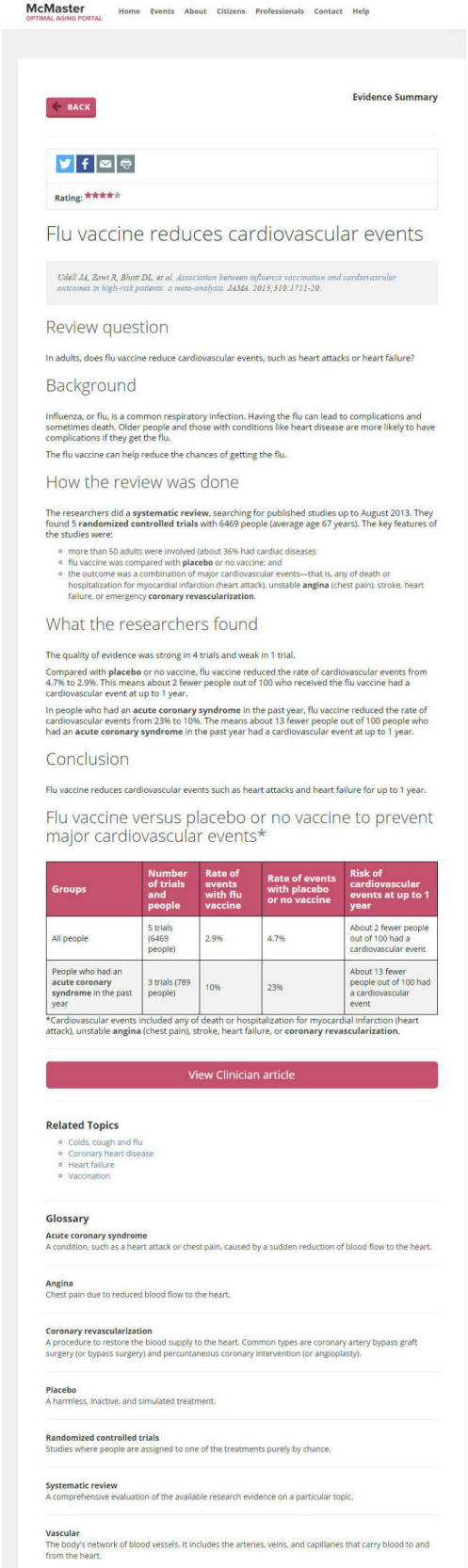
Methods

Evidence Summaries and Blog Posts

A full account of the evidence summaries and blog posts are published elsewhere [11]. In short, evidence summaries describe the findings from the best available research (typically, systematic reviews) on a particular topic in plain language. The research comes from 3 professional databases containing systematic reviews and individual studies that have been critically appraised for scientific merit: McMaster Premium LiteratUre Service (McMasterPLUS) [18,19], Health Evidence [20], and Health Systems Evidence [21,22]. To be included in the Portal, the content must be relevant to healthy aging and health care for older people. The summaries are written by trained Portal research staff, who each have graduate degrees in health research methodology or a related field. They are organized into the following sections: declarative title, descriptive title, subject of the study, research question, background, how the review (research) was done, what the findings are, and definitions of key technical terms (Figure 1).

Blog posts are discussions or commentaries on the best available, recent scientific evidence specific to healthy aging. The topics were determined by consensus of the Portal's expert advisory committee. The committee consists of professionals with expertise in diverse fields, such as aging, epidemiology, geriatrics, health policy, health informatics, and rehabilitation. Blog posts typically contain the following: feature image about the topic being discussed, text about the topic's importance, research on the topic, why the research findings are important, bottom line messages, references, links to other relevant blogs or items on the Portal, and author details. The writer of the blog post is chosen on a case by case basis. Blogs that cover a specific topic area (eg, sleep disorders, cognitive functioning) are written by an invited scientist or practitioner that is an expert in that field. Some blogs focus on the research featured in an evidence summary; these are written by a professional writer and reviewed for accuracy by a content expert. Both types of blogs are edited by a professional editor (Figure 2).

Figure 1. Evidence summary on the McMaster Optimal Aging Portal.



McMaster OPTIMAL AGING PORTAL

Home Events About Citizens Professionals Contact Help

BACK

Evidence Summary

Rating: ★★★★☆

Flu vaccine reduces cardiovascular events

Udell JA, Zawi R, Bhatt DL, et al. Association between influenza vaccination and cardiovascular outcomes in high-risk patients: a meta-analysis. JAMA. 2013;310:1711-20.

Review question

In adults, does flu vaccine reduce cardiovascular events, such as heart attacks or heart failure?

Background

Influenza, or flu, is a common respiratory infection. Having the flu can lead to complications and sometimes death. Older people and those with conditions like heart disease are more likely to have complications if they get the flu.

The flu vaccine can help reduce the chances of getting the flu.

How the review was done

The researchers did a **systematic review**, searching for published studies up to August 2013. They found 5 **randomized controlled trials** with 6469 people (average age 67 years). The key features of the studies were:

- more than 50 adults were involved (about 36% had cardiac disease);
- flu vaccine was compared with **placebo** or no vaccine; and
- the outcome was a combination of major cardiovascular events—that is, any of death or hospitalization for myocardial infarction (heart attack), unstable **angina** (chest pain), stroke, heart failure, or emergency **coronary revascularization**.

What the researchers found

The quality of evidence was strong in 4 trials and weak in 1 trial.

Compared with **placebo** or no vaccine, flu vaccine reduced the rate of cardiovascular events from 4.7% to 2.9%. This means about 2 fewer people out of 100 who received the flu vaccine had a cardiovascular event at up to 1 year.

In people who had an **acute coronary syndrome** in the past year, flu vaccine reduced the rate of cardiovascular events from 23% to 10%. The means about 13 fewer people out of 100 people who had an **acute coronary syndrome** in the past year had a cardiovascular event at up to 1 year.

Conclusion

Flu vaccine reduces cardiovascular events such as heart attacks and heart failure for up to 1 year.

Flu vaccine versus placebo or no vaccine to prevent major cardiovascular events*

Groups	Number of trials and people	Rate of events with flu vaccine	Rate of events with placebo or no vaccine	Risk of cardiovascular events at up to 1 year
All people	5 trials (6469 people)	2.9%	4.7%	About 2 fewer people out of 100 had a cardiovascular event
People who had an **acute coronary syndrome** in the past year	3 trials (789 people)	10%	23%	About 13 fewer people out of 100 had a cardiovascular event

*Cardiovascular events included any of death or hospitalization for myocardial infarction (heart attack), unstable **angina** (chest pain), stroke, heart failure, or **coronary revascularization**.

View Clinician article

Related Topics

- Colds, cough and flu
- Coronary heart disease
- Heart failure
- Vaccination

Glossary

Acute coronary syndrome
A condition, such as a heart attack or chest pain, caused by a sudden reduction of blood flow to the heart.

Angina
Chest pain due to reduced blood flow to the heart.

Coronary revascularization
A procedure to restore the blood supply to the heart. Common types are coronary artery bypass graft surgery (or bypass surgery) and percuntaneous coronary intervention (or angioplasty).

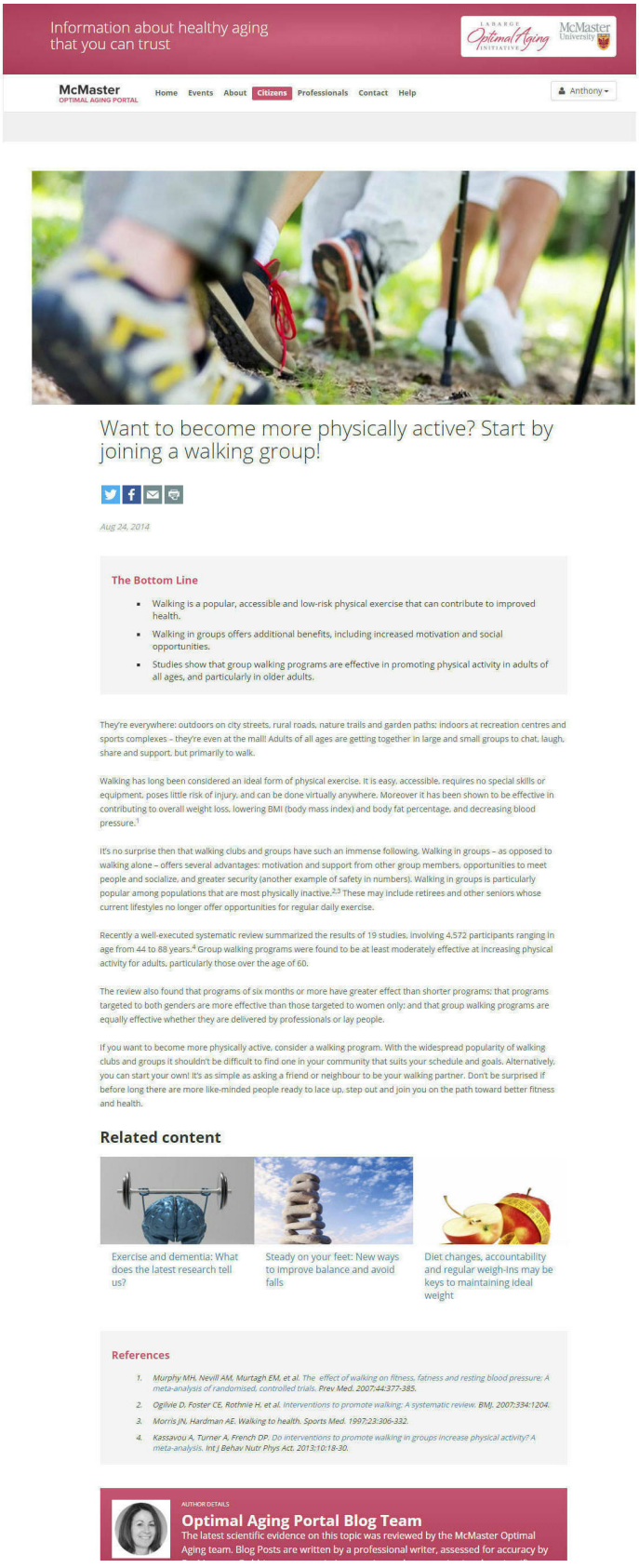
Placebo
A harmless, inactive, and simulated treatment.

Randomized controlled trials
Studies where people are assigned to one of the treatments purely by chance.

Systematic review
A comprehensive evaluation of the available research evidence on a particular topic.

Vascular
The body's network of blood vessels. It includes the arteries, veins, and capillaries that carry blood to and from the heart.

Figure 2. Blog post on the McMaster Optimal Aging Portal.



Participants

We used purposive sampling to form a sample composed of (1) citizens aged 50 years and older, and (2) informal caregivers (persons who provide unpaid care to an older parent/family member/friend/loved one). Participants were required to have access to a computer with an Internet connection.

Recruitment was done in conjunction with usability testing of the entire website [11]. We distributed and posted advertisements for both projects through local community and

academic networks (4 academic or research group listservs, 3 recreation centers for seniors, 1 retired community, 1 professional organization, and informal contacts through members of the Portal team). Interested individuals contacted the interviewer. After screening for eligibility, participants were emailed confirmation of the interview details and the consent form.

Procedures

One author (AMB) conducted all the one-on-one interviews, either in person (in a laboratory on the McMaster University campus), by telephone, or using Skype, based on participant preference. The choice to review summaries or blogs was also made by participants. The concepts of evidence summaries or blog posts were introduced to participants using the copy available on the Portal. Participants were instructed to choose what to review from a list of selected evidence summaries or blogs available on the Portal.

We used the think-aloud method [23], whereby users verbalize their thoughts as they read through the summaries or blogs. Participants were probed if they became quiet (eg, "What are you thinking?" "What are you looking at?" "What do you think about what you are reading?") Then, a semistructured interview guide (Multimedia Appendix 1) was used to elicit further feedback, based on a modified version of Morville's User Experience Honeycomb [24,25], whereby the following elements of information create a valuable user experience: findable, accessible, desirable, understandable, usable, credible, and useful. Interview questions included: "Why did you choose this one to review?" "Have you been looking for anything like this?" "What do you think of how the information was presented?" "How clear was the information?" "If you found this on your own, what would you do with it?" Following the interviews, participants were asked sociodemographic questions.

Data Analysis

Interviews were audiotaped, transcribed, and checked for accuracy. We used a framework approach, encompassing both thematic analysis and case analysis [26,27]. Thematic categories and patterns were compared between and within participants and linked from the identified theme to the original data. A framework approach was used because we had clear research goals in advance, but also wished to identify new themes emerging from the data. A subset of interviews were dual-coded by 2 authors (AMB, AJL), who met regularly to discuss coding, indexing, and interpretation of the results. We organized themes according to Morville's user-experience elements. QSR NVivo 9 software was used for coding and data management.

Ethical approval was granted by the Hamilton Integrated Research Ethics Board. This work was supported through the Labarge Optimal Aging Initiative.

Results

Study Participants

Sixty-three people contacted the interviewer in response to study advertisements. Fifteen respondents (15/63, 24%) participated in usability of the overall Portal, but did not evaluate the evidence summaries or blogs. Twenty-six (26/63, 41%) people were excluded from participation: 17 were considered noncitizens (ie, clinicians or public health professionals), 7 had scheduling conflicts, and 2 respondents did not use computers.

Twenty-two participants (22/63, 35%) were included in the following study. Eleven people (11/22, 50%) chose to evaluate evidence summaries, 7 (7/22, 32%) chose to evaluate blog posts, and 4 people (4/22, 18%) volunteered to review both. Twenty summaries and 14 blogs (11 written by experts and 3 written by the professional writer) were evaluated by at least 1 participant (Table 1).

The sample consisted of 12 citizens and 10 other citizens that were also informal caregivers (Table 2). Citizens were retired and all but 1 person reported having a health condition. Caregivers were mostly women (all but 1) and younger in age compared with noncaregivers (mean years, 58 vs 75). Each participant was given a study identification, which follows their quotes in the findings.

All participants were recruited from the Hamilton area in Ontario, Canada between July and September 2014. Sessions lasted from 30 to 67 minutes (mean = 43). Eleven interviews were conducted in person, 7 over the telephone, and 4 by Skype.

Table 1. Sample of evidence summaries and blog posts reviewed.

Content type	Health area	Title
Evidence summaries		
	Exercise	Yoga reduces pain and disability at up to 1 year in people with low back pain
	Memory and cognition	Tests detect dementia in older people; cognitive stimulation or some drugs may slightly improve cognitive function
	Heart disease	Multiple lifestyle changes in people with established coronary heart disease reduce the risk for cardiovascular events
	Health information technology	Computer-delivered interventions have a small effect on knowledge and some health behaviors
	Testing and treatment decisions	Unnecessary medication use in frail older adults can be reduced through team-based care, providing education to providers and reviewing prescribing practices
	Psychological and mental health	Meaningful social roles may improve health and well-being for people in retirement
Blog posts		
	Exercise	How fast should I walk to cross the road safely? Fast facts about walking speed
	Nutrition	Does salt really affect blood pressure?
	Memory and cognition	Treating behavioral problems of dementia: when confusion leads to controversy
	Social health	Loneliness hurts. How to recognize loneliness as a health concern
	Sleep disorders	Sleep and aging: how many zzz's are optimal to stay healthy?

Table 2. Participant demographic characteristics.

Group	Study ID	Age	Gender	Employment status	Health status	Education
Citizen						
	I-01	62	Female	Retired	Healthy	Some post-graduate
	I-02	66	Female	Retired	One or more health conditions	Some college/university
	I-03	66	Female	Retired	One or more health conditions	Some college/university
	I-04	70	Male	Retired	One or more health conditions	Post-graduate
	I-05	74	Male	Retired	One or more health conditions	Some college/university
	I-06	76	Female	Retired	Healthy	College/university
	I-07	79	Male	Retired	One or more health conditions	Post-graduate
	I-08	80	Female	Retired	One or more health conditions	College/university
	I-09	81	Female	Retired	One or more health conditions	College/university
	I-10	82	Male	Retired	One or more health conditions	Post-graduate
	I-11	84	Male	Retired	One or more health conditions	Some college/university
	I-12	84	Male	Retired	One or more health conditions	Post-graduate
Caregiver						
	A-13	23	Female	Part-time work, part-time student	Healthy	College/university
	A-14	48	Female	Full-time work	Healthy	Post-graduate
	A-15	55	Female	Retired	Healthy	College/university
	A-16	59	Female	Full-time work	Healthy	College/university
	A-17	60	Female	Part-time work	Healthy	High school
	A-18	60	Male	Retired	One or more health conditions	Post-graduate
	A-19	67	Female	Retired	One or more health conditions	College/university
	A-20	67	Female	Retired	Healthy	College/university
	A-21	70	Female	Retired	Healthy	Post-graduate
	A-22	75	Female	Retired	Healthy	College/university

Table 3. Findings, organized into 4 aspects of the user experience, themes, and subthemes.

User experience element and explanation	Theme
Desirability: users feel the product is worth having and have a positive emotional response to it	Personal relevance
Understandability: users comprehend both what kind of product it is and its content	Language comprehension; grasping the message; dealing with uncertainty
Usability: users can use the product easily, effectively, and with satisfaction	Volume of information; use of numbers
Usefulness: users find the product has practical value	Intention to use the information; facility for sharing

Findings

For this study, we describe the themes that fall under 4 user-experience categories (Table 3). Findability, accessability, and credibility are also important facets of the user experience, but have been discussed elsewhere as part of the usability of the overall Portal [11]. For additional exemplar quotes, please see Multimedia Appendix 2.

Desirability

Personal Relevance

Universally, participants selected a resource to review because the title contained a topic that was personally significant or applicable. Participants were concerned about a condition or situation that they were presently dealing with, had previously dealt with, or anticipated they would face in the future. Eight

citizens and 8 caregivers were specifically drawn to topics that affected loved ones.

> *I often look online for stuff about this for over the last about 11 years or so, since 2003, about diabetes and exercise and I have been looking online recently for what I key in is osteoarthritis. My mother had osteoarthritis towards the end of her life. I have developed a little bit, not bad yet, so I look up ways to deal with osteoarthritis and diabetes.* [A-18]

During the interview, 7 people specifically acknowledged the importance of aging on health and, overall, people responded positively to the Portal resources. In general, readers wanted information related to a specific topic and were less concerned about the type or format of the content (evidence summary, blog post, or other). However, 7 people wanted to understand what the summaries and blogs were supposed to be so they could read the information in the appropriate context.

Seven participants wanted to read a summary or blog because its topic was perceived as an important social issue or was featured recently in the media.

> *I was listening to a program on the radio about social isolation. And it found that when people are in a neighborhood where they feel safe and are familiar with, the general health of the elderly was much better, even in terms of lower heart attacks and stuff like that.* [A-20]

Engagement or absorption with the material was often demonstrated when 13 participants paused during reading to tell a personal anecdote or story. Two people claimed they would only read segments that were personally relevant and skim or skip the rest. Some participants related the information to their own situation by paraphrasing what they read. Sixteen users reacted emotionally (eg, reassured, alarmed, surprised) to what they read, especially by study conclusions.

> *Wonderful, the results are good news!* [I-01]
>
> *Oh shit! Really? So that would scare me because I have a problem keeping my sleep patterns normalized.* [A-16]

Users' prior knowledge about a subject also influenced the desire to read the information. Those who knew little were interested to find out more by reading carefully compared with participants who felt they were already well-versed about the topic and scanned the information. Four users chose a resource to learn more about an unfamiliar medical concept (eg, multimorbidity, psychotropics).

Each summary has a declarative title, stating the key result(s) of the study or systematic review succinctly. Seven people felt these titles were long and difficult to understand or "mouthfuls." Having a title that "grabs a reader" was seen as important, whereas the declarative titles were "not enticing." Some users felt the title was a "spoiler," which did not motivate them to read the content.

> *The title sounds like the conclusion. I would rather have a title that was more descriptive as to what I could expect in the article. This one is a bit disappointing. It really does not tell you much more than what is in the title.* [I-01]

One user assumed the titles of the summaries were the original article titles. On the other hand, 2 people commented that the blog titles were appealing and "catchy."

Understandability

Language Comprehension

Twelve participants, some of whom had some familiarity with research or the medical profession, thought the information in the evidence summaries was clear and easy to understand. In contrast, 8 participants felt that the summaries were written "by professionals for professionals" and questioned whether citizens would fully understand them.

> *It looks as if it is meant for professionals because of the wording. I think if you are aiming at older people, you don't want it to be patronizing but I think slightly less scientific wording would be more attractive.* [A-22]

When the cursor hovers over a bolded term in the body of an evidence summary, a pop-up box with the definition appears. This feature was received positively, as was the inclusion of the glossary at the end of some summaries, especially as most people were uncertain of the meanings of words such as 'systematic review' and 'randomized controlled trial'. Four participants recommended that a glossary be added to all summaries and also to blog posts. Some wanted the glossary to be expanded to include other scientific terminology, such as 'intervention', 'outcome', 'control (group)', 'quality of evidence', and 'meta-analysis'. Some participants struggled with certain phrases (eg, "range within which the average value might fall") and medical concepts (eg, dementia vs cognitive impairment). Many were unfamiliar with professional organizations (eg, Cochrane Collaboration), measurement instruments (eg., AMSTAR tool), and specific medications (eg, Nonsteroidal anti-inflammatory drugs or NSAIDs) or herbal products (eg, gingko biloba), unless they were taking them or they had been featured in the news (eg, Celebrex). In total, 17 participants identified terminology with which they were not completely familiar.

Grasping the Message

Eleven participants understood the key message(s) by looking at the conclusions in the evidence summaries or the "Bottom Line" in the blogs. At least 5 people said they would look at these sections first. Some wanted to re-read the resource more closely once they scanned it to comprehend the message. Participant A-15 stated "So a part of my habit is to always just to skip up and down and just to kind of get an overall view before I dig into an article."

Five people read parts of the text (sentence or paragraph) a second time (aloud or to themselves) to make sure they understood what they were reading. Fourteen respondents looked to the facilitator for confirmation that they understood the summary's meaning. "What the researchers found" was felt to contain the most important piece of information. "How the review was done" was of least interest. Four individuals wanted

to know more about the actual intervention. According to participant A-17, "I thought it would give you the exercises or some examples of what not to do."

Users were very satisfied if the intervention-related studies were described in enough detail that they might implement them (eg, specific drugs to discuss with their physician; small group activities to stimulate thinking and memory).

Dealing With Uncertainty

Two participants were cognizant that research did not always provide clear cut answers or provide "a magic pill." However, another 2 were exasperated. After reading that the research findings were not certain, participants were unsure why the information was presented. One participant reacted "Now, I am cranky," and explained further:

> *"Bottom line, the research shows that the amount of sleep, the quality of your sleep may change as we age." That means nothing to me. That's the kind of thing that a person tells you when they don't want to tell you anything important. So I understand that that's what the research says, but it's frustrating because I read to the end of this blog and there are no answers to my questions. I am getting gobbledygook. It started with a question and ends with a question.* [A-16]

Usability

Volume of Information

Eleven people who evaluated the evidence summaries felt the one page had "just the right amount of information." Some readers did not notice the length, rather they pointed out that the standardized format and layout made the content easy to read. The shortness of the summary guaranteed that most people would actually read it rather than only skimming it. Links to related content were appreciated by those who were interested in additional information.

> *They do not get into a ton of details, but I think that that is what some people are looking for. They are just looking for a kind of a summary and recap, or an introduction to some of these things.* [A-13]

Perceptions about the length of the blogs varied. Some commented that they were approximately the length of a magazine article, which was appropriate. However, at least 2 people felt they were too lengthy. Satisfaction with length was often associated with engagement; that is, 7 users did not mind reading longer articles or even remark on length if they were engrossed by the content.

Use of Numbers

Overall, 11 participants were happy with the presentation of data in table format (eg, summing up the findings of a systematic review) and found it informative. One participant felt,

> *"the table is easier to grasp than reading lines and lines of information"* [A-17]

Eleven people looked for demographic information (eg, ages of research participants); and 7 people looked for sample size (eg, number of participants in the systematic reviews or studies, number of studies included in the systematic reviews). Three participants said they liked the use of percentages.

> *I want to know how effective something is, quantification. Numbers help make things clearer and more useful.* [A-18]

On the other hand, 2 participants claimed they were not "number people" and preferred the focus to be on individuals (eg, how many people were helped rather than percentages or statistics). Four people wanted nonscientific information.

> *I am a person, not a statistic. So, I wanted to know the anecdotal evidence, because I could be the person outside the standard deviation. As a human being, all I care about is: Will this affect me? Will it hurt me?* [A-16]

Usefulness

Intention to Use the Information

Ten participants were satisfied with resources if they learned something new: "I didn't know exercise could help me with dementia" [I-02]. Others were pleased to reconcile any new information with their existing knowledge or understanding.

As mentioned above, many felt a discrepancy between the type of information available and their information needs. Eight participants wanted more detailed practical information that could be applied to improve their own health (especially regarding treatment or preventative activities).

> *The one thing that I would want is what should I do differently? This one has nothing about that. They didn't actually talk about the interventions. I would have been interested in knowing what they were. So I didn't learn anything… a little disappointing.* [I-01]

The resource was useful if the information could be applied to their demographic or personal situation. If the information was indeed relevant, 10 participants intended to apply it. Participant I-09 felt that "the information is good in that it gives me some choices and the pros and cons; and then it is up to me."

Some readers felt they would have benefitted if they had access to the information when they were dealing with a past situation (eg, making treatment decisions, dealing with the diagnosis in a parent). Others felt the summaries would be useful for future reference.

> *I chose this one about fall prevention because my grandmother fell and broke her hip, and my mother fell and broke her hip, I am assuming that is probably what will happen to me.* [I-02]

Facility for Sharing

Thirteen participants were keen to discuss the information with family and friends, and were pleased that the resource itself could be easily shared: "I know a lot of people with sleep apnea who don't realize they have it, and would share this with them" [A-16].

Five participants wanted to discuss the applicability of the information with their health care provider. Several felt that Portal resources should be available through physician offices

and other health care settings. One participant decided: "I will ask my doctor about whether there are any decision aids available for me" [A-21].

Discussion

Principle Findings

This study was conducted to better understand citizens' perceptions of the desirability, understandability, usability, and usefulness of the evidence summaries and blog posts available on the McMaster Optimal Aging Portal. By studying user's impressions, we can improve the translation of research evidence for citizens.

Participants recognized that high-quality evidence on aging was valuable. Their intended use of the information was influenced by how much it applied to their own health circumstances or those of a loved one. Participants wanted to read information about a specific health topic regardless if it was presented as a summary or blog. Nevertheless, specific formatting features were preferable (eg, consistent layout, content organized by subheadings, catchy titles of the blogs vs the declarative titles of the summaries). Participants wanted a narrative summary and information on how many people were helped or harmed by the intervention. Numerical information was preferably summarized in a table. While many participants were unfamiliar with research or medical terminology, there was a desire to learn it as demonstrated by the enthusiastic response to the glossary.

The study also suggested several challenges in presenting research evidence to citizens. Several participants perceived the evidence summaries to be written for professionals rather than a citizen audience. This suggests that, despite deliberate efforts of the Portal team to simplify the language, the information remained complex in the eyes of some. Systematic reviews typically investigate the effectiveness of an intervention in a specified population (eg, how effective are interventions with multiple lifestyle components in reducing the risk for cardiovascular events in patients with established heart disease?) However, patients and caregivers want to know how statistical results should be translated for individuals.

Participants often absorbed the evidence in the context of their own or other peoples' experiences. Some users were puzzled or frustrated by research with weak evidence or that did not have definitive conclusions. This highlights the need for instructional resources for citizens to learn that uncertainty is always present in health research (eg, a primer, meaningful graphics, or other multimedia formats to facilitate learning about research methods). Others have recommended the use of personal narratives to elucidate research outcomes [28].

Comparison With Previous Work

The findings of this study are in accordance with previous studies on the presentation of health information. The Cochrane Collaboration tested their Plain Language Summaries with citizens [29,30]. They also found a lack of familiarity with research-based concepts and individual variation in how users wanted research findings to be displayed (ie, text or numbers, or both). Like our study, their participants also wanted quantitative results to be presented in a table. They also preferred summaries divided by headings; and preferred headings in question format, which is similar to our participants' suggestions that the titles of the Portal summaries be in the form of an appealing question.

Work in disease-specific settings has found that seekers of Web-based health information have similar needs as our study participants. For example, people with multiple sclerosis also desire information that is personally applicable and educational tools (such as a glossary and methodological information), had emotional responses to information, and wanted integrated Web-based information with existing knowledge or information from other channels [31,32]

One page was perceived as an ideal length for the Portal evidence summaries. This is reinforced by consistent study findings that too much information can reduce comprehension [33]. Similar to our findings about blog length, other research has found that citizens differ on their notions of how much information is too much based on their preferences and needs [33].

The "fuzzy trace theory" of medical decision making argues that people want the gist of information and its bottom-line meaning as opposed to the literal details [34]. Our study observations support this theory in that our participants appreciated that information was presented in "chunks," which reduced cognitive load and allowed them to concentrate on specific chunks (ie, what the researchers found) and scan the remaining content.

Our findings also agree with survey research indicating that approximately one-third of older adults will talk about the health information they obtained from the Internet with their doctor [35]. Studies have found that patients will prepare for a doctor's visit by looking for health information [5]. Information access allows patients to evolve from passive recipients to active partners in their health care, and clinicians to transform from having an authoritarian role to being a partner in the care of their patients [16]. Physician encouragement and guidance regarding Internet usage by patients can also improve patient-physician communication [36]. Therefore, having high-quality evidence summaries and blog posts can empower patients, resulting in better discussions during clinical consultations and higher patient satisfaction.

Other studies have also found that citizens have difficulty in applying the findings of systematic reviews or individual research studies to their own individual situation [28,37,38]. While many users felt it was useful to be informed of current research in aging, at least one-third were looking for information that would help them make a personal decision, especially regarding treatment. We are currently exploring the addition of resources that will assist citizens in implementing research findings while addressing their values and preferences; specifically, patient decision aids and patient versions of clinical practice guidelines.

Limitations

We did not test a random sample, which may affect the generalizability of the findings. Participants were well-educated. Our testing occurred in an artificial setting; participants were

not accessing or reading the Portal resources in the context that is expected, and this could have affected responses. We did not formally assess health literacy, which is especially pertinent for older adults and will have affected how individuals processed and understood the information [39,40].

Conclusions

We identified factors that influence the usability of the Portal evidence summaries and blog posts. These factors will be used to improve the content and design templates for development of future summaries and blogs. To feature the Bottom Line more prominently, it will moved from the end of each blog post to the beginning. Because participants made a decision about whether to print or share a blog once they had read it, we will add the "sharing" buttons (now featured only at the top of the blog page) at the end of the blog as well. A prompt to describe an evidence summary for novice users will be added to the top of the Web page. At the end of an evidence summary, we will include additional related content on the Portal, such as "Related Evidence Summaries" and "Related Web Resources." Future research will focus on the impact of the enhanced formats on understanding, applicability, decision-making, and behavior of both citizens and health professionals in real-life settings.

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Authors' Contributions

AMB designed the study, conducted the usability testing and interviews, analyzed the data, and wrote the paper. AJL contributed to the study design, implementation and analysis, and cowrote the paper. MD, RBH, AI, and JNL contributed to the design and provided critical revisions to the paper.

Conflicts of Interest

None declared.

Multimedia Appendix 1

Interview guide for evaluation of evidence summaries / blog posts.

[PDF File (Adobe PDF File), 63KB - humanfactors_v3i2e22_app1.pdf]

Multimedia Appendix 2

Themes and quotes related to elements of the user experience.

[PDF File (Adobe PDF File), 55KB - humanfactors_v3i2e22_app2.pdf]

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Original Paper

Integrating Patient-Generated Health Data Into Clinical Care Settings or Clinical Decision-Making: Lessons Learned From Project HealthDesign

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Abstract

Background: Patient-generated health data (PGHD) are health-related data created or recorded by patients to inform their self-care and understanding about their own health. PGHD is different from other patient-reported outcome data because the collection of data is patient-driven, not practice- or research-driven. Technical applications for assisting patients to collect PGHD supports self-management activities such as healthy eating and exercise and can be important for preventing and managing disease. Technological innovations (eg, activity trackers) are making it more common for people to collect PGHD, but little is known about how PGHD might be used in outpatient clinics.

Objective: The objective of our study was to examine the experiences of health care professionals who use PGHD in outpatient clinics.

Methods: We conducted an evaluation of Project HealthDesign Round 2 to synthesize findings from 5 studies funded to test tools designed to help patients collect PGHD and share these data with members of their health care team. We conducted semistructured interviews with 13 Project HealthDesign study team members and 12 health care professionals that participated in these studies. We used an immersion-crystallization approach to analyze data. Our findings provide important information related to health care professionals' attitudes toward and experiences with using PGHD in a clinical setting.

Results: Health care professionals identified 3 main benefits of PGHD accessibility in clinical settings: (1) deeper insight into a patient's condition; (2) more accurate patient information, particularly when of clinical relevance; and (3) insight into a patient's health between clinic visits, enabling revision of care plans for improved health goal achievement, while avoiding unnecessary clinic visits. Study participants also identified 3 areas of consideration when implementing collection and use of PGHD data in clinics: (1) developing practice workflows and protocols related to PGHD collection and use; (2) data storage, accessibility at the point of care, and privacy concerns; and (3) ease of using PGHD data.

Conclusions: PGHD provides value to both patients and health care professionals. However, more research is needed to understand the benefit of using PGHD in clinical care and to identify the strategies and clinic workflow needs for optimizing these tools.

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KEYWORDS

mobile applications; chronic disease, self-management; doctor-patient relations

Introduction

Patients with chronic conditions often require continuous management of care rather than brief, single-focused interventions [1]. Data collected between visits can inform ongoing care management and provide important insights into a patient's health and well-being. As technology advances and patients also become more actively engaged in producing their own health data, the amount of health data produced grows substantially [2].

Patient-generated health data (PGHD) are "data created, recorded, and gathered by and from patients" [3]. Generating and capturing PGHD (eg, physical activity, food consumption) are increasingly common, particularly among patients with chronic illnesses [4-14]. Observations of daily living (ODLs) are one type of PGHD and are defined as patient observations and recordings of "the patterns and realities of daily life...diet, physical activity, quality and quantity of sleep, pain episodes, and mood" [15]. ODLs are unique from other types of PGHD because they are patient-informed; patients record the aspects of daily life they identify as most relevant to track [16]. These decisions can be made individually or in collaboration with health care professionals, and ODLs such as PGHD can be used for personal tracking and improvement as well as to inform clinical care [13,17,18]. PGHD collected through a range of different types of smart devices and other new technologies can provide patients with innovative ways to actively manage their health [11,19-21], improving patient self-knowledge [12], and management of health concerns, including diabetes [4-6,14,22], physical activity [8,10], and behavioral health triggers such as anxiety [7,9,23].

PGHD is distinguished from other types of patient experience data, such as patient-reported outcomes (PRO) (eg, NIH PROMIS) [24] and data generated through ecological momentary assessment (EMA) [25,26]. PRO data are standardized questions and surveys designed to understand patients' experiences of health such as mood and work-life function. The collection of PRO data are stimulated, driven, and informed by health care professionals and practices, and data are often collected through clinic-based tools such as electronic health records (EHRs) or patient portals [27-29]. In contrast, PGHD is patient-directed and patient-informed and is not collected through clinic tools but through a range of readily available commercial off-the-shelf tools such as mobile phone apps and wearable activity trackers [22]. PGHD is also distinguished from EMA, which is a data collection method where study participants repeatedly report on, for instance, a symptom or behavior [19]. While reporting is done in the natural environment, as is the case with PRO, what is measured is researcher-driven, not patient-driven. Additionally, the purpose of collecting EMA data is research, not self-management of one's health, as is the case with PGHD.

PGHD are a unique and important type of data relevant for health care settings, and for informatics experts that support information management in these settings. PGHD has the potential to impact health care delivery, and the patient-clinician relationship [21,30-32], including the possibility of reducing the demand for face-to-face clinic visits [33,34]. However, little is known about health care professionals' experiences with PGHD and their willingness to use it in the outpatient setting [33,35,36]. We begin to fill this gap by examining the experiences of health care professionals, working in a range of outpatient settings, who cared for patients collecting PGHD.

Methods

Setting

We conducted an evaluation of Project HealthDesign (PHD), a US national program of the Robert Wood Johnson Foundation that involved 2 rounds of funding. This paper focuses on Round 2 of the PHD program conducted between April 2010 and July 2012, which required grantees to develop and pilot innovative health information technology (health IT) tools to enable PGHD collection with the goal of using that information to promote patient engagement and to inform both personal health management and clinical decision-making. The program funded 5 US-based academic research teams who worked with patients to support the collection of PGHD through a range of apps, sensors, and/or websites.

Sample

The sample for this study constitutes the 5 studies funded through the PHD program, which provided a unique opportunity to identify a group of health care professionals that had been exposed to using a range of different PGHD in clinical care. We invited health care professionals, including clinicians, nurses, and health coaches associated with each of the 5 PHD studies for interviews. We interviewed 12 health care professionals who cared for patients using health IT tools. In addition, we invited study team members who worked closely with health care professionals to participate in interviews because they had important experiences and perspectives on health care professionals use of these data in the clinic. We interviewed 13 PHD study team members participating in the PHD studies to understand, from their perspective, the benefits and challenges health care professionals experienced when using PGHD. This study was approved by the Institutional Review Board of Oregon Health & Science University.

Data Collection

As the evaluators of the PHD program, we had access to documents about each PHD study, including details about their project (eg, aims, study design, study team, participants), the tools they developed, and access to some data they collected as part of their own evaluations. We used this to gain an understanding of each PHD study and identify interview participants.

DJC and SRK conducted one-on-one, semistructured interviews with participants, either in person or by Internet-enabled video conferencing software (eg, Skype, Microsoft Inc., Redmond,

WA, USA). We had to conduct 3 interviews by telephone, but we did not have access to visually-based nonverbal behaviors.

Our team developed 2 interview guides, one for health care professionals and the other for study team members. Both these guides were quite similar and focused on asking about the background of the individuals, their roles in the practices or the study, their understandings or definitions of PGHD, their experiences using PGHD with patients (health care professionals) or experiences helping health care professional use these data (study team members), and what they thought about how PGHD might be integrated into routine clinical care processes.

Data collection and analysis was an iterative process, wherein we conducted one or two interviews, analyzed them, and used emerging findings to refine the interview guides as needed, and monitored when saturation was reached. Saturation is the point at which themes repeat during the data collection process and no new findings emerge. In our study, we hit saturation after completing the interviews of 10 health care professionals and 11 study team members, after which we conducted 4 additional interviews to confirm or disconfirm preliminary findings.

Interview Data Management

Interviews were audio-recorded and professionally transcribed. We de-identified transcripts and entered them into Atlas.ti (version 7.0, Atlas.ti Scientific Software Development GmbH, Berlin, Germany) for data management and analysis. Study data were saved on a password-protected networked drive maintained by Oregon Health & Science University.

Analysis

We used an immersion-crystallization approach [37] to analyze data, meaning that we approached data without *a priori* hypotheses in mind but rather with the aim of identifying emergent findings. Due to the uniqueness of each PHD study, we engaged in this process for each case (a single PHD study) first. We started by analyzing the documents and information we had about each PHD study to identify the study's focus (eg, patients with asthma), the study's purpose (what kind of tool was developed and what the team was testing), and who, if anyone, in the clinical setting was exposed to PGHD. Next, we analyzed interview data to examine health care professionals' experiences when exposed to PGHD. We examined how they used these data with patients, explored how clinical processes accommodated the use of these data, and what concerns and benefits they saw for future use of these data in clinical care. We paid particular attention to similarities and differences in viewpoints among health care professionals and study team members.

After the single case analyses were completed, we conducted a cross-case comparison to identify patterns and variations across PHD studies. During this phase, we paid particular attention to variations in how PGHD were integrated into clinical practices based on the type of disease or illness and care setting, and to other factors influencing use of these data at the point of care. In the final phase, we iterated the preliminary results with consultants DAD, DFS, JSA, and GRH for feedback and to gain a multi-disciplinary perspective on the data and our preliminary findings. We used this input to refine our findings.

We further specified observed variation to the extent in which PGHD were integrated into clinical care, as part of the refinement process. We developed the following rating system: Highly integrated – PGHD were integrated clinical workflows and protocols of the doctor-nurse dyads; moderately integrated – there were no formal workflow changes to accommodate PGHD use, but some health care professionals reviewed data with patients, but this was outside of the typical care process; and minimally integrated – it was left to patients whether or not to share data with health care professionals; use of PGHD in the context of a clinical visit was minimal.

Results

PHD Study Attributes

Participants in the 5 PHD studies we examined included adults living with asthma (Project 1), elders at risk for cognitive decline (Project 2), overweight young adults (Project 3), people living with Crohn disease (Project 4), and caregivers of premature infants (Project 5). The involvement of the health care team (ie, how the care team received and acted on data), the focus of each project, the tools that were developed for collecting PGHD, and the extent to which PGHD were integrated into primary clinical workflows varied, as described in Table 1. In what follows, we triangulated data from health care professionals and study team members to understand the value of PGHD in clinical care, the experiences implementing PGHD into the clinical care setting, and features that support integration of PGHD data into clinical processes.

Table 1. Description of PHD studies and level of integration.

Study ID	Project overview	Data patients collected (PGHD)[a]	Type of health care professionals that used PGHD	Extent to which PGHD integrated into care	How PGHD were integrated into clinical workflow
1	Primary health issue: Moderate to severe asthma Patients used an app to collect health-related PGHD. Health data from these PGHDs were monitored by nurses at their primary care clinic	Medication usage, environmental factors, peak flow measurements	Primary care physician or nurse dyads	High	Nurses review data weekly via a Web-based dashboard for high-risk patients Nurses reported to their team clinician for patients who were at highest risk Nurses followed a standard protocol for interacting with the patient (phone call to change treatment, scheduling patient)
2	Primary health issue: Elders at risk for cognitive decline Passive sensors, connected to a remote server, were placed in elders' homes to collect PGHD data. Elders and caregivers could use summary data to identify likelihood of decline	Assessed task completion (making coffee) as proxy for cognitive decline (ability to correctly sequence tasks)	Health care professionals were not exposed to PGHD in clinical settings	Minimal	Data were not integrated into clinical care Patients had the option to decide how, when, or if they shared summaries with care providers
3	Primary health issue: Adolescent behavioral health Participants (from local high school and hospital) tracked a variety of ODLs[b] on an app. Participants also met regularly with a health coach to review ODL data and set goals	Food intake, physical activity, mood	Health coaches employed in primary care practice	Moderate	Health coach reviewed PGHD data on a Web-based dashboard and used data to support patient behavior change Health coach monitored for mental health "red flags" and reported them to appropriate health care provider
4	Primary health issue: Crohn disease Patient participants met with a physician to develop a list of ODLs to be tracked	Weight, physical activity, mood, and symptoms relevant to their illness	Gastroenterologists	Moderate	Patients had the option to share data with physician during regular visits Health care professionals reviewed data as part of visit and this informed treatment decisions
5	Primary health issue: Problems associated with premature infants Case manager of a high-risk infant follow-up program worked with caregivers of high-risk infants and reviewed PGHD	Infant's weight, food consumption, elimination patterns	High-risk infant case managers	Moderate	Case manager reviewed data on Web-based platform (daily) Interactions with caregivers via appointment reminders and messages Caregiver's discretion to share data with other providers

[a]ODLs: observations of daily living.

[b]PGHD: patient-generated health data.

Health Care-Related Perspectives on PGHD

Health care professionals and PHD study team members reported that PGHD fostered a deeper and more accurate understanding of a patient's illness through tracking of key symptoms and reported having better informed visits with patients who collected PGHD. This is because PGHD helped clinicians identify and understand how patients' symptoms varied over longer periods of time, helped them to catch problems that might otherwise go unnoticed, and helped them and their patients better manage their disease:

> *The weight data turned out to be a great proxy for someone's health status with Crohn's because it actually fluctuates significantly week-to-week. And, you know, it might be sometimes like ten pounds. I mean it's amazing the things you can catch on a Wi-Fi scale if you step on it every day. And the providers were really enthusiastic about that data, especially because they only see weigh-ins like every three months or so. And so this allowed, I think, patients and providers to have a really clear starting point into sort of the ebb and flow of how things were actually progressing.* [Project 4, Study Team Member]

> *(PGHD gives me) more of an appreciation and more empathy for what patients go through on a day-to-day basis. Because it's so easy for us when we see the patient in the clinic. Like, oh, tell me about your bowel frequency over the last few days or last week. And they give a range or give you a number and I'm like, okay good, I'm glad that you're doing well. But when you're forced to look at all this additional information in the way of like, oh, well, actually this is just a good week. For the past month prior you were actually doing really badly.* [Project 4, Nurse Practitioner]

Health care professionals also reported that the ability to monitor and assess patient data between clinic visits allowed them to identify patients who were not reaching health care goals. For example, in Project 1, nurses monitored asthma patients' peak flow readings and reported contacting patients by phone to refine treatments or reeducate patients about medication use. As one clinician in Project 3 noted, there were benefits to keeping patients out of the clinic by managing their treatments at home: "The more we can keep people home and giving us the information that we need to know...the better."

Practice Protocols for PGHD Collection and Use

Health care professionals recognized that if PGHD were to become a routine part of practice, they might have some responsibility in engaging patients in collecting PGHD. A clinician participating in Project 1 speculated that patient engagement might be a 2-step process in his practice involving assessment of the patient's level of asthma control, then engagement of those patients who would benefit from using the asthma application:

> *I could envision a two-step process where you would make that part of your standard asthma visit. You would either do the asthma control test or you would do a consistent defined asthma controlled assessment. Those (patients) that are truly intermittent or mild and well-controlled maybe don't really need this. But the folks that are scoring as uncontrolled and/or the folks that thought they were well controlled, but when you actually do the assessment they're really not, those might be the folks who this would be a more high yield tool for integrating.* [Project 1, Clinician]

In addition, health care professionals reported that there might be a need to negotiate with patients when determining which data elements to collect:

> *If a patient had chronic inflammation or if they had perianal disease or they had small bowel disease, then I would set up generic template based on what the disease location is. These are the items I think might be helpful for us to monitor going forward. And then I'd leave it open-ended if there was anything else that they want to gather, so that there's some buy-in to more than just what I want to collect. (Chuckles) And then I would go from there, and I would just have like a generic, kind of prescription so to speak, on each patient depending on where their disease is.* [Project 4, Nurse Practitioner]

In addition, health care professionals reported that they would need to set patients' expectations for communication about PGHD, letting patients know that they would not be contacted if everything was normal.

When the staff was responsible for reviewing and acting on PGHD, both health care professionals and study staff reported that practice protocols were needed to guide staff decisions and actions. For example, in Project 1, patients collected peak flow measurements, asthma triggers, and medication usage. Using these data, the Web-based dashboard assigned patients to one of three zones of asthma control: Poor control (indicated by a red flag), moderate control (indicated by a yellow flag), and good control (indicated by a green flag). Each physician's nurse reviewed the dashboard weekly, and one nurse describes how it guided her actions:

> *I know definitively if they were in the red zone all the time, I would call them. Sometimes I'd even just make sure they were using their medications correctly, because sometimes you'd see where they were using rescue meds, but they weren't using their controller medications. So, I would look at it and look for the red flags, so to speak, the little things that were red that said that they were having problems, or where their peak flow wasn't where we wanted it to be* [Project 1, Asthma, Nurse]

This nurse knew definitively when to contact patients in the red zone because the practice had developed a protocol to guide this behavior (see Figure 1).

Data Storage, Accessibility, and Privacy, and Ease of Using PGHD

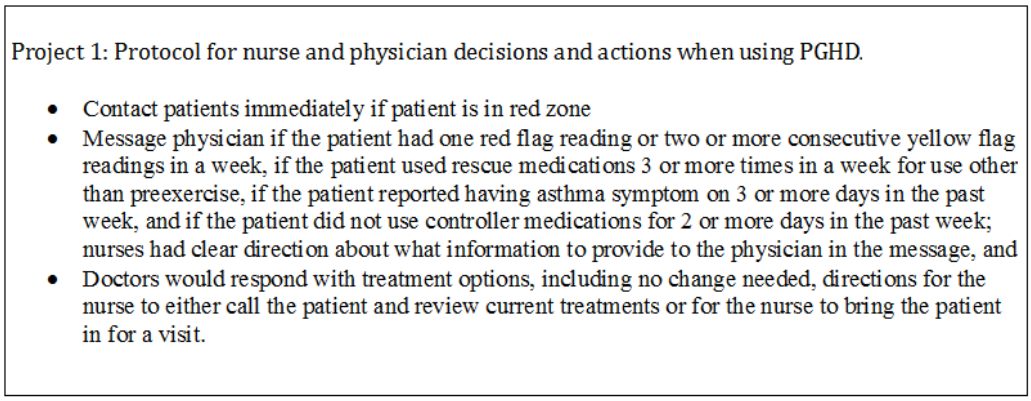
In addition to the practice changes identified above, health care professionals and PHD study teams identified data storage, accessibility at the point of care, and privacy concerns, and ease of using PGHD as important areas to consider when implementing health IT tools to assist patients with collecting PGHD.

Data Storage, Accessibility, and Privacy

PHD study teams handled data storage for participating clinical practices and avoided integrating the data patients' generated into practices' EHRs. Using a range of applications, data were protected on study team servers, and made available to health care professionals through Web-based platforms. Health care professionals reported wanting data integrated in the EHR to make it easier to use and more accessible at the point of care. For example, one nurse described her experience:

> *What we had to do was go into another window, you know, go into... I went into it. Then I had to type in my password again. But it would be nice if it were actually something that could be part of the EHR where you just click on it and it pops up.* [Project 1, Nurse]

Figure 1. An example of practice protocol for using patient-generated health data (PGHD).



Health care professionals' preference to have PGHD integrated in the EHR was tempered by legal concerns related to patient privacy and data storage. Health care professionals and study team members reported that, outside of the study context, data storage would be the responsibility of clinical practices, the larger health care organization, or a third party who would host these data; they questioned whether "third party" data storage providers would be Health Insurance Portability and Accountability Act (HIPAA)-compliant.

Health care professionals also reported concerns about security of communications with patients and maintenance of privacy and confidentiality. For example, in the study in which health coaches were using standard mobile phone texting functionality to communicate with adolescents about their health behaviors, they shared concerns that someone other than the teen (eg, a parent) might see these communications:

> *There are some things that when they talk to us about sexually related issues, substance abuse, mental health, after age 12, they're protected from us talking to their parents about it. There would be a selective bias, you know, probably about what they enter. So if they're drunk or had a wild weekend and had some sexual partners or something, I'm not going to put that in here.* [Project 3, Health Coach]

Out of concern that parents might view the messages, health care professionals reported taking precaution when determining what they would communicate to adolescents via text.

Ease of Use: Synthesizing and Visualizing Tools for PGHD

All 5 PHD projects provided health care professionals with data dashboards, which are Web-based tools that aggregate, summarize, and visualize PGHD. Participants reported that the ability to sort or summarize data in a descriptive manner, or to graph it in different ways, helped health care professionals to more quickly see patterns in the data patients' generated, and to extrapolate something meaningful from these data:

> *Because that was our concern from a provider standpoint that just going through this much data was going to be so time consuming. So that ability to put all of the data on top of each other, transpose it so we could see all the graphs at once, and see if anything correlated was helpful.* [Project 4, Nurse Practitioner]

In addition to being able to visualize and manipulate data, health care professionals reported the need to customize their dashboards. For example, the nurse care manager in charge of reviewing the data for Project 5 reported that she customized her dashboard homepage so the most relevant patient information (in this case, alerts) was the easiest to see. As the following example from the asthma project shows, if the information displayed in a Web-based dashboard could not easily be rearranged to meet user needs, it reduced ease of use and efficiency:

> *(Referencing the dashboard) ...you pulled up the list of everybody. And then you were like, okay, now where are my patients? They weren't necessarily even in alphabetical order. When they added them on, they might have been on the second page. But now because we have more, they bumped them to another page. Yeah. So that would be great if you had folders that you could just say, these are the patients I'm following and put them in that folder. And you could open your folder and all your patients would be right there. That would be good.* [Project 1, Nurse]

In the above quote, the screen described by the nurse displayed patient information for all the patients in the study, yet nurses only needed to locate and see data on their own team's patients. The trouble, the nurse notes, is the inability to sort the data by clinician, and this added time to her tasks.

Discussion

Principal Findings

The data patients collect about their own health-related activities, support their self-management activities [19,30,38], and may also inform their interactions with health care professionals [30]. Our study of the Round 2 PHD projects shows that health care professionals recognize both the potential value of using PGHD in the clinical care process and the potential concerns that may arise related to data storage, privacy, and clinic workflow. We highlight some of these issues that must be addressed when making PGHD part of the formal clinical care

process. Our work contributes to a nascent body of research identifying what motivates patients to collect data about themselves [39] and also how these data might be useful in clinical care [20,22,40-43].

We found that the usefulness of PGHD in the outpatient setting rests not only on data having clinical relevance but also relies on patients to collect these data. There is recognition among health care professions that using PGHD tools to inform health care requires balancing the data patients want to and are willing to collect with the data health care professionals find valuable. While little has been written about how to strike this balance in the PGHD development process, most of the PHD teams engaged multiple users in the development of tracking tools. Those interested in developing PGHD tools might benefit from reviewing published work in the area of groupware development, which identifies steps for developing products to benefit different types of group members [44].

Requirements must be met to use PGHD in clinical outpatient settings. For example, PGHD needs to be summarized so that patterns can be easily visualized by health care professionals who also saw benefits in being able to manipulate these data. Both of these functions were important for rapid sensemaking and decision-making [2,36,45]. The effort and cost that goes into making PGHD data useful at the point of care not only adds value but may influence whether or not health professionals utilize these tools and/or the data generated by their patients. Operational issues to consider include ensuring secure data storage and developing standards and guidelines for patient privacy [45,46], which may include teaching patients the basics of protecting their own data [47], as providing hardware and software to support patients in collecting these data, as well as clinic team members available to train patients in tracking data. These needs, which span health IT functionality and practice operations, need to be fully considered when integrating the collection and use of PGHD into clinical settings [2].

Health care professionals reported a preference for integrating PGHD into practice-operating structures and existing clinical infrastructure, such as the EHR. However, other options, such as keeping these data as part of a patient-owned record, may be more viable and avoid some privacy concerns also identified by health care professionals. Importantly, such an approach would keep ownership of these data with the patients generating it and leave it to their discretion how, when, and/or if these data are shared with health care professionals. Patient ownership is an important characteristic of PGHD, one that distinguishes it from other types of patient experience data, such as PRO data. Keeping ownership of these data with the patients changes the position of health care professionals (to one where they are negotiating a “prescription” for data collection with patients), and this represents a level of patient empowerment and autonomy that is not always present in clinician-driven health care. In such an empowered relationship, patients might begin to expect a different level of service and engagement than is typical in the current landscape. In addition, keeping ownership of these data with patients might avoid some of the legal complications of having the outpatient organization maintain PGHD. (For more on the legal perspectives related to patients’ PGHD use in clinical settings see McGraw et al [47-49]). Regardless, this study suggests the efficacy of collecting and using PGHD data in health care [50,51]. More research is needed to establish the effectiveness of using PGHD data in clinical care [41], to determine the best strategies for implementing these data into clinical care process, and to consider the ethical implications of these different strategies.

Limitations

This study has several important limitations. First, Institutional Review Board restrictions limited our ability to interview patients to determine their experiences when sharing PGHD with health care professionals. Thus, we can only portray how health care professionals and study team members experienced collection, sharing, and/or use of PGHD. More research is needed to appreciate patients’ experiences. Second, to accommodate the busy schedules of health care professionals and PHD study team members, we had to conduct 3 interviews by telephone. While we recognize that bodily-based nonverbal behavioral communicates important information in an interview, we thought it was more important to get the interview by telephone, than to other wise miss interviewing someone because face-to-face was a requirement. We compared telephone interviews with other interviews (in persons and through virtual platforms), and they were not remarkably different. Third, while the validity and reliability of other types of patient experience data has been established (eg, PRO), little is known about the validity, reliability, and effectiveness of using PGHD on clinical outcomes, which were all outside the scope of our study. Fourth, the 5 studies we examined, represented a broad range of approaches for collecting and using PGHD data, which added to the richness and breadth of our findings. However, the studies themselves were small and of limited duration and scope. Thus, the study teams and health care professionals we interviewed (and their patients), did not have long-term experiences with collecting and using PGHD, and therefore, we know little about how a longer duration of PGHD collection might affect perceptions and experiences.

Conclusions

PGHD can provide value in the outpatient setting but must be implemented with attention to patient privacy and clinic workflows. More research is needed to understand patients’ and clinicians’ long-term experiences with using PGHD [52] to distill the benefits of using PGHD in clinical care and identify strategies for optimizing the use of these tools and to establish an evidence base supporting the use of PGHD in outpatient settings.

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Conflicts of Interest

None declared.

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Abbreviations

EHR: electronic health records
EMA: ecological momentary assessment
HIPAA: Health Insurance Portability and Accountability Act
IT: information technology
ODL: Observation of daily living
PGHD: Patient-generated health data
PHD: Project HealthDesign
PRO: patient-reported outcomes

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Original Paper

Do Gender-Specific and High-Resolution Three Dimensional Body Charts Facilitate the Communication of Pain for Women? A Quantitative and Qualitative Study

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Abstract

Background: Chronic pain is more prevalent among women; however, the majority of standardized pain drawings are often collected using male-like androgynous body representations.

Objective: The purpose of this study was to assess whether gender-specific and high-resolution three-dimensional (3D) body charts facilitate the communication of pain for women.

Methods: Using mixed-methods and a cross-over design, female patients with chronic pain were asked to provide detailed drawings of their current pain on masculine and feminine two-dimensional (2D) body schemas (N=41, Part I) or on female 2D and 3D high-resolution body schemas (N=41, Part II) on a computer tablet. The consistency of the drawings between body charts were assessed by intraclass correlation coefficient (ICC) and Bland-Altman plots. Semistructured interviews and a preference questionnaire were then used to obtain qualitative and quantitative responses of the drawing experience.

Results: The consistency between body charts were high (Part I: ICC=0.980, Part II: ICC=0.994). The preference ratio for the masculine to feminine body schemas were 6:35 and 18:23 for the 2D to 3D female body charts. Patients reported that the 3D body chart enabled a more accurate expression of their pain due to the detailed contours of the musculature and bone structure, however, patients also reported the 3D body chart was too human and believed that skin-like appearance limited ‘deep pain’ expressions.

Conclusions: Providing gender-specific body charts may facilitate the communication of pain and the level of detail (2D vs 3D body charts) should be used according to patients’ needs.

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KEYWORDS

mHealth; app; android; pain measurement; chronic pain; three dimensional pain drawing; digital communication

Introduction

Pain is the primary symptom for 40% of all visits to the primary care physician [1]. The most common cause of pain is of musculoskeletal origin [1,2], and almost all anatomical sites are reported to have a higher prevalence of chronic pain for women [3]. Additionally, the prevalence for neuropathic, widespread, and abdominal pain is also higher among women [4]. Various

tools and questionnaires have been developed to document and communicate a patient's pain experience and associated symptoms to health care professionals and researchers [5]. Of these methods, pain drawings are widely used to communicate pain extent and location as the drawings can depict symptoms and ultimately assist in diagnosis [6-9]. Traditionally, paper versions of two-dimensional (2D) outlines of the body are provided to the patient for them to indicate and draw the area or pattern of their perceived pain. These traditional 2D outlines of the body are deemed androgynous but they are clearly more masculine [8-11] and whether this influences a woman's ability to clearly express the extent and location of her pain is unknown. Androgynous body charts can hide clinically relevant anatomical differences between the genders, such as the width and contour of the hips, waist, chest, and shoulders.

An accurate and careful assessment and communication of pain from patient to a health care professional is an essential step toward diagnosis and pain management [12]. However, assessment and communication of pain are influenced by two types of error: the assessor and the communication tool. When using 2D androgynous body charts women with chronic musculoskeletal pain report similar pain intensities to their male counterparts; however, women tend to report slightly larger pain areas than men in all anatomical sites [13]. Is this difference in pain area between the genders a true depiction and is there any clinical relevance between the differences? Few studies, have employed gender-specific or more feminine body charts [14-16]; however, no studies have cross-validated a female to a male body chart nor investigated whether the patient prefers using gender-specific body charts for expressing and communicating their pain. Indeed, it has been proposed that men and women experience and communicate pain differently [17], the question is whether a female body chart provides the otherwise missing and necessary anatomical guidance required for women to more clearly and accurately express their pain; and if so, does the use of high-resolution, three-dimensional (3D) body charts further improve this form of communication?

The aim of this study was to determine whether a feminine, as compared with a masculine version, of a 2D body chart is preferred by women for the communication of pain extent and to evaluate drawing behavior by assessing the level of agreement between the drawn pain areas between the gender body charts. In a similar fashion, this study set out to determine whether enhanced anatomical detail would further improve the ability to express current pain. It was hypothesized that female patients would prefer a feminine body chart with enhanced anatomical detail and that drawing behavior would be influenced by the gender of the body chart.

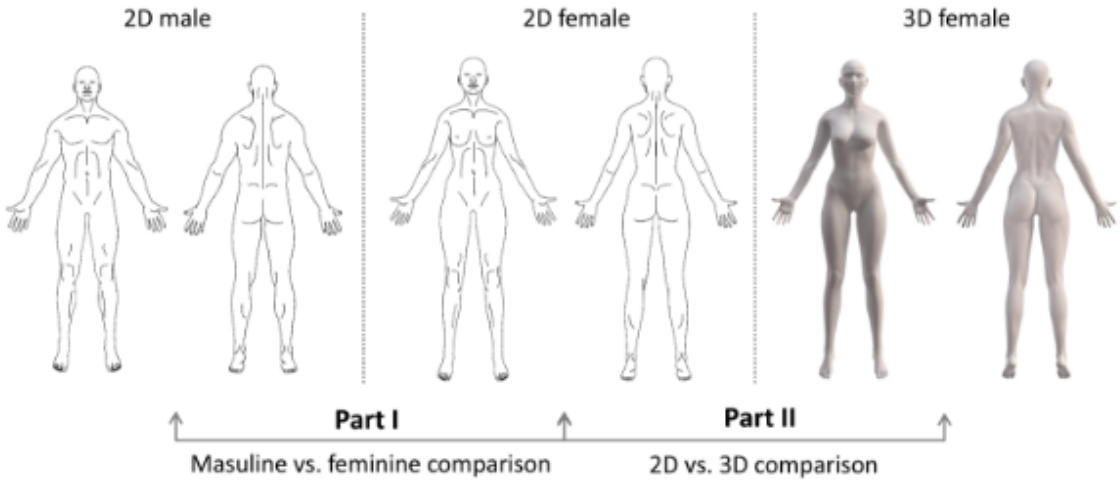
Methods

Overview

This mixed-methods study was conducted with female patients referred to a multidisciplinary pain clinic for the purpose of chronic pain management, in order to assess the drawing behavior, preference, perception, and drawing experience of using masculine and feminine body charts (Part I) or traditional 2D line and high-resolution 3D female body charts (Part II), as shown in Figure 1. A randomized cross-over design for both Part I and II was implemented. All participants were asked to indicate the area and location of their current pain on two body charts in randomized order, in accord with either Part I or II. A questionnaire was administered to assess preference of body chart immediately after the pain drawings. Further, a semistructured interview was conducted in order to assess the user experience and the impact of using body charts with (Part I) masculine and feminine features or (Part II) enhanced anatomical detail for the communication of pain extent.

In Denmark, approval from the local ethics committee for survey and interview studies is not legally required. Nevertheless, this study was performed in adherence to ethical rules and guidelines with respect to voluntary participation and confidentiality and the study was reported to the Danish data protection agency. Signed informed consent was obtained before participation and the study was conducted according to the Helsinki Declaration.

Figure 1. Overview of the body charts compared in Part I and II. Part I compares the masculine and feminine body charts and Part II compares the female 2D and 3D body charts.



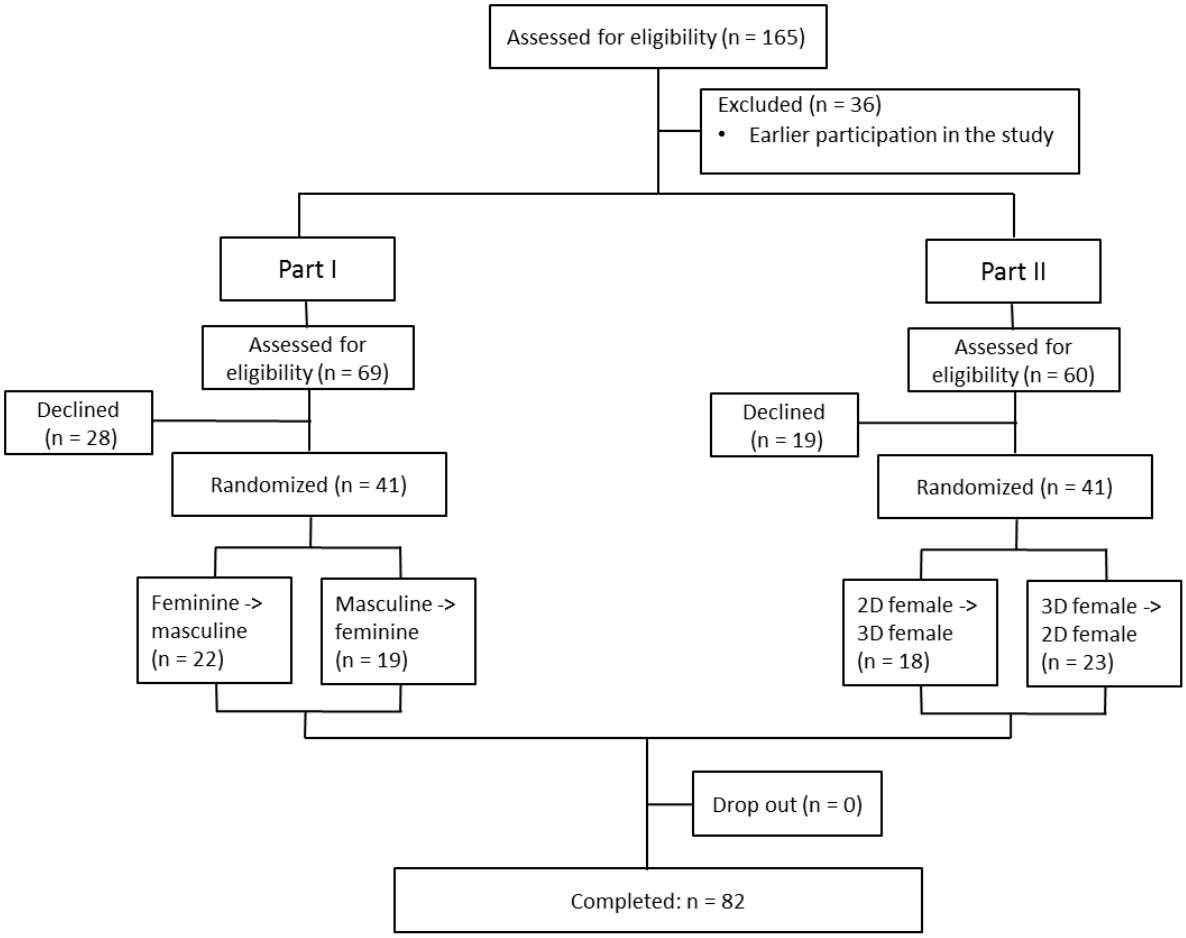
Recruitment

Female patients were recruited from the waiting room of a multidisciplinary pain clinic (Tværfagligt Smertecenter, Aalborg, Denmark), and therefore represent a convenience sample consisting of heterogeneous diagnosis (Table 1). Individuals with chronic pain and corrective vision were included, and those with known neurologic or movement disorders that could potentially affect motor control of the hand-eye coordination or drawing ability were excluded. For this study a total of 82 patients agreed to participate, resulting in 41 participants (mean age: 43.3±15.9, range: 18-84) in Part I and 41 participants (mean age: 40.6±14.2, range: 20-69) in Part II (see Figure 2 for CONSORT diagram).

Table 1. The distribution of patient's self-reported diagnosis divided into categories of musculoskeletal, neuropathic, visceral, and idiopathic pain; diagnosis not fitting in the four main categories are placed in the "other" category.

Category	Part I	Part II
	n (%)	n (%)
Musculoskeletal pain	18 (44)	23 (56)
Neuropathic pain	4 (10)	7 (17)
Visceral pain	2 (5)	0 (0)
Idiopathic pain	10 (24)	8 (19)
Other	7 (17)	3 (7)

Figure 2. CONSORT flow diagram. The progress of participants through the study is shown. Group Part I=comparison of masculine and feminine body charts; group Part II = comparison of female 2D and 3D body charts.



Body Charts, Tablet, and Drawing Pen

Drawings of pain extent and location were collected on a Samsung Galaxy Note 10.1 tablet with Android 4.1.2 (Jelly Bean) using the Navigate Pain app. A digital display of the masculine, feminine, 2D, and 3D body charts were viewable on the tablet screen. Participants were asked to draw with an S Pen (pen tip is approximately 1.5 mm), which is an accessory that accompanies the Samsung Galaxy Note 10.1 tablet. In order to make the recording conditions as similar as possible, the thickness of the line created by the S Pen was kept the same (~10 pixels). Participants were asked to draw the area(s) of their current pain as accurately as possible and to the best of their ability. The masculine and feminine 2D line drawings depicted main landmark features, such as the knee, elbows, and navel, whereas the 3D female body chart depicted both main landmark features and contour shadings. A short time-interval (1 minute) between the administrations of each body chart version was chosen to minimize variation in pain extent and location between the two body chart versions.

Assessment of Preferences and Perception of Body Charts

Immediately following completion of the pain drawings, participants were asked to fill out a short questionnaire in order to determine the preference and drawing experience between the masculine and feminine or 2D and 3D body charts. The evaluation questionnaire consisted of three questions, one assessing preference of body chart (two alternative forced choices), and two questions assessing the drawing experience of the two body charts on a 7-point Likert scale (very difficult, difficult, slightly difficult, neutral, slightly easy, easy, very easy).

Interviews With the Participants

Both Parts I and II of the study concluded with a semistructured interview (~10 minutes). The semistructured interview consisted of open-ended questions where participants could explain and provide the reasons for their choices. The purpose of the interview was to gain insight and a detailed understanding of the participants' preferences and drawing/user experience, specifically: perception of body chart and drawing experience, identification with the body chart, and suggested improvements.

During the semistructured interviews, thorough notes were taken including precise quotes from each participant. The qualitative data from the interviews was analyzed using thematic content analysis inspired by Kvale [18]. On the basis of 41 participants in each of the two parts of the study, it was possible to deduce and isolate typical and unique themes/characteristics.

Digital Quantification of Pain Area

The pain areas marked on the body charts were objectively quantified using the Navigate Pain software as total number of pixels and expressed as a percentage of the total drawable pixels in each view of the body chart (pixel density). The 2D female body chart drawing is an outline of the 3D female body chart and the total drawable pixels for the 2D female body chart are 194,542 pixels on the anterior view and 200,309 pixels on the posterior view, and 188,611 pixels on the anterior view and 194,096 pixels on the posterior view for the 3D female body chart. The masculine body chart has 194,922 pixels on the anterior view and 204,410 pixels on the posterior view. For participants requiring two views of the body charts, that is an anterior and posterior perspective, to express their pain area(s), the average pixel density of the two views was used for statistical analysis so that the total number of drawable pixels was equivalent between subjects and comparisons.

Statistical Analysis

In order to determine the consistency of the drawn pain areas between the different body charts a reliability analysis on pixel density was performed by computing a two-way, mixed-model (test value=0) intraclass correlation coefficient (ICC) between the masculine versus feminine and between the 2D versus 3D female body charts. In order to determine if the natural variation in the drawing behavior was maintained across methods, a Levene's test for homogeneity (one-way analysis of the variance) was used on the pixel density to test for equal variance within masculine versus feminine and 2D versus 3D body charts. Further, a one-sample *t* test comparing the difference in pixel density (subtracting masculine from feminine; 2D from 3D) to zero was performed to test for differences in the size of the drawings between the body charts. In order to understand any differences in drawing size between the body charts a Bland-Altman plot with 95% limits of agreement (LOA) was used to investigate the level of agreement in pixel density between masculine versus feminine and 2D versus 3D body charts. A systematic disagreement in pixel density between masculine versus feminine and 2D versus 3D body charts was defined as a fixed bias (a difference in drawn area between the body charts is a constant) and proportional bias (a difference in the drawn area between the body charts is a factor). Fixed bias was assessed by using the calculated mean of the difference in pixel density from the Bland-Altman plot. Proportional bias was assessed by a two-tailed Pearson correlation between the difference in pixel density and the mean in pixel density from the Bland-Altman plot. Absolute proportional bias was assessed by a two-tailed Pearson correlation on the rectified data from the Bland-Altman plot (absolute error, rectified difference between the drawn areas on the body charts is a factor). All statistics were performed in SPSS 22 and α=0.05 was used as level of significance. Results are presented in mean ± standard deviation (SD).

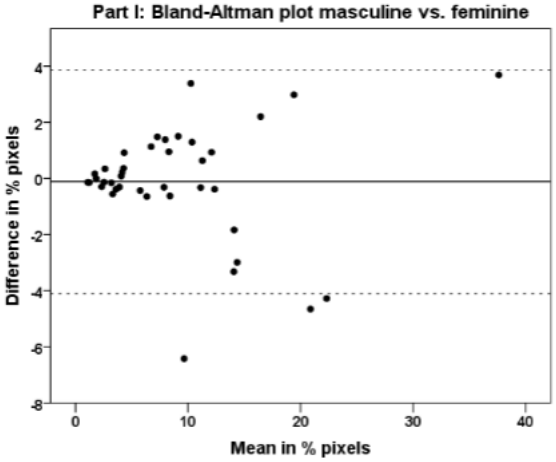
Results

Comparison of Drawn Pain Area Between the Masculine and Feminine Body Charts (Part I)

Two outliers were excluded because the difference between the pixel densities of the masculine and feminine body charts were more than 2 SD away from the group mean. The LOA between the pixel densities of masculine and feminine body charts was high (ICC=0.98, F=51.15, df=38, *P*<.001). One-sample *t* test of the difference between the pixel densities of the masculine and feminine body charts was not significant (mean difference=−0.12 ± 2.04; *t*=−0.365, *P*=.717). Levene's test for homogeneity showed no statistical difference in variance between the pixel densities of the masculine and feminine body charts (Levene statistic=0.038, *P*=.943). A Bland-Altman plot

for comparing the pixel densities of the masculine and feminine body charts (Figure 3) shows a mean difference in pixel density of −0.12%; with upper and lower LOA 3.87% and −4.11%, respectively. A fixed-negative bias was found (−0.12) indicating that the pain areas were drawn slightly smaller on the masculine than on the feminine body chart. No proportional bias was found between the pixel densities of the masculine and feminine body charts (Pearson correlation=−0.002, *P*=.991). Most notably, an absolute proportional bias was found between the pixel densities of the masculine and the feminine body charts (Pearson correlation=0.694, *P*<.001) indicating that the difference in drawn areas became larger when patients report larger areas of pain.

Figure 3. Bland-Altman plot for Part I: masculine compared with feminine body charts. The data is presented in % pixels. The data on the x-axis is the mean of the pain areas drawn in the two body charts and the data on the y-axis is the difference between the pain areas drawn in the two body charts. The dashed lines illustrate the 95% LOA.



Comparison of Drawn Pain Area Between the Two- and Three-Dimensional Female Body Charts (Part II)

Two outliers were excluded because the difference between the pixel densities of the 2D and 3D female body charts were more than 2 SD away from the group mean. The LOA between the pixel densities of 2D and 3D female body charts was high (ICC=0.994, F=161.888, df=38, *P*<.001). One-sample *t* test of the difference between the pixel densities of the 2D and 3D female body charts was not significant (mean difference=0.14±1.30; *t*=0.674, *P*=.504). Levene's test for homogeneity showed no statistical difference in variance between the pixel densities of the 2D and 3D female body charts (Levene statistic=0.002, *P*=.963). A Bland-Altman plot for comparing the pixel densities of the 2D and 3D female body charts (Figure 4) shows a mean difference of 0.14%; with upper and lower LOA of 2.69 and −2.41, respectively. A fixed-negative bias was found (0.14) indicating that pain areas were drawn marginally larger on the 3D than on the 2D female body chart. No proportional bias was found between the pixel densities of the 2D and 3D female body charts (Pearson correlation=0.016, *P*=.924). Unlike the comparison between the pixel densities of the masculine and feminine body charts, no absolute proportional bias was found between the pixel densities of the 2D and 3D female body charts (Pearson correlation=0.181, *P*=.271).

Preference of Body Charts and Drawing Experience

Preference was assessed by two alternative forced choices. The level of difficulty for drawing and expressing pain extent and location was assessed by a 7-point Likert scale where 4 was 'neutral' and 3 levels of difficult/easy could be chosen on each side of neutral. For simplicity the results are pooled on each side of 'neutral'.

Masculine and Feminine Two-Dimensional Body Charts (Part I)

The distribution of masculine and feminine body chart preferences are outlined in Table 2. With respect to the drawing experience on the feminine body chart, only 1 participant reported some degree of difficulty, 1 participant was neutral, and remaining 39 participants reported some degree of easiness in drawing their pain. The participant who reported difficulty in expressing pain on the feminine body chart also indicated a preference for the masculine body chart. With respect to the drawing experience on the masculine body chart, only 5 participants reported some degree of difficulty, two participants were neutral, and 34 participants reported some degree of easiness in drawing their pain. Notably, 4 of the participants who reported difficulty in expressing pain on the masculine body chart also indicated a preference for the feminine body chart.

Figure 4. Bland-Altman plot for Part II: female 2D and 3D body charts. The data is presented in % pixels. The data on the x-axis is the mean of the pain areas drawn in the two body charts and the data on the y-axis is the difference between the pain areas drawn in the two body charts. The grey dashed lines illustrate the 95% LOA.

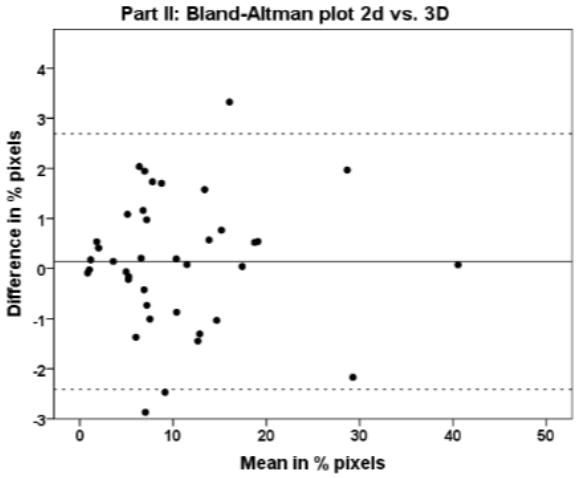


Table 2. the distribution of body chart preferences in response to the forced choice questionnaire and subsequent qualitative assessment.

		Body chart preference	
		Quantitative – Forced choice	Qualitative assessment
		n (%)	n (%)
Part I (N=41)			
	Feminine	35 (85)	18 (44)
	Masculine	6 (15)	2 (5)
	Ambivalent	0 (0)	21 (51)
Part II (N=41)			
	Two-dimensional female	18 (44)	16 (39)
	Three-dimensional female	23 (56)	20 (49)
	Ambivalent	0 (0)	5 (12)

Two- and Three-Dimensional Female Body Charts (Part II)

The distribution of 2D and 3D female body chart preferences are outlined in Table 2. With respect to the drawing experience on the 2D female body chart, only 5 participants reported some degree of difficulty, 1 participant was neutral, and 35 participants reported some degree of easiness in drawing their pain. The 5 participants who reported difficulty in expressing their pain on the 2D female body chart clearly preferred the 3D female body chart. On the other hand, with respect to the drawing experience on the 3D female body chart, 5 participants reported some degree of difficulty, 1 participant was neutral, and 35 participants reported some degree of easiness in drawing their pain. Two participants who reported difficulty in expressing pain on the 3D female body chart preferred the 2D female body chart; however, 1 participant still preferred the 3D female body chart. The 2 remaining participants reported difficulty in expressing pain on both the 2D and 3D body charts.

Semistructured Interviews

Five identical themes were identified for the semistructured interviews in Part I and II: difference between body charts, preference (explained), identification with the body charts, accuracy/drawing experience, and improvements. The themes and associated quotes are compiled in Tables 3 and 4 for Part I and II, respectively. The quotes presented in Tables 3 and 4 are translated from Danish to English with emphasis on the meaning of the content and not the direct translation.

Masculine Version Feminine Two-Dimensional Body Charts (Part I)

The semistructured interviews investigating preference and drawing experience between the masculine and feminine 2D body charts (Table 3) revealed that the 2 presented body charts were indeed, perceived as feminine and masculine. However, for some participants the gender difference between the body charts was not apparent until both body charts were presented simultaneously. When explaining the preference for a specific body chart, half of the participants indicated that the choice was random or that it did not matter which body chart they used (21/41, 51%). However, for a number of participants (18/41, 44%) it was very important that the body chart was female and the preference for the female body chart felt natural. Interestingly, only 2 participants truly preferred the masculine body chart and this was attributed to the familiarity of this body chart and the feeling of anonymity when expressing their pain.

When asked about identification with the body charts, some participants expressed that identification itself was not important or that they could identify with both body charts. For some participants identification with the (feminine) body chart was very important because it enabled a more accurate and personal expression of their pain. Only 1 participant identified more with the masculine body chart and this was attributed to the perception that this body chart was larger than the feminine body chart (whole body); despite the fact the actual true difference in size is 0.4%. Regarding the drawing experience, participants mainly focused on the ability to reproduce their pain pattern. For the feminine body chart, the curves and shapes (hips, waist, breasts, and shoulders) were emphasized as being important factors for an accurate portrayal or communication of pain. Some participants found 'it took more thought' to project their pain pattern onto a masculine body chart. However, for 1 participant, who preferred and identified with the masculine body chart, the perception of a larger representation of specific areas on the masculine body chart was important for an accurate communication of pain. The suggestions for improvements when communicating their pain on the body charts were the option to indicate the quality and intensity their pain and clear indications of left and right body sides as this could lead to confusion when drawing different areas of pain.

Two- Versus Three-Dimensional Female Body Charts (Part II)

The semistructured interviews investigating the preference and drawing experience between the 2D and 3D female body charts (Table 4) indicated that the 2D female body chart was perceived as more 'anonymous', 'clinical', and 'natural'; in comparison to the 3D female body chart, which was perceived as 'human', 'alive', and 'more detailed'. However, the 2D female body chart was also perceived as 'artificial' or 'flat' and the 3D female body chart as 'alien-like' or 'robotic'. When explaining the preference for a specific body chart, the clear dichotomy in preference between the 2D and 3D body charts appears to be influenced by implicit attitudes and perception of detail in the specific body chart. When asked about identification with the body charts, a few participants expressed that they did not identify with any of the body charts or that identification with the body charts was unimportant. However, the majority of participants identified with the body charts and indicated that identification was an important factor for expressing pain accurately on a body chart. Similar to the participants who compared feminine and masculine 2D body charts, the drawing experience was expressed as the ability to reproduce the pain pattern accurately (or not being able to). Those participants who indicated that their pain was best reproduced or accurately communicated on the 2D female body chart, the level of detail, the lines, and the fact that it was 'clean' or 'empty' were important factors. Additionally, they indicated that the more realistic illustration of the body on the 3D female body chart (including the perception of skin on the chart) was distracting and unpleasant. For those who believed that the best reproduction of their pain pattern was on the 3D female body chart, the contours, and location of muscles and joints enabled a more personal and accurate communication of their pain. In line with this preference, the simplicity, the lines, and the lack of detail in the 2D female body chart increased the difficulty for communication of their pain. The suggestions for improvements were access to zoomed (enlarged) images of specific body parts and visibility of structures under the skin, such as the muscles, tendons, and bones.

Table 3. Part I: Five emergent themes from the semistructured interviews regarding male and female body charts (left column).

Qualitative data from semistructured interviews			
Themes	Examples[a]		
	Comparative/ambivalent	Feminine body chart	Masculine body chart
Differences between body charts	Comparative: *That is a man and that is a woman* *I don't think that there is a big difference between the two body schemas* *I only noticed the difference afterwards* [when the body schemas were presented simultaneously]	*She has hips and breasts* *She has feminine curves* *That looks like a ladies buttocks*	*He has no hips* *He has no waist* *He is like a square, a box* *The lines on the man seemed like they were out of place*
Preference (explained)	Ambivalent: *It's a random choice* *It doesn't matter – I have pain no matter which one I choose* *I didn't notice that it was a man and a woman*	*This feels right because it's a woman…it's more natural for me* *This one reminds me of myself. It looks more like a woman* *It is of 100% importance that it's a woman* *I'm a woman. That's why I choose the woman*	*That's the one* [body schema] *you usually get* *The man is more anonymous than the woman and that's why it's easier to draw on the man*
Identification with body charts	Ambivalent: *It's not important to identify with the body schema* *It's just a figure* *I can identify with both body schema*	*I can better identify with the female body schema because I'm a woman* *It's more personal and feminine* *It makes more sense*	*I can see myself in him…when I see myself from the outside then I see myself as bigger – that's why it's easier to reproduce the pain and explain the pain*
Drawing experience/accuracy		*It was easier to draw on the woman because I have pain in my hips…* [the hips] *are missing on the man* *I can find the exact spot where the pain is* *I can add more details* *It's difficult* [to draw] *on the woman because she is more real – I can better locate where my pain is, and I know what that feels like on my own body*	*The man is easier to draw on because he is larger…It's important that there is a lot of space* [to express the pain] *It's strange to draw on a man* *It required more thought* [to draw on the man] *I was aware that my drawing on the man didn't turn out the way I wanted…he was wrong and I couldn't draw the way I wanted* *It describes something that doesn't really exist when it's drawn on a man*
Improvements	Indicating left and right on the body chart (confusion) Better marking of the spine/skeleton Show front and back on the same screen Possibility for more colors for different pain qualities/intensities A larger/thicker pen Adding hair on the head (suggestion from a cancer survivor)		

[a]Quotes from patients are displayed within each theme and divided into responses/opinions to the feminine and masculine body charts as well as comparative/ambivalent responses.

Table 4. Part II: Five emergent themes from the semistructured interviews regarding 2D and 3D body charts (left column).

Qualitative data from semistructured interviews			
Themes	Examples[a]		
	Comparative/ambivalent	2D[b] female body chart	3D[c] female body chart
Differences between body charts	Comparative: *3D looks more realistic whereas 2D looks artificial* *3D is a figure with skin…it's alive…2D is more flat* *Maybe 3D is more personal and 2D is less personal* *Not much of a difference – they have the same shape*	*More anonymous* *Appears more clinical* *More tangible* *More like a sketch* *More natural* *Contrasting colors* *Looks like a man* *Just a drawing*	*A real person* *More human* *More detailed* *More serious* *Looks more realistic* *It has calming colors* *It looks too much like a human or a man* *It looks grey…alien-like* *Looks like a robot woman*
Preference (explained)	Ambivalent: *they're both OK to draw on* *It doesn't matter which one I draw on*	*I have seen this one more often so it's natural for me* [to draw on] *It's just more clear* *I just don't like the other one*	*It looks more realistic* *It gives a better overview* *You can relate to it because it has skin* *It's just a little prettier*
Identification with body charts	Ambivalent: *No, I didn't think about if I could identify with the body schema* *There is no difference in identification with either body schema* *Relating to the body schema is not important*	*I can see myself in this one* *I can better relate to the structure* *The body schema can be anyone – It's more anonymous* *It's like it's not a person* *You don't really sense that it's your body*	*It's like me…It looks like a human being* *I can see myself…I wish that I looked like that* *I can identify with the 3D figure – that's what makes the difference* *It just seems totally wrong because it's not me*
Drawing experience/accuracy		I *t's easier to see where it hurts. It's more detailed inside* [the body] – *my pain is inside* *It's easier to draw on the 2D - absolutely…The lines help to specify the location* *It's easier to explain and draw the pain on the 2D* *It's easier to draw on the 2D because there is nothing on it* *It's too much like the VAS scale* *The lines* [on the abdomen] *are annoying* *It's harder to see where I should draw* *I can't see what the pain looks like*	*I feel like I draw more and more pain areas – I become more focused* *It's a more accurate reproduction* [of the pain] *It's easier to draw on the 3D…and to make others understand where the pain is* *Here it's easier to see where the muscles are compared to the 2D* *I feel like the pain is more present on the 3D* [I can see] *the elbows, see the shapes, and sense the shoulder blades* *I only see skin on the 3D figure* *It's unpleasant to draw on another person* *She looks real – that's distracting*
Improvements	Using an image of one self Split the figure into sections (arm/leg/torso/head) Possibility to "take the skin off" to show muscles and bones (the pain is on the inside) Another skin color on the 3D (it's too pale) Zoom of different areas to enable a more detailed pain drawing Show side view of the body Possibility for more colors for different pain qualities/intensities Indicate the depth of the pain		

[a]Quotes from patients are displayed within each theme and divided into responses/opinions to the female 2D and 3D body charts as well as comparative/ambivalent responses.

[b]Abb: two-dimensional.

[c]Abb: three-dimensional.

Discussion

Preference Tendencies for Gender-Specific Three-Dimensional Body Charts

This study investigated the differences and similarities in drawing behavior, preference, and perception of masculine versus feminine and 2D versus 3D female body charts. Drawing behavior, assessed by reliability analysis, showed very high consistency between masculine and feminine body charts, though pain areas were drawn slightly larger on the feminine body chart, and this error (bias) became gradually larger as the pain area increased in size. When asked about preference, 6 participants preferred the masculine and 35 preferred the feminine body chart. However, the semistructured interviews revealed that only 2 participants truly preferred the masculine, 18 preferred the feminine, and 21 did not really have a preference. Drawing behavior between 2D and 3D female body charts showed very high consistency, though pain areas were drawn marginally larger on the 3D female body chart. When asked about preference, 18 participants preferred the 2D and 23 preferred the 3D female body chart. However, the semistructured interviews revealed that 16 participants truly preferred the 2D, 20 preferred the 3D, and 5 did not really have a preference. The analysis of the semistructured interviews revealed five emergent themes for both masculine versus feminine and 2D versus 3D (Differences between body charts, Preference (explained), Identification with body charts, Drawing experience/accuracy, and Improvements). In summary, the analysis of the quantitative and qualitative data showed that it was important to have a female body chart for women to express their pain correctly; however, with regards to the 2D and the 3D versions of the body chart the preferences were high for both body charts and were driven by factors dependent on the pain depth or location.

Transition From Masculine to Feminine Body Chart

The majority of research uses a masculine or androgynous body chart to quantify pain areas [8-11], which may prevent women from providing an accurate representation of their pain areas. Expressing pain can be very difficult and verbal language is often insufficient to capture the full pain experience [19,20]. Women with chronic pain communicate the nature of their pain experience with more emphasis on the affective dimension of pain [17,21,22] where men focus on the sensory dimension [22]. As a consequence, chronic pain patients are often misunderstood by health care professionals and have a desperate need to express and explain their pain in hopes of a diagnosis or to establish a symptom management plan [23,24]. Although the consistency between the masculine and feminine body charts was high, the results from the qualitative analysis showed that when women were drawing on the masculine body chart it required more thought to project their pain and the masculine body chart limited detailed expressions. Drawing on the feminine body chart, however, was more natural and ‘makes more sense’. Additionally, the error in the drawn areas between the masculine and feminine body charts became larger as pain areas increased in size, which supports the notion that the use of gender-specific body charts matters. In fact, the results support that women may actually underestimate the extent of their pain distribution on masculine body charts. However, this may also be an indication of that widespread or multisite pain is more difficult to reproduce on 2 consecutive pain drawings than focal pain [14]. Whether this could increase the likelihood that women’s pain drawings are labelled as ‘nonorganic’, a condition that has been suggested to stem from a psychosocial disturbance, given that the criterion for this condition is a wide distribution of pain over many anatomic regions [25], is unclear. In this study, the reported difficulties for women drawing on male body charts were expressed as a lack of female anatomy and identification with the body chart. This raises the possibility that masculine body charts may distort the shape or pattern of the pain areas as they are drawn and moreover, how they are ultimately perceived. A logical next step would be to explore site-specific driven investigations within multiple homogeneous groups. For example, is the need for masculine and feminine body charts equally relevant when reporting knee pain versus hip/groin pain?

Half of the participants indicated that use of the feminine body chart was important; however, a couple of participants preferred the masculine body chart due to familiarity and anonymity. The need for anonymity creates a distance to the pain, which may serve as a coping mechanism and be related to women’s desire to conceal their pain from others [21]. Given that nearly half of the participants had a clear preference for the feminine body chart, with the remaining having no preference, the appropriate choice would be to have gender-specific body charts. Further, when assessing the reliability of the masculine and feminine body charts, the fixed bias was small (1% pixel density) and the variance in drawing size is similar, which indicates that the transition from a masculine to a feminine body chart would not introduce significant distortions in the data. On the contrary, the advantages of using gender-specific body charts may facilitate communication and enhance clinical insight. A limitation of this study, however, was that participants were not offered an androgynous version of a body chart when selecting a preference, and thus those that were indifferent may have preferred an androgynous version.

Transition From Two- to Three-Dimensional Female Body Chart

Three-dimensional image technology has the advantage of adding more detail and realistic representations of the body. Body charts using different 3D techniques, such as contoured sketches [26], photographs [27], and 3D illustrations or body charts [28-35] have been developed, and are generally preferred by patients [31,35]. This study showed that the preference for 2D versus 3D body charts was dichotomous, meaning that 50% of participants preferred the 3D and 40% preferred the 2D (10% did not have a preference). Both body charts portrayed female anatomy, hence the preference appears related to implicit attitudes and personal perception of the body charts and which one (2D or 3D) allowed for the most accurate representation of their pain. Further, it was evident from the qualitative data that identification with the body chart was important for most participants. Drawing one’s pain on a body chart requires an imagined spatial transformation of the body, so-called self-other transformations. When performing self-other transformations

different reference frames can be employed. An allocentric reference frame codes object-to-object relationships where both an observers and one's own perspective is used; whereas an egocentric reference frame codes relationships according to the body axes on the self. Women are more likely to use an egocentric reference frame [36], which could be interpreted as identifying with the body chart, and may enable them to express the affective dimension of the pain experience more easily [17,21,22]. When identifying with the body chart, participants expressed that it was easy to draw an accurate representation of their pain pattern but when identification was not felt, the drawing experience was reported to be 'wrong' and 'unpleasant'. It would be of interest to further discern which types of patients, as defined by their symptoms/diagnosis, render the body charts less effective for communicating pain, why this is so, and which solutions can be developed to overcome the lack of identification.

The 2D and 3D body charts are the same size, the difference being the contours on the 3D body chart. When assessing the reliability the fixed bias was small (1% pixel density) and they produce similar variance, which would suggest that the 2D and 3D body charts can be used interchangeably. However, given the dichotomy of the preference for 2D and 3D body charts and that the drawing experience can be affected by the choice of body chart, both body charts should be presented to participants and the appropriate choice should be based on preference. An overall technical limitation of this study is that the location and shape of the pain area itself were not systematically compared. If indeed the 3D body charts provide more guidance for the patients then shape or distribution around, for example, the knee joint or lower back it may impart new meaning and significance.

Perspectives for Gender-Specific Pain Drawings

Medical treatment has shifted from being a person-oriented qualitative approach where the patient was perceived as a person to an object-oriented quantitative approach where the patient is perceived as a case [37]. The focus of objectivity in medical practice has nearly excluded the patient's voice in medical knowledge [37]. However, the subjective pain experience cannot be assessed by current medical technology or imaging, rendering it "invisible" to clinicians, hence the diagnosis of musculoskeletal disorders relies largely on the patient's narrative. If the patient's narrative is not heard fully or understood, the possibility of diagnostic and therapeutic error increases [38]. In the same manner as medical imaging, pain drawings can be used to observe and compare differences over time, both for the clinician and the patient and possibly be a tool to align expectations to treatment outcomes.

It is generally accepted that pain and unpleasantness, sensory disturbances, or symptoms are difficult to verbally express [24], and often patients feel that their vocabulary does not fully capture the pain experience [19,39]. Visual communication thus appears as a means to overcome the verbal language barriers and facilitate an understanding of pain and illness [39]. Integrating the use of pain drawings into primary care, and not just in secondary care where it is used more often, may provide health care professionals with useful information, which assists in the clinical reasoning about the origin(s) and cause of pain, ultimately leading to an early diagnosis and appropriate pain management strategy.

Conclusion

The main quantitative difference between the masculine and feminine body charts emerged when patients reported larger areas of pain. The qualitative findings of this study further support the need for gender-specific body charts as a tool to facilitate communication of pain. Given the dichotomy of preference, 2D and 3D body charts should be used according to the individual's preferences. Detailed and accurate pain drawings may lead to improvements in pain communication, and thus facilitate clinical reasoning and treatment strategies. In addition, providing gender-specific body charts will allow participants the opportunity to identify with the body chart and enhance their ability to communicate their pain.

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Authors' Contributions

All authors participated in the conception and design of the study. TSC, IMP, and DSB performed the data acquisition. LLE analyzed the data and drafted the manuscript. All authors discussed the results, participated in writing the manuscript, and approved the final version.

Conflicts of Interest

None declared.

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Abbreviations

2D: two dimensional
3D: three dimensional
ICC: intraclass correlation coefficient
LOA: limits of agreement
SD: standard deviation

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Original Paper

Strengthening Interprofessional Requirements Engineering Through Action Sheets: A Pilot Study

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Abstract

Background: The importance of information and communication technology for healthcare is steadily growing. Newly developed tools are addressing different user groups: physicians, other health care professionals, social workers, patients, and family members. Since often many different actors with different expertise and perspectives are involved in the development process it can be a challenge to integrate the user-reported requirements of those heterogeneous user groups. Nevertheless, the understanding and consideration of user requirements is the prerequisite of building a feasible technical solution. In the course of the presented project it proved to be difficult to gain clear action steps and priorities for the development process out of the primary requirements compilation. Even if a regular exchange between involved teams took place there was a lack of a common language.

Objective: The objective of this paper is to show how the already existing requirements catalog was subdivided into specific, prioritized, and coherent working packages and the cooperation of multiple interprofessional teams within one development project was reorganized at the same time. In the case presented, the manner of cooperation was reorganized and a new instrument called an Action Sheet was implemented. This paper introduces the newly developed methodology which was meant to smooth the development of a user-centered software product and to restructure interprofessional cooperation.

Methods: There were 10 focus groups in which views of patients with colorectal cancer, physicians, and other health care professionals were collected in order to create a requirements catalog for developing a personal electronic health record. Data were audio- and videotaped, transcribed verbatim, and thematically analyzed. Afterwards, the requirements catalog was reorganized in the form of Action Sheets which supported the interprofessional cooperation referring to the development process of a personal electronic health record for the Rhine-Neckar region.

Results: In order to improve the interprofessional cooperation the idea arose to align the requirements arising from the implementation project with the method of software development applied by the technical development team. This was realized by restructuring the original requirements set in a standardized way and under continuous adjustment between both teams. As a result not only the way of displaying the user demands but also of interprofessional cooperation was steered in a new direction.

Conclusions: User demands must be taken into account from the very beginning of the development process, but it is not always obvious how to bring them together with IT knowhow and knowledge of the contextual factors of the health care system. Action Sheets seem to be an effective tool for making the software development process more tangible and convertible for all connected disciplines. Furthermore, the working method turned out to support interprofessional ideas exchange.

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KEYWORDS

personal electronic health record; requirements engineering; interprofessional cooperation; software development; scrum

Introduction

In this paper, we describe how the cooperation of interprofessional teams working on the development of a personal electronic health record was reorganized in order to better integrate user requirements. As studies on computer-supported cooperative work have already revealed, successful cooperative work between different actors is a core aspect of designing products to meet the demands of future users [1,2]. In developing solutions for the health care sector, this does not only mean to take into account the multitude of future users such as patients, physicians, nurses, and so on but also to be able to cooperate when working out the characteristics of the future product. In the present case, social scientists analyzed the requirements of future users and passed relevant data on to medical information technology (IT) specialists whose task it was to implement the requirements technically.

The development of software solutions for health care is confronted with different challenges, and developer teams have to face a steadily increasing demand for IT solutions that go hand in hand with continually changing technical capabilities. Furthermore, it has become indispensable in today's development practice to take the living and working environment of all potential future users into account [3-7]. As new and less savvy computer users receive access to online health applications such as personal electronic health records, the issue of usability becomes more critical. If newly developed software fails within the health care system because important general conditions of the care setting have not been considered, this will not only result in frustration on the part of users but in financial risks for the developing organization [8,9]. Highly qualitative requirements engineering is an essential part of efficient software development [10].

Development teams face a number of challenges connected with the effort of building up user-centered software architecture. Those challenges are located in the following areas: development tools and environment, communication and contacts, design knowledge, project management, and cultural differences [11-13]. Chen et al [14], for example, proposed an approach to bring user requirements, system design, and testing of the developed nuclear medicine software together in a 3-part model in order to meet challenges regarding development tools and environment. Communication and contacts was the second most named problem area identified by Komi-Sirviö and Tihinen [11] and was mainly connected with cultural differences and language barriers. According to the authors, efforts should be made to overcome those challenges especially by improving knowledge transfer.

An important factor of how to transfer knowledge is the way it is prepared and fed into the development process [15]. In general, there are traditional and newer ways of bringing information into the project: user-centered design (UCD) and agile software development [16,17]. While the former is characterized by a pursuit of defining the final product more or less in detail before the actual development process starts, the latter strives to build small bundles of functionalities and realize them in very short time periods [17]. It is not uncommon that both are running simultaneously within the same project context. In those cases it is important to find a way of bringing UCD and agile software development (ie, scrum) approaches together [18].

Lack of flexibility, a high amount of documentation, and little user integration are often criticized in regard to traditionally established development processes. By using agile methods, such as scrum, those problems should be overcome [19]. Scrum uses a number of roles and methods in order to systematize the software development process. The process itself is subdivided into sprint phases that last for 2 to 4 weeks. Within these time periods, prioritized features of the software are realized that were previously defined on the basis of the initial user requirements. During the sprint planning prior to a sprint, the product owner determines the tasks of the developer's team for the next period. Afterwards the development progress is monitored within a sprint review meeting. This proceeding ensures that the developers can quickly react to changing demands and that after every sprint phase a functioning partial solution is available.

In the present case, attention was paid to the future users' perspective right from the beginning. Thus, social scientists spent their effort on collecting data referring to the users' opinion on what a personal electronic health record should be like and compile this information in a thorough requirements catalog. Meanwhile, a team of medical IT specialists built up the infrastructure and user interfaces of the future product by using the scrum approach. In the course of the project it became clear that the proceeding of the medical informatics site was quite opaque for all those who were not directly connected with the technical development. In addition, the social scientists had problems conveying the data obtained from user surveys to the medical IT specialists.

The following research question was the basis of the described methodology development: How can user-reported requirements be better integrated into the software development process?

This paper presents the results of a newly developed methodology of bringing those two approaches together in order to smooth the development of a user-centered software product and to restructure interprofessional cooperation.

Methods

Overview

A pilot project called Information Technology for Patient-Centered Health Care (INFOPAT), funded by the German Federal Ministry of Education and Research

(2012-2016), has been initiated in the Rhine-Neckar region [20]. This project aims to improve care across different health care settings especially for chronically ill patients. A central component for reaching this aim is the development of a patient-controlled electronic health record (PEPA) [21,22]. The PEPA endeavor is divided into a technical research and development project and an implementation project. The first deals with the concept, design, and implementation of the PEPA's system architecture and its components as well as integration aspects. The latter focuses on the composition of user requirements and on the challenges of PEPA implementation into the care process of colorectal cancer patients. The study was approved by the Ethics Committee of the University Hospital Heidelberg (S-497-2012). All participants gave their written informed consent. Participant anonymity and confidentiality was ensured throughout the study.

Within the first project phase of the development project, the PEPA infrastructure has been developed and implemented by a team of scientific and industrial partners [23]. At the same time, a requirements catalog was compiled by members of the implementation project [21,24]. The foundation of this profile has been laid by performing focus groups with patients, physicians, and other health care professionals (HCPs). One goal of the INFOPAT project was to gain wide-ranging knowledge on colorectal cancer care. The complexity of this illness and the cross-sectoral health care setting might be positively influenced by a more active patient role according to managing their illness with the help of information and communication technologies (ICTs). Therefore, 10 semistructured focus groups (N=47) were conducted with patients diagnosed with colorectal cancer, representatives from patient support groups, and physicians and other HCPs in the Rhine-Neckar region in order to gain knowledge on the participants' experiences regarding colorectal cancer care and their attitude referring to the PEPA concept [24]. Patients were recruited through the National Center for Tumor Diseases (NCT) in Heidelberg, Germany, and an umbrella organization for patient support groups in Heidelberg. Physicians and nonphysician HCPs (eg, nurses, stoma therapists, social workers, physiotherapists, and nutritionists) were either involved in colorectal cancer care at the NCT or in the ambulatory setting (general practitioners, oncologists) All focus group meetings were audio- and videotaped, transcribed verbatim, and thematically analyzed using qualitative content analysis. Based on these data, a systematized and prioritized version of the requirements catalog containing 245 user demands was developed which then could be realized within the already existing PEPA infrastructure [21]. For this development step, a close feedback cycle between both teams (medical IT experts and social scientists) is mandatory [25]. In the course of the project it proved to be difficult to gain clear action steps and priorities for the development process out of the requirements catalog. Even if a regular exchange between both teams took place there was a lack of common language. Therefore, the following steps were conducted with the result that all partners agreed to use the resulting instrument, called Action Sheet, with the objective of improving the interproject cooperation.

Problem Analysis

In order to identify general problems of information exchange between the development project and the implementation project part, several interprofessional meetings took place. A list of identified weaknesses was created that included, for example, missing acceptance criteria, a need for specific user stories, or too little involvement of already elaborated concepts of PEPA functionalities.

Review of Literature

To identify papers referring to the specific problem contexts, a literature search was carried out. The main goal of this search process was to gain insights into the management of user requirements within other projects especially referring to development of health IT solutions. The review was performed by social scientists working in the application team. The literature sources mainly had a strong focus on the medical informatics perspective. Therefore, it was hard to gain comprehensive knowledge on possible solution approaches within a short period of time. Nevertheless, a number of common practices were recommended by the development project team that appeared to be helpful for overcoming the existing challenges.

Interprofessional Discussion

After receiving general knowledge of different possibilities for managing user requirements, both teams agreed on those which seemed to be most relevant and applicable for the current project context. On this basis the structure of Action Sheets and necessary categories was drafted. The draft versions of the structure and scopes of Action Sheets were discussed in two interproject meetings. Both teams agreed on the mandatory structure of the instrument for the forthcoming project steps. Furthermore, the scopes were prioritized regarding their necessity for the upcoming milestones like, for example, provision of usability tests with patients or professionals.

Results

Formalization of User Requirements

Until the decision for restructuring interprofessional cooperation was made, the implementation project team provided a more epic kind of requirements catalog. One user requirement, for example, was summed up by a sentence like "The PEPA has to provide the opportunity to upload data manually." Along with this statement an explanatory paragraph was handed over to the development team in order to enter it into the scrum-based development process. In order to improve the interprofessional cooperation the idea came up to align the requirements arising from the implementation project with the scrum approach of the technical development team. Therefore, based on intensive interprofessional discussion, a number of formalization techniques was agreed on between both teams that should be used in the ongoing steps of usability design of the PEPA. The following development methods were chosen for restructuring the already existing requirements catalog of the social scientists:

- Scenarios
- Sketches

- User stories
- Acceptance criteria

Those methods are used in most UCD projects but were not worked out for the project context so far because the original development was based on the mentioned requirements catalog. Furthermore, the team agreed on a series of additional categories for communicating a feeling for how the PEPA should be like from the user's point of view that is as tangible as possible. Those categories and their fusion in the form of Action Sheets will be described in the following paragraphs.

The Idea of Action Sheets

Since the new instrument was meant to push the interprofessional work, the name of the newly developed working papers was more or less obvious-Action Sheets were born. In a first step the implementation project members provided a set of 26 Action Sheets that were discussed with the development team in order to make sure that the content was aligned according to all requirements whether arising from technical feasibility or user demands. Generally, Action Sheets are meant to illustrate the way future users want the product to be in a standardized manner. Therefore, they delve more or less deeply into the different aspects of characteristics and functionalities but without getting lost in the details. The initial PEPA requirements catalog, for example, contains 245 user demands that were gained from the focus group discussions. Those demands were restructured and prioritized and form the basis of Action Sheets. Every Action Sheet follows the same layout structure and consists of the same elements (see Figure 1).

All PEPA Action Sheets should serve as specific example cases that help to advance the prototype functionalities in a targeted manner. In order to attain this objective, every Action Sheet consists of 14 categories but not all of them are mandatory for each requirement set (see Table 1). The title, connected requirements from the initial catalog, and a definition are part of every Action Sheet. With the elaboration of the catalog, a paper-based mock-up of a possible conceptual implementation of user requirements was designed as well. Parts of this document are integrated into the Action Sheets as sketches whenever possible in order to demonstrate a thinkable logical structure of the health record and its user interface.

Table 1. General content of Action Sheets.

No.	Category name	Content/meaning
1	Title	Designation of connected PEPA features or characteristics
2	Connected requirements	Most important aspects/user demands
3	Definition	Short description of the purpose of the Action Sheet and its importance for the PEPA concept
4	Sketches (if applicable)	Images of design proposals for PEPA features if applicable
5	User Story	Short and precise summary of user demands addressing the questions "Who wants what?" and "What is the aim?"
6	Preconditions	Prerequisites that must be met in order to make the user story come true
7	Relevance	Facts added to the explanatory statement briefly mentioned within the user story
8	Risks	Factors that might endanger a successful realization of the Action Sheet
9	Open issues	Uncertainties or contradictions that must be clarified for a successful practical application
10	Next steps	Activities that must be carried out for successful realization of the respective requirement
11	Acceptance criteria	Ways to test if the user story can be declared as fulfilled
12	Dependencies	Direct relations between different working papers
13	Complementary documents	Other possible references
14	Attachments	Other supplementary material

A necessary component of Action Sheets is the user story, which contains a short and precise summary of user demands covered by the respective working paper. According to the scrum method, the user story should encourage the developers to think of their work from the perspective of who will use it using tangible examples. Typically the user stories should be structured in a certain way following the questions "Who *[end user]* wants what *[requirement]*? What is the aim *[explanatory statement]*?".

The next category is Preconditions and as the name suggests it covers necessary prerequisites that must be met in order to make the user story come true. The Relevance category highlights the importance of the issues that are summed up in a Action Sheet. This category offers space to add facts to the explanatory statement that is briefly mentioned within the user story. If a successful realization of the requirements covered by an Action Sheet may be in danger because of certain surrounding conditions, those conditions will be listed in the Risks paragraph. The Open Issues section provides the opportunity to make ambiguities or contradictory aspects a subject of interprofessional discussion. User-centered software development is a complex, iterative process, so every emerging step of development depends on related topics that have to be clarified beforehand. Those topics are registered under Next Steps.

The Acceptance Criteria is a measure to gauge whether all requirements covered by the user story are met or not. Similar to the user story it is geared to the scrum method and follows a fixed structure consisting of prerequisite, action, and result: assumed [...], if [...], then [...].

Since many requirements that have been summed up in Action Sheets are interdependent, the category Dependencies shows direct relations between the different working papers. Under Complementary Documents a link to the initial requirements catalog as source of user demands and to important other resources will be created. As some of the initial requirements are redundant and some others are not that relevant for the overall context, the Connected Requirements paragraph at the head of each Action Sheet only consists of the most important user demands. Other connected issues are summed up at the bottom section called Attachments. Once the components and overall structure of Action Sheets was agreed upon between the development and the implementation project teams, it was a challenge to decide for which subject areas particular Action Sheets are needed. After a number of central issues (eg, graphical user interface, data security, emergency access, and creation of folders) were defined from the entirety of requirements, the associated requirements were subordinated. Based on the central issues, the first version of Action Sheets was set up with an iterative design and became the origin of the ongoing development process.

Figure 1. Standardized structure of Action Sheets.

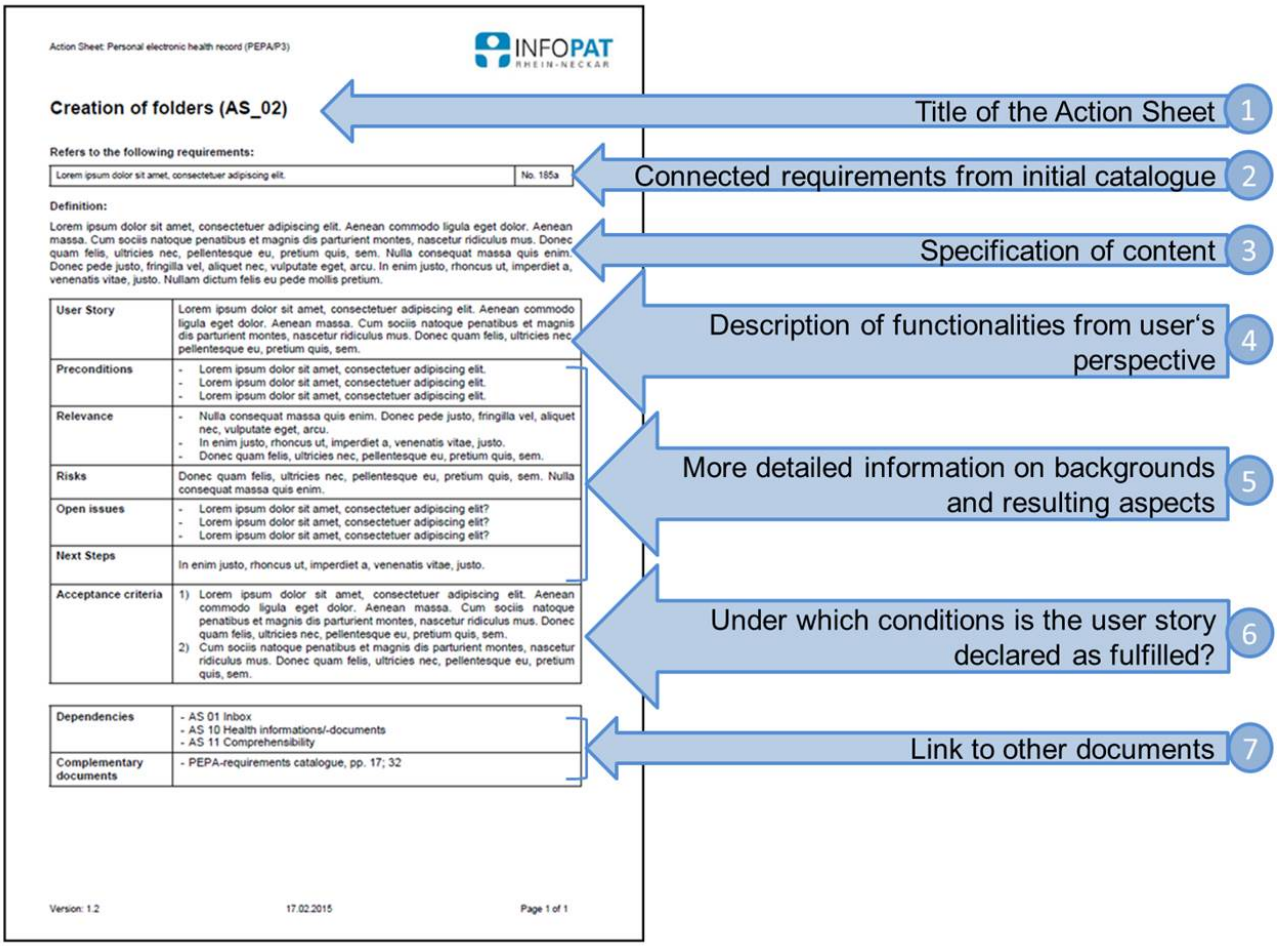
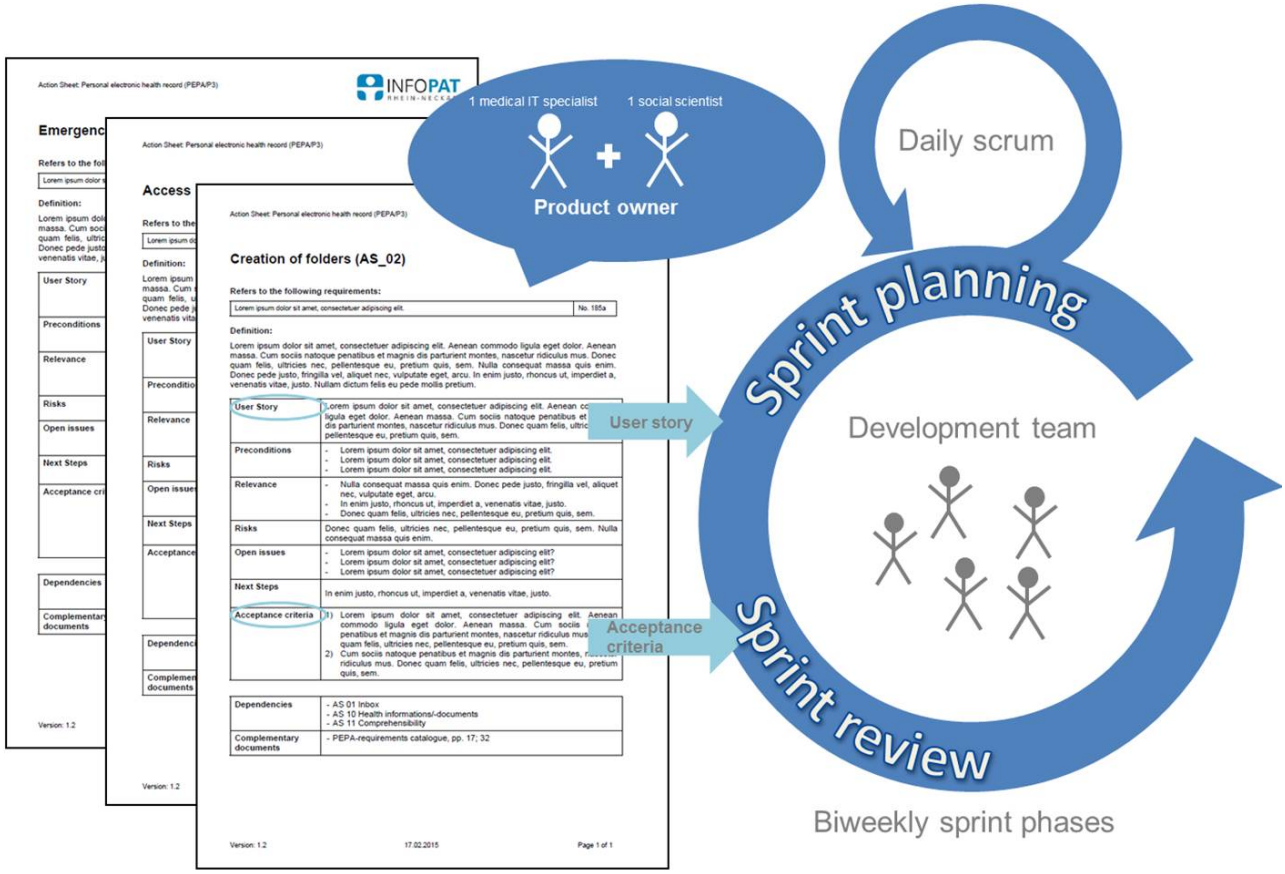


Figure 2. Action Sheet-based feedback cycle.



Integration of Action Sheets Into the Development Process of the PEPA

As already mentioned, the scrum approach applied by the technical development team was adapted. As a slight modification of the scrum working manner, the role of the product owner became split up into two responsible persons, one medical IT specialist from the development project and one social scientist from the implementation project. Those two persons take responsibility for the consolidation of guidelines for the PEPA development by creating, rating, and explaining the product properties that should be built up to the developers. An additional central aspect of this role is to decide which steps should be taken during the 2-week sprint phases.

The product owner team agrees on the content of the Action Sheets and on the order of bringing those requirements into the sprint process (see Figure 2). Thus, both persons responsible for the product owner role take the Action Sheets as groundwork for discussing the actual action fields with the developer team within the sprint planning and the sprint review meetings. Based on these discussions, the 2-week sprint phases are scheduled according to previously set priorities and with regard to the tasks of the preceding sprint phase that were not yet solved to satisfaction. At the start of every new sprint phase, the user stories of the Action Sheets serve as input for the sprint planning because they set a clear frame of functionalities that have to be fulfilled in order to let the respective user story be realized. The acceptance criteria helps to test if the user story can be declared as fulfilled within the sprint review meeting at the end of every 2-week period.

Experiences With Action Sheet–Based Cooperation

The first feedback from the development and the implementation project members indicates that it is easier for all persons involved to capture other points of view and mindsets. One example for this finding is the first Action Sheets–based discussion referring to the topic *inbox*. According to user requirements an Action Sheet was created that summed up available and relevant information on an inbox within the PEPA. Patients participating in the focus groups stated that they would like to be informed about new entries and documents in their PEPA, similar to the inbox of their email account. For this reason, a first meeting was arranged between social scientists knowing about the future user idea of this inbox and medical IT specialists knowing about the technical feasibility. The Action Sheet helped to follow a structured procedure in order to discuss all relevant factors referring to this topic. Social scientists learned that an inbox that worked exactly the way patients wanted it to be would be unrealizable because of technical circumstances. In addition, medical IT specialists understood why it was so important for patients to have the possibility to build up their own folder structure in order to systematize documents within their PEPA according to their own logic. Based on this joint brainstorming, the Action Sheet was revised so that it could serve as guideline for continuing development steps.

Textbox 1. Advantages and challenges of Action Sheet–based cooperation.

Advantages

- Clearer understanding of user demands
- Close supervision of project progress
- Quick identification of divergent interpretations
- Easier achievement of common wording

Challenges

- Expenditure of time for elaboration of Action Sheets
- High administrative effort for Action Sheet fundamentals
- Time-consuming, closer interdivisional collaboration
- Accidental omission of important features

In total, 14 team members were closely involved in the Action Sheets–based work. For most of them, the introduction of Action Sheets was associated with a higher expenditure of time for a renewed processing of the requirements catalog. Additionally, time was needed for more frequent interprofessional consultations and appointments. It took about 3 months of close interprofessional coordination until the first version of Action Sheets was compiled.

However, the discussion on important aspects of the development process became much more focused, and the expectation of the project partners was promoted. Textbox 1 gives an overview of advantages and challenges arising from the Action Sheet–based operating principles identified by all team members.

Even if the entire requirements catalog was used as basis for the Action Sheet development and a relative large scale of knowledge is transported via this measure, it is still possible that important features could accidentally not be taken into account or not yet completely be integrated into the working process. However, it only became possible to unfold a common understanding and wording because of the focused and detailed Action Sheet–based debate about what needs to be done within the development progress. Divergent interpretations of user requirements were identified quickly so that a common consensus could be achieved.

Of course, this debate was associated with quite an expenditure of time for the elaboration of Action Sheets. But hand in hand with this time effort went the fact that a really close supervision of the integration of user demands into the development of underlying user stories was enabled. This was mainly influenced by the closer interindividual collaboration that was put into practice by realizing a number of team meetings. For example there were a lot of out-of-turn ballot meetings taking place in addition to the biweekly sprint review meetings held in the presence of at least one member of the implementation project team. The most striking challenge that had to be faced when implementing the Action Sheet workflow was the high administrative effort for building up the first Action Sheet fundamentals. It was a complex process to work out a standardized Action Sheet prototype, to make a first draft of all necessary Action Sheets and, last but not least, to adjust all of them in interprofessional collaboration. Still, this was a good way to get a clear understanding of user demands which is the most central aspect of the PEPA concept.

Discussion

Principal Findings

This research project examined how user-reported requirements can be integrated into the agile software development process based on scrum in a better way. In the present project context it was a challenge that requirements named by future users sometimes did not meet the theoretical understanding of IT specialists or rather the technical realizability in the first place. Therefore, both teams made up their minds to introduce an approach that enables a common, iterative development process of the PEPA prototype. It was a broad-based consensus that the social scientists and the medical IT perspectives had to be joined and circumscribed in a way that is generally intelligible. For that reason, both sides agreed that it would be beneficial to elaborate a working base that is matched to the respective viewpoints.

In this context, it proved to be helpful to make use of an instrument called Action Sheets in order to integrate the user requirements more directly into the development process. Action Sheets serve as a communication bridge between different methodological approaches, enable a more standardized action, and were implemented as a commonly accepted working base. Bossen et al referred to boundary objects in a similar context [26]. They stated that for developing and implementing health IT solutions persons without medical expertise should be included into the design processes. In their example the role of medical secretaries in a hospital setting for successful implementation of an electronic health record was shown [26]. According to Star and Griesemer's (1989) concept of boundary objects [27,28], Bossen et al say that "coordination mechanism can become boundary objects that facilitate and stabilize cooperation between different social worlds, whose actors relate differently to but cooperate through these" [26]. Action Sheets as vehicles for combining the social scientific viewpoint and the medical IT perspective in the present case therefore also could be seen as a kind of boundary objects.

The necessity to uncover dependencies of software functionalities as early as possible within the development process is already known from other studies [29]. The reason is that only on the basis of a clear picture of user requirements a prioritization of development tasks can be carried out. But it is also known that those dependencies of functionalities and general user requirements can be addressed in different methodological ways: UCD or agile development concepts are examples. In practice, those methods often collide when used at the same time by different organizations of the same development context [17]. Nevertheless, experience shows that a combination of UCD and agile development within the same project also holds benefits for the final product as far as different preconditions are fulfilled [18]. Inayat et al name user participation, team structure, and communication culture as important prior conditions of successful combination of both working methods [18].

Another essential success factor in development processes is efficient knowledge management. Whenever players who often do not share the same professional background are part of a development process, misunderstandings and uncertainties can occur. These tend to influence the quality of the development itself and therefore of the resulting product [11]. Chen et al presented their approach for overcoming this obstacle which covers the whole product development process from managing user requirements to testing of a final product [14]. However, Action Sheets need to be differentiated from this approach since they are not that far-reaching. They rather could serve to support working on the first (requirements analysis and project planning) and maybe the second (solution exploration and system design) milestone mentioned by the authors.

A further core element of accomplishing integration of user demands especially into agile methods is continuous validation of collaboration patterns [10,30]. In order to generate good performance it is essential to communicate about the thinking of other team members. For that reason, it sometimes can be beneficial to reorganize teamwork, for example, to enable the breaking up of established ways of communication or uniform thinking patterns [31,32].

An Action Sheet–based approach addresses exactly the above mentioned aspects. It helps to set a new basis for collaboration and breaks through previous communication and agreement procedures. Additionally, it creates a more tailored picture of user requirements because of systematic reorganization of knowledge on demands and technical feasibility. Generally spoken, the Action Sheets approach is an instrument that supports the merging of agile working methods and UCD.

Taking into account the growing importance of ICT in health care, it can be assumed that instruments like this gain importance as well. Whenever something is meant for usage in a health care setting it is more or less clear that different ideas of the product of software development must be merged in consideration of technical aspects. Therefore, it is indispensable to take the user demands into account from the very beginning and bring them together with IT know-how and knowledge of the contextual factors of the health care system. Action Sheets seem to be an effective tool for making the software development process more tangible and convertible. The working method supported interprofessional ideas exchange and helped to reveal areas of the concept or the prototype that need further discussion on how to realize the user's image of the future product.

Strengths and Limitations

Because the development of the PEPA is still going on, it cannot be concluded that the modified working method will have sustainable positive impact on the process of interprofessional cooperation. Still, for the ongoing PEPA development process it was very helpful to see the project context in a new light by the help of Action Sheet implementation.

With the repeated dealing with the content of the requirements catalog the possibility arose to put the emphasis of PEPA development in more concrete terms. This had positive impact on the project progress because a more focused and uniform destination route was exposed. Still, the split product owner role might lead to situations where it is not clear who has the final decision-making power. This weak spot of the concept should be overcome by a generally accepted solution for concrete disputes, for example, by involving the steering board of the overall project. Furthermore, it should not be concealed that the development of Action Sheets was connected with a high amount of administrative efforts as mentioned above. These efforts do not meet the scrum demand for little documentation in the first place [19]. But, if Action Sheets would have been integrated into the development process earlier this double effort would not have been necessary. Therefore, it can be recommended to implement the Action Sheet instrument before the development process actually starts.

Implications for Research Practice

As part of the second project phase, the operable PEPA prototype will be evaluated within the real care setting of cancer patients. Therefore, usability tests and interviews with patients treated for gastrointestinal tumors, patient family members, and health care professionals will be conducted in a first step. Afterwards the prototype will be customized according to user feedback and then brought into test use for 3 months. Within this test phase, patients suffering from colorectal cancer and being treated at the NCT in Heidelberg will get the opportunity to use the prototype for preparation of and follow-up of their regular medical appointments within the center and in family practice. These evaluations will lead to further feedback necessities between both project teams. If the Action Sheet–based cooperation proves beneficial, it will be possible to revert to an already established working method within the second project phase. The user feedback could be reflected immediately so that the optimization of the prototype will hopefully work more quickly and smoothly.

All persons involved should be asked for their assessment regarding the initiated Action Sheets working manner. Therefore, a structured user evaluation is planned after the development project has ended. The results will help to further improve the application of Action Sheets as working method, and more information can be obtained on how to structure interprofessional cooperation in a development process right from the beginning.

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Conflicts of Interest

None declared.

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Abbreviations

HCP: health care professional
ICT: information and communication technologies
IT: information technology
INFOPAT: Information Technology for Patient-Centered Health Care
NCT: National Center for Tumor Diseases
PEPA: patient-controlled electronic health record
UCD: user-centered design

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Original Paper

Designing for Risk Assessment Systems for Patient Triage in Primary Health Care: A Literature Review

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Abstract

Background: This literature review covers original journal papers published between 2011 and 2015. These papers review the current status of research on the application of human factors and ergonomics in risk assessment systems' design to cope with the complexity, singularity, and danger in patient triage in primary health care.

Objective: This paper presents a systematic literature review that aims to identify, analyze, and interpret the application of available evidence from human factors and ergonomics to the design of tools, devices, and work processes to support risk assessment in the context of health care.

Methods: Electronic search was performed on 7 bibliographic databases of health sciences, engineering, and computer sciences disciplines. The quality and suitability of primary studies were evaluated, and selected papers were classified according to 4 classes of outcomes.

Results: A total of 1845 papers were retrieved by the initial search, culminating in 16 selected for data extraction after the application of inclusion and exclusion criteria and quality and suitability evaluation.

Conclusions: Results point out that the study of the implications of the lack of understanding about real work performance in designing for risk assessment in health care is very specific, little explored, and mostly focused on the development of tools.

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KEYWORDS

primary health care; triage; clinical decision support systems; health information systems

Introduction

In health care, patient triage and risk assessment has always been a major concern [1-4]. Keeping patients safe and ensuring that they receive the right treatment has been studied in different research areas such as psychology [5,6], software engineering [7,8], ergonomics [9-11], and others. These studies of how health care workers make decisions in such complex systems have given some insights into how to design for patient safety.

Furthermore, in order to improve patient triage, system designers must understand functional work requirements and constraints in the beginning of the design process; otherwise, it becomes difficult to incorporate human factors after the design is

completed [12]. While interacting with a complex physical environment, only a few elements of a problem can be within the span of human conscious attention simultaneously [13]. Moreover, different levels of complexity exist, and it is virtually impossible to reduce the number of variables of a complex system without losing its essential properties [14].

Thus, the objective of this paper was to present a systematic literature review that aimed to identify, analyze, and interpret available scientific evidence related to the contributions of cognitive engineering [15,16] to the design of tools, devices, and work processes to support patient triage and risk assessment. This paper reviews the state-of-the-art research in this theme, identifying gaps in order to suggest further investigation. We explore the topic of decision-making in patient triage, examining the extent to which empirical evidence supports or contradicts the theoretical hypothesis that formative approaches, such as those commonly included in cognitive engineering approaches, are important for the design for the health care domain.

The conceptual significance of this paper resides in providing the means to help researchers understand how the disciplines of ergonomics and human factors contribute to the improvement of work situations in health care, enhancing the design of devices and work processes to support effective behaviors [17] in the patient triage and risk assessment process.

Methods

Databases and Search

The authors performed an electronic search on 7 bibliographic databases: ScienceDirect, PubMed, SpringerLink, ACM Digital Library, Wiley Online Library, Scopus, and IEEE Xplore. We considered these databases appropriate because of the quantity of indexed journals and coverage of relevant disciplines such as health sciences, engineering, and computer sciences. The flexibility of their search engines (for combining search terms) and the ability to export results to formats accepted by reference managing software were also considered in the selection of academic databases.

Research Question

In this literature review we collected, classified, and analyzed recent work related to the topic of risk assessment in health care. We have highlighted scientific evidence on the efforts that have been made to improve the design of technology, medical devices, tools, and processes, to support decision making in patient risk assessment. The following research question motivated this review: What are the contributions, advantages, and disadvantages of using cognitive engineering in the design of software for risk assessment during patient triage?

Selection Criteria

This literature review included original journal papers published in English between 2011 and 2015, including papers available online in 2015. This time frame was chosen in order to concentrate on more recent contributions and represent the current status of research related to our topic. Conference papers, books, chapters, and reports have not been included in this literature review.

Table 1 presents a summary of the search terms and respective variations derived from the research question. We have used free search terms with no controlled descriptors in order to have a broader search.

Table 1. Search terms and variations.

Term	Variations
Cognitive engineering	Cognitive ergonomics; cognitive systems engineering; cognitive work analysis; cognitive task analysis; human factors; ergonomics
Risk assessment	Triage; patient triage; risk management
Health care	Medical care; clinical care; emergency care

We used variations of search terms to match eventual synonyms, abbreviations, alternative spellings, and related topics. The authors performed trial searches using various combinations of search terms in order to check the search terms against lists of already known primary studies, using the following search query: (“Human factors” OR “Ergonomics” OR “Cognitive ergonomics” OR “Cognitive engineering” OR “Cognitive systems engineering” OR “Cognitive work analysis” OR “Cognitive task analysis”) AND (“Risk assessment” OR “Triage“ OR ”Patient triage” OR “Risk management”) AND (“Health care” OR “Medical care” OR “Clinical care” OR “Emergency care”).

We describe inclusion and exclusion criteria in Textbox 1.

Textbox 1. Inclusion and exclusion criteria.

Inclusion criteria

- Studies that assess difficulties, critical factors, challenges, or problems in applying human factors and ergonomics in the design of risk assessment support tools or processes in health care
- Studies that present good practices, lessons learned, and success factors in applying human factors and ergonomics concepts in the design of systems for patient triage and risk assessment
- Studies presenting models, processes, techniques, or tools to enable the improvement of patient triage and risk assessment in health care

Exclusion criteria

- Studies that do not address any of the research questions
- Literature reviews

In addition to general inclusion and exclusion criteria, the quality of primary studies has been evaluated, as well as their suitability to the presented research questions, in order to investigate whether quality differences provide useful explanations, guide the interpretation of findings, and determine the strength of inferences, as well as how they address the research questions. The quality of a scientific study relates to the extent to which it minimizes bias and maximizes internal and external validity [18]. The following aspects have been evaluated in the study:

- The objective, research questions, and methods are well defined
- The contributions are well described
- The kind of scientific study is clearly stated
- The source population is identified
- The interventions or strategies are sufficiently described to allow reasonable replication
- The outcome is defined and measurable
- The objectives are accomplished and research questions are clearly answered
- The study addresses the research question

Selected publications were given scores from 1 to 5 for each aspect, where 1 corresponds to “strongly disagree” and 5 “strongly agree.” The sum of the scores determined their methodological quality and suitability to research question as follows:

- Very high, 100% of the methodological quality aspects met
- High, 75%-99% met
- Medium, 50%-74% met
- Low, 0%-49% met

A committee of 4 researchers applied the inclusion and exclusion criteria and performed the assessment of methodological quality of the selected papers. Committee members were doctorate students in systems design engineering and had similar levels of expertise in ergonomics and human factors. A tenured professor, head of the ergonomics and human factors laboratory, supervised the committee during the process. After reading the papers, the committee met in order to present their evaluation. The final score for each criterion for methodological quality represents the consensus of committee members. A study proceeded to data extraction when it met a score of at least 50% on methodological quality.

Definition of Outcomes

We stratified the selected papers according to 4 classes of outcomes as follows:

- Class A—design of risk assessment decision support for health care: papers fit this class when the outcomes proposed the implementation of new tools to support decision making in health care risk assessment work situations;
- Class B—design frameworks, processes, and methods for risk assessment in health care: this class related to publications where outcomes presented frameworks or processes applied to the design of risk assessment work situations in health care environments;
- Class C—recommendation or implementation of improvements in risk assessment work situations in health care: this class of outcomes was met by papers that suggested transformations in the work place, environment, equipment, or processes in risk assessment work situations in health care;
- Class D—analysis of the effect of new technology or processes to risk assessment in health care: this class was met by papers that presented studies about the implications of transformations made by new devices or processes for risk assessment in health care environments.

Papers selected for data extractions were also classified according to the type of study: case study, experimental study, exploratory study, empirical study, or field study.

Results

Outcome Statistics

Among the 7 databases searched, 5 of them had their results exported to a library in the reference management software Zotero (Roy Rosenzweig Center for History and New Media, George Mason University). The results of 2 of them (IEEE Xplore and SpringerLink) could not be exported to Zotero because of limitations of the search engine but could be exported in CSV format and organized in Microsoft Excel spreadsheets. The steps for paper selection included reading the title, abstract, and full paper. Exclusions on the first and second steps were based on how titles and abstracts of papers indicated relations with the topic we explored in this literature review [18-20]. On the third step, inclusion and exclusion criteria were applied in

order to select papers for data extraction. Table 2 presents the results of paper selection steps and the distribution of the papers across the various databases.

Table 2. Summary of search results.

Database	Selected papers				
	Search results, N	Selected after title reading	Selected after abstract reading	Selected after full reading, n	Percentage of selected papers, %
ScienceDirect	403	55	8	4	1.0
PubMed	249	19	6	5	2.0
SpringerLink	149	27	3	2	1.3
ACM Digital Library	159	18	3	2	1.3
Wiley Online Library	238	22	5	1	0.4
Scopus	33	10	5	1	3.0
IEEE Xplore	614	31	6	1	0.2
Total	1845	182	36	16	0.9

We retrieved 1845 papers in the initial search. After reading the titles and abstracts 36 papers were selected for full reading. Among these, 16 papers met the inclusion and exclusion criteria and were submitted to quality and suitability evaluation, as well as data extraction. Table 3 summarizes the key elements of these selected papers. The outcome code refers to the outcome categories that were defined in the Definition of Outcomes subsection. All papers listed in Table 3 reached 50% or more on the score for methodological quality.

Most of the studies are case studies (8 papers), followed by exploratory studies (6 papers). Finally, 2 of the 16 selected papers are experimental studies. We proceeded with the data extraction and the stratification of papers according to the 4 classes of outcomes described in the Definition of Outcomes subsection and listed in the Outcome column of Table 3. In Table 4, the distribution of these outcome types, across the various databases, is presented. The final distribution of papers by the databases was examined as it gives some guidance in terms of where future researchers may wish to look for relevant high-quality papers in the human factors and ergonomics approaches to health care.

Table 3. Summary of selected papers.

Authors	Summary	Type of study	Outcome
McClean et al [26]	McClean et al propose the use of a framework for modeling the care process in hospitals in order to improve the assessment of patients' clinical status and define the length of their stay at the hospital. The paper presents a case study based on data extracted from patients of a hospital in Belfast and demonstrates results of patient survival rates when using their length of stay and destination as outcomes.	Case study	B
Alemdar et al [24]	The authors adopt techniques for human behavior analysis from a medical perspective through the analysis of daily activities in terms of timing, duration, and frequency and propose an evaluation method applicable to real-world applications that require human behavior understanding through an experimental study.	Experimental study	A
Hundt et al [25]	According to Hundt et al most vulnerability in the design of computerized tools to support physician order entry occur by not considering the work system in which the technology is implemented; therefore, the authors state that the human factors engineering discipline offers a range of approaches for anticipating vulnerabilities, enabling designers to address them before technology implementation.	Case study	A
Card et al [27]	Card et al present a case study that shows the rationale for taking a proactive approach to improving health care organizations' emergency operations. It demonstrates how the Prospective Hazard Analysis Toolkit can drive organizational learning and improve work situations.	Case study	B
Pennathur et al [28]	Through a study conducted in hospitals, Pennathur et al propose an information trail model for capturing fundamental characteristics of information that workers in emergency departments create and use for patient care. The model proposed by Pennathur et al addresses our research subquestions by presenting a method for tackling complexity and prevents failures by increasing understanding of the information flow in the process of assessing patient conditions, based on the idea that people in a complex cognitive work system organize information on their own.	Exploratory study	B
Aringhieri et al [30]	In their paper, Aringhieri et al present an exploratory study on the ambulance location and management in the Milano area, in which they evaluate the current emergency system performance. According to the authors, despite the availability of technological support, in Italy, the use of resources in emergency departments is based on operators' experience.	Exploratory study	C
Iakovidis and Papageorgiou [22]	Iakovidis and Papageorgiou propose a model and evaluate its effectiveness in two scenarios for pneumonia risk assessment. Their results indicate that the major contribution of the proposed model is that it incorporates additional information regarding the hesitancy of the experts in the definition of the cause-effect relations between the concepts involved in the health care domain. Iakovidis and Papageorgiou state that the proposed approach is capable of modeling real-world medical decision-making tasks closer to the way humans perceive them.	Exploratory study	A
Kong et al [23]	Kong et al propose the employment of a belief rule-base inference methodology using the evidential reasoning approach in order to support modeling and reasoning with clinical domain knowledge. According to Kong et al, the approach they propose helps in reducing uncertainties in clinical signs, clinical symptoms, and clinical domain knowledge, which are critical factors in medical decision making.	Exploratory study	A
Cagliano et al [29]	Cagliano et al propose a framework that operationalizes Reason's theory of failures [42] by developing a methodology for investigating health care processes and related risks in patients based on expert knowledge. They apply their approach to the pharmacy department of a large hospital.	Exploratory study	B
Park et al [39]	Park et al studied how the design of electronic medical record (EMR) systems affects medical work practices. They analyzed consequences of EMR on clinical work practices and related design issues, such as usability or functionalities of EMR systems, in order to associate the work practices changes led by the EMR system with the actual design of the system.	Case study	D
Hepgul et al [31]	Hepgul et al present an examination of the role of clinical expertise and multidisciplinary teams in identifying patients at risk of developing depression, and in monitoring those receiving treatment for the occurrence of depression.	Case study	C

Authors	Summary	Type of study	Outcome
Glasgow et al [40]	Glasgow et al propose a comparison between risk estimates from statistical models previously developed and evaluated and risk estimates from the patients' surgeons. Through this comparison, they are able to evaluate the predictive validity of the decision support model for safer surgery in predicting risk for specific complications. Moreover, they enable the assessment of the validity of this model by correlating its predictions to the ones made by experienced surgeons.	Exploratory study	D
Johnston et al [32]	Johnston et al describe the importance of overcoming hierarchical barriers between junior and senior surgeons as a crucial success factor for prioritization of health care.	Case study	C
Ferguson and Starmer [35]	Ferguson and Starmer highlight the role of expertise in risk assessment in health care facilities and evaluate the effects of framing risks on the improvement of interpretation in such environments.	Experimental study	C
Norris et al [33]	In their paper, Norris et al describe a project that takes a systems approach to identify risks, engage health care staff and patients, facilitate ideas, and develop new designs for the bed-space in order to demonstrate the application of human factors to a complete design cycle.	Case study	C
Hastings et al [34]	Hastings et al propose a method to classify older adults in the emergency department according to health care use, by examining associations between group membership and future hospital admissions.	Case study	C

Table 4. Publications classified according to outcomes, distributed by databases.

Database	Outcomes			
	A Design of risk assessment decision support for health care	B Design frameworks, processes, and methods for risk assessment in health care	C Recommendation or implementation of improvements in risk assessment work situations in health care	D Analysis of the effects of new technologies or processes to risk assessment in health care
ScienceDirect	1	1	1	1
PubMed	-	-	4	1
SpringerLink	-	1	1	-
ACM Digital Library	1	1	-	-
Wiley Online Library	-	1	-	-
Scopus	1	-	-	-
IEEE Xplore	1	-	-	-
Total	4	4	6	2
Percentage, %	25	25	38	12

In the next subsections, we present an overview of the selected publications, describing how they address our research questions.

Design of Risk Assessment Decision Support for Health Care

Cognitive ergonomics is concerned with mental processes, such as perception, memory, reasoning, and motor response, as they affect interactions among humans and other elements of a system [21]. Thus, Iakovidis and Papageorgiou [22] and Kong et al [23] explore methods for modeling human performance to increase understanding of context and domain, including aspects of memory usage, and reasoning. With this approach, they try to bridge some gaps between analysis and the design of health care decision support tools.

Regarding our research question, Iakovidis and Papageorgiou propose the use of fuzzy cognitive mapping, which includes concepts that can be causally interrelated and represent uncertain and imprecise knowledge through fuzzy logic. These concepts encompass tools for modeling and simulation of dynamic systems, based on domain-specific knowledge and experience. The analysis of the domain and cause-effect relations among the system provides additional clues regarding the experts' knowledge and way of thinking, which increases understanding of work conditions.

Kong et al suggest that the complexity of inference mechanisms and difficulties in representing domain knowledge hamper the design of clinical decision support systems such as the ones used in patient risk assessment. Therefore, representation of human reasoning and uncertain medical knowledge are critical areas that require refined methodologies and techniques.

The paper by Alemdar et al [24] also addresses the challenges in understanding information flow during work performance in order to enable the construction of a health conditions assessment device based on models of machine learning. They also explore the implications of poor understanding of how work is performed in technology design, and its effect on workflows and processes.

Hundt et al [25] highlight that proactive risk assessment methods demand high commitment by team members, and their effectiveness for health information technology implementations has not yet been examined. Although the physician order entry is not a risk assessment process per se, managing patients involves the evaluation of their health conditions and the prioritization of treatment, which is similar to the patient triage process.

Design Frameworks, Processes, and Methods for Risk Assessment in Health Care

Papers organized in this class of outcomes support the idea that work in health care involves significant information-based cognitive activities; however, it's mostly supported by exogenously designed information systems. This means that gaps of information about the domain and insufficient input from end users on their needs and practices might bring limitations to the design process.

McClean et al [26] aim at identifying better pathways to patients based on their characteristics such as age, gender, and diagnosis. Therefore, determining the pathway of the patient enables the assessment of patients' risks.

According to Card et al [27], risk management in health care is largely concerned with routine risks that stem from everyday service provision, which makes it possible for health care organizations to learn from experience and make risk management more effective. However, regarding emergency operations, workers do not often use previous experience to improve risk management processes.

Pennathur et al [28] study situation awareness during diagnosing—starting with the identification of patients' complaints and laboratory tests results—as the major concern in designing for decision support in patient triage. Understanding the way workers interpret quantitative and qualitative information from patient history, physical conditions, and many other aspects is essential in generating diagnosis and treatment plans. Moreover, there is strong need for understanding the triggering events of medical errors as well as their correlations in order to decrease the probability of occurrence [29].

Recommendation or Implementation of Improvements in Risk Assessment Work Situations in Health Care

Papers in this class of outcomes demonstrate some approaches that aim at transforming work situations in patient triage. Many approaches could be found such as mathematical programming, resilience engineering, process management, and so on. We highlight the work of Aringhieri et al [30], in which they state that huge amounts of data about health care workers' activities are never used for improving the system performance and the prioritization of resources. Thus, they suggest that modeling, simulation, and mathematical programming can be successfully applied to an emergency service, in order to evaluate its current performance and to provide suggestions to improve the way resources are prioritized.

We also highlight some studies we present in this section that show the differences between the actions of experienced and inexperienced workers as potential object for analysis in order to enable the design of suitable tools for supporting patient triage [31,32]. Understanding human performance and context variables involved in transferring information from junior staff to senior staff—and, eventually, to nursing staff—is an essential aspect in designing work processes in patient triage, as deficiencies in this process may occur because of not only lack of experience but also unavailability of information about patient conditions, poor risk assessment guidelines, communication failures, and lack of consideration to the human, technical, and patient factors involved in this critical process.

Moreover, we find that some authors seek knowledge and understanding into the health care processes and studying patterns through observations carried out jointly by the research teams in order to ensure multidisciplinary perspectives and enable the improvement of work situations and the design of effective support devices [33-35]. We can see similar approach in use for field researches in ergonomics and human factors [17,36-38].

Analysis of the Effects of New Technologies or Processes to Risk Assessment in Health Care

The 2 papers in this category [39,40] study how human factors enable the analysis of workers' strategies and workload in patient triage situations. For example, according to Park et al the use of the electronic notes led to an increased workload for residents because of the longer charting times and the shifted responsibility from workers. Moreover, according to Glasgow et al optimal strategy for patient risk mitigation might be identifying risk at the individual level, although minimal knowledge exists on the accuracy of risk assessment with or without decision support tools.

These studies support the claim that the design of technological devices for medical use should not necessarily follow the design adopted by professionals in their current physical notes, as the social nature of clinical work might be hampered if the specific documenting locations, the medium, and the information needed to complete tasks are not properly addressed.

Discussion

Principal Findings

Among the 20 papers discarded after full reading, 11 of them did not address the research question. A total of 2 publications were discarded because of low methodological quality according to the aspects we had defined. The 2 databases that presented more search results initially were IEEE Xplore (614 publications) and ScienceDirect (403 publications). However, in the final assessment, more relevant papers were found in the PubMed and ScienceDirect databases. This may suggest that other researchers looking to obtain high-quality papers in the

areas of human factors and ergonomics in health care would be best served to approach these sources first.

We believe that the broad range of the ScienceDirect database contributed to a large number of references found, as well as a large number of relevant papers in the final selection. The ScienceDirect database collects publications from diverse fields, from physical sciences and engineering, life sciences, health sciences, and social sciences and humanities. The PubMed database is relatively more specialized, concentrating on publications from the life sciences and biomedical topics—it uses the Medical Subject Headings (MeSH) controlled vocabulary [41].

Our results suggested that there is some interest in the literature in understanding work performance in patient risk assessment. Furthermore, many different approaches have been taken to try and understand the human cognitive work of patient risk assessment. A broad definition of cognitive engineering was applied here, looking for papers that looked at cognition or work processes, and the perspective was broader than more typical cognitive engineering methods. There were more findings in sources specific to medical applications, although some relevant work was still found in engineering and computer science sources.

A total of 2 papers proposed human factors methods for coping with complexity in risk assessment but were not directly applicable to health care and, therefore, discarded. This finding points out the significance of studies about judgment and uncertainty in risk assessment in multiple domains. It also shows that risk assessment in health care presents many opportunities for the use of human factors and ergonomics to improve work situations.

We found that the most selected papers are related to recommendations for improvement (6 publications), decision support tools (4 publications), and design methods (4 publications), while 2 publications explore the effect of new technologies and processes. Recommendations for improvements typically seek transformations in work situations in order to help people work better, more comfortably, mitigating harmful situations, and reducing problems to workers. Studies that examined decision support tools presented the general aspects of developing technology to support decision making in patient triage, such as guidelines, implementation aspects, and milestones in the adoption of decision support tools for patient triage. Design methods refer to techniques, concepts, and modeling tools for coping with complexity.

Some approaches taken by our selected papers related to each other to some extent, especially in developing an understanding of human behavior in complex systems and in finding ways to improve these work situations. For example, some papers presented technologies for patient triage, while discussing how some technologies affect the workload for practitioners. Similarly, design methods were often related to technology as some papers presented design techniques, concepts, and tools that enable the identification of opportunities for information technology or the design of medical decision support. Moreover, opportunities for information technology are, essentially, opportunities for improvement in workflow and practice.

Therefore, the results showed that most related research explored the potential of cognitive engineering to provide tools to improve the design for complex work situations such as risk assessment in health care work environments, although the effects of these applications on human performance have not been extensively assessed.

Conclusions

This literature review gathered recent contributions to multiple areas, from engineering to biomedical, that cognitive engineering gives for the design of tools for health care risk assessment, especially by contributing knowledge about work performance in such settings. In this paper, we presented information about how this research topic has been approached, results, accomplishments, and opportunities for further research.

Papers selected for review were very diverse in terms of the aims of the study, the underlying theoretical frameworks and methodologies used, reflecting how interdisciplinary our research topic is, and the wide range of research backgrounds employed in finding answers to our research question.

Furthermore, results included studies from several areas such as medicine, engineering, and computer science. We did not present specific research question associated with each area; therefore, some papers might have been excluded for not addressing the research question, although they might have explored our research theme to some extent.

An opportunity for further studies would be to expand the search to include other contributions of human factors and ergonomics to the design for health care—rather than specific contributions to patient risk assessment—as well as the contributions of other areas to the risk assessment in health care. This could address important aspects, for example, which areas have made recent contributions to the improvement of health care services, and subsequently to the risk assessment in health care environments. Moreover, as risk assessment is a topic present in many areas, further research might be interesting to collect studies about the design for risk assessment in other areas rather than health care.

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Conflicts of Interest

None declared.

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