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Original Paper

Patients' Utilization and Perception of an Artificial Intelligence–Based Symptom Assessment and Advice Technology in a British Primary Care Waiting Room: Exploratory Pilot Study

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Abstract

Background: When someone needs to know whether and when to seek medical attention, there are a range of options to consider. Each will have consequences for the individual (primarily considering trust, convenience, usefulness, and opportunity costs) and for the wider health system (affecting clinical throughput, cost, and system efficiency). Digital symptom assessment technologies that leverage artificial intelligence may help patients navigate to the right type of care with the correct degree of urgency. However, a recent review highlighted a gap in the literature on the real-world usability of these technologies.

Objective: We sought to explore the usability, acceptability, and utility of one such symptom assessment technology, Ada, in a primary care setting.

Methods: Patients with a new complaint attending a primary care clinic in South London were invited to use a custom version of the Ada symptom assessment mobile app. This exploratory pilot study was conducted between November 2017 and January 2018 in a practice with 20,000 registered patients. Participants were asked to complete an Ada self-assessment about their presenting complaint on a study smartphone, with assistance provided if required. Perceptions on the app and its utility were collected through a self-completed study questionnaire following completion of the Ada self-assessment.

Results: Over a 3-month period, 523 patients participated. Most were female (n=325, 62.1%), mean age 39.79 years (SD 17.7 years), with a larger proportion (413/506, 81.6%) of working-age individuals (aged 15-64) than the general population (66.0%). Participants rated Ada's ease of use highly, with most (511/522, 97.8%) reporting it was very or quite easy. Most would use Ada again (443/503, 88.1%) and agreed they would recommend it to a friend or relative (444/520, 85.3%). We identified a number of age-related trends among respondents, with a directional trend for more young respondents to report Ada had provided helpful advice (50/54, 93%, 18-24-year olds reported helpful) than older respondents (19/32, 59%, adults aged 70+ reported helpful). We found no sex differences on any of the usability questions fielded. While most respondents reported that using the symptom checker would not have made a difference in their care-seeking behavior (425/494, 86.0%), a sizable minority (63/494, 12.8%) reported they would have used lower-intensity care such as self-care, pharmacy, or delaying their appointment. The proportion was higher for patients aged 18-24 (11/50, 22%) than aged 70+ (0/28, 0%).

Conclusions: In this exploratory pilot study, the digital symptom checker was rated as highly usable and acceptable by patients in a primary care setting. Further research is needed to confirm whether the app might appropriately direct patients to timely care, and understand how this might save resources for the health system. More work is also needed to ensure the benefits accrue equally to older age groups.

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KEYWORDS

human-centered design; innovative; health care apps; eHealth; symptom checker; primary care; general practice; app; usability; acceptability; utility

Introduction

Background

When a person experiences a new medical symptom, there is an ever-expanding menu of health care–seeking options available. The option they choose may be influenced by factors such as age, sex, the nature of the complaint, chronic ill health, trust in their physician, socioeconomic factors [1], and where applicable, out-of-pocket costs [2]. Within the traditional UK medical system, they might seek care from a hospital emergency department, general practitioner (GP), telephone triage service (eg, 111 in the UK), pharmacist, or urgent treatment center [3]. More recently, internet-enabled options have emerged such as using a search engine to look up symptoms (Dr Google), high-quality online resources such as NHS Choices [4], symptom checkers [5,6], telehealth consultations by phone or videocall [7], *Minute Clinics* [8] that can be booked via smartphone, and peer-to-peer networking [9]. Some two-thirds of patients have searched their symptoms online before a doctor visit [10], with risks of inappropriate information and a lack of appropriate triage for urgent cases [5].

Against the background of an aging population, high burden of chronic conditions, growing consultation rates, and lengthening clinical visits, the overall workload on primary care [11] and emergency medicine [12] is increasing substantially [11]. Accordingly, supply-orientated improvements to traditional processes such as diversion of nonurgent patients [13], nurse triage, fast-tracking [12], and telephone triage [14] seek to more optimally use professional resources. On the demand side, public health campaigns admonish patients via marketing campaigns with blunt messages such as *Don't go to A&E*. However, in a chronically under-resourced system, making relatively minor adjustments will yield relatively small results [13], and applying a broad approach to dissuading use of medical resources may have unintended negative consequences; most people cannot adequately distinguish between problems that are *urgent*, *emergency*, and *routine care* [15]. While there is much excitement about the potential for video consultations and the UK National Health Service (NHS) GP contract even states "every patient will have the right to online and video consultation by April 2021," the accumulated experience has been that health IT solutions within the NHS tend to suffer "non adoption, abandonment, and challenges to scale-up, spread, and sustainability" [16,17].

One potentially transformative and more scalable approach to these challenges is digital symptom checkers [5]. Put simply, a patient enters the symptoms they are experiencing in a question-and-answer *chat* format, and receives suggestions as to what the problem might be (diagnostic possibilities), the level of care that would be appropriate (triage), and often the level of urgency with which action should be taken. These software tools rely variously on a digitized body of medical knowledge, decision trees, predictive algorithms, Bayesian inference, and testing against representative case sets to provide accurate advice. Examples include tools developed by health providers such as the Mayo Clinic or NHS as well as private companies. The potential benefits include escalation of urgent cases to appropriate care, the diversion of nonurgent cases to self-care, the deterrence of antibiotic overprescribing, reducing physician burden, less need for telephone triage services [4], saving money for the health system, and saving the patient's money and time (an average of 3 hours per visit) [5,18].

Patients seem ready to embrace such approaches given the preponderance of technology in their daily lives [19]. A recent survey of over 1000 London residents conducted by Healthwatch Enfield [20] suggested that most patients (63%) would welcome use of a trusted symptom checker, though there were much higher degrees of willingness reported by those under the age of 40 (71%-74% agreed) than over the age of 70 (just 34% agreed). Among the reasons why those surveyed would *not* want to use a symptom checker, concerns were raised over misdiagnosis, health anxiety, digital illiteracy, ease of use, and wanting to see a doctor or nurse face-to-face. Although similar rates of interest were expressed for the use of video consultations (eg, Skype) or email, these would have much higher burdens on professional time than fully digital symptom checkers. This survey has been influential in UK health policy circles, receiving press attention and prompting responses from NHS England and NHSX, a UK government policy unit with responsibility for developing best practice and national policy for technology in health [21].

Aim

A recent review of patient-facing digital symptom checkers proposed a series of next steps that should be undertaken by the field to evaluate such tools [22]. In this study we used one of the proposed approaches, that is, "Early observational studies in clinical settings" to "test symptom checkers in a safe, observational manner, where patients continue to receive standard care." We sought to ascertain the usability, acceptability, and utility of one such symptom assessment technology, Ada, in a primary care setting. Our aim was to assess the potential to more effectively meet patient needs and to consider how the use of similar technology at home might improve patient flow in a busy primary care setting. In response to the Healthwatch Enfield report finding a significant factor of age in driving acceptability of symptom checkers, we explored this issue as a secondary question of interest.

Methods

Recruitment

Potential participants were initially informed about the Ada study by the clinic receptionist as they were checking in. These potential participants were then approached by an Ada member of staff and asked if they would be interested in testing a new technology, on the understanding that there would be no change

to their usual care, that participation was entirely voluntary, and that there would be no compensation for taking part. Potential participants were excluded if they were attending for a nonclinical reason (eg, requesting a doctor's letter), or if they were attending for a routine chronic disease follow-up appointment (without acute symptoms). If they agreed, participants were given a study smartphone preloaded with a special test version of Ada, completed an assessment, and handed the smartphone back to the research team. A total of 3 study smartphones were in use simultaneously. The research team then asked each participant to complete a paper questionnaire to gather feedback. They then attended their doctor consultation as normal.

Measures

Participants were asked to complete a paper questionnaire including their full name, date of birth, sex, and Likert-scale multiple choice questions on how likely they would be to recommend Ada, their ease of use, whether Ada provided helpful advice, whether they would use it again, and whether using Ada changed a decision about what to do. A copy of the questionnaire is provided in Multimedia Appendix 1.

Statistical Analysis

As a descriptive usability and acceptability study, we had no falsifiable hypotheses and so did not undertake a formal power analysis. The sample gathered was based on a convenience sample for the resources available; 2 full-time medical students embedded within the clinic for 5 weeks. Missing data were described per analysis and participants were not excluded for missing data. For comparison with a prior survey, the Healthwatch Enfield report [20], user age was recategorized into the same age groups used in that study, <17 years, 18-24, 25-39, 40-54, 55-69, and 70+. Because data from the <17-year age group were not reported by Healthwatch Enfield [20], they were excluded from usability analysis. A Student *t* test was used for comparison of two group means in normally distributed continuous data. A chi-square test was used to compare nonparametrically distributed or categorical variable differences or both, with statistical significance set at $P<.05$, two-tailed. Statistical analyses were conducted in SPSS version 21 (IBM).

Ethics

Ethical standards associated with product testing and usability research were applied to this research. To understand the relevant ethical guidelines in the UK, we employed the NHS Health Research Authority decision tool [23], which confirmed this study would not be considered research by the NHS because the study participants were not randomized, did not require a change in standard care, and were not intended to provide generalizable findings outside the setting of interest. All data were securely collected by Ada in a manner compliant with ISO27001 (quality standard for information security). In addition, Ada has a Class I medical device CE mark, is EU General Data Protection Regulation (GDPR) compliant, and is certified by "Bundesverband der Internetmedizin," the German Federal Association of Internet Medicine.

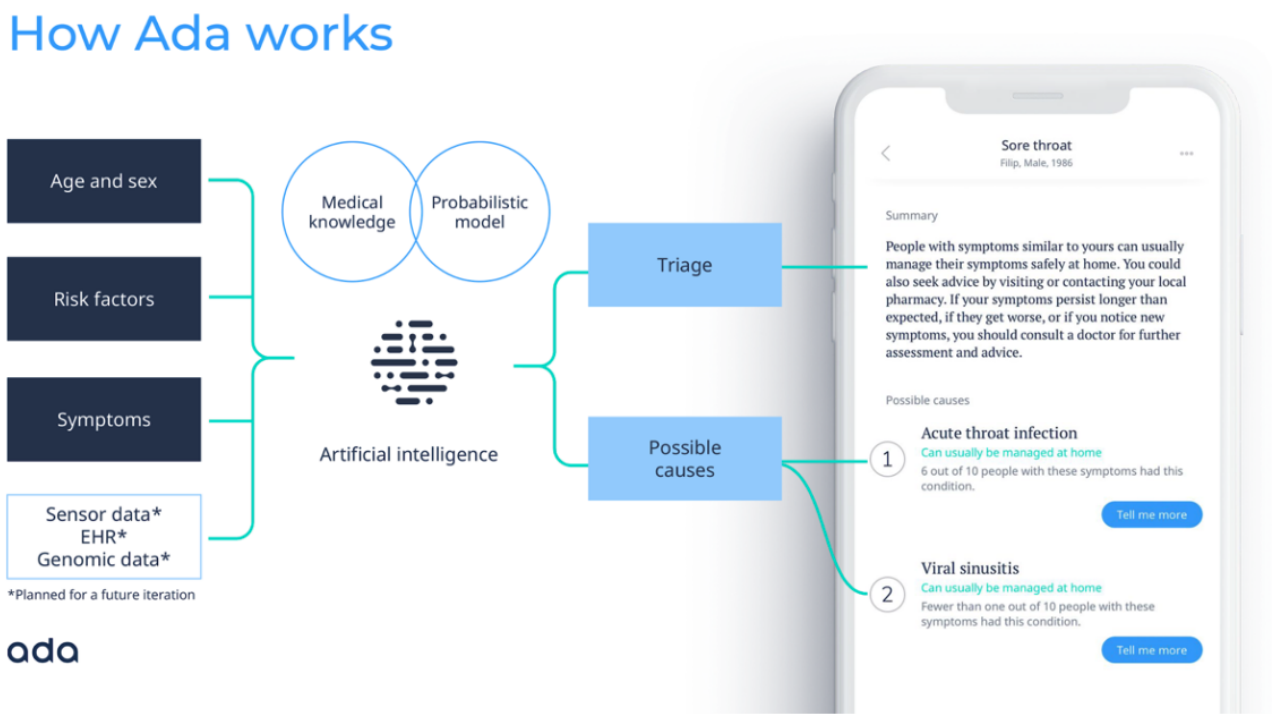
Design and Setting

The observational study was conducted between November 2017 and January 2018 at Paxton Green Group Practice, a large primary care clinic in the South London borough of Lambeth with 11 working GPs caring for around 20,000 registered patients. The team is supported by 6 practice nurses, a primary care assistant practitioner, a clinical pharmacist, and an associate physician, alongside 19 administrative and reception staff. Relative to national estimates in the UK, the practice's population skews younger (aged 25-40 years), having a higher-than-average degree of income deprivation, and with a higher-than-average proportion of black and ethnic minority groups (59% white vs UK population average of 80%) [24], with about 1 in 4 patients identifying as black. A daily *Walk & Wait Clinic* is available each morning for patients without an appointment, from which participants in this study were drawn.

Description of the Ada Symptom Assessment Tool

The basic principles of the Ada medical intelligence are as follows: In the assessment, the user inputs basic health information (eg, age, sex, smoking status, diabetes status), and is then asked for their most troubling current symptoms (presenting complaint). The user is then asked a series of questions by the app, with each question asked being dynamically chosen by Ada's reasoning engine based on the probabilistically determined optimal question. This question is determined by the reasoning engine, based on all previously supplied basic health information and symptoms. The reasoning engine has been designed to ask a balanced number of questions that allow reasonable identification of conditions from medical history without being overly burdensome to complete (Figure 1).

Figure 1. Conceptual overview and screenshot of the Ada symptom checker. EHR: electronic health record.



The reasoning engine infers disease probability estimations based on a representation of medical knowledge. The medical knowledge base is used to define a Bayesian network, on which approximate inference is carried out, and following which information-theoretical methods are used to decide which questions to ask to the user. The knowledge base was built and reviewed by medical doctors in a curated process of knowledge integration from medical literature. It is being expanded continuously following this standardized process. It consists of disease models of all common conditions and several hundred rare diseases, including their corresponding symptoms and clinical findings. The disease models and their related symptoms are added to the knowledge base and modeled according to evidence from peer-reviewed medical literature. Symptoms/clinical findings can be further refined with additional attributes, for example, intensity or temporality and epidemiological data are used to derive the prior probabilities of diseases to allow for correct disease probability estimations. Ada's medical intelligence (meaning the combination of Ada's reasoning engine and medical knowledge) is continually validated against a set of several thousand internal test cases, which comprise diseases from different medical specialties and include both common and rare diseases. The set includes cases based on medical literature (eg, published case reports) as well as typical clinical case scenarios that reflect different levels of diagnostic certainty. A team of Ada medical doctors constantly reviews the system's inherent medical knowledge based on these quality assurance measures. Ada's medical intelligence is further verified on a continual basis through a second process, in which a verification tool is used to test each update of Ada's medical intelligence, using hundreds of cases written by external doctors. These cases are kept confidential from the Ada medical doctors who curate the medical knowledge base and the set of cases is regularly updated.

At Ada, usability engineering is directly integrated in the product development process. The usability process and respective activities heavily overlap with general design and user research activities, yet emphasize the importance of documentation and transparency of product decisions. At the beginning of the product development process, generative user research is conducted (eg, user interviews, shadowing, expert interviews) to gain a better understanding of the user and potential opportunities. Insights generated from this phase are passed on to design, where initial concepts, based on user requirements, are crafted. These concepts are often made tangible via prototypes which range from low to high fidelity, so that they can be evaluated with representative end users. Nonetheless, other methods such as heuristic evaluations or cognitive walk throughs are used to gather feedback on the general usability and user experience of the interface. Findings such as use errors or usability problems are then fed back into the next design iteration until a suitable solution has been found. This evaluative work is usually referred to as formative evaluations. They take place throughout the iterative product development until the product reaches its final state to control for risk and ensure safety by design. Prior to release, a summative evaluation (ie, a final evaluation of the product) is conducted to ensure the product is effective and safe to use. Furthermore, after product release, user feedback is collected via surveys, contextual interviews, and large-scale research studies, which is part of the postmarket monitoring activities and can initiate design iterations to improve user experience, usability, and safety of the product. If usability problems or areas of potential usability improvement are identified in the postmarket phase, then design improvements are introduced using the same process as described above.

Results

User Statistics

Over a 3-month period, 523 patients completed an Ada assessment and the questionnaire. Although data on nonconsenting patients were not gathered, we estimate that around two-thirds of those approached agreed to participate. Most participants were female (Table 1, n=325, 62.1%), with about one-third male (n=185, 35.3%) and 13 cases with no sex reported. Relative to 2011 UK Census data, and the practice's own data for all registered patients, this represents a higher proportion of females, although females are known to use health care services more frequently [1].

Mean age of patients was 39.79 years (SD 17.7 years), with age data missing for 17 participants (3.3%). Relative to 2011 UK Census *broad age group* data, this population had a larger proportion (81.6%) of working-age individuals (aged 15-64) than the general population (66%), with smaller proportions of children (aged 0-14, 7.9% vs 18% nationally) and smaller proportions of older people (aged 65+, 10.5% vs 16% nationally). There were no significant differences in mean age between males (39.05 years, SD 19.06) and females (40.27 years, SD 17.00) using the Student *t* test (t_{501}=.739, *P*=.460). Relative to the practice's registered population, the sample included fewer parents reporting on behalf of children and more middle-aged adults (Figure 2).

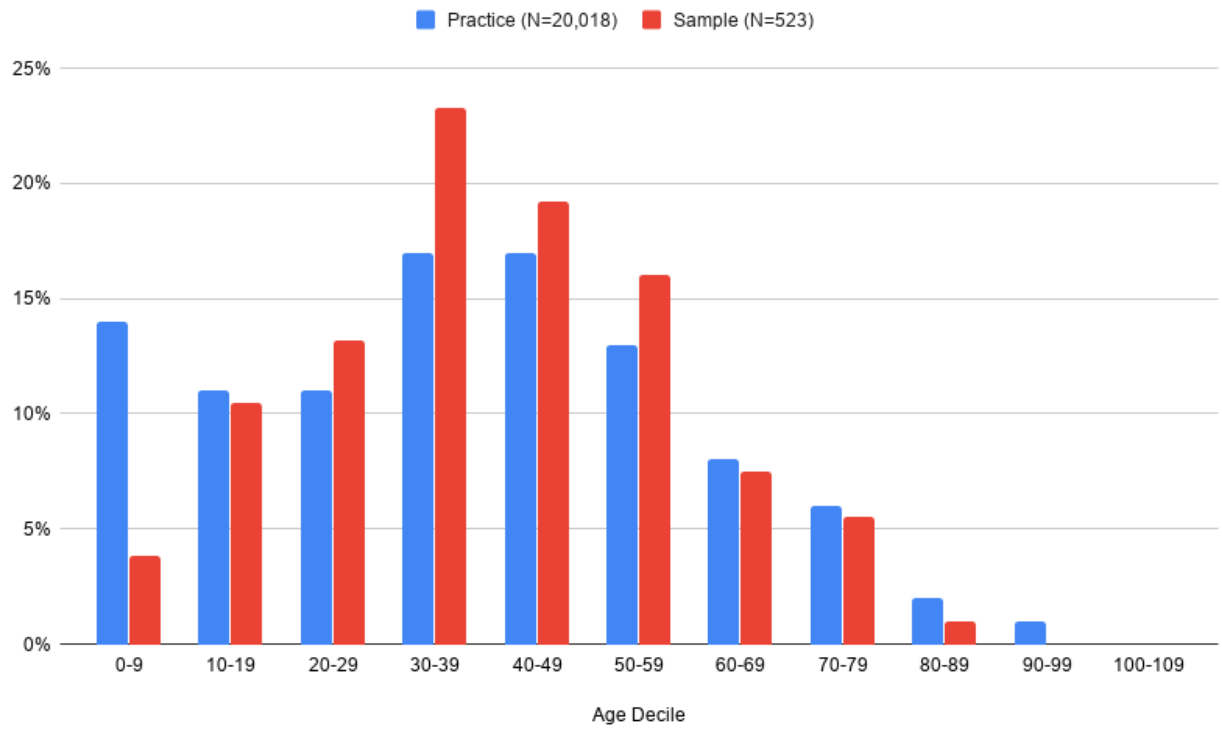
Table 1. Participant sex distribution compared with practice population.

Sex	Sample, n (%)[a]	Practice, n (%)[b]
Female	325 (62.1)	10,331 (51.61)
Male	185 (35.3)	9687 (48.39)
Not reported	13 (2.4)	0 (0)

[a]N=523.

[b]N=20,018.

Figure 2. Age distribution of registered patients at the Paxton Green practice compared with sample respondents.



Usability and Acceptance Testing

Overall, participants rated ease of use highly, with most participants (348/522, 66.7%) reporting it was *very easy* to use Ada; most of the remaining participants reported *quite easy* (163/522, 31.2%), with just 11 reporting issues (9/522, 1.7%, *quite difficult*; 2/522, 0.4%, *very difficult*; and with 1 participant missing data). As shown in Table 2, relative to the Healthwatch Enfield study, we saw a much higher degree of acceptance from actual users who had interacted with Ada than from (an admittedly different) group of survey respondents being asked how likely they thought they would be to use a (unspecified) symptom checker.

While we had no preplanned hypotheses to test statistically, inspection of the means suggests that there is a trend for higher

levels of enthusiasm, utility, willingness to use again, potential impact on clinical decisions, and potential diversion away from clinic by age group. For example, while 22% (11/50) of those aged 18-24 suggested that using Ada would have changed a decision had they used it before attending the GP, no patients over the age of 70 (0/28, 0%) agreed with this statement (though numbers were small, 28/427 respondents or 6.6% of the sample). Nonparametric chi-square testing found no sex differences on any of the usability metrics described in Table 2 (analysis not shown).

Table 2. Usability and acceptance responses stratified by Healthwatch Enfield [20] respondent age categories.[a]

Age category	Healthwatch Enfield "would use a symptom checker before seeking advice from GP" (N=1071)[b]	Extremely Likely/Likely to recommend Ada to a friend or relative (N=447)	Very/Quite easy to use Ada (N=450)	Yes, Ada Provided Helpful Advice (N=437)	Yes, Would Use Ada Again (N=433)	Yes, Using Ada Changed a Decision (N=427)	Yes, Would Still Have Come to Clinic if Had Used Ada Before (N=443)
18-24, n/N (%)	74	50/54 (92.60)	54/54 (100)	49/53 (92.45)	50/54 (92.59)	11/50 (22.00)	51/53 (96.23)
25-39, n/N (%)	71	125/147 (85.03)	146/147 (99.32)	116/145 (80.00)	129/145 (88.97)	17/140 (12.14)	132/145 (91.03)
40-54, n/N (%)	69	121/141 (85.82)	137/143 (95.80)	108/138 (78.26)	120/133 (90.23)	19/137 (13.87)	125/140 (89.29)
55-69, n/N (%)	51	64/72 (88.89)	72/73 (98.63)	53/69 (76.81)	59/70 (84.29)	11/72 (15.28)	66/72 (91.67)
70+, n/N (%)	34	25/33 (75.76)	32/33 (96.97)	19/32 (59.38)	22/31 (70.97)	0/28 (0.00)	32/33 (96.97)

[a]N values vary due to missing data; n=17 did not provide age and n=56 participants under the age of 17 were excluded from this comparison.

[b]Only percentage is reported due to missing n/N value.

Urgency Advice Levels and Redirection

One aim of a digital symptom assessment tool is to give appropriate advice and, where appropriate, to encourage self-care (eg, self-limiting illnesses such as upper respiratory infections). Participants were asked to self-report whether using the Ada assessment would have changed their decisions about what to do next. Overall, most respondents (425/494, 86.0%) said they would not have changed their decision, with other responses shown in Table 3.

Table 3. Self-reported predicted change in care navigation as a result of using a symptom checker.

Did using Ada change your decision about what to do next?	n (%)[a,b]
No	425 (86.0)
Yes—Changed my mind from wanting to see a GP[c] to self-care at home	23 (4.6)
Yes—Changed my mind from wanting to see a GP to visiting the pharmacy	20 (4.0)
Yes—Changed my mind from wanting a same-day appointment to delaying my appointment for a few days	20 (4.0)
Yes—Changed my mind from wanting to see a GP to visiting A&E[d]	6 (1.2)

[a]Missing data: 29.

[b]Total valid entries: 494.

[c]GP: general practitioner.

[d]A&E: accident & emergency.

Discussion

Principal Results

In this real-world usability study, participants in a South London primary care setting endorsed Ada's ease of use, with the majority saying they would use Ada again. These data from people given the opportunity to use a real product contrast with the Healthwatch Enfield report survey collected in a similar time range in the same city where respondents asked by survey whether they would, in theory, be willing to use a briefly described symptom checker were less enthusiastic, particularly those in older age groups [20].

Given the product's intent of providing improved access to health care to everyone, it was reassuring to find no sex differences in perceived usability or utility of the symptom checker app. However, we did find age differences on several key factors including willingness to use again, perceived usefulness, and likelihood of changing a health decision. Prior research in the field has identified age-related differences in willingness to use technology [20], but this is also confounded by the nature of the health problems presented by different age groups. For example, a number of apps have reported a much younger user base than the general population, and younger users may also reflect more engaged users.

Although speculative, the fact that older people found the app just as easy to use but reported less engagement might suggest

that the issue is not one of usability or familiarity with technology. Rather, future research could explore whether older potential users might have more interest in face-to-face interaction with a clinician, want to discuss chronic conditions or issues of multimorbidity, or that, having had more experience with the health system, they might see potential risks in a digital approach that younger people may not perceive.

Limitations

As a small feasibility study, our approach had a number of limitations which we will seek to address with hypothesis-driven research in the near future. Asking patients already in a GP's waiting room what they *might have done* in a questionnaire may have poor predictive validity compared with other markers such as their prior behavior [25]. Unmeasured factors in this study such as the quality of a patient's relationship with the GP have been shown to be an important driver of health-seeking behavior and should be taken into account [26]. While most respondents said using the symptom checker would not have changed their decision to see the GP, it is worth noting that at the point of enrollment they were on the cusp of seeing their doctor face-to-face, and were therefore quite committed to their current path. Our sample contained a higher proportion of females than either the practice's data suggest are registered or the UK census data; this may be explained by females being more frequent users of health care services [1]. Future studies should study real-world patient behavior before they have a clinic appointment booked.

Comparison With Prior Work: Usability

This study suggested a high degree of usability, with nearly all respondents (511/522, 97.8%) reporting a high degree of ease of use. Similarly, an independent study by an external academic group unrelated to Ada sought to understand the applicability of a multidimensional short form *User Engagement Scale* [27] in mobile health apps, using the Ada symptom checker as an example [28]. In a convenience sample of 73 German-speaking Swiss participants (49% female; mean age 39 years, SD 15.4 years; range 18-73), they reported ratings were high for *perceived usability* and *aesthetic appeal* [28]. Studies of other symptom checkers also report a high degree of perceived utility. In a convenience sample of 304 US users of the Isabel symptom checker, 90.1% (274/304) agreed or strongly agreed that it gave them useful information, and a similar proportion said they would use the tool again [29].

Comparison With Prior Work: Redirection

In terms of reducing the burden on primary care, some 12.8% (63/494) of respondents in this study predicted that they would have used a less urgent care option such as a pharmacist or self-care had they used Ada before visiting the doctor. It remains to be seen how many patients would actually follow advice on where to go next, but in the survey of US Isabel symptom checker users, about half (14/26, 54%) of those advised to go to the emergency department reported that they did so [29]. Another recent paper reported broadly similar findings from over 150,000 encounters with the Buoy Health symptom checker: 18.8% of patients who had planned to visit primary care reduced the urgency of care they would seek, and 2.6% increased the urgency of their intended level of care [30]. The differences in findings between the studies are not large, and likely primarily reflect the major design difference between the studies: our study explored those patients who have already chosen to attend the primary care practice, whereas the Buoy study explored intentions expressed at home. Both approaches have advantages and disadvantages: this study excluded those patients who would later change their mind about attendance after app use, whereas patient intention may have changed after being recorded in the Buoy study, even without changed symptoms. Our study explores a patient population who made a proactive decision to attend the surgery: likely a population with more severe symptoms. Other likely less significant reasons for differences in results between the two studies may be associated with cultural differences (UK vs USA), differences in the platform (mobile phone vs web based), and differences in the presentation of advice levels between the two symptom assessment apps.

Iterative Product Improvements in Response to User Feedback

One limitation of the Ada version used in this study was difficulty interpreting many of the phrases that patients used to express their initial symptoms as free text. We have sought to address this poststudy by developing a more sophisticated approach to recognizing the free text phrases patients are using to describe their symptoms. This approach leverages machine learning, which is applied if the user query does not match any results in an internal library of recognized terms and phrases. The machine learning approach then suggests entities from Ada's medical knowledge database, using algorithms that have been trained on previous user queries. The net effect of this for the user is that Ada now recognizes a variety of different phrases, and links these back to specific symptoms in the database. This approach also means that Ada can now recognize new phrases after they have been entered a few times by users. It also became clear that patients often misspelled. We worked with our product team to address this issue, and Ada is now able to recognize and automatically correct a wide range of incorrectly spelt terms. Another piece of feedback received was Ada should have been made available on the primary care clinic website to facilitate at-home usage. We developed a *web embed* version deployed at scale to Sutter Health, a large health system in the United States. Several patients in the study made comments on how we could improve the treatment advice given to individuals at the end of an assessment, especially when self-care is suggested. The app now features condition-specific, high-level treatment advice for a range of minor conditions where self-care is typically appropriate.

Future Research

Currently, the Ada symptom assessment tool is intended to be used at home. This study adds information on how patients' intention for a primary care practice visit may change based on home use of an app. The study also provides data on the potential for symptom checkers to be used as a waiting room tool. Here, the combined ability to collect, record, and assess patients' symptoms, and to provide advice about the most appropriate care may find a role in practice; for example,

perhaps based on a fast-track app-supported doctor triage, or based on redirecting a patient to a nurse, pharmacist, or other health care practitioner within the GP practice. Such approaches will be investigated in further clinical evaluation, which will address the absolute appropriateness and safety of changes in patient intention after symptom checker use.

In addition to usability, novel digital approaches must undergo rigorous evaluation of diagnostic coverage, accuracy, and safety. In a preprint from our group (currently undergoing peer review), we evaluated the performance of 8 popular symptom checkers against one another and 7 human GP raters, as well as a *gold-standard* diagnostic suggestion using 200 clinical vignettes [31]. There was a range of coverage from the apps, with up to half of potential users being ineligible to use the symptom checker because they were too young, too old, or were pregnant; Ada offered 99.0% of users a suggested condition diagnosis. When suggesting potential diagnoses, human GPs made correct suggestions among their top 3 an average of 82.1% (SD 5.2%) of the time; the symptom checkers ranged from a low top-3 condition diagnosis accuracy of 23.5%, to Ada's top-3 condition diagnosis accuracy of 70.5%, coming up on top of the symptom checker range and therefore closest to the performance of human GPs. In terms of safety, human GPs made a safe recommendation of what a symptom checker user should do next an average of 97.0% (SD 2.5%) of the time; Ada's performance was identical at 97.0%.

Symptom checkers that undergo rigorous testing and certification have the potential to become useful tools to deploy alongside human medical staff to reduce diagnostic errors, prioritize sparse health resources, and improve documentation and efficiency of history taking. Diagnostic errors are all too common in our existing primary health care systems, with a systematic review commissioned by the World Health Organization suggesting around 2-3 safety incidents per 100 consultations in primary care, with many of these relating to incomplete or incorrect documentation and insufficient communication between patients and providers [3]. Another analysis from a large US population suggests a misdiagnosis rate by physicians of about 5% [22]. While software can be systematically updated, upgraded, and patched at scale, the same is not true for the existing medical system. The ideal situation would be scalable digital systems that can help the time of physicians be more appropriately allocated to the many skills that are beyond the current reach of digital technologies.

Conclusions

Digital symptom checkers such as Ada could have a useful role to play in more appropriately directing patients to the right care in the right place at the right time.

Acknowledgments

We are grateful to all the participants who took part in our study.

Conflicts of Interest

SM is employed as Senior Partner by Paxton Green Group Practice. SG and VV are employees of Ada Health. PW is a paid consultant to Ada Health.

Multimedia Appendix 1
Paxton Green NHS Study Survey Instrument.
[DOC File , 24 KB - humanfactors_v7i3e19713_app1.doc]

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Abbreviations

GP: general practitioner
NHS: National Health Service

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Original Paper

Applying a Human-Centered Design to Develop a Patient Prioritization Tool for a Pediatric Emergency Department: Detailed Case Study of First Iterations

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Abstract

Background: Overcrowding in the emergency departments has become an increasingly significant problem. Patient triage strategies are acknowledged to help clinicians manage patient flow and reduce patients' waiting time. However, electronic patient triage systems are not developed so that they comply with clinicians' workflow.

Objective: This case study presents the development of a patient prioritization tool (PPT) and of the related patient prioritization algorithm (PPA) for a pediatric emergency department (PED), relying on a human-centered design process.

Methods: We followed a human-centered design process, wherein we (1) performed a work system analysis through observations and interviews in an academic hospital's PED; (2) deduced design specifications; (3) designed a mock PPT and the related PPA; and (4) performed user testing to assess the intuitiveness of the icons, the effectiveness in communicating patient priority, the fit between the prioritization model implemented and the participants' prioritization rules, and the participants' satisfaction.

Results: The workflow analysis identified that the PPT interface should meet the needs of physicians and nurses, represent the stages of patient care, and contain patient information such as waiting time, test status (eg, prescribed, in progress), age, and a suggestion for prioritization. The mock-up developed gives the status of patients progressing through the PED; a strip represents the patient and the patient's characteristics, including a delay indicator that compares the patient's waiting time to the average waiting time of patients with a comparable reason for emergency. User tests revealed issues with icon intuitiveness, information gaps, and possible refinements in the prioritization algorithm.

Conclusions: The results of the user tests have led to modifications to improve the usability and usefulness of the PPT and its PPA. We discuss the value of integrating human factors into the design process for a PPT for PED. The PPT/PPA has been developed and installed in Lille University Hospital's PED. Studies are carried out to evaluate the use and impact of this tool on clinicians' situation awareness and prioritization-related cognitive load, prioritization of patients, waiting time, and patients' experience.

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KEYWORDS

emergency department; triage systems; ergonomics; design; human-centered design; patients

Introduction

Background

Emergency department (ED) overcrowding occurs when demand for emergency services exceeds the capacities to provide care [1-4]. Overcrowding has been shown to increase waiting times and, as a consequence, delay time-sensitive treatments and procedures for serious conditions, which in turn increases patient mortality and morbidity [5,6]. In 2004, the United Kingdom's National Health Service introduced indicators to ensure patients are seen, admitted, and discharged within 4 hours of presentation to the ED [7]. Those indicators led to the development of specialized call centers, dedicated emergency units, mobile emergency medical teams [8], acute medical units [9], and new organizational protocols [10]. In the meantime, other strategies have been shown to improve patient flow and reduce waiting time [11,12], for example, having hospitalists manage beds [13], having nurses support patient movement [14], having physicians conduct early evaluation and manage patient flow [15], or performing patient registration at the bedside [16].

Triage of patients at their arrival is a long-established strategy to identify patients with critical conditions [17]. As soon as patients arrive in the ED, the severity of their condition is assessed and their treatments are prioritized accordingly [18,19]. This task is usually performed by triage nurses but is more efficient when performed by a senior physician [20] or by a physician and a nurse [21]. In this task, clinicians may use paper-based [22] or electronic triage systems [23-25].

Despite the weak evidence supporting the effectiveness of triage, this strategy is acknowledged to decrease waiting time [12] and to be a determinant of health care system performance [26]. However, the data used by today's electronic patient triage systems must often be entered manually by clinicians; this is problematic when the ED is overcrowded and therefore limits the system's usage and potential positive impact. Moreover, sorting algorithms implemented in the electronic triage systems are not based on actual strategies employed by the clinicians [24,25]. Therefore, there is a risk that those systems conflict with clinicians' workflow and disturb their work.

Study Context

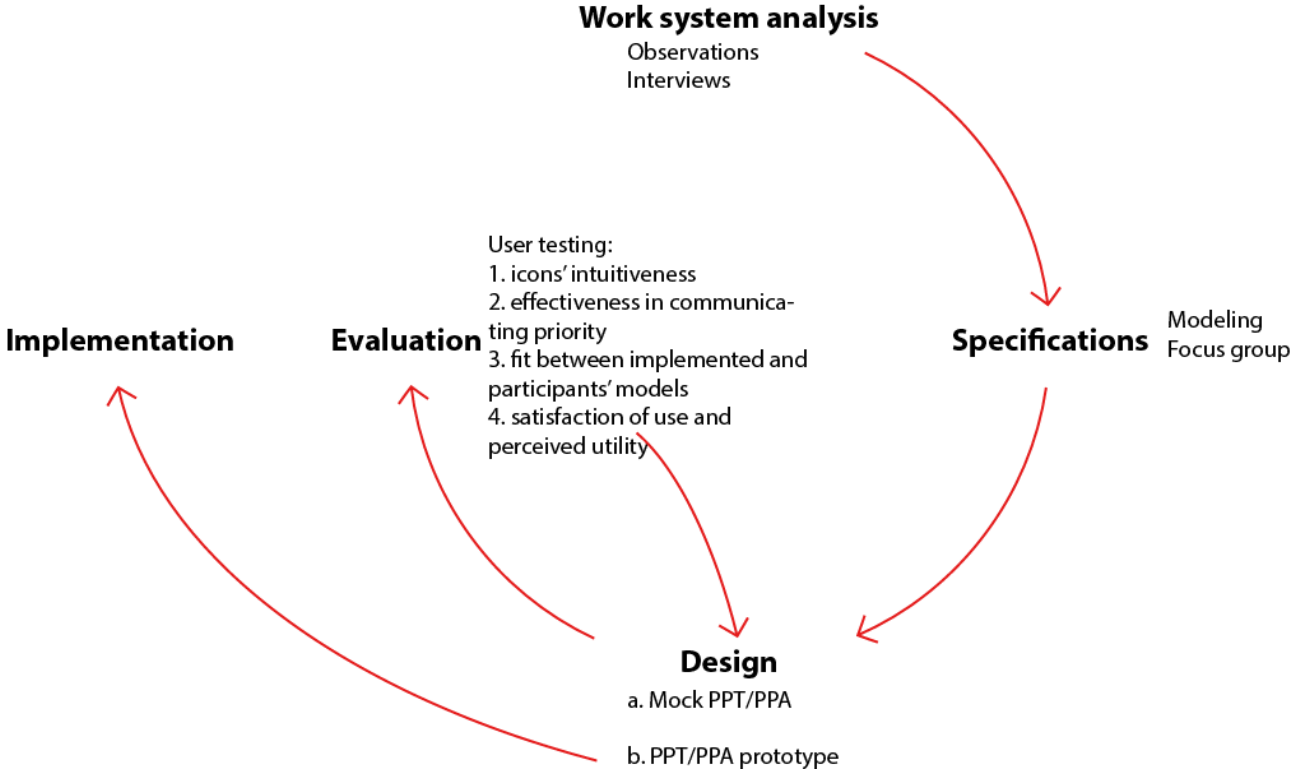
The pediatric emergency department (PED) of Lille University Hospital has a capacity of approximately 30,000 patients per year. A total of 10 doctors and 8 nurses (plus residents and trainees) work in the department to take care of the patients. The department is currently equipped with ResUrgences (Berger-Levrault), a patient management software that tracks patients from their arrival in the PED through discharge. ResUrgences is independent of the hospital's electronic health records but is interconnected with the laboratory information system and the picture-archiving and communication system from which it receives notifications when results are available.

The PED's clinicians enter the patient's data (eg, name, age, reason for admission, triage decision) and their own observations in ResUrgences. The patient record is progressively completed as the patient moves through the care process. However, ResUrgences does not prioritize the patients or organize their care accordingly, so clinicians must mentally compare the status of different patients and determine which one should be managed first. The Optimum project aims to develop and install in the PED a patient prioritization tool (PPT) as an extension to ResUrgences that does not require clinicians to enter additional information, but which enables them to have an accurate awareness of the waiting situation of patients and suggests to them which patient they should see next based on their current prioritization strategies. The information provided by the PPT should assist clinicians in prioritizing patients, thereby helping to decrease their cognitive load and optimize patient management in real time. Ultimately, using this tool could contribute to reduced waiting time, especially the waiting time for critical patients and for time-sensitive treatments and procedures.

Poor design of health technologies can ruin their expected benefits [27,28]. In addition, design problems are a serious problem for hospitals around the world, contributing to clinician burnout and impacting patient care [29,30]. Methods of the human-centered design process, a design process in which usability and users of the technology are the focus of attention at all design stages [31], contribute to the development of health technologies that correspond to the real needs of end users, respect users' workflow, and reduce risk of use errors [32-36]. Thus, applying these methods to design a technology helps to reduce the risk of technology rejection on the one hand and to ensure that systems are more effective and efficient on the other [37-39].

For the developed PPT to align with clinicians' workflow and needs, the PPT was developed using a human-centered design process [31]. A work system analysis was performed and specifications were defined; then a mock tool was developed and underwent a usability evaluation (Figure 1). This case study presents the development of a PPT and of the patient prioritization algorithm (PPA) it relies on to show how to apply human-centered design methods to the design of triaging systems.

Figure 1. Representation of the human-centered design process applied during the study. First, a work system analysis was performed through observations and interviews. Then specifications were developed using modeling and a focus group session. A mock PPT/PPA was designed and then evaluated by user testing. Results from the evaluation helped improve the usability of the PPT/PPA prototype before implementation. PPA: patient prioritization algorithm; PPT: patient prioritization tool.



Methods

Work System Analysis and the Tool's Functional Specifications and Design

The work system analysis had two main objectives. First, it aimed to identify the needs of clinicians and the constraints that shape their work. This required an in-depth understanding of the organization of the PED and how clinicians manage the flow of patients and prioritize them in overcrowded conditions. Second, it aimed to learn to what extent it was possible to use the data entered in ResUrgences to feed the PPT and PPA. This required knowing whether the data entered in the software accurately represented the actual state of patient care (ie, verifying that the data were entered quickly enough to track each patient's progress through the various steps in care).

The data were first collected by structured observations performed by a human factors specialist using an observation grid built with iCoda (Studiocode). The observation unit consisted of the actions taken and the prioritization decisions made by the clinicians so that we could map the care process in detail and understand the prioritization decisions in depth. On a voluntary basis, 4 physicians and 4 registered nurses from the PED were individually shadowed during busy periods of the day (10 AM to 2 PM and 4 PM to 8 PM) over a 3-week period in February 2014 until the observations no longer provided new information.

Each action taken by clinicians was characterized in the observation grid as a communication with other clinicians, patients, or relatives; an interaction with documents or technologies (including ResUrgences); a move; an examination; a care; or an intervention. For each action observed, the grid made it possible to collect the step concerned in the care process; the action sequence in which the action took place; the profile of the clinician (eg, physician, registered nurse); the location; the type of information gathered, exchanged, or entered/written down (particularly prescriptions for care or procedures); etc. The data collected were time stamped so that the time interval between occurrence and data entry could be measured to know whether events were documented in ResUrgences in a timely manner.

In addition, clinicians were interviewed whenever the workload eased. They were asked to state and explain their reasons for patient prioritization, define the information on which their decisions were based, and state how and where they had collected this information. Furthermore, the same clinicians were formally interviewed at the end of their work shift with a focus on the data used to determine which patient should be taken care of first and how patients are prioritized. These interviews were audiorecorded and transcribed.

Data collected from the work system analysis were modeled through Unified Modeling Language diagrams [40] in order to highlight, for each step of the care process, interactions between clinicians, their usage of ResUrgences (eg, data consulted, data entered), and the data used to advance the process.

Clinicians' explanations of how they prioritize patients were analyzed qualitatively to extract common implicit and explicit patient-sorting rules that clinicians apply, the contexts in which these rules are applied, and the information used to make these

prioritization decisions. Sorting rules were modeled using decision trees. Patient-sorting rules were combined and integrated into a PPA. All models and decision trees were validated by the clinicians observed and interviewed.

The information needs to be met by the PPT were deduced from the work model and the prioritization rules applied by clinicians. These needs mainly concerned the information to be presented, as well as to whom, when, for what type of patient, and how the information would be presented. The list of these needs led to the formulation of specifications for the PPT graphical user interface (GUI).

Early mock-ups based on these specifications were developed by a human factors specialist using Axure (Axure). These mock-ups represented static screenshots of the whole PPT GUI and used interface components and mock but realistic patient data to look as much like a real interface as possible and to present a realistic occupancy of the PED.

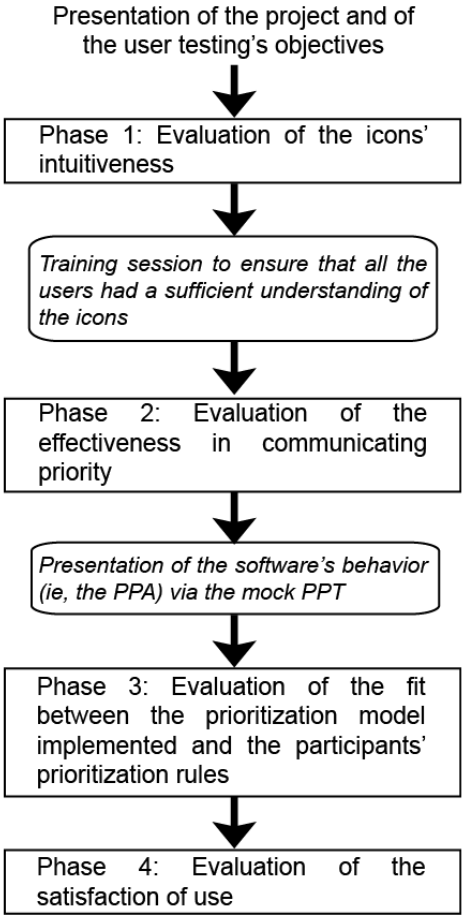
The mock-ups were presented to a focus group comprising 3 physicians, 2 registered nurses, 2 human factors specialists, and 2 software engineers. The final set of functional specifications as revised by the focus group was used to improve the mock PPT.

Evaluation of the PPT's Usability and Sorting Rules

The usability of the mock PPT and the relevance of the sorting rules integrated into the PPA were tested during a user testing session with 12 volunteers, in accordance with the recommendations for formative evaluations [41,42] (7 registered nurses and 5 physicians, none of whom took part to the work system analysis). User testing is a method for evaluating a product by directly observing the way users use the product. It makes it possible to identify the difficulties encountered by the users and the origin of the problems in the product [43].

A test session was divided into 4 phases alternating testing and training sessions (Figure 2).

Figure 2. Rollout of the user testing. Testing sessions are presented in the straight-lined boxes and training sessions are presented in italic font. PPA: patient prioritization algorithm; PPT: patient prioritization tool.



Phase 1 tested the intuitiveness of the icons used to characterize the status of each patient. Participants were shown a mock-up of the tool that displayed 10 patients and were asked to explain how they interpreted each icon and each patient's status. At the end, participants were given a training session on the icons so that they could perform phase 2.

Phase 2 tested the effectiveness in communicating priority. Participants were shown the same mock-up, in which 2 screenshots differed regarding the presence or absence of new patients and the current level of overcrowding. For each screenshot, participants were asked to identify the patient to whom they should first attend and to justify this decision. At the end, participants were shown a presentation of the system's behavior to ensure that they had enough knowledge to perform phase 3.

Phase 3 tested the fit between the prioritization model implemented (the PPA) and the participants' prioritization rules. This phase was inspired by the model-in-the-loop testing paradigm, a technique that simulates a model using an abstraction (eg, illustrations, text) to evaluate the behavior of that model [44,45]. This allows the model to be evaluated earlier in the design process with end users who are not experts in modeling and programming. For this phase, we created a simulator based on successive PPT screenshots to emulate the patient's progress through the PED. This simulator presented 5 different patient scenarios covering all sorting rules integrated into the PPA. At certain points, the simulator was paused, and the participant was asked (1) to state what the next step in the PED process would be for the patient and (2) to place the patient at the corresponding location on the GUI.

In phase 4, we assessed the satisfaction of use and the perceived utility of the PPT. Participants were asked to fill out a French-language version of the System Usability Scale (SUS) [46] and to give their opinion of the PPT and on the prioritization rules implemented.

Data collected during the 4 phases were analyzed as follows.

In phase 1, to evaluate the intuitiveness of the icons, we calculated the proportion of participants that correctly interpreted each icon. In the event of misinterpretation, we sought to understand the reasons for poor intuitiveness of the design by qualitatively analyzing participants' verbal statements.

In phase 2, effectiveness in communicating priority was analyzed. For each screenshot, we compared the participants' choice of the top-priority patient with the patient indicated as such by the PPA. We sought to understand problems by analyzing participants' verbal statements. If clinicians' prioritization and their justification for this decision were consistent with the organization proposed by the GUI, we presumed that the organization matched their work habits.

In phase 3, the fit between the prioritization model implemented (the PPA) and the participants' prioritization rules was assessed by rating participants' decisions on the patient's position on the GUI as correct or incorrect compared with the patient's position according to the PPA. In the event of discrepancies between participants' choices and the application of the PPA, we analyzed verbal statements.

In phase 4, to assess satisfaction of use and perceived utility, the SUS score of all participants was averaged and compared with the standard established by Bangor et al [47]. A content analysis of the participants' verbalizations was carried out to identify the perceived advantages, drawbacks, and limitations of the PPT and PPA by the participants.

Compliance With Ethical Standards

All procedures performed in studies involving human participants were in accordance with the French ethical standards and with the 1964 Declaration of Helsinki and its later amendments, or comparable ethical standards. Informed consent was obtained from all individual participants included in the study.

Results

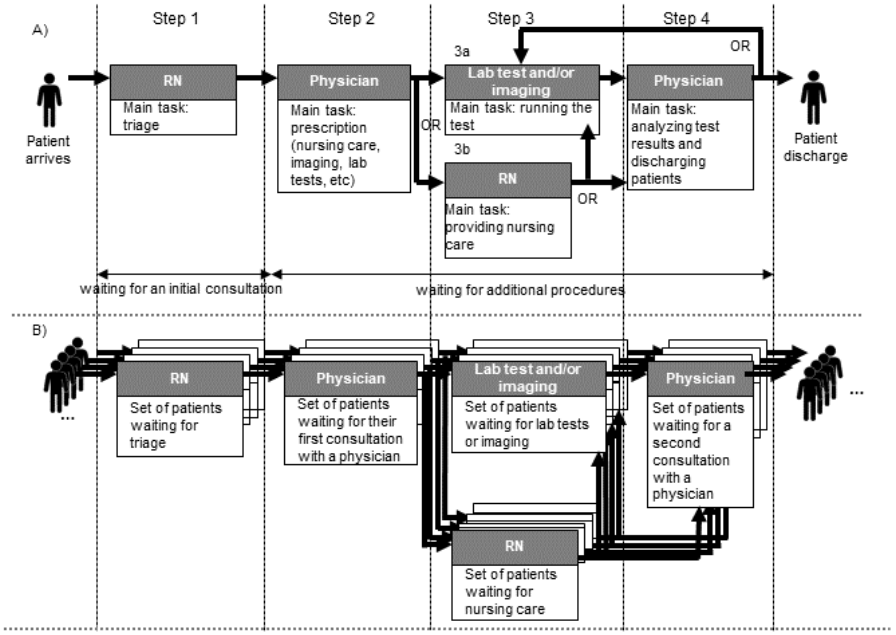
Work System Analysis and the Tool's Functional Specifications and Design

Work System Analysis

A total of 1264 actions and 43 prioritization decisions were observed during the shadowing sessions (total of 27 hours). The care process is organized into 4 main steps regardless of the PED's workload (Figure 3). Upon arrival in the PED, the patient is evaluated by a registered nurse (step 1), who determines the corresponding triage status. The patient then enters the care process. First, the patient sees a physician (step 2), who makes an initial diagnosis and prescribes the necessary lab tests, imaging, or nursing care. Next, the patient undergoes the prescribed lab tests or radiological examinations (step 3a) or nursing care (step 3b). When the lab test and imaging results are available or nursing care has been completed, the patient sees the physician again (step 4); the physician may prescribe further treatment or authorize the patient's discharge. Throughout the patient flow process, physicians enter data into ResUrgences and complete the patient's records (patient status, prescriptions, lab test results, notes, etc).

To streamline patient flow through the PED, registered nurses and physicians apply various rules to prioritize patients to be attended. The main data used by clinicians to apply those rules are depicted in Textbox 1. Figure 4 provides an example of the sorting rules applied by registered nurses (Multimedia Appendix 1 for physicians).

Figure 3. Schematic description of patients' progression through the pediatric emergency department. Panel A describes the main tasks to be performed by the registered nurses and the physician at each step in the care process for a single patient. Panel B highlights that the pediatric emergency department care process is the same for all patients. RN: registered nurse.



Textbox 1. Main data used by the clinicians to manage patient flow during busy periods.

Patient's information

- Name
- Age
- Reason for admission
- Triage number

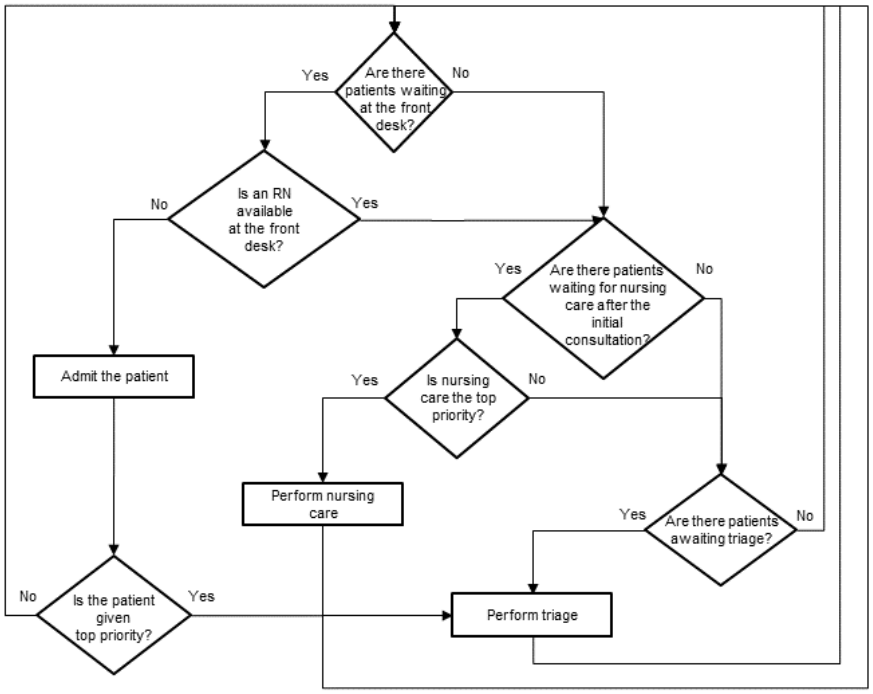
Patient's current position in the care process

- Treatment by a registered nurse or physician
- Waiting time for further examinations
- Patient's overall length of stay in the pediatric emergency department

Patient tests

- Tests prescribed
- Tests to be completed

Figure 4. Example of RNs' sorting rules. Actions are presented in the rectangular boxes and conditions for decision in the diamond-shaped boxes. RN: registered nurse.



Our observations of the timeliness of ResUrgences data entry showed that the data were representative of PED activity, even during busy periods. The median time between the receipt of data by the physicians and their data entry into ResUrgences was 136 seconds (IQR 67-345 seconds). During busy periods, even data that were first collected on paper were entered into ResUrgences no more than 2 minutes later (for details, see Schiro et al [48]). These results showed that ResUrgences data could be used to automatically feed the PPT and the PPA and inform clinicians on the progress of the patient through the care process.

Requirements and Specifications

The work system analysis enabled us to identify requirements for the PPT; it must (1) meet the needs of both physicians and registered nurses, (2) show physicians and registered nurses how the patients are distributed across the steps in the care process, and (3) display the current caseload and the corresponding priority levels.

Discussions during the focus group provided a consensus on more detailed specifications. First, patients in a life-threatening situation must not be affected by the algorithm because they are always treated with the highest level of priority. Second, the PPT should sort waiting patients according to whether they must see a nurse, see a physician, or undergo lab tests or imaging. Third, the PPT should prioritize patients to be seen by the registered nurses and the physicians. Patients waiting for lab tests or imaging results should be sorted as a function of their waiting time. Fourth, the tool should be fed directly with ResUrgences data so that clinicians do not have to enter the same data twice.

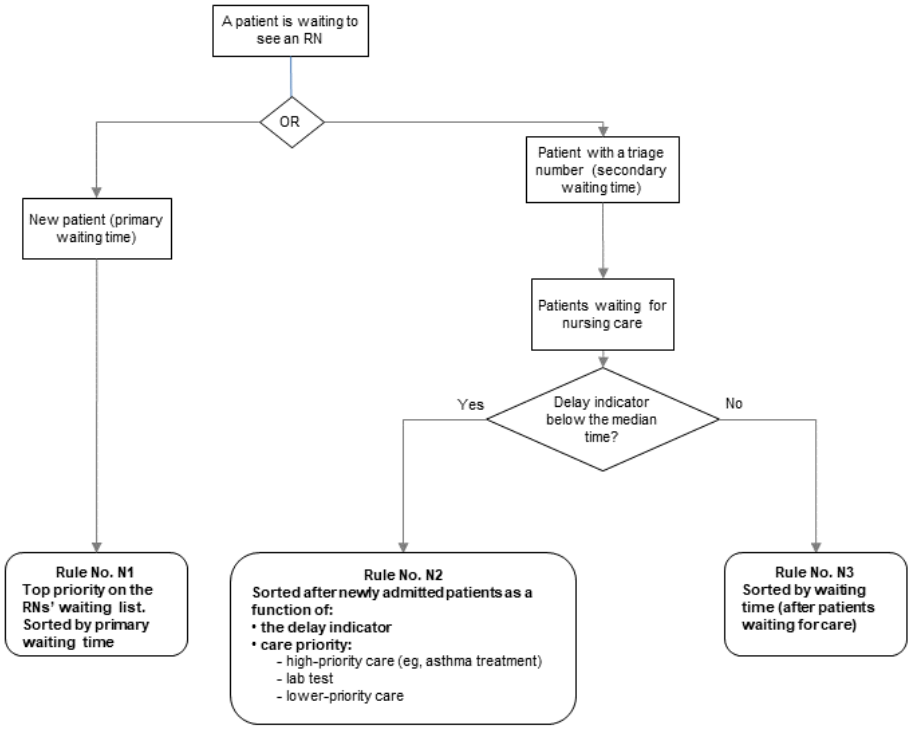
Design of the Mock PPT

To meet the requirements, the mock PPT gives the status of patients progressing through the PED, along with an overview of all the patients in the PED (Figure 5). Each strip represents the patient, as well as the patient's age, waiting time, reason for emergency (represented in the mock PPT by "pathology"), in-progress and pending cares/acts, triage number, and a delay indicator that compares the patient's waiting time with the average waiting time of Lille University Hospital's patients with a comparable reason for emergency (green ribbon when the patient's waiting time is less than the average waiting time, orange or red otherwise).

Figure 5. Mock-up patient prioritization tool's main screen, which gives an overview of the patients and information on each patient. RN: registered nurse.

Based on the staff's strategies to prioritize patients, a set of sorting rules was developed for the registered nurses (Figure 6) and the physicians (Multimedia Appendix 2) and then aggregated into a PPA. This algorithm is automatically fed with data from ResUrgences. It calculates the status of each patient in real time and moves the patient's strip through the blocks on the interface, which represent the main steps of the emergency care process, and through the lines within the blocks, suggesting the level of priority.

Figure 6. Sorting rules for the registered nurses, as integrated into the patient prioritization algorithm. Patients with life-threatening medical emergencies are always considered the highest priority and therefore do not appear in these sorting rules. RN: registered nurse.



Evaluation of the PPT's Usability and Sorting Rules: User Testing

Phase 1: Intuitiveness of the Icons

Most of the icons were interpreted correctly (Figure 7). Only icons depicting a doctor's bag were not well interpreted, as only 2 of the 7 registered nurses and 1 of the 5 physicians interpreted them correctly. An analysis of the verbal statements showed that the participants either did not understand the icon's meaning at all or thought it represented the patient's records or a consultation with a specialist. Furthermore, the color coding (gray for "to do" and a color for "done") was more easily understood for lab tests or imaging (5/7 registered nurses and 4/5 physicians) than for care provision (2/7 registered nurses and 1/5 physicians). The delay indicator was properly understood by all physicians but only by 3 of the 7 registered nurses. In fact, the registered nurses tended to interpret the delay indicator solely as a measure of the time elapsed since the patient's arrival in the PED (Table 1, quote 3). Physicians valued the delay indicator because it removed the need to schedule a discharge time, which would have constituted a source of stress (Table 1, quote 1).

Figure 7. Results of phase 1 of the user testing: proportion of correct interpretation for each icon according to the profile of the participant. RN: registered nurse.

Icons	Meaning of the icons	Proportion of correct answers	
		Registered nurses	Physicians
	New patient	5/7	4/5
	Triage number	5/7	5/5
	Lab results available and imaging in progress	4/7	4/5
	Lab and imaging results available	6/7	4/5
	Prescription of laboratory tests Patient awaiting lab test	5/7	4/5
	Provided RN care	2/7	1/5
	Patient awaiting RN care and discharge letter available	1/7	1/5
	Provided RN care and awaiting the discharge letter	1/7	1/5
	Good delay indicator Medium delay indicator Poor delay indicator Bad delay indicator Critical delay indicator	3/7	5/5

Table 1. Quotes from registered nurses and physicians during phase 1 of the user testing.

Participant	Quote
Physician No. 1	"It's good not to have an estimated discharge time, which is what I feared with this project. With the color coding, it's easier to understand."
Physician No. 2	"The 'lab' icon is easy to recognize, and the color change to indicate that the result is available is clear. But what happens when the result has been read and interpreted by the doctor, does it change? because this is another step in the care process."
Registered nurse No. 3	"I did not understand the delay indicator immediately, but actually it's not bad – it's important to help us know who to see first."
Registered nurse No. 5	"The delay indicator is very interesting. You have to bear in mind that it's not just the time."

Phase 2: Effectiveness in Communicating Priority

For the view with new patients, 6 of the 7 registered nurses and all physicians understood that the high-priority patients were those at the top of their respective column. However, 2 registered nurses considered that the choice also depended on the patient's health status (Table 2, quote 4). For the view with no new patients, all registered nurses and 4 out of 5 physicians agreed with the GUI's organizational structure. The only inconsistent answer was related to the application of a different strategy by a physician (Table 2, quote 1).

Table 2. Quotes from registered nurses and physicians during phase 2 of the user testing.

Participant	Quote
Physician No. 4	"I'd first see the nurse and tell her to take care of the patients at the top of the list, so that they can get discharged."
Physician No. 5	"Sometimes there are patients who are still under our responsibility but for whom there is no longer anything urgent because they are just waiting to be discharged; it is not the same as waiting to see the doctor for a diagnosis."
Registered nurse No. 1	"For some decisions, it's going to depend on how busy the ward is, how many patients there are."
Registered nurse No. 2	"It depends on the severity of the new patients' status. If I see that a new arrival has a minor injury, I'll do a blood test for another patient first because I know that it'll take a while to get the results."

Overall, our analysis of the participants' verbal statements did not identify any difficulties in understanding how the information was organized or how the patients were located in the GUI. A nurse did indicate that it was necessary to provide a view of the department's occupancy to help him make certain care decisions (Table 2, quote 3). A doctor pointed out that, in the doctor column, two types of patients were mixed: those waiting for an auscultation or a diagnosis and those waiting to be discharged. However, the urgency is not the same for these two types (Table 2, quote 2).

Phase 3: Fit Between the Prioritization Model Implemented (the PPA) and the Participants' Prioritization Rules

Overall, participants tended to agree with the PPA's decisions—they placed the patients in the expected column with the expected priority. Proportions of correct decisions were 87% (61/70) for registered nurses and 98% (49/50) for physicians (Table 3). Overall, the PPA was validated by most of the users.

Table 3. Results of phase 3 of the user testing: proportion of correct prediction according to the patient case and the profile of the participant, along with explanations in case of erroneous prediction.

Scenarios		Physicians' answers			Registered nurses' answers		
Patient case	Rule	Column, n/N	Block/line, n/N	Explanation	Column, n/N	Block/line, n/N	Explanation
Case 1	Rule No. Ph3	5/5	4/5	Patients do not always progress to the next step when lab results are available (n=1)	7/7	4/7	Patient not prioritized (no block or line) (n=2) or without the expected icon (n=1)
Case 2	Rule No. Ph1	5/5	5/5	N/A[a]	7/7	6/7	Patient not prioritized because the RN[b] needs to know the type of pathology to place the patient (n=1)
Case 3	Rule No. N3	5/5	5/5	N/A	6/7	6/7	One RN failed to understand that, after discharge, the patient had to be moved outside the interface (n=1)
Case 4	Rule No. N2 Rule No. Ph4 Rule No. Ph5 Rule No. Ph6	5/5	5/5	N/A	6/7	5/7	One RN did not move the patient to another column (n=1) Another relied exclusively on the delay indicator and opted for the wrong block (n=1)
Case 5	Rule No. N1	5/5	5/5	N/A	7/7	7/7	N/A

[a]N/A: not applicable.

[b]RN: registered nurse.

Because of the use of the term "pathology" instead of an actual reason for emergency on the mock-up, some clinicians found it difficult to place the patients as presented in the patient strip. They also pointed out a limitation concerning the time elapsed

between the availability of test/imaging results and the moment of their interpretation. In fact, lab results seldom arrive simultaneously; in some situations, the physician checks that all the results are available before seeing the patient or deciding about discharge (Table 4, quote 1). However, the PPA only accesses the availability of the lab and imaging results to calculate the new position of the patient. This may lead to discrepancies between the actual step in the care process that the patient is in and the displayed step.

A few participants also criticized that the PPA did not include subjective elements that may enter into clinicians' decision for prioritizing patients (Table 4, quote 3).

Table 4. Quotes from registered nurses and physicians during phases 3 and 4 of the user testing.

Participant	Quote
Physician No. 2	"There's a missing step here: the physician might read the lab results but not do anything [because some lab results are still missing]; the 'R' [indicating that the lab results are available] disappears from ResUrgences because the results have been accepted and the patient has been seen by the physician, but nothing happens and s/he does not move through to the next step."
Physician No. 3	"This appears to be quite useful. It would be good to have screens in the [emergency department]. We'll need access to the computer, as with ResUrgences. Then, I can help out even if I'm not caring for a patient...because sometimes ResUrgences shows you that there are lots of people waiting but that's not the reason why the [emergency department] is disorganized."
Physician No. 5	"I'm not sure whether we need to base our actions on that or not, because we use subjective criteria that cannot be taken into account. However, the system has already done a huge amount of work in organizing the patients!"
Registered nurse No. 1	"I think it's a good idea. I will go see patients at the top of the list in ResUrgences. That will help me to avoid consulting them one by one..."
Registered nurse No. 7	"I'll place more trust in what I'm told [by my colleagues] than in a tool but this is a good add-on."

Phase 4: Satisfaction of Use and Perceived Utility

The average SUS score was 70 (on a scale ranging from 0 to 100), which highlighted a good satisfaction [47]. Overall, the PPT was perceived as being helpful for prioritizing patients (eg, Table 4, quote 2). However, participants said that they would continue to consult ResUrgences in addition to the PPT to organize their work (Table 4, quote 4). Physicians found the PPT very useful as an overview of the department's activity and, at the same time, an indication of work that they must do immediately (Table 4, quote 2). Registered nurses found it useful too and stated that it would save time when compared with using ResUrgences alone (Table 4, quote 4).

Discussion

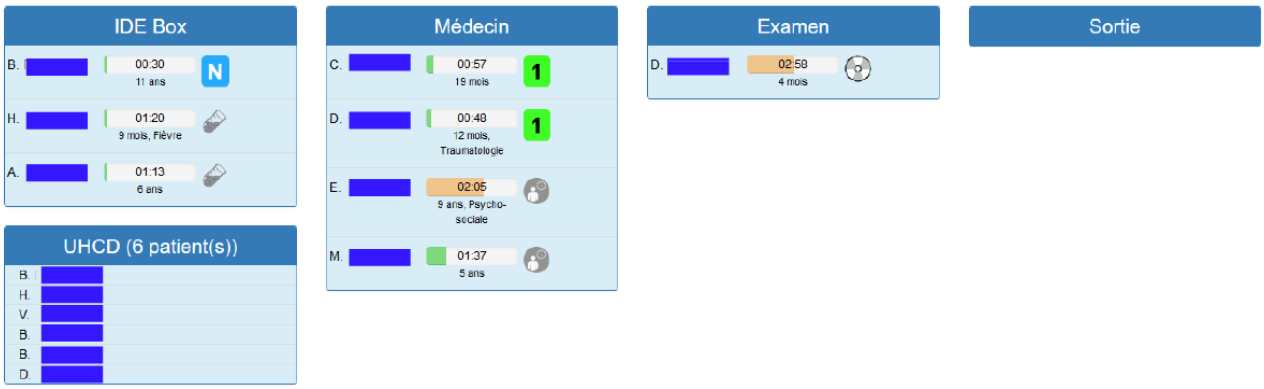
Principal Results

This case study aimed to present the human-centered design of a PPT and of the PPA it relies on to show how to apply human-centered design methods to the design of a prioritization system. Representative end users were involved early in the design process. We performed a work system analysis and, based on the specifications ensuing from it, we designed a PPT along with a PPA. Finally, we performed user testing on mock-ups simulating how the PPT and PPA work.

Results of the work system analysis underpinned the entire design process, from specification of the users' needs to the development of the PPA. The work system analysis enabled us to understand how the PED was organized and how clinicians managed the patient flow. This analysis also showed a short data entry time in ResUrgences, which would indicate that these data represent the patient's management in real time and therefore can be used to automatically populate the PPA and PPT. Furthermore, this analysis provided specifications needed to design the tool. Lastly, the work system analysis enabled us to build scenarios for designing the PPA and the PPT's GUI and helped us design the evaluation plan.

In the user testing, we simulated how the PPT and the PPA would work by animating successive screens of the mock-up, populated with fake but realistic sets of ResUrgences data. Applying an adapted model-in-the-loop testing paradigm [44,45] during the early steps of the design process enabled us to obtain feedback on the GUI before developing the prototype PPT and to ensure that health care professionals understood the PPA they evaluated. The results of the user testing were used to make decisions to improve the PPT and the PPA. Figure 8 represents the new version of the PPT.

Figure 8. Screenshot of the prototype patient prioritization tool after re-engineering (blue rectangles hide patient identity).



Most of the changes concern the icons and the GUI's organization. For example, the doctor's bag icon had several meanings depending on its color and its combination with another symbol ("nursing care" or "discharge letter available"). It was either not understood or was mistaken for a representation of the patient's records or a consultation with a specialist. In order to avoid this polysemy, it is no longer associated with the discharge letter and represents only the realization of nursing care. In addition, the delay indicator was misinterpreted by nurses because this type of indicator is not usual and not present in other software. Explanations of the calculation of this indicator and its meaning were given to users during training sessions, as well as in posters displayed next to the PPT screen in the department. In regard to the GUI, the time of patient presence in the ward was integrated in the center of the progress indicator (instead of to the left) to show that it was associated with the calculation of the indicator. Another issue was that the mock-up presented only patients present in the emergency department care and consultation sector and excluded the emergency department short-stay hospitalization sector. However, for some decisions, clinicians need to know the occupancy rate of the entire department. To provide clinicians with access to this information, a box summarizing the number of patients in the hospitalization sector was added. Finally, patients waiting for a doctor to sign their discharge letter were previously mixed in with patients waiting for a consultation. However, from a physician work organization point of view, having a lot of patients waiting for their discharge letter does not have the same consequences as having a lot of patients waiting for a diagnosis. The doctor can quickly release several patients by signing the discharge letters one after the other. Therefore, a fourth block, "Discharge," was added to the GUI for patients who are waiting for their discharge letter to leave the PED. The addition of this block allowed us to eliminate the icons representing that a patient is waiting for discharge letter.

A number of sorting rules in the PPA were also modified or created. For instance, rules were changed to enable a distinction between the test and imaging results that were available in ResUrgences and those that had been interpreted by the doctor, because these represent different steps of patient care.

Overall, this human-centered design methodology was useful to design a PPT that complies with clinicians' workflow and that automatically retrieves data from the patient management software.

Taking account of end users' feedback early in the design process helped deliver solid specifications to the developers and enabled us to develop the prototype PPT very quickly (10 person-months, including integration with ResUrgences). The PPT prototype has been deployed in Lille University Hospital's PED. Four PPT screens were implemented, 2 in the physicians' rooms (main office and residents' office) and 2 in nursing rooms, each time right next to the ResUrgences screen that summarizes the PED's patient information but that does not prioritize the patients or organize their care accordingly.

This way, when watching ResUrgences, clinicians can quickly access patient prioritization suggestions on the adjacent screen without having to reenter data. Until now, clinicians had to search for information about patients, such as their reason for entry and their waiting time, and then compare them to decide who to take care of first. Now this cognitive effort should be alleviated by the PPT's prioritization suggestions, which are based on decision trees that clinicians were implementing. Using the PPT may help physicians and nurses have a better awareness of the PED crowding and help them improve the management of the department's resources and beds. Consequently, this tool can help reduce patients' waiting time, especially for critical patients and before time-sensitive treatments and procedures.

Limitations

This case study presents the first iterations of a human-centered design of a PPT and PPA. A formative evaluation by user testing was conducted and the results were used to modify the GUI and the PPA. In a conventional human-centered design, a summative evaluation would have been conducted to ensure that the usability of the PPT and PPA had been improved and that there were no residual issues that could impede use or generate adverse events. However, clinicians expressed a desire to see the tool installed quickly in the PED. With respect to the intent of use of the tool (to help prioritize patients, excluding patients in a life-threatening situation, without imposing this prioritization), the potential risks arising from usability issues would be misinterpretations of the information provided, with the worst consequence being a possible increase in waiting times for some patients and a rejection of the tool by clinicians. These risks were deemed acceptable and, in agreement with the department head, the tool was installed while ensuring a support and monitoring program to continuously evaluate its use and usability. During presentations of the tool and observations about its use at the time of its installation and during ongoing

studies, the impressions and comments of clinicians were collected and analyzed. This feedback did not identify any usability issues that hindered users; they helped us clarify the interface further (eg, with the addition of a “pending decision” icon to inform users that the patient is waiting for a specialist's opinion or of a “homecoming” icon to distinguish between patients who are discharged and returned home and patients who are discharged but waiting for hospitalization). Even after the installation of the PPT prototype, end users remain at the heart of the design and evaluation process to ensure the PPT fits their needs and is useful.

A second limit relates to the designed tool. Its design was based on data that could be retrieved from ResUrgences and used by clinicians to prioritize patients. However, some marginally used elements are not entered into ResUrgences. For example, emotional elements such as crying infants can sometimes prompt clinicians to see a patient more quickly when this is not to the detriment of other patients. Because they are not entered into ResUrgences, these emotional factors cannot be taken into account when suggesting the next patients to see. Despite this technical limitation, the tool is useful because it provides all the other information clinicians need to get an idea of the next patients to see and suggestions for prioritization on the same interface. Clinicians are then free to consider other contextual elements when making their prioritization decision.

Future Research

This study was the first step of the Optimum project. Now that the PPT and PPA have been developed and installed in Lille University Hospital's PED, studies are being carried out to evaluate the use and impact of this tool. A first study was conducted to ensure that the information displayed on the PPT screen correctly reflected the stage of care of the patient. Although there were a few discrepancies due to late entry of information, the distribution of patients in the different stages of care on the screen accurately reflected the actual distribution of patients [48]. Another research study is running to assess how clinicians are appropriating and using the PPT, how the tool is integrating their activity, and how it is satisfying their needs. This study is a prerequisite for investigating the impact of the usage of this tool on clinicians' work, and it raises future research questions: Has the use of the PPT changed their situation awareness and their cognitive load when choosing a patient? What is the impact of the use of the PPT on the prioritization of patients and ultimately on time-sensitive treatments and procedures for serious conditions?

Finally, the PPT and PPA were designed following a human-centered design, in which end users were the doctors and nurses of the PED of Lille University Hospital in France. The tool therefore integrates a work model as well as decision trees that correspond to those applied in the hospital's PED. Before this prioritization tool can be deployed in other EDs of Lille University Hospital (eg, general, ophthalmological, psychiatric, etc), it will be necessary to ensure that the workflow and prioritization rules are the same there; if not, then the PPT and PPA will have to be adapted to these new contexts. Similarly, transposing the PPT and PPA to other hospitals or other countries would first require analyzing future work contexts and adapting the PPT and PPA accordingly.

Conclusion

This study details the integration of human factors into the design process for a PPT and PPA for a PED. A human-centered design allowed the needs of end users and their work constraints to be considered early in the design cycle. Workflow analysis allowed us to (1) identify the information needed for clinicians to prioritize patients, (2) model prioritization decisions in order to implement them as an algorithm in the PPT, and (3) verify that the information entered in the patient management software was entered quickly enough to represent the progression of patient management. A mock-up was developed based on the results of the workflow analysis. It was tested by user testing. Although some usability issues were identified, the majority of clinicians understood the GUI and the prioritization algorithm and felt that the tool could help them in their task. The results of the tests led to minor modifications to some elements of the GUI and the prioritization algorithm in order to improve the usability and usefulness of the PPT. A prototype version of the PPT has been developed and implemented in the PED.

Including end users throughout the design process through user-centered design helps guide the design and evaluation of health technologies so that they align as closely as possible to the reality of users’ needs and activities.

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Authors' Contributions

JS designed the protocol, collected and analyzed data, and approved the paper. SP provided feedback and approved the manuscript. RM help design the protocol and wrote the manuscript. AM provided feedback and approved the manuscript. FD provided feedback and approved the manuscript. MCBZ wrote the manuscript, provided feedback on it, and approved it.

Conflicts of Interest

None declared.

Multimedia Appendix 1

Example of physicians' sorting rules. Actions are presented in the rectangle boxes, conditions for decision in the diamond-shaped boxes.
[PNG File , 66 KB - humanfactors_v7i3e18427_app1.png]

Multimedia Appendix 2
Sorting rules for the physicians as integrated into the PPA. Patients with a life-threatening medical emergency are always considered with the highest priority and therefore do not appear in those sorting rules.
[PNG File , 43 KB - humanfactors_v7i3e18427_app2.png]

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Abbreviations

ED: emergency department
GUI: graphical user interface
PED: pediatric emergency department
PPA: patient prioritization algorithm
PPT: patient prioritization tool
SUS: System Usability Scale

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Original Paper

Twelve-Month Review of Infusion Pump Near-Miss Medication and Dose Selection Errors and User-Initiated "Good Save" Corrections: Retrospective Study

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Abstract

Background: There is a paucity of quantitative evidence in the current literature on the incidence of wrong medication and wrong dose administration of intravenous medications by clinicians. The difficulties of obtaining reliable data are related to the fact that at this stage of the medication administration chain, detection of errors is extremely difficult. Smart pump medication library logs and their reporting software record medication and dose selections made by users, as well as cancellations of selections and the time between these actions. Analysis of these data adds quantitative data to the detection of these kinds of errors.

Objective: We aimed to establish, in a reproducible and reliable study, baseline data to show how metrics in the set-up and programming phase of intravenous medication administration can be produced from medication library near-miss error reports from infusion pumps.

Methods: We performed a 12-month retrospective review of medication library reports from infusion pumps from across a facility to obtain metrics on the set-up phase of intravenous medication administration. Cancelled infusions and resolutions of all infusion alerts by users were analyzed. Decision times of clinicians were calculated from the time-date stamps of the pumps' logs.

Results: Incorrect medication selections represented 3.45% (10,017/290,807) of all medication library alerts and 22.40% (10,017/44,721) of all cancelled infusions. Of these cancelled medications, all high-risk medications, oncology medications, and all intravenous medications delivered to pediatric patients and neonates required a two-nurse check according to the local policy. Wrong dose selection was responsible for 2.93% (8533/290,807) of all alarms and 19.08% (8533/44,721) of infusion cancellations. Average error recognition to cancellation and correction times were 27.00 s (SD 22.25) for medication error correction and 26.52 s (SD 24.71) for dose correction. The mean character count of medications corrected from initial lookalike-soundalike selection errors was 13.04, with a heavier distribution toward higher character counts. The position of the word/phrase error was spread among name beginning (6991/10,017, 69.79%), middle (2144/10,017, 21.40%), and end (882/10,017, 8.80%).

Conclusions: The study identified a high number of lookalike-soundalike near miss errors, with cancellation of one medication being rapidly followed by the programming of a second. This phenomenon was largely centered on initial misreadings of the beginning of the medication name, with some incidences of misreading in the middle and end portions of medication nomenclature. The value of an infusion pump showing the entire medication name complete with TALLman lettering on the interface matching that of medication labeling is supported by these findings. The study provides a quantitative appraisal of an area that has been resistant to study and measurement, which is the number of intravenous medication administration errors of wrong medication and wrong dose that occur in clinical settings.

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KEYWORDS

medication library; smart infusion pumps; near-miss error; medication safety; lookalike-soundalike

Introduction

Background

Infusion programming is a far more complex process than oral medication administration, and it frequently involves the administration of medications from the highest risk groups [1], including heparin, insulin, sedatives, opiates, and critical short half-life medications such as norepinephrine and dopamine [2]. While some work has been done on the role of smart pumps that are capable of reporting their status to centralized monitoring systems to help ensure maintenance of critical short half-life infusion [3] and on the role of medication library hard and soft dose limits during set-up and during titrations of medications [4], it has been generally accepted that even with aggressively managed medication libraries, extensive and ongoing training, and compliance monitoring, only 28% of intravenous (IV) medication errors can be averted with dose error reduction software (DERS) alone [5], as DERS cannot detect errors of right patient, right medication, right order, right documentation, right therapy, and right time [5].

The current paper challenges this assumption to some degree. Our first hypothesis is that many potential lookalike-soundalike (LASA) errors made during medication selection from the pump's medication library may be prevented by the presence of full names, large characters, and TALLman medication displays on the pump during programming, that wrong dose selection may also be reduced by the presence of standardized concentrations, and that concentration limits built into the pump's DERS will also catch a high number of "death by decimal point" errors [6].

In one observational study [7], in a high-fidelity simulation laboratory designed to assess the impact of infusion pump technologies (comparing a traditional pump, smart pump, and smart pump with a barcode reader) on nurses' ability to safely administer intravenous medications, nurses remedied "wrong patient" errors more often when using the barcode pump (88%) than when using the traditional pump (46%) or the smart pump (58%). The barcode pumps were not integrated into the electronic medical record (EMR); therefore, the nurses' remedial changes were entirely based on a visual check between the pump screen and the patient's ID wristband of what was either manually entered as patient ID or populated on the pump via scanning of the patient's ID wristband. Essentially, having to undertake patient identification verification on the barcode pump greatly increased the nurses' resolution of the "wrong patient" error (the patient identification armband on the mannequin did not correspond to the patient information on the physician order). We suggest that clear and well-presented information on a smart pump screen, which can be verified against other identifiers (in the case of the study facility medication name and dose are clearly printed on each medication in the pharmacy [not handwritten]), may lead to "good catches" of errors during programming of smart pumps for administration of IV medications.

We also recognize that among all of the parts of the medication chain (from prescription to administration), intravenous medication errors, which occur at the point of administration, are the hardest to detect and that in terms of failure mode effect analysis (FMEA), the process consistently scores as a high-risk activity by virtue of the score for "likelihood of detection," with a high score commonly being applied by organizations utilizing FMEA (scale: 0 [minimum] to 10 [maximum]) [8,9].

Our second hypothesis is that analysis of smart pumps' DERS logs for near-miss wrong medication or wrong dose selections will help to further extend our understanding of the incidence of these administration errors.

This is important as the existing methods of assaying IV medication administration error and general medication administration failure in any of the general "administration rights" (right patient, right medication, right order, right documentation, right therapy, and right time) are limited and cannot give an accurate idea of the extent of the problem. For example, in one study, an extensive chart review found 398 adverse drug (medication) events (ADEs) at the administration stage, while in the same time period, voluntary reports via the hospital's anonymous ADE and near-miss event reporting system detected only 23 events [10].

This needs to be viewed against quantitative evidence from what we can see of the iceberg. In a study of voluntary and near-miss reporting of errors in pediatric patients and neonates, which lasted for 1 year, it was found that of 989 reported medical errors, 401 (40.5%) were related to medication. Additionally, 88.0% (353/401) of these errors reached the patient and 33.4% (118/353) of the dose-related errors were related to administration. Moreover, 13.2% (53/401) of errors were of omission [11].

In one well-constructed study of self-reporting by nurses and physicians, the observed rate of parenteral medication administration errors per 100 patient days was 74.5, with 12 patients (0.9% of the total study population) experiencing permanent harm or death [12]. Of course, deriving metrics from self-reporting will always underestimate the frequency and consequences of errors, as many will be undetected by the user. We suggest that adding quantitative data pertaining to medication and dose selection by users, which are derived from smart pump medication library logs, will help shed further light on the murky area of point of care IV medication administration.

Attempting a more accurate "count" of the IV medication administration error rate, owing to its impact on costs, length of stay, and treatment of any sequelae, is, of course, central to delivering value-based health care [13] and to creating a systematic approach for patient safety. It also speaks directly to a central issue in modern health care, that is, cost benefit, as

systems employing interoperability between the patient's EMR and bidirectional interoperable smart pumps for closed-loop bidirectional IV pump-EMR autopopulation utilizing barcode medication administration require extensive investment, but are capable of mitigating wrong time, omitted medication, wrong patient, wrong medication, and wrong dose-type administration errors [14]. Thus, while these systems have been shown to reduce self-reported safety events related to infusion pump programming by a ratio of 3:1 [15] and it has been suggested that "until barcode pumps are integrated with other systems within the medication administration process, their role in enhancing patient safety will be limited" [7], it would be of great value to have a "harder" number for wrong medication and wrong dose-type administration errors from preimplementation data to more concretely prove the economic value of the solution of bidirectional IV pump-EMR autopopulation utilizing barcode medication administration.

Similarly, the documentation available in smart pump event logs and DERS library records has not previously been extensively used as a comparative tool to routinely check the veracity of the medication administration record and is commonly only used in the case of sentinel events. Autodocumentation of continuous infusion and intermittent medications administered via smart pumps directly in the patient's record is certainly superior to manual completion of the medication record, as manual infusion documentation may be delayed or inaccurate because clinicians attend to emergent situations or have distractions [16]. Once clinicians return to their documentation after a patient care event, such as medication administration, they often transcribe from memory. It would be useful to have the ability to rapidly compare and contrast information derived from the smart pump's library data to manual chart entries.

Objectives

The overall objective of this study was to establish, using an easily reproducible and reliable methodology, baseline data to show how metrics in the set-up and initial programming phase of intravenous medication administration can be produced from review of medication library "near-miss" reports from infusion pumps used in varied disciplines and care areas across large facilities with many thousands of IV pumps.

Of particular interest were user-initiated corrections of the more common "death by decimal point" errors of incorrect dose or concentration selection and corrections of wrong medication selection, which is often related to medication name LASA issues. The study also focused on the time taken by clinicians to correct these set-up errors.

Two hypotheses were decided upon at the outset of the study as follows:

1. We hypothesized that potential LASA errors during medication selection in a smart pump's medication library may be greatly reduced by the presence of full names, large characters, and TALLman medication displays on the pump during programming, that wrong dose selection may also be reduced by the presence of standardized concentrations, and that concentration limits built into the pump DERS will catch a high number of potential "death by decimal point" errors.
2. We hypothesized that analysis of smart pumps' DERS logs for near-miss wrong medication or wrong dose selections will help to further extend our understanding of the incidence of these administration errors and add quantitative measurement to a process that has, up to now, only been assayed with self-reporting of near-miss errors and recognized errors, simulation laboratory studies, chart reviews, and observational studies, all of which have inherent weaknesses.

Methods

Study Design

We undertook a 12-month retrospective review of medication library near-miss error report logs from 2044 wireless-connected modular infusion pumps (846 syringe driver modules, 3662 large-volume pump modules, and 62 patient-controlled analgesia modules [one modular infusion pump can accommodate a mix of up to four syringe, large-volume, or patient-controlled analgesia modules]) used in 15 disciplines/care areas across a large facility with 1852 inpatient beds and 12,601 inpatient admissions yearly, which serves the heart of metropolitan Riyadh, in order to obtain metrics on the set-up phase of intravenous medication administration. The DERS used in this study records any attempt by the user to use a dose outside of the accepted hospital formulary range for each medication. A particular feature of the DERS used in this study is that it records all cancelled infusions, medication concentration limit breaches, and resolutions of infusion alerts by the user. Date-time stamps are automatically applied to all of these alerts and actions by the device.

Data are continually collected from the smart pump logs in our facility, and all nursing and medical staff are aware of this ongoing collection and analysis of near-miss events, as the DERS library itself was created and is updated through a multidisciplinary team feedback mechanism as part of our facility-wide process of Joint Commission International (JCI) quality improvement, Magnet accreditation, and zero-harm targets. The smart pump DERS library data are constantly available to the pharmacy department, and according to the facility protocol, the pharmacy department owns the data and is recognized as the lead department for medication safety. While nursing and medical staff are aware that data are constantly obtained on good catches in medication safety, they were not informed that a particular period would undergo a deeper analysis beyond standard quarterly reviews. This is important as we wanted to get as close as possible to "normal behavior" with our data. As with all observational and self-reporting studies, the Hawthorne effect is a very real danger, and the advantage of "passive" data collection, such as collection in this study, is that users will not alter their behavior as they might during a time-limited study.

There is a regular process of engagement with nursing leadership and clinical educators to provide feedback on good catches, compliance levels, and the need for functional changes to the DERS library as part of the hospital's zero-harm program and

ongoing Magnet and JCI accreditation processes. The risk-management committee for IV medication therapy in the facility will be appraised of the implications of the study with regard to proposed moves to IV medication interoperability and barcode medication administration.

An analysis was undertaken using patient anonymized data for infusions in all areas of the facility. Decision times of clinicians were calculated from the time-date stamps of the pumps' DERS logs (the pump logs report in hh:mm:ss). The pumps are wirelessly connected to a central server that maintains universal and accurate time keeping for all connected devices. The wireless connectivity also allows for pumps in all areas of the facility to be updated regularly and rapidly with current medication libraries and allows for continual download of medication library and clinician performance, as well as library compliance data.

The study was limited to one pump brand (BD Alaris™ System 8015LS PC Units with Guardrails™ 9.33 DERS software). These smart pumps are connected to a central server (BD Alaris™ Systems Manager) that allows for wireless deployment of medication libraries to the pumps and continuous medication library performance data download from them to a central SQL database, which can be accessed via reporting software (BD Alaris™ CQI Reporter 10.17). These pumps are modular, and each PC unit can carry a mix of up to four large-volume pumps, syringe pumps, or patient-controlled analgesia pumps. All these modular pumps share a common DERS. The DERS has maximum hard limits for dose and duration/rate, above or below which the clinician cannot titrate or set-up an incorrect delivery dose (rate or concentration), and maximum and minimum soft limits, which when breached give an alert to the clinician, who must then decide whether to override the warning. Each distinct group of events from the first alert to resolution is tied together by a unique sequence identification number.

Within the Guardrails™ DERS, the pharmacist may create up to 10,000 medication set-ups with 30 care areas or "profiles" carrying medications and concentrations specific to the care area. Medications may also be set up with free text entry for the clinician at the point of care for dose and volume. These free text dose and volume entries can be limited with concentration limits, which require that any entries are within the minimum and maximum limits for dose/mL. Each profile can also have hard limits placed for maximum patient weight and body surface area.

A DERS master library contains a standard list of medications that can be added with new medications. The DERS master library will accept free text entries for medication names. The maximum character count for each medication entry is 20 characters.

The Guardrails™ software present in these devices allows for the creation of "therapies" that allow the clinician to select the medication name and then select a specific usage for which the dose limits, duration, or rate may differ according to specific indications. For intermittent infusions, specific therapeutic durations and individual weight-based dosing and body surface area–based dosing can be added for each use of a specific medication. Table 1 presents examples of continuous and intermittent infusion therapies.

If the "therapy" option is utilized, each medication may be identified in up to 20 characters, and the therapy listed below the medication name can also be identified by a further 20 characters. In this study, the therapy option was active in all care areas and used extensively in the oncology department's profile.

Several treatment options for individual medications were also present as separate entities in the libraries, and examples are presented in Table 2.

Table 1. Examples of therapies.

Core medication	Therapy title	Variations
Midazolam	Short-term vent	Continuous and bolus dose limits
Midazolam	Conscious sedation	Continuous and bolus dose limits
Midazolam	Status epilepticus	Continuous and bolus dose limits
Cisplatin	Cisplatin 10 mg/m^2/24 h	Dose by BSA[a] and by duration (for different oncology regimens)
Cisplatin	Cisplatin 100 mg/m^2/2 h	Dose by BSA and by duration (for different oncology regimens)
Cisplatin	Cisplatin 25 mg/m^2/1 h	Dose by BSA and by duration (for different oncology regimens)

[a]BSA: body surface area.

Table 2. Examples of individual entities for medications.

Core medication	Treatment option	Variations
Amiodarone	Amiodarone load	Dose and rate/duration
Amiodarone	Amiodarone maintenance	Dose and rate/duration
Alteplase	Alteplase loading	Duration
Alteplase	Alteplase 0.5 mg/mL	Duration
Amphotericin	Ampho B (liposomal)	Dose and rate/duration
Amphotericin	Amphotericin B	Dose and rate/duration
Insulin (Actrapid)	Insulin hyperkalemia	Dose total and rate/duration
Insulin (Actrapid)	Insulin continuous	Dose total and rate/duration
Heparin	Heparin low dose	Maximum dose/hour
Heparin	Heparin high dose	Maximum dose/hour

The DERS can also present clinical advisories after the medication selection has been made, giving specific information about the medication to be administered, such as observations to be made during administration, intravenous administration line type, and specific precautions. Acknowledgement of a clinical advisory must be made by the clinician before the pump allows progress through the programming sequence. Textbox 1 presents examples of clinical advisories.

The pumps are capable of bidirectional communication with the EMR and have the capability to have orders sent directly via wireless technology from the EMR to the pump, thus reducing manual programming and allowing for bidirectional IV pump-EMR autopopulation utilizing barcode medication administration of the pump and autodocumentation of medication delivery. No pumps in this study were connected to the EMR.

Textbox 1. Examples of clinical advisories.

Clinical advisories requiring confirmation/acknowledgement by the clinician

- 0.22 micron filter required
- Via central line only
- For patient 60 kg or less
- For hyperkalemia
- Loading dose

Study Procedure

The data were patient anonymized, and no personal information items, such as hospital number, gender, name, date of birth, diagnosis, and other identifiable material, were recorded for analysis.

The BD medical affairs department was engaged for a deeper analysis of the data than is undertaken in our standard quarterly reviews. The BD medical affairs department operates as a distinct arm outside of the commercial operations of the company.

Inclusion Criteria

All infusions started from within the medication library (and therefore identifiable in terms of medication name selection, medication dose selection, and medication concentration selection) over the 12-month period were included in the study. These included continuous and intermittent infusions, weight-based and nonweight-based infusions, and body surface area–based infusions.

Exclusion Criteria

Infusions started from outside of the medication library using the “basic infusion” (mL/h) option, which does not record medication name or dose data for the infusion, and medications run through the pumps’ medication calculation option, which also does not record medication name data, were excluded from the study. The DERS and reporting software used in the study allowed for a rapid appraisal of compliance with the medication library in percentage terms from all care areas in the study facility. This metric was included in the study as a check for the veracity of the data included.

Results

Compliance with medication library usage was 74.29% (1,050,531/1,414,191) of all infusions given in the 12-month period across the facility, and this allowed for a high volume of identifiable infusions to be entered into the study. Intravenous medications (continuous and intermittent) and intravenous fluids (plain and with additives) were present in the library.

Cancelled infusions represented 15.37% (44,721/290,807) of all medication library alerts (Table 3), making them more

common than hard-limit alerts that are designed to prevent potentially lethal overdoses.

Within the cancelled infusion group, wrong medication selection represented 22.40% (10,017/44,721) of the cancelled infusions. Among these cancelled medications, all high-risk medications, oncology medications, and all IV medications delivered to pediatric patients and neonates required a two-nurse check according to the local policy. Wrong dose selection was responsible for 19.08% (8533/44,721) of infusion cancellations. A total of 603 infusions were cancelled in response to a concentration limit alert. These are always related to so-called "wildcard" or custom concentrations [6]. In the medication library used in this study, these alerts are captured under the group "reprogram limit alert" (Table 4).

Table 3. All medication library alerts by type.

Alert type	Value (N=290,807), n (%)
Reprogram limit alert (hard limit)	40,184 (13.81)
Override limit alert (soft limit)	141,474 (48.65)
Cancelled infusion	44,721 (15.37)
All other alerts	64,428 (22.17)

Table 4. Incidences of the causes for cancellation of infusion.

Cause	Percentage of cancelled infusions	Percentage of all medication alerts	Value (N=44,721), n	Comments
Incorrect medication selected	22.40	3.45	10,017	See note on medication name and position of the LASA[a] error.
Wrong dose selected	19.08	2.93	8533	See note on factor of error.
Indeterminate cause	58.46	8.99	26,144	No evidence of dose error or LASA medication selection error. Possible causes: - IV[b] access failure - Patient condition change - Therapy discontinuation - Infusion administration backlog with limited IV access
Wrong channel selected	0.04	—[c]	17	Medication for patient-controlled analgesia initially loaded in syringe driver.
Dose cancelled	0.02	—	10	Drug library exited and drug calculator utilized.
Concentration limit breached	N/A[d]	0.21	603	Captured in "reprogram limit alert"

[a]LASA: lookalike-soundalike.

[b]IV: intravenous.

[c]Value is too small to report.

[d]N/A: not applicable.

In terms of the error factor for dose corrections, generally, the potential overdose was not substantial (median 1.5 times the corrected dose); however, the mean (14.52, SD 57.89) was skewed by some very large outliers, as there were 11 corrections made with a dose error factor greater than 100 times the corrected dose (maximum was 500 times the corrected dose).

The average error recognition to cancellation and correction times were 27.00 s (SD 22.25 s, maximum 113 s, minimum 4 s, median 21 s) for medication error correction and 26.52 s (SD 24.71 s, maximum 116 s, minimum 6 s, median 19 s) for dose correction.

It is notable among the results that the difference between the second attempt (and presumably correct) drug selection and the first selection was more prevalent for misidentification in the beginning of the medication's name, but there was also a substantial number of middle and end name errors being corrected. Examples are provided in Tables 5 and 6.

Table 5. Examples of cancelled infusion medication names and corrected medication names.

Cancelled drug/fluid	Final drug/fluid	Key letter position
Sodium bicarbonate	Sodium phosphate	Name end (3)
Abatacept <60 kg	Acetaminophen	Name beginning (1)
Acetylcysteine	Acyclovir	Name middle (2)
Ceftazidime	Ceftriaxone	Name middle (2)
Flucloxacillin	FLUconazole	Name middle (2)
Calcium chloride	Calcium gluconate	Name middle (2)
Cefazolin	Ceftazidime	Name middle (2)
Ceftazidime-Continuo	Ceftazidime-extended	Name end (3)
0.45% NS	0.9% Normal saline	Name beginning (1)
Insulin high non-ICU	Insulin hyperkalemia	Name middle (2)

Table 6. Incidence by word/phrase error position.

Word/phrase error position	Incidence (N=10,017), n (%)
Name beginning (1)	6991 (69.79)
Name middle (2)	2144 (21.40)
Name end (3)	882 (8.81)

Discussion

An extensive study of errors in critical care concluded that “most serious medication errors in critical care occur during the execution of treatment, with performance-level failures outweighing rule-based or knowledge-based mistakes” [17]. This conclusion is supported by our findings. Furthermore, it is evident that smart pump libraries with dose limits can prevent performance-level errors in terms of serious set-up errors that can lead to classic “death by decimal point” errors, such as the 11 near-miss errors of doses greater than 100 times the corrected value. The study also indicates that thorough and scrupulous attention to detail when creating the DERS library for smart pumps can improve patient safety. By example, the number of concentration limit breaches in our study was small and certainly far smaller than that suggested in a 2018 United States survey of the use and application of this DERS safety net, with only 50% of practitioners reporting understanding the value of a hard stop for minimum concentration limits and almost half of all respondents, including 29% with direct responsibility for DERS libraries, being confused by the question or unsure whether their pumps had a hard stop for minimum concentration limits for custom concentrations [6]. This is probably related to the extensive use of standardized concentrations in the facility and the avoidance of wildcard or custom concentrations through alignment from the formulary and computerized prescription order entry system to the smart pump DERS library.

In terms of the average error recognition to cancellation and resolution times being relatively short, with 27 s (SD 22.25) for medication name error correction and resolution and 26.5 s (SD 24.71) for dose correction and resolution, the system in place in the study facility may be an important factor here with all IV medications being prepared and labelled with large clear printing in the central pharmacy, as the medication is “in hand” during programming. This makes it a more effective “independent source of truth” as neither the administering nurse nor the second checker has prepared or labelled the medication to be administered.

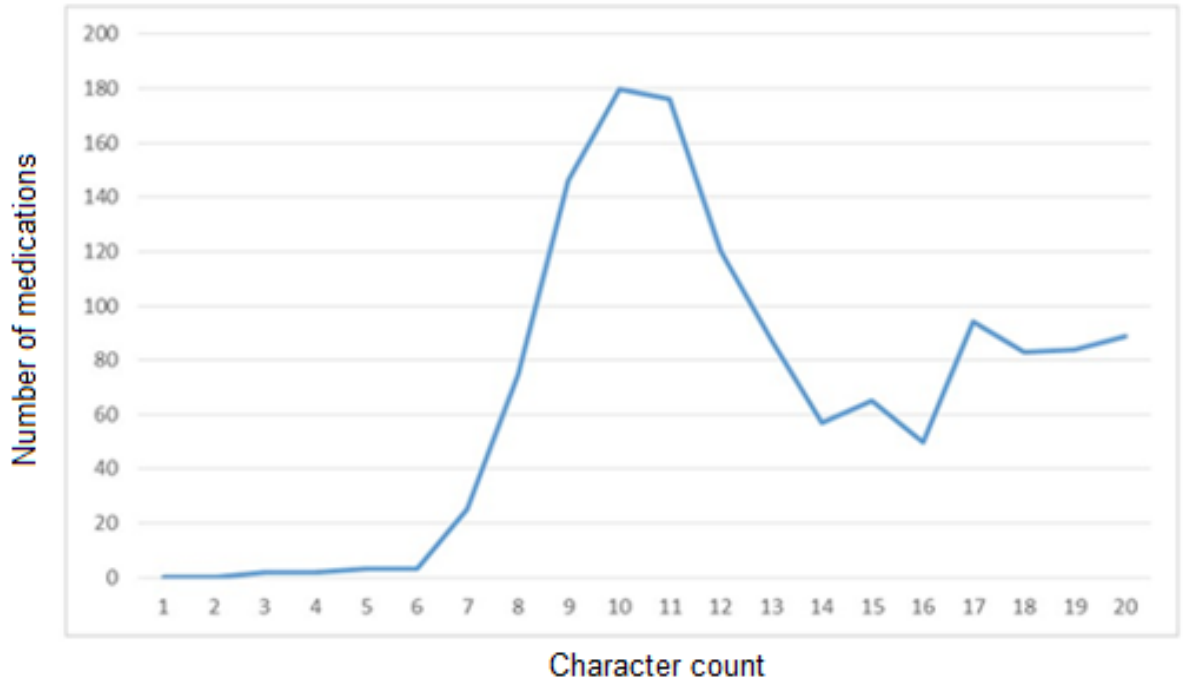
What is clearly also important in terms of the recognition and correction of wrong drug name errors at the bedside is that corrections of medication name selection were spread among differences in the beginning, middle, and end of each medication’s name. Older studies on the psychology of reading generally accepted that the beginning and end of words influence readers and tend to make them “guess” the rest of the word, and randomizing letters in the middle of words has little or no effect on the ability of skilled readers to understand text [18]. This is useful for reading at speed, but the deleterious implications of “guessing” for medication safety are obvious as middle letter identification proceeds largely independently of position, and information that the reader gains from the middle letters may operate via the reader using “probability” rather than absolute reading in order to “recognize” the word.

It was chiefly for this reason that the TALLman system of nomenclature was created for LASA medications, and it ensures that “word shape” [19] is disruptive and distinctive for LASA medications. More recent work in cognitive psychology has indicated that when humans read, they use the letters within a word to recognize a word [19]. It was stated that “word shape is no longer a viable model of word recognition. The bulk of scientific evidence says that we recognize a word’s component letters, then use that visual information to recognize a word” [19]. Given what we noted in the spread of the “beginning, middle, and end” of medication names being corrected in this study, it seems reasonable to conclude that more information in terms of letters available to the reader is associated with a

higher likelihood of an accurate choice, as the presence of more characters for review is associated with a greater possibility of the reader's initial instinctive reading (or guessing) being overtaken by "new information" [20]. It is clear that LASA medication errors and near-miss errors are relevant problems for nurses administering IV medications, just as they are for pharmacists dispensing medications, as indicated in a UK survey showing that LASA errors represented 25.9% of total dispensing errors in the last quarter of 2019 [21].

The intravenous pumps used in this study carry a 20 character maximum, and this maximum capacity was used in many of the medication names in the library. The mean average was 13.04, with a heavier distribution toward higher character counts (Figure 1).

Figure 1. Character count distribution for medication nomenclature in the study facility's dose error reduction software library.



A general recommendation of this study is that intravenous pumps should have character counts of at least 17 characters, given that this was the mean average character count for medications that were corrected by the user. Furthermore, it is recommended that no pump should truncate entire medication entity names during runtime, as this impedes the clarity of information on current infusions required for effective nursing hand-offs.

Given the growth in monoclonal antibody medications in the last few years (518 are currently listed as active medications, with a mean character count of 12 [SD 3.74]) and the fact that we can expect to see an increasing number of these medications, it is worth noting that almost all of these medications end with the suffix "-mab" and have a propensity for using the same or similar name beginnings. Clearly, the need for full naming in medication libraries is critical with these medications. Indeed, in some of these medications, only the second part of their nomenclature differs. Table 7 presents examples of monoclonal antibody naming.

Table 7. Examples of monoclonal antibody medications currently in the market, with character counts.

Name	Character count
Cantuzumab mertansine	21
Cantuzumab ravtansine	21
Altumomab pentetate	19
Anatumomab mafenatox	21
Talizumab	9
Tanezumab	9
Trastuzumab	11
Vadastuximab talirine	21
Vandortuzumab vedotin	21

In classic FMEA planning [9], for any high-risk activity, particularly that with a high risk of "low chance or no chance" of error detection, the activity is broken down into a number of steps, each of which can mitigate, correct, or annul any error in the previous steps. The addition of a clinical advisory to known high-risk LASA medications as an extra step in the programming process may therefore be of value. In this study, clinical advisories were commonly used in the oncology profile, as many of these drugs require specific line types. For example, for taxols, the clinician is told via a pop-up advisory screen "paclitaxel: use low-sorbing set with 0.2 micron filter."

To select this drug, the eight steps for programming (six steps may act to draw the clinician's attention back to the medication being administered and allow a FMEA stop to be applied) are according to the approach presented in Table 8.

In the adult oncology profile of the medication library, the therapy option, which effectively doubles the character count available to the pharmacist creating the medication library, was used for approximately 60% of all the medications in this profile, with medications, such as carboplatin, having eight distinct therapies and those, such as cisplatin, having thirteen distinct therapies. It was notable that despite the large volume of infusions administered by oncology nurses, the number of wrong medication name errors in the oncology profile was only 55 compared with 322 in the adult general profile and 139 in the adult critical care profile.

Table 8. Example of programming a drug associated with a therapy and clinical advisory using failure mode effect analysis steps.

User action	Pump response	FMEA[a] + action if error detected
CHANNEL SELECT	Presents: Drug library Fluids library Basic infusion	Drug library is the first presented option
GUARDRAILS DRUGS	A-Z in five groups	Can cancel infusion if selection is incorrect
PACLitaxel	Presents therapy options: PACLitaxel 3 weekly PACLitaxel weekly	Can cancel infusion if selection is incorrect
PACLitaxel weekly	PACLitaxel ___mg in ___ml was selected. Is this correct? YES/NO	NO and can cancel infusion if selection incorrect.
YES	Clinical advisory pop up: PACLitaxel: Use low-sorbing set with 0.2 micron filter	NOT CONFIRMED and can cancel infusion if selection is incorrect.
CONFIRM	PACLitaxel weekly User has to complete: ___ mg ___ mL BSA[b] ___	Can cancel infusion if selection is incorrect.
CONFIRM	PACLitaxel weekly User verifies: Dose Volume BSA Duration (NB[c] dose/m^2) is controlled by library limits for this drug, and BSA is controlled by maximum limits per profile. Duration can be default set and controlled according to minimum-maximum in the drug library per drug.	Can cancel infusion if selection is incorrect.
START	Begin infusion	NO START and can cancel infusion if selection is incorrect.

[a]FMEA: failure mode effect analysis.

[b]BSA: body surface area.

[c]NB: nota bene (note well).

General advice from this process would be to ensure that the full name of the medication is given in every step and that it is present in the clinical advisory (this should be a free-text option in smart pumps with this feature).

The JCI organization has noted that half of the cases of preventable harm from medications are associated with the following three categories of medications: opiates, insulin, and heparin [22]. The commission also recommends each facility to create a list from its formulary of LASA medications

alongside that of its high-risk medications. A regular review of cancelled infusions and medication name corrections could assist in designing and monitoring the effectiveness of such a strategy. Risk management DERS strategies should aim for a balance of clarity and ease of use, as well as measurement of the usage of the library (compliance). Specialist uses of medications need to be present in therapies, but too many similar options can cause confusion at the bedside. Therapy titling should clearly match the computerized provider order entry system, and this too requires a high capacity character count to be available.

As discussed earlier, the true level of medication administration error for both medication and dose is unknown, despite the best efforts of researchers from every region. It is however clear from the study and from existing literature that the problems of wrong medication selection with LASA medications and wrong dose selection are considerable. It is suggested that bidirectional IV pump-EMR autopopulation utilizing barcode medication administration processes would substantially reduce these two risks to patient safety and also reduce the risk of wrong patient-wrong medication errors. However, bidirectional IV pump-EMR autopopulation is not always deployable for every patient event, as in the case of stat or verbal orders, and there is a need for manual programming in nonnetwork-served areas. Thus, there is still reliance on the local pump-deployed DERS to keep the patient safe, so the principles of full medication name and standardized dose and concentration limits still apply. Furthermore, bidirectional IV pump-EMR integration should only offer autopopulation of smart pumps, as autoprogramming takes too much control away from the clinician at the bedside who may need to hold an infusion for emergent clinical reasons. Indeed, in this study, there were 26,144 cancelled infusions with no specific error identified.

This study makes it clear that how medication information (chiefly name and dose) is presented to smart pump end users using DERS libraries is central to medication safety. An assay of name/dose errors and corrections, particularly for medications used in multiple therapies and with differing dosing, will assist pharmacies in creating safer and more user-friendly DERS libraries. The ability to capture data of near-miss infusion medication errors through wireless systems that can capture every smart pump's data and to rapidly correct and update DERS libraries across all the facility's pumps in response to analysis of "what works and what does not" is an important component of any risk management strategy for medication safety, as it quickens the plan, do, check, and act cycle.

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Conflicts of Interest

RAJ certifies that she has no financial affiliations with or involvement in any organizations or entities with a financial interest. ASAJ certifies that he has no financial affiliations with or involvement in any organizations or entities with a financial interest. JW certifies that he has no financial affiliations with or involvement in any organizations or entities with a financial interest, beyond his employment in the Medical Affairs Department at Becton, Dickinson and Company (BD). TK certifies that he has no financial affiliations with or involvement in any organizations or entities with a financial interest, beyond his employment in the Medical Affairs Department at Becton, Dickinson and Company (BD).

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Abbreviations

ADE: adverse drug event
DERS: dose error reduction software
EMR: electronic medical record
FMEA: failure mode effect analysis
IV: intravenous
JCI: Joint Commission International
LASA: lookalike-soundalike

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Original Paper

Embedding the Pillars of Quality in Health Information Technology Solutions Using "Integrated Patient Journey Mapping" (IPJM): Case Study

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Abstract

Background: Health information technology (HIT) and associated data analytics offer significant opportunities for tackling some of the more complex challenges currently facing the health care sector. However, to deliver robust health care service improvements, it is essential that HIT solutions be designed by parallelly considering the 3 core pillars of health care quality: clinical effectiveness, patient safety, and patient experience. This requires multidisciplinary teams to design interventions that both adhere to medical protocols and achieve the tripartite goals of effectiveness, safety, and experience.

Objective: In this paper, we present a design tool called *Integrated Patient Journey Mapping* (IPJM) that was developed to assist multidisciplinary teams in designing effective HIT solutions to address the 3 core pillars of health care quality. IPJM is intended to support the analysis of requirements as well as to promote empathy and the emergence of shared commitment and understanding among multidisciplinary teams.

Methods: A 6-month, in-depth case study was conducted to derive findings on the use of IPJM during *Learning to Evaluate Blood Pressure at Home* (LEANBH), a connected health project that developed an HIT solution for the perinatal health context. Data were collected from over 700 hours of participant observations and 10 semistructured interviews.

Results: The findings indicate that IPJM offered a constructive tool for multidisciplinary teams to work together in designing an HIT solution, through mapping the physical and emotional journey of patients for both the current service and the proposed connected health service. This allowed team members to consider the goals, tasks, constraints, and actors involved in the delivery of this journey and to capture requirements for the digital touchpoints of the connected health service.

Conclusions: Overall, IPJM facilitates the design and implementation of complex HITs that require multidisciplinary participation.

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KEYWORDS

health information technology; health care quality; data analytics; multidisciplinary research; mobile phone

Introduction

Prior Work

Significant investment continues to be directed toward service reform strategies to deal with the sizable challenges facing health care sectors [1]. These challenges include, but are not limited to, an increasing demand for chronic care, shortages in skilled medical labor, and an aging population [2,3]. In the United Kingdom, the government pledged a £20.5 billion (US $27 billion) increase in the National Health Service's budget between 2019 and 2024 to foster widespread performance improvements across both primary and secondary care with the aim of tackling these challenges [4]. This trend toward increased spending is likely to continue into the future as nations across the globe seek to deal with large-scale economic and demographic changes [1].

Health care service redesign through the adoption of health information technology (HIT) is being proposed as a means of increasing both the efficiency and effectiveness of health care services, reducing waiting times, and improving the standards of patient care [5,6]. In particular, connected health has emerged as a promising area of research for addressing some of the current challenges [7-9]. This blends the physical and digital realms by capturing real-time data from numerous connected HIT devices (eg, smartphone apps, weighing scales, blood pressure monitors, etc) to ensure that health care stakeholders (eg, patients, carers, clinicians, etc) are provided with timely, accurate, and pertinent information regarding the patient's status [8,10]. Combined with advanced data analytics, connected health platforms can also contribute to the improvement of health outcomes through targeted and early interventions [11]. For instance, data analytics can provide clinicians with key insights derived from patterns in large patient data sets, which can in turn contribute to improved clinical decision making. This can help reduce decision makers' reliance on *gut feeling* or intuition by fostering a data-driven, evidence-based approach to clinical decision making and decision support [12-14]. Connected health platforms, combined with the use of smartphone apps, also offer the possibility of deploying coaching on a broad scale to improve adherence and outcomes for those affected by a variety of conditions, such as diabetes [15-17].

However, Chen et al [18] noted that these targets can only be achieved through appropriately designed interventions. This requires inputs from all relevant stakeholders to design connected health solutions that not only fit the needs of patients [19] but also fit within the health care ecosystems and are viable and sustainable in the long term [18]. The mapping tool that we present in this paper is aimed specifically at eliciting and channeling the opinions and preferences of a varied group of stakeholders around the possible use of HIT across a medical pathway.

According to Doyle et al [20], there are 3 core pillars of health care quality, which health care reform strategies (including those involving connected health) must cater to, clinical effectiveness, patient safety, and patient experience. Their contention has been broadly supported by other researchers (for instance, the study by Anhang et al [21]), with their paper receiving over a thousand citations and many researchers adopting their 3-pillar framework. The core argument in this stream of research is that the relationship between patient experiences and other aspects of care is symbiotic and critical. We agree with the view that patient experiences are an integral aspect of care quality (even if they may not be directly related to clinical processes and outcomes [22]. We strongly agree that we need to understand how patient experiences are associated with the effective use of structures, the underlying health care processes, and the occurrence of health outcomes. This knowledge ought to be directed toward improving the efficiency and effectiveness of care [21]. Thus, in this study, we adopted the 3 pillars of health care quality by Doyle et al [20] as a guiding framework.

To date, health service reform initiatives have focused on measures of clinical effectiveness and patient safety, with patient experience receiving less attention [5,23]. It does not follow that an efficient and compliant service will mean a good patient experience. For instance, a patient might receive an appointment quickly, but their overall experience may be poor if, for example, they feel that their unique needs are not catered to. In most cases, connected health solutions involve patients who directly engage with apps, often in their homes or in the community. Given the absence of direct supervision, it is critical that the apps and devices are easy to use and that they promote appropriate, accurate, and safe usage. Generally, connected health solutions raise significant and new ethical concerns, which need careful consideration [24]. Therefore, it is crucial that their design considers all 3 central pillars of health care quality (clinical effectiveness, patient safety, and patient experience) in tandem [20,25]. Failure to consider these pillars may mean that key requirements and constraints are overlooked, leading to problems later—poor quality data, low utilization of health care services, ineffective decisions by health care professionals, or unethical use of data [20,26].

Although methods are available for exploring each pillar of health care quality in isolation, to the best of our knowledge, there is no single design tool currently in use that addresses all 3 pillars collectively, and more particularly in the context of technology-intensive and multidisciplinary fields such as connected health. This paper, goes some distance to address this shortfall by presenting a design tool we developed called *Integrated Patient Journey Mapping* (IPJM). This tool is primarily aimed at supporting the analysis and design of connected health apps. Inspired by the concept of journey mapping, it allows researchers and practitioners to simultaneously and explicitly consider the factors of clinical effectiveness, patient safety, and patient experience in tandem. The tool has primarily been validated through its use in a series of projects. In this paper, we focus on its use in a project called *Learning to Evaluate Blood Pressure at Home* (LEANBH) that involves the development of a connected health app focused on the investigation of preeclampsia, a disorder of pregnancy that can lead to a variety of adverse outcomes.

The remainder of the paper is structured as follows: On the basis of a review of existing literature, the Introduction section offers a background to the development of the mapping tool in the context of connected health and describes IPJM. The Methods section explains the methods, while the Results section provides

results from the LEANBH project on the use of IPJM in a perinatal context. A discussion of the findings as they pertain to academic and practitioner communities is outlined in the Discussion section.

Background

Connected Health and Data Analytics

Connected health has been defined as a novel, conceptual model for health care management "where devices, services, or interventions are designed around the patient's needs, and health-related data is shared, in such a way that the patient can receive care in the most proactive and efficient manner possible" [10]. Connected health aims to provide all actors involved in the delivery of health care services with timely, accurate, and pertinent information around the patient's current state of well-being [8,10,27,28]. This is made possible by the development of information technology (IT) platforms that seamlessly integrate numerous *connected* health devices, which allow real-time management and monitoring of patients' well-being across different settings [28-30]. This has been made possible through the increasing availability of new wireless networks (eg, Wi-Fi, Bluetooth, and 4G or 5G networks) that enable high-speed seamless integration of connected health devices and secure data repositories for storing health-related data.

Connected health platforms also enable health care actors to take effective measures for managing the patient's state of well-being by analyzing health data from these devices [10,30]. Collected data from connected devices can be continuously analyzed and shared to provide actors with key insights that allow them to take effective action. For instance, feedback can be derived from an analysis of a patient's home-based blood pressure readings or blood glucose levels taken from wearable body sensors or connected devices that record patients' vitals [31,32]. In addition, rule-based systems can be employed to act as *early warning systems* whereby health care professionals are notified when a patient's vitals pass certain thresholds, as detailed in the relevant clinical guidelines [33].

Connected health solutions and data analytics support a proactive model of care in which all stakeholders are provided with critical feedback at key touchpoints between the patient, the connected health platform, and the health care service [10,34]. At the same time, this provides a clear opportunity to re-engineer relevant pathways to boost their effectiveness while also leveraging leading-edge technology to reduce the transaction cost or increase the throughput of key health care services. However, the mapping of these touchpoints can be a challenging task, given the complexity of the pathways as well as the ubiquity and diversity of patient data in connected health scenarios [35]. Existing modeling techniques often fail to identify the ideal placement and configurations of connected health solutions within the health care service network [35].

Central Pillars of Health Care Quality

Quality improvement is the primary goal of all modern health care service organizations, which strive for better patient health care outcomes, service performance, and professional development in the delivery of health care services [36]. According to Doyle et al [20], there are 3 central pillars that constitute health care quality

Clinical Effectiveness

Clinical effectiveness concerns the improvement of the current clinical practices and their related health care service outcomes [25]. Clinical effectiveness can be improved through the identification of nonvalue adding steps that fail to directly improve the quality of patient care [37]. Workflow analysis can help improve the effectiveness, efficiency, and efficacy of clinical services based on an in-depth understanding of the status quo [38,39]. For instance, workflow analysis can be undertaken to investigate and identify potential variations in service delivery and to identify issues such as bottlenecks and resource constraints.

Patient Safety

Patient safety aims to safeguard different dimensions of patient well-being through regulation and proactive measures in practice [25]. The health care sector is a highly regulated environment, which demands that patient safety is taken into consideration in service reform initiatives. Examples of the constraints that ought to be considered when addressing patient safety include medical protocols and clinical guidelines (eg, the National Institute for Health and Care Excellence guidelines), ethical standards (eg, the Hippocratic Oath), medical device certification (eg, Food Drug Administration approval in the United States and Conformité Européene (CE) Marking in the European Union), and data protection (eg, General Data Protection Regulation). These factors act as guide rails that aim to improve patient safety [40].

Patient Experience

Patient experience centers on a patient's "personal interpretation of the service process and their interaction and involvement with it during their journey or flow through a series of touchpoints" [41]. Zomerdijk and Voss [42] state that experiences are constructed based on the interpretation of encounters and interactions designed by the service provider. Although providers cannot directly offer an experience, they can create the foundational basis on which stakeholders (eg, customers, patients, and employees) can derive their own experiences. Although operational service quality looks at whether a service is delivered to its predefined specification, patient experience is based on the patient's feelings, judgments, and perceptions of the benefits derived from the service [41,43]. Patient experience is a key factor in ensuring compliance with recommendations as patients are much more likely to disregard or abandon tools and practices if they contribute to a poor experience. Patient experience must also be considered from an ethical viewpoint where patients must be fully aware "of the nature, scope, and granularity of data collected and what information they are actually consenting to provide" [24].

However, although some methods for improving clinical effectiveness and managing patient safety are relatively well established in the health care sector (eg, process mapping, service blueprinting, etc), methods for enhancing patient experience are less entrenched, particularly within connected

health [5,23,35]. The following section looks at journey mapping as a patient-centric tool for designing health care service reform.

Journey Mapping

Journey maps have been used in several areas to offer pictorial illustrations of complex processes or interactions that would otherwise be difficult to apprehend. Howard [44] noted that journey maps evolved from the field of service design when designers sought to re-engineer or optimize the service delivery of organizations or developed blueprints for new services (see the study by Stickdorn and Schneider [45]).

In particular, journey maps can be used to depict the health care service from the perspective of different actors, such as patients [37,42,46]. In the case of the patient, they are based on mapping consecutive *touchpoints* between the patient and the service, the nexus of where patient experience is actively shaped [23,42,47]. They see the relationship between the patient and service organization as something emergent, dynamic, and ubiquitous within the larger context and go beyond the more static view provided by other service design methods [42]. Percival and McGregor [48], for instance, proposed a mapping technique that includes a number of layers: staff roles, processes, information creation or movement, HIT solutions, IT infrastructure, patient needs or practice guidelines or policies, and metrics. Journey maps incorporate both physical and emotional aspects of the patient's journey with the aim of capturing and shaping the patient's behavior, feelings, motivations, and attitudes across the episodes of care, taking into account such important factors as the environment or context. They also help professionals to visually externalize their disciplinary knowledge and collect multidisciplinary insights. This promotes alignment but also empathy toward patient groups by placing the patient at the heart of the modeling process [49] and by creating a visually compelling story of the patient's experience [43].

User representations are developed to categorize and personify different target groups through the description of fictional users, that is, name, picture, personal background, and goals. User personas involve creating representations of typical users to help design teams to better understand and take account of the mental models of these groups, that is, their expectations, prior experience, and anticipated behavior [50]. LeRouge et al [50] stated that user personas address the limitations of common modeling tools such as Unified Modeling Language diagrams by integrating the conceptual model of users, their cognitive structures, and present behavior that drives health care thinking, future behavior, and demand.

Journey maps can be combined with user personas in the requirements gathering process to direct increased attention toward patient experience. The added contribution of personas to journey maps is that instead of being static representations of demographic profiles, they offer dynamic views of customers and users' experiences in their interactions with current and proposed products and services. The combined approach can then be employed to make design decisions and evaluate design solutions according to the unique needs of each persona. This stimulates creativity among team members when trying to address user needs and usability across numerous different real-life scenarios [51]. Critically, a small number of personas have been found to support the consideration of large, diverse populations, making the concept particularly useful for health care scenarios [52].

Developing Complex Apps

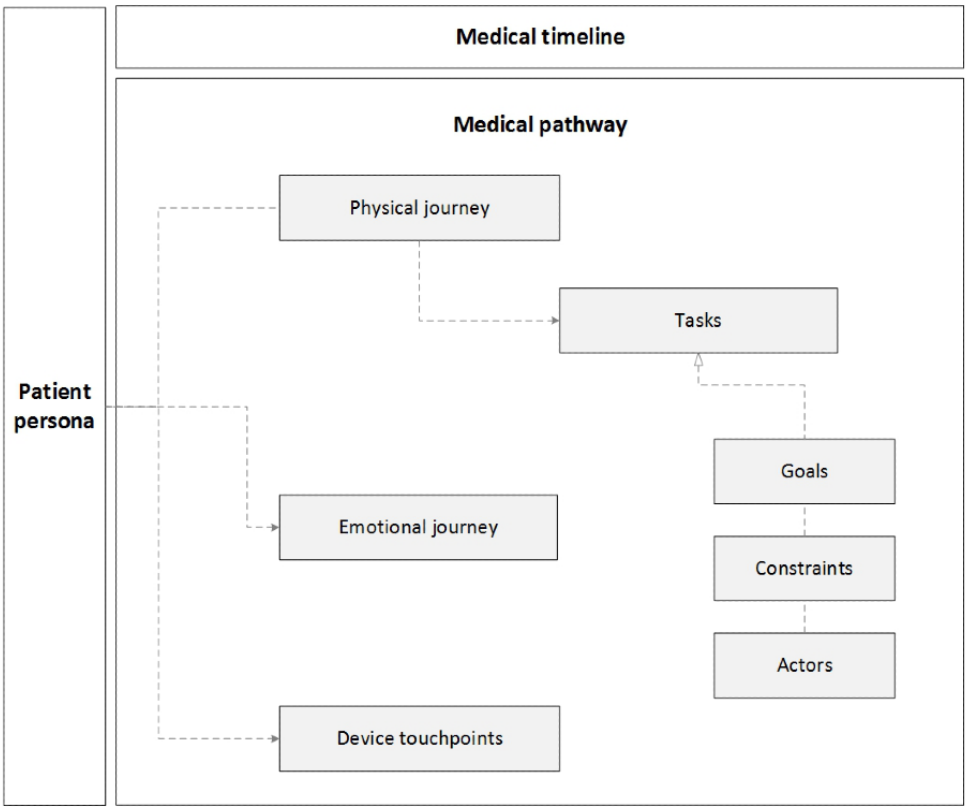
The area of HIT development has received considerable attention over the last 40 years. This time has seen the emergence of increasingly sophisticated platforms and development environments. Recently, the availability of cloud-based solutions, smart interconnected devices, and mobile apps has unleashed the potential for connected health apps. Unfortunately, these benefits can often be offset by the complexity and cost of developing connected health apps. The set of required development skills is becoming increasingly specialized, as is the complexity of the project management of the multidisciplinary teams required when developing such solutions. Mapping tools might be a useful approach for building cohesion within such teams, but at the same time, they must be understandable by diverse groups and professions to ensure that shared knowledge can be nurtured during the development process.

In the following section, we describe IPJM, a visual tool developed to help design teams to meet these challenges and to understand how to best reconcile the sometimes divergent requirements arising out of the need for clinical effectiveness, patient safety, and patient experience when designing connected health solutions. IPJM is also intended to promote harmonious team performance by negotiating and finding the right balance between the somewhat competing needs of different groups. This requires collaboration between different competencies on multidisciplinary teams. It also requires the management of conflict, which is likely to emerge from a comprehensive consideration of all viewpoints [53-55]. As a result of using IPJM, we hope that robust and high-quality designs will emerge for the solutions being considered.

IPJM

The IPJM tool was built using an ontology that conceptualizes the journey of a patient along a medical pathway. The ontology aims to promote a common vocabulary [56] among multidisciplinary design teams based on the 3 core pillars of health care quality. It captures the key elements of the journey: the structure of elements, relationships between elements, and implicit rules that govern the behavior of elements [57]. The ontology depicted in Figure 1 is provided in the literature. In addition, it has been validated through qualitative feedback from a number of projects that involve the use of IPJM, including the LEANBH project, which is described in the Methods section of this paper.

Figure 1. Integrated Patient Journey Map Ontology.



The ontology is split into 3 main areas: the *patient persona*, the *medical timeline*, and the *medical pathway*. First, the *patient persona* provides a characterization of a user group under consideration (eg, an expectant mother who is at risk of hypertension) and is inextricably linked to all other elements of the ontology. The *medical timeline* adds a temporal aspect to the episode of care by dividing it across a defined time frame (eg, the weeks of a pregnancy). The *medical pathway* centers on the consecutive events or steps in the episode of care [46] and consists of 7 subcomponents that are defined and described in Textbox 1. In particular, the *medical pathway* describes the *physical journey*, the *emotional journey*, and the *device touchpoints* associated with an episode of care. The *physical journey* is further divided into *tasks*, and these tasks are further subdivided into *goals*, *constraints*, and *actors*.

Textbox 1. Components of the medical pathway.

- Physical journey: maps the movement of the patient across an episode of care as she moves from one touchpoint to another in different settings (eg, patient's home, general practitioner clinic, or emergency room) where the health care service is delivered and the patient experience is derived
- Emotional journey: shows how the patient's experience changes as she moves through the different touchpoints
- Device touchpoints: lists the technological solutions utilized by the different actors (eg, doctor, general practitioner, and patient) at each touchpoint
- Actors: lists the stakeholders involved in the delivery of the health care service (eg, hospital doctors, general practitioners, and nurses)
- Task: details the tasks undertaken by each actor in the health care service delivery (eg, measuring the patient's blood pressure and registering appointments)
- Goals: comprises the desired outcomes that actors aim to deliver when carrying out tasks (eg, clinical, operational, and administrative goals)
- Constraints: outlines the constraints such as treatment guidelines based on medical protocols, governance, safety, and clinical guidelines

In this way, the ontology provides the foundational basis for IPJM by outlining the context in which the patient journeys transpire. Going back to the underpinnings of the concept of journey maps, the mapping tool (through the use of the ontology) visualizes the journey of a persona facing a scenario. This can sensitize designers and developers to the intricacies of individual personas and scenarios and minimize the risk of designing for *normative* situations that do not reflect the real situations of actual patients. Commercial firms and public sector agencies have used such ontologies very successfully in seeking to develop interaction mechanisms with their customers and with members of the public who need to access their services, such as in the case of disabled people who have special mobility and cognition needs [58].

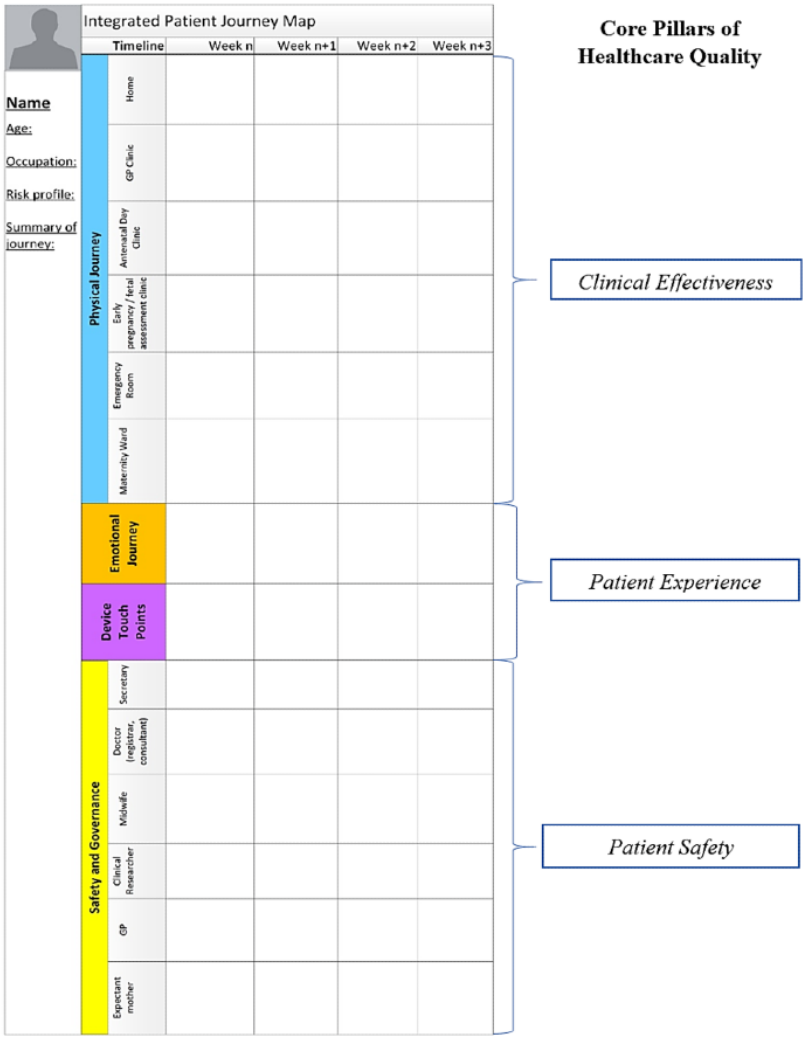
IPJM can be used to show the *as is* and the *to be* comparison between the existing medical pathway and the intended modified pathway enhanced with technology, devices, apps, and other new components and interactions. This ensures the tool's usefulness for negotiation and communication of the design of

the proposed connected health solution, especially between clinical specialists and designers or developers of the solutions. In seeking to make a *business case* for new pathways, the map can be used to demonstrate to relevant health care authorities the potential impact of proposed changes.

IPJM Template

Building on this ontology, we iteratively designed and evaluated the visual elements of a journey mapping tool called IPJM. An example of a base template, constructed iteratively using the ontological components, is shown in Figure 2. The patient persona is situated on the left side of the template, the medical pathway and its subcomponents are positioned in the center, and the medical timeline is displayed horizontally on the top of the template. Tasks, goals, constraints, and actors are listed within the safety and governance component.

Figure 2. Base Integrated Patient Journey Map Template.



Each of these areas of the IPJM maps to the 3 core pillars of health care quality previously outlined in the Background section. For instance, the *physical journey* aims to provide insights into the clinical effectiveness of the health care service by plotting the sequence of steps involved in the delivery of care. This, in turn, can be used to examine the steps to identify those that do and do not add value to the health care service. The *emotional journey* deals with patient experience. This is based on the likely emotional response of the patient to individual steps in the health care service. Finally, *safety and governance* maps the aspects of patient safety based on the responsibilities of different actors and their associated regulatory constraints.

The device touchpoint area caters for the connected health context and maps the different *connected* devices and data analytic solutions that are employed by actors when delivering the service. For instance, one touchpoint between the patient and the health care service could involve the use of a smartphone app and a connected medical device for tracking and sharing data on the patient's state of well-being. Another touchpoint could involve the use of data analytics by clinicians to gain insights into the patient's state of well-being, forecasting potential health issues and intervening when required.

A design science approach was followed to ensure that there was a rigorous basis for the construction of the tool [59]. A description of the researchers' approach to design science was previously presented in a study by McCarthy et al [60]. Following O'Raghallaigh et al [56], the design science approach consisted of 2 central activities: (1) *identifying and generating foundational abstract knowledge* from academic and practitioner

literature to guide, explain, and justify the design approach and (2) *using and refining abstract foundational knowledge* in developing and evaluating prototypes through engagement with potential users of the tool. The approach thus sought to integrate both *design practices* (construction of the artifact supported by existing knowledge) with *design science* (generation of knowledge through the construction and evaluation of the artifact). For example, the initial version of the ontology was developed from a scientific understanding of the academic literature. On the other hand, the first version of the mapping tool was largely developed through practice.

Prototypes of the IPJM tool were evaluated using different techniques. Evaluation primarily focused on examining the use of the tool by design teams during projects focused on increasing health care quality (clinical effectiveness, patient safety, and patient experience). In addition, the general evaluation looked at IPJM as an analytical tool to support the collection of requirements for connected health apps. In the case of the LEANBH project, evaluation involved a multidisciplinary team of stakeholders working together to populate IPJM templates for 8 personas across diverse scenarios (such as white-coat hypertension, chronic hypertension, gestational hypertension, and preeclampsia). A separate template was used to map the journey for each persona facing a scenario. Post-it notes were used to *fill in* the components of the journey, and these were positioned across the 4 areas of the template. This approach allowed the journey to be easily modified by iteratively adding, moving, or removing the post-it notes. Different colored markers were used to connect and codify post-it notes and to indicate where changes needed to be made to the journeys based on discussion among the team members. Table 1 provides a summary of the evaluation techniques used during the LEANBH project.

The following section outlines the in-depth case study of the *LEANBH* project.

Table 1. Techniques used to evaluate the Integrated Patient Journey Mapping during the Learning to Evaluate Blood Pressure at Home project.

Data collection	Brief description	Purpose
Workgroup	Four full-day workshops involving a multidisciplinary group of stakeholders. The workshops focused on deriving requirements for a connected health system that would monitor the well-being of expectant mothers across different settings such as the antenatal clinic, general practitioner's practice, and an expectant mother's home	Exploratory design of the modeling tool
Semistructured interviews	Semistructured interviews each lasting about 1 hour were conducted with the 10 individual team members to gain further in-depth insights into the IPJM[a] tool. Interviews were conducted with the principal investigator, project manager, 2 developers, a funded investigator, data architect, clinical lead, clinical researcher, research nurse, and the director of a commercial partner	Individual stakeholder's subjective evaluation of IPJM
Analysis of supporting documents	A range of sources were used to ensure that IPJM considered clinical effectiveness, patient safety, and patient experience goals. This involved analyzing best practices around managing the patient pathway using sources such as the UK's National Institute for Health and Care Excellence guidelines for managing hypertension during pregnancy. In addition, information requirements were investigated based on the Health Service Executive's maternity health record in Ireland and Data Protection Act guidelines around health care research	Evaluation of the prototype's ability to represent the current best practices

[a]IPJM: *Integrated Patient Journey Mapping*.

Methods

Case Study Approach

An in-depth case study approach [61] was undertaken to explore the use of visual tools for embedding health care quality in the design of connected health solutions. The in-depth case study in question followed the guidelines provided in studies by Yin [62,63]. It centered around the *LEANBH* project, a pilot research project that provides remote health care monitoring for expectant mothers to improve the detection and treatment of hypertension during pregnancy.

The LEANBH Case Study

Hypertensive disorders in pregnancy (eg, preeclampsia and gestational hypertension) are a major cause of maternal and neonatal mortality and morbidity worldwide, accounting for 16% of maternal deaths in developed nations such as Ireland and 25.7% of maternal deaths in the developing nations of Latin America and the Caribbean [64]. In particular, preeclampsia is a hypertensive disorder of pregnancy characterized by high blood pressure (>140/90 mm Hg), the presence of protein in urine, and other associated symptoms such as headaches and edema, which can lead to serious complications during pregnancy [65].

The LEANBH project was a collaborative effort that involved organizations from academia, the health care sector, and the industry. The multidisciplinary project team consisted of a principal investigator, a project manager, a full-time and part-time developer, an analyst, and a data architect (which made up the *information systems* [*IS*] *subgroup*) and a clinical lead, a clinical researcher, and a research nurse (which made up the *clinical subgroup*). The primary goals of the project were to increase clinical effectiveness, patient safety, and patient experience in a perinatal care context. The project team was tasked with building a connected health platform that integrates several IT artifacts, including a smartphone app, a home blood pressure monitor, and a urine analyzer for use by expectant mothers. An electronic health record was included to capture vitals for use by clinicians. The project also aimed to develop

novel forecasting algorithms for predicting the likelihood of gestational hypertension and preeclampsia.

The project was an observational study in which each patient followed the standard pathway and had access to both the standard care and the connected health platform. This simplified the ethical approval process, which was mostly concerned with providing complete and precise information to participants and in eliciting their consent on recruitment. This was achieved by creating a comprehensive patient information leaflet and assigning a dedicated research nurse to recruiting patients and training them in the use of the smartphone app, blood pressure monitor, and urine analyzer. Ethical approval was granted by both the University Clinical Research Ethical Committee and the Health Service Executive via the Hospital's Local Information Governance Group Research and Audit Committee. The authorization covered 2 rounds of recruitment of 50 patients each: the first group was an initial low-risk group and the second group was a more representative group of pregnant women, including women with preeclampsia.

Data Gathering

Qualitative data were triangulated using 3 data gathering techniques: participant observations, interviews, and project documents. First, the lead author was granted exceptional access to the live project setting, which allowed him to carry out over 700 hours of in-depth participatory observations in the field for a period of 6 months (June 2015 to January 2016). Participant observations allowed the lead author to gain rich insights into peoples' actions and directly observe events as they unfolded. In addition, semistructured interviews, each lasting about 1 hour, were then conducted with the 10 individual team members to gain further in-depth insights into the project. The interviews provided rich accounts of the subjects' own words. Finally, the lead author also had access to project documents throughout the development phase, which included emails, reports, and project management outputs. These documents offered a concrete account of the phenomenon of interest.

Data Analysis

Content analysis [66] was used to organize data into common themes and triangulate findings from interviews, project documents, and participatory observations. The content analysis centered on both *reflection-in-action* and *reflection-on-action* [67], with clinicians and IT specialists asked to validate IPJM and the individual journey maps. This hybrid approach was in keeping with our use of the case study method, in an intrinsic rather than an instrumental mode [68].

The journey map was first evaluated through reflection-in-action, with participant observations by the lead author using vignettes. As noted by Denzin and Lincoln [69], "it is important to keep in mind that when conducting qualitative research, the researcher is the main tool for analysis." Vignettes provided "a focused description of a series of events taken to be representative, typical, or emblematic in the case" [70]. Vignettes were used in the first instance as many parameters were emergent in our data analysis, and we wanted to stay as close to the data as we could. This technique allowed the researcher to produce, reflect, and learn from data around key moments in the *everyday life* of the project [70,71]. Gaining familiarity with the data, although arguably time consuming, was a positive aspect of the data analysis process and helped deliver a better artifact as well as a deeper understanding of its efficacy.

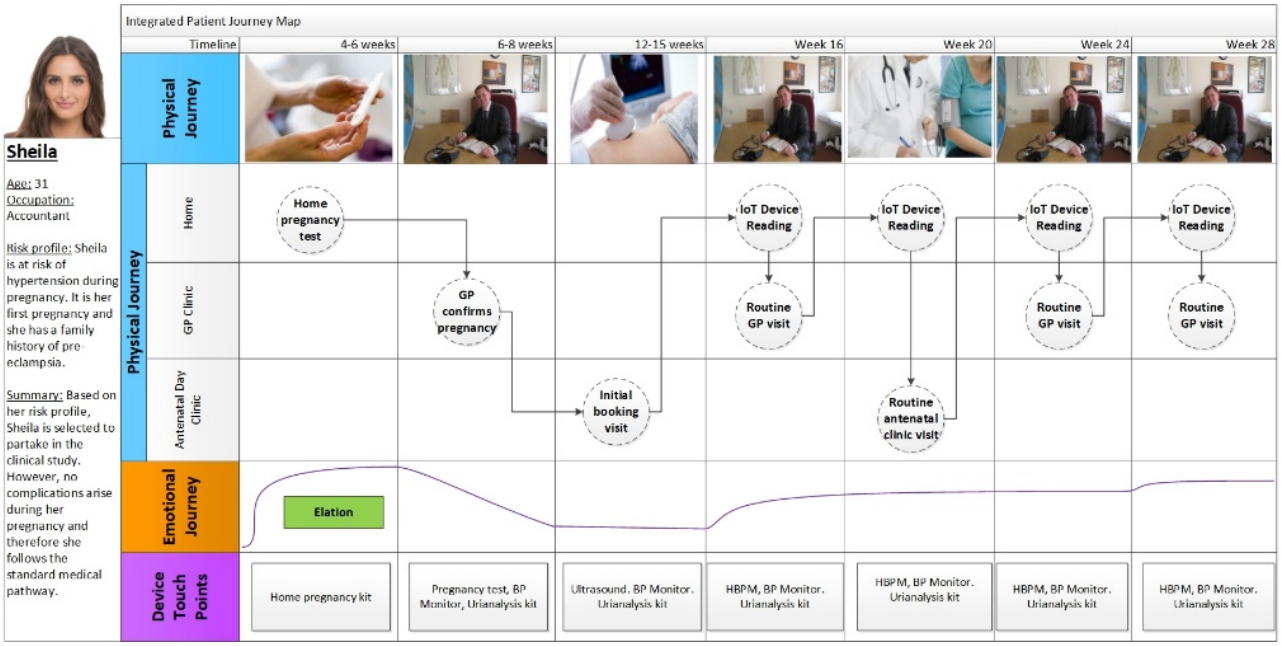
The efficacy of the journey map was also validated through reflection-on-action by analyzing interviews. To enhance the rigor in our data analysis, we used the computerized software provided by NVivo (QSR International) to analyze the interview transcripts. The lead author identified the codes of interest, including variables such as concepts and properties as well as the relationship between these variables [70]. As part of the data analysis and evaluation process, the researcher's perception of variables and relationships, otherwise referred to as theoretical sensitivity, was influenced by a reading of literature. The lead author continuously reread interview transcripts and used NVivo to manage the coding inventory.

Results

During the project initiation phase, the project manager organized 4-day-long participatory design workshops that aimed to build a collective vision for the project and to gather requirements for the connected health platform. These workshops involved stakeholders from the IS and clinician subgroups. During the workshops, the project manager encouraged the groups to work together in utilizing IPJM to map the physical and emotional journeys of pregnant women across the touchpoints of the proposed connected health service. In this way, IPJM provided a canvas for the groups to explore an improved antenatal pathway, technical considerations of the connected health platform, and the needs and capabilities of different stakeholders (eg, expectant mothers, clinicians, developers, nurses, midwives, and other health care practitioners). The groups used markers and post-it notes to dialogically work through potential challenges faced by personas in engaging with the proposed service. Owing to delays in the ethical approval process, the interdisciplinary team did not have direct contact with expectant mothers during this time.

The project team used IPJM during successive workshops to superimpose the journeys of fictional personas of different expectant mothers who would use the connected health service. In total, 8 fictional personas were identified by the team to represent the different hypertensive disorders that can occur during pregnancy and the medical scenarios that can occur. This included *Sheila*, a 31-year-old first-time expectant mother at risk of hypertension during pregnancy because of a family history of preeclampsia (Figure 3). Her journey through the standard antenatal pathway was now complemented with her use of the proposed connected health solution. Other personas included *Denise*, a 25-year-old expectant mother who developed preeclampsia, and *Fiona*, a 29-year-old expectant mother who developed gestational hypertension.

Figure 3. Snapshot of a Completed IPJM.



The project manager viewed the use of fictional personas as vital in that they acted as surrogates for real expectant mothers in the participatory design phase. This gave a voice to individuals who could not be physically present in the room. As a result, IPJM helped to build a bridge between multiple voices both inside and outside the design process, including the missing voices of expectant mothers. Interestingly, these missing voices often acted as the *arbitrator* during group discussions. For example, when individuals disagreed on a point, they would often revert to asking one another what the personas would want. This challenged the siloed thinking of both the clinical and IS subgroups. Individuals would often speak out on behalf of one of the personas and assert how certain decisions would affect the physical and emotional journey of this expectant mother. One powerful example of this emerged during discussions around the journey of *Brenda*, an expectant mother who (due to the white-coat syndrome) is incorrectly diagnosed with gestational hypertension and admitted to the hospital. The group discussed the emotional impact that this event would have on Brenda and challenged itself to come up with ways in which the connected health platform could be designed to avoid the unnecessary hospitalization of Brenda.

IPJM proved useful in helping individuals to build a deeper understanding of the challenges faced by different users of the proposed connected health platform. An example is the case of an expectant mother, Denise, who had young children to care for during her pregnancy. Denise's journey generated discussions around the challenges she would face if the smartphone app forced her to take blood pressure readings at strict time intervals, which could interfere with her childminding obligations. This challenged the group's prior assumptions. They ended up altering the service to provide flexibility when blood pressure readings could be recorded.

IPJM enabled the group to develop a common language around the antenatal pathway. It became a powerful means of building a shared understanding. For example, the IS subgroup faced a steep learning curve to reach an understanding of the obstetrics domain and the various health care settings in which the connected health platform would be deployed. Similarly, clinicians had limited knowledge of the technical aspects of the connected health platform. IPJM challenged siloed knowledge around the clinical and technology pathways and helped bridge disciplinary boundaries. The synergies arising from this confluence of disciplinary knowledge were essential for highlighting IT and clinical challenges, both previously known and unknown. As pointed out by the developer:

> *It was useful. It was only when I walked through the journey map explaining how the [smartphone] app would work that I realised that others had different interpretations.*

It also emerged that the IPJM tool was equally a means of generating shared commitment among the groups. Individuals later noted how participatory design activities using IPJM allowed the group to leverage the full range of capabilities possessed by the interdisciplinary group. As stated by the project manager, these activities represented a significant milestone where:

> *Technical concerns and clinician concerns were starting to be addressed as a unit as opposed to being two separate entities... For the first time people realised that the journey wasn't a clinical journey, it wasn't a medical journey, but neither was it a technological journey. It was all combined together.*

In using IPJM, many individuals were largely unaware that they were generating requirements for the proposed platform. However, the analyst was able to capture requirements for the platform from the discussions taking place as individuals worked together in filling out the journey maps. The resultant journey maps became a record of all relevant design knowledge. Owing to the visual and instinctive nature of the journey maps, individuals were able to handle the complexity of the medical scenarios, whereas this would not have been possible if

traditional modeling techniques had been used, as these require a level of familiarity that some individuals did not possess.

Discussion

Principal Findings

The findings suggest that IPJM can support multidisciplinary teams in exploring connected health solutions that consider the 3 pillars of health care quality: patient experience, clinical effectiveness, and patient safety [20]. It supports groups in understanding and negotiating conflicting requirements that can arise during transformational projects. This is achieved using journey mapping and user personas for graphically externalizing key domain knowledge. IPJM also promotes creative thinking around service reform goals and fosters dialogue among stakeholders, potentially leading to better solutions overall [72]. In addition, the ontology behind IPJM places constraints on groups, although it also allows the modeling to be easily adapted to different specialties, such as cardiology. The accessibility of the IPJM tool means that it can become a valuable boundary object [73,74], for discussions between multidisciplinary teams of stakeholders. For instance, IPJM enables ideas to be shared, interrogated, and visually externalized at both individual and group levels [56]. The use of mediums such as post-it notes means that the template is easy to use and modify as well.

Compared with other mapping tools, IPJM offers the possibility to focus on the comparison between the *as is* and *to be* versions of the pathway under study—this is a significant advantage in projects that pursue specific improvement targets. Its reliance on a visual grammar that does not require pre-existing knowledge (unlike other systems analysis and design approaches, such as Data Flow Diagrams or Value Stream Mapping, which require substantial training before participants can use them meaningfully) is also an advantage. The comparison with other techniques, such as Patient Journey Model architecture (PaJMa), the method proposed by Percival and McGregor [48], for instance, shows that IPJM manages to accumulate and represent a similarly broad variety of knowledge but with greater economy and without passing on the complexity of tasks and process steps onto the participants in the design process or, generally, onto the readers of the documentation. Both PaJMa and IPJM offer improvements over other mapping tools by allowing analysts to consider a much broader range of knowledge, but the use of personas in IPJM delivers a sharper focus on human aspects, such as the human experience, of patients, which is fundamental for connected health solutions that entail a context of use where patients are alone when using apps. In contrast to PaJMa, IPJM is likely to be more user friendly and more flexible in the case of first-time digitalization of medical pathways that involve mobile components that either patients or clinicians will use remotely.

IPJM can be used as a cornerstone for modeling health care service reform where stakeholders collaborate to derive an understanding of and commitment to requirements [75,76]. Textbox 2 summarizes the benefits inherent in the use of IPJM identified in its use during the LEANBH project.

Textbox 2. Strengths of Integrated Patient Journey Mapping.

- Embeds pillars of quality: considers clinical effectiveness, patient safety, and patient experience in tandem
- Externalizes knowledge: allows stakeholders to externalize their domain knowledge and build a shared understanding
- Stimulates creativity: facilitates dialog between different stakeholders around developing creative solutions
- Accessible: easy for multidisciplinary stakeholders to understand, use, and modify
- Adaptable: can be adapted to the requirements of different contexts and specialties
- Emancipatory: facilitates the alteration of medical pathways and the development of solutions for addressing their shortcomings
- Educational: acts as a platform for communicating proposed changes, their impacts, and the intentions and ambitions of the teams

Beyond the benefits identified in Textbox 2, we argue that IPJM can boost team cohesion during the execution of novel design projects. Existing literature suggests that team cohesion is essential to the performance of teams consisting of individuals from diverse organizational and geographical backgrounds [77]. Team cohesion can be defined as the extent to which team members are aligned in their shared understanding of and shared commitment to project tasks, for example, the actions that individuals and groups seek to perform based on agreed plans [78,79]. Shared understanding involves a social process whereby the divergent knowledge of individuals is transformed to generate collaborative knowledge building [75,80]. Shared understanding is required to explore design spaces and overcome siloed thinking through the combination of existing knowledge in new ways. Meanwhile, shared commitment goes beyond shared understanding alone and requires team members to commit time, effort, and resources in line with proposals that have gained shared understanding [76,81].

Shared understanding and shared commitment are crucial to the success of projects involving stakeholders from different organizational and disciplinary backgrounds [54]. In the absence of both shared understanding and shared commitment, the perspectives and intentions of team members can become increasingly fragmented, as individuals may not even be aware of the intricacies of the issues around which they disagree [76]. IPJM provides team members with the opportunity to challenge assumptions embedded in *prebaked* project proposals and contribute diverse knowledge around the design of IT solutions. This helps ensure that design efforts promote both a shared understanding of users' diverse needs and capabilities and a shared commitment to the delivery of solutions that cater to these needs. However, during the LEANBH project, not all group members were equally committed to leveraging the tools and to journey maps for modeling the problem domain and gathering requirements. This is a key concern as there is a possibility of a link between the involvement of stakeholders

during the modeling process and their understanding of and engagement with the project overall. Therefore, future versions of the modeling tool need to consider how best to engage practitioners from different backgrounds so that the entire team rally around the journey maps and their validation.

Conclusions

The health care sector is currently facing the monumental challenge of minimizing the costs associated with health care delivery while simultaneously improving quality. Connected health solutions can play a significant role in meeting this challenge by transferring health care delivery to the least expensive setting (ie, a patient's home) in a way that does not compromise quality. However, the successful design of connected health solutions is far from a straightforward task, and the success hinges on a quality-centric approach being embodied during every step of the development lifecycle. At this point in time, health care systems around the world are seriously affected by their reliance on a one-to-one mode of care delivery, where patients often wait for weeks and months to see overstretched specialists. Crucially, connected health apps can allow clinicians to better care for more patients by giving them more frequent attention in a remote fashion and without the need for face-to-face visits far more effectively [8].

It is here that the use of design tools such as IPJM can offer significant value. This paper contributes theoretical and practical insights into how visualization tools can be used to embed the pillars of health care quality in the design of connected health solutions. For instance, case study findings suggest that IPJM can provide multidisciplinary teams with a canvas for designing connected health solutions tripartite goals of clinical effectiveness, patient safety, and patient experience. In particular, IPJM can help ensure that patient experience is given ample consideration when designing health care services, in tandem with more traditional concerns such as resource efficiency, waiting times, financial costs, and treatment efficacy. In particular, IPJM can help bridge the gap, which is often identified too late between the intended use of apps and the observed system-in-use postimplementation. Such gaps often lead to the occurrence of *silent errors* and require the complete rethinking of apps and devices at considerable expense in time and money, both of which are in short supply in the health care sector [82].

Limitations and Future Research

However, IPJM is not without some limitations. For instance, IPJM does not make explicit reference to key performance indicators, such as throughput and waiting times, or other metrics, such as productivity and cost-efficiency, although these may be essential elements of the performance and success of the services being designed. This clearly applies to the scenario of a connected health solution being implemented to increase the throughput of a medical pathway, to deliver cost savings, and to improve visibility on patients' conditions. Although incorporating this element in the tool would be useful, there is also a risk that increasing the level of detail may compromise the overall accessibility and reliability of the maps. As a result, it may be difficult to capture some of the inherent complexity in health care systems, that is, when a patient is transferred from a hospital during treatment. On the other hand, the tool can be adapted according to the unique context in which it is to be used to address any key elements that are missing. Its use within the context of specific pathologies and medical specialties has the potential to rapidly bring medical teams up a steep learning curve toward developing connected health care apps.

Specifically, in the case of our research, we encountered other limitations, although it may be unclear whether these were circumstantial or if they were likely to also occur in other cases and settings. We found it difficult at times to secure participation from certain groupings in some meetings. For example, clinicians sometimes found it difficult to commit time to use IPJM, as they felt they were too busy and that the journey maps were for the development team rather than for themselves. Resolving these misconceptions is essential to producing maps that are accurate and robust in the face of real-life scenarios.

Future research may also seek to develop a more interactive version of IPJM to provide a more accessible view of the patient's journey. IPJM currently requires a large physical display to ensure that all components are visible and legible. During the project, we experimented with different display dimensions and orientations before deciding on an A2 portrait format. However, it may be necessary to consider whether certain elements need to be reorganized so that the tool can be displayed more easily across a variety of media and spatial dimensions. A software program that would allow users to drill down into subpathways and map components more effectively could also be a useful extension.

Clearly, there are cognitive and presentational limitations that apply to the mapping of macroservices, for instance, a national or even transnational architecture for managing a certain pathology or group of patients with dedicated needs. Although the mapping of such a broad pathway might be desirable or even essential as a communication tool for reaching a common agreement, evidently difficulties will arise when attempting to compile such a map where the need to be holistic and comprehensive might be traded off against the necessity for visual representations to remain comprehensible by most people and therefore useful. Setting some boundaries that accommodate both the need to capture the whole system as well as some of its key components will be useful, although our research does not provide clear avenues pertaining to how this may be achieved. Weick [83] characterized the *Bonini paradox* (by reference to Charles Bonini and his work on simulation, published in 1963 [84]) as illustrative of situations where models were proposed that were so complex in and of themselves that it was no easier to understand them than it was to understand the real world as observation could reveal it. We can hypothesize that the *Bonini paradox* applies to journey maps and that *die hard* attempts to capture a world without any ontological boundaries would only yield theoretically excellent but practically useless representations that would hamper design efforts rather than help. The need for ontological boundaries, such as those provided by the IPJM tool, is much needed and is underresearched. Future research on this topic should explore this new dimension.

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Conflicts of Interest

None declared.

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Abbreviations

HIT: health information technology
IS: information systems
IT: information technology
IPJM: *Integrated Patient Journey Mapping*
LEANBH: *Learning to Evaluate Blood Pressure at Home*
PaJMa: Patient Journey Model architecture

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Viewpoint

Document-Engineering Methodology in Health Care: An Innovative Behavioral Science–Based Approach to Improve Patient Empowerment

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Abstract

Engaging patients in their treatment and making them experts of their condition has been identified as a high priority across many medical disciplines. Patient empowerment claims to improve compliance, patient safety, and disease outcome. Patient empowerment may help the patient in shared decision making and in becoming an informed partner of the health care professional. We consider patient empowerment to be in jeopardy if written medical information for patients is too complex and confusing. We introduce document-engineering methodology (DEM) as a new tool for the health care industry. DEM tries to implement principles of cognitive science and neuroscience-based concepts of reading and comprehension. It follows the most recent document design techniques. DEM has been used in the aviation, mining, and oil industries. In these very industries, DEM was integrated to improve user performance, prevent harm, and increase safety. We postulate that DEM, applied to written documents in health care, will help patients to quickly navigate through complex written information and thereby enable them to better comprehend the essence of the medical information. DEM aims to empower the patient and help start an informed conversation with their health care professional. The ultimate goals of DEM are to increase adherence and compliance, leading to improved outcomes. Our approach is innovative, as we apply our learning from other industries to health care; we call this cross-industry innovation. In this manuscript, we provide illustrative examples of DEM in three frequent clinical scenarios: (1) explaining a complex diagnosis for the first time, (2) understanding medical leaflet information, and (3) exploring cannabis-based medicine. There is an urgent need to test DEM in larger clinical cohorts and for careful proof-of-concept studies, regarding patient and stakeholder engagement, to be conducted.

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KEYWORDS

document design; 1-pager; empowerment; patient engagement; cognitive science; health care; cross-industry thinking; malpractice in health care; written information

Setting the Scene

> *The only thing more expensive than education is ignorance.* [Benjamin Franklin]

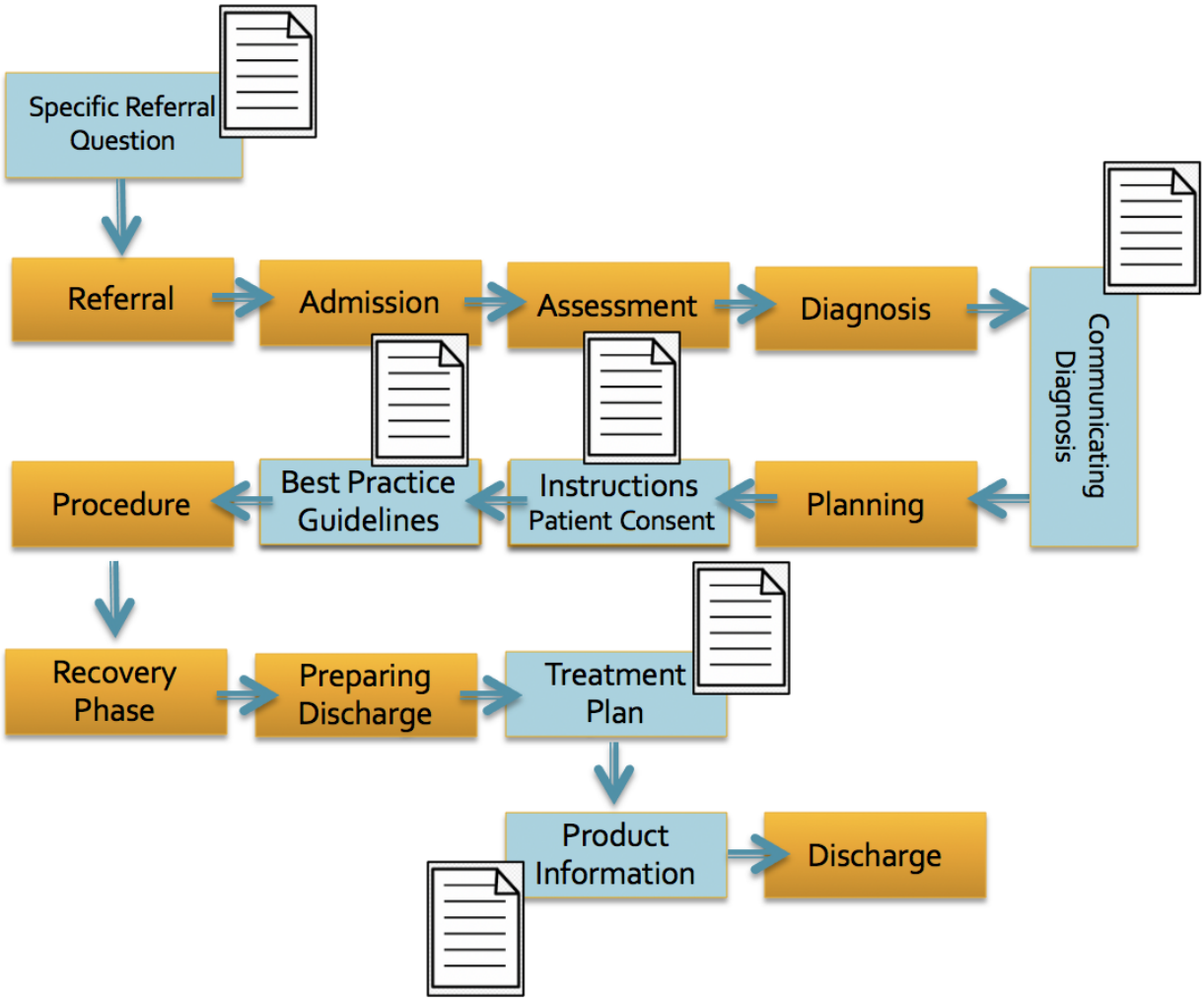
Fortunately, modern medicine in the second millennium provides people in need of health care a constantly growing range of options, both in the diagnostic field and in the treatment field. Leading the way are the vast resources of medical information available on the web. Paradoxically, the described scenario can be overwhelming for the individual patient who finds it hard to navigate an increasingly complex health care system and make the right choices. In this manuscript, we postulate that there is a real need for well-designed and easy-to-understand written medical information to get patients

engaged, informed, and ultimately empowered to positively impact their own disease outcomes.

Active engagement of patients and patient-centered care have been recognized for decades as priorities [1,2]; it has been suggested more specifically to enlist patients and families as allies in designing, implementing, and evaluating health care systems [1]. These concepts, driven by the vision to make the patient the expert, resulted in shared decision making, improved compliance, and improved adherence to medication [3]. Encouraging patient participation and self-management helped patients to gain control over their medical conditions and ultimately feel empowered [4,5]. How best to engage patients, doctors, and other stakeholders in designing comparative effectiveness studies has become an extensive field of research [6-8]. There is an ongoing need to investigate the dividends of engaged research and how to evaluate these effects [9].

Despite all these efforts, medical mistakes and malpractice still occur on a large scale. In North America, the number of people dying in hospitals as a result of malpractice and adverse drug events exceeds the number of deaths as a result of car accidents [10]. In a seminal paper almost 20 years ago—*No Toyotas in health care: Why medical care has not evolved to meet patients' needs*—the missing "business case of quality" in health care was criticized [11]. Meanwhile, many health care organizations adopted the Toyota Production System as the performance improvement approach, often called the LEAN health care management system [12]. The LEAN improvement process focuses on defining value from the patient point of view, mapping value streams, and eliminating waste in an attempt to create continuous flow [12]. These attempts are in line with the extensive quality improvement movement, which aims for better patient and population outcomes, better professional development, and better system performance [13]. Surprisingly, the scope of insufficiently written documents for malpractice in health care has never been systematically assessed in an epidemiological study. This finding is an interim result of an ongoing, not-yet-published, PhD research project at the University of Heidelberg, Germany, under supervision of the main author (BP). This is surprising, as written documents are used routinely at multiple intersections of an individually complex health care delivery process. These intersections include referral letters, information brochures about diseases, product information, consent forms, procedure guidelines, and treatment protocols (see Figure 1).

Figure 1. There are multiple steps in the successful delivery of health care with critical phases, where clearly written and easy-to-understand communication documents are key.



This is also in contrast to the fact that health literacy—the ability to read, write, and understand—has been recognized as an important milestone of the empowerment learning process for patients [14]. Health literacy allows the patients to perform knowledge-based literacy tasks in order to acquire, understand, and use health information for making their own health-related decisions. It has been postulated that these skills—applied in various environments, such as a home, community, or health clinic setting—will help the informed patient to prevent medical mistakes and increase their safety [15].

Lack of health literacy with subsequent misinterpretation of written material is still a current concern. In the European Health Literacy Survey, 1 in 2 (47%) out of 8000 participants in eight different European countries had limited (ie, insufficient or problematic) health literacy [16]. Several studies confirmed that lack of health literacy has significant impact on safety, specifically on desired patient health outcomes. These include higher rates of medication errors as a result of misinterpretations of prescription drug label instructions [17], reduced patient recollection and understanding of informed consent [18], decreased cancer screening and immunization rates, and, finally, more emergency department use [19]. Furthermore, a very recent systematic review evaluated the readability of online health information in the United States and Canada: based on 3743 references, 157 cross-sectional studies, and 13 different scales, the mean readability grade level was by far too difficult to comprehend for the targeted audience. It ranged from grades 10 to 15, while a grade 6 reading level for the general public is recommended [20].

In the following section of this paper, we will introduce document-engineering methodology (DEM) for designing medical information. The idea of DEM comes from industries such as aviation and oil, which proposed that DEM will help users to prevent errors, measurably reduce risk for injuries, and, overall, increase safety by designing an easy-to-read document [21]. In an innovative approach, we introduce DEM for the first time to the medical field.

Document-Engineering Methodology: A Cognitive Science–Based Approach?

It has been well known for more than 100 years that the brain is not perfect at all; it naturally produces errors while receiving, selecting, and processing information. We will provide two famous examples from cognitive neuropsychology and behavioral science.

In 1907, the Hungarian neurologist and psychiatrist Bálint wrote, “It is a well-known phenomenon that we do not notice anything happening in our surroundings while being absorbed in the inspection of something; focusing our attention on a certain object may happen to such an extent that we cannot perceive other objects placed in the peripheral parts of our visual field, although the light rays they emit arrive completely at the visual sphere of the cerebral cortex” [22].

The natural limitation of the brain to process and identify all visual information at the same time was further supported by the behavioral experiment of Simons and Chabris [23]. In their seminal paper, the authors describe an experiment in which a dancing gorilla was entirely missed on a video by observers when they were told to strictly focus on ball contacts of two teams of basketball players playing in front of the dancing gorilla. This phenomenon was subsequently called “inattentional blindness.”

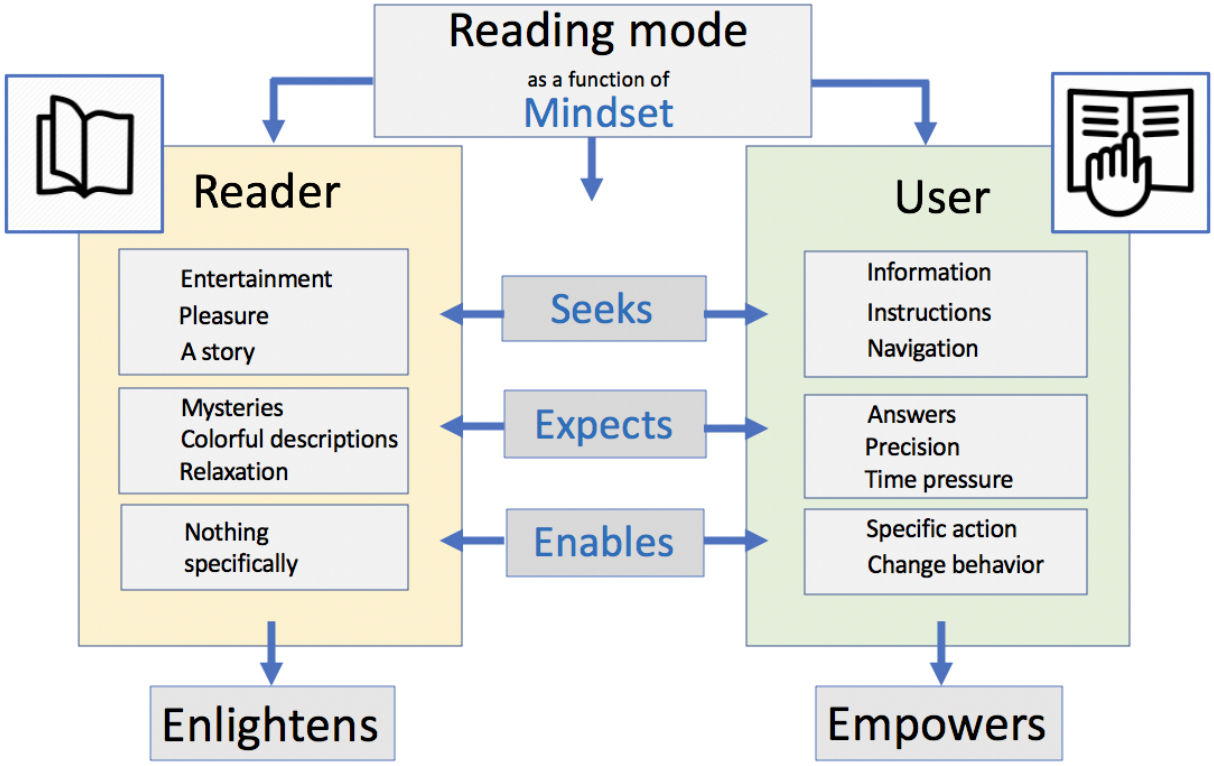
Document design as a new research field integrated these basic insights of the brain processing visual information and added several other components. Karen Schriver, an early scientist in technical writing, pioneered this approach. Her groundbreaking, extensive research is summarized in the comprehensive textbook *Dynamics in Document Design: Creating Text for Readers* [24]. Her insights about writing, reading, and visualizing documents defined the art of document design. The author emphasizes the importance of typography and space to improve readability and communication. Well-known principles of Gestalt psychology (ie, closure, symmetry, asymmetry, proximity, similarity, continuity, grouping, hierarchy, and balance) are implemented in the framework of document design [24].

Document design, with the main question on how we process and *read* written information, has been influenced by a multidisciplinary field of research. It spans over four decades and ranges from the classic psychological *theory of reading* by Just and Carpenter [25] to studying neuronal networks and circuits via advanced magnetic resonance imaging techniques while reading. The focus of this research was on visualization of subtle sequential processing steps within the brain while reading [26,27]. Other studies addressed the role of eye tracking for scanning and skimming written information, an issue that gets even more important in a fast-paced modern world using short messages for information dissemination on smartphones and other portable devices [28].

More recent research focuses on the *user* perspective in industry and how the user processes and *reads* procedural instructions [29]. The author suggests that the user *consults* a document in an interactive way rather than reading it in a linear manner [29]. Document design factors based on cognitive neuropsychology are introduced to allow reading with understanding, action planning, carrying out specific actions, and executive control activities [29]. These document design characteristics include a chronological or modular organization of the text, clear and precise headings, and using textual instructions where the word order strictly corresponds with the required action, question, or task to fulfil [29]. Design rules and design models based on cognitive and perceptual science have been proposed to further support engineering methods for interactive system design [30].

These approaches are in line with our recently proposed model [31] that *readers* (of books) and *users* (of written information) have different mindsets (see Figure 2 [31]). While the mindset of readers is driven by curiosity (ie, seeks reading for entertainment), users want to have immediate answers to their questions, often with a sense of urgency. Users need to be able to quickly navigate written information and need to be enabled to perform a specific action [31]. Recognizing the different mindsets between a reader and a user has enormous implications for designing a document.

Figure 2. Two mindsets of processing and perceiving written information: readers reading versus users reading [31].



The original term *document engineering* comes from the software and hardware computer industry [32]. In its strictest sense, it is a document-centric synthesis of complementary ideas from information and systems analysis, electronic publishing, business process analysis, and business informatics. It attempts to unify these different analysis and modeling perspectives and helps to specify, design, and implement documents and the processes that create and consume them [32].

The way we will use the term *document engineering* is quite different from the original description. We define DEM as an innovative subspecialty methodology of document design–implementing principles of cognitive science and neuroscience. The *engineering* part in our approach to DEM refers to our process of *putting parts together* of the outlined frameworks required to process written information in the most effective way [24-29]. Applying this current scientific knowledge, we hypothesize that DEM will enable the user, in our case the patient, to easily read and understand written information and to perform actions and tasks quickly, safely, and efficiently.

Several industries outside of health care have used DEM in order to improve user performance, prevent harm, and increase safety. Proof-of-concept research studies are unfortunately missing. The biggest lessons learned come from the aviation industry, where safety is the number one priority and difficult-to-read, user-unfriendly information has repeatedly caused fatal and avoidable incidents [33].

Corporate psychology in the oil and gas industry has also applied this behavioral science–based methodology to help the brain *navigate* more easily through complex document-based information, such as procedural instructions. However, the statement “The user is enabled to take the right action fast and efficiently with measurably reduced risk of harm, hereby increasing safety” [21] still needs reconfirmation through practical research-based trials.

DEM-1-Pager to Ease Communication in Health Care

We suggest use of the DEM in health care. It is an opportunity to further establish the methodology and to test its added value in controlled trials. We provide three illustrative examples for potential use of a *DEM-1-pager*. In all three proposed examples, we produced an easy-to-read, single-page document, following DEM. The two authors of this paper pioneered and introduced the concept of *DEM-1-pagers* to health care only recently [31]. We use this as our *first* example in this manuscript.

As our target group, we chose people with a complex brain disease called psychogenic nonepileptic seizures (PNES). We sensed the suffering and the confusion of the people affected by PNES as we talked with them. They expressed, in particular, their frustration regarding insufficiently easy-to-understand learning material about their condition when communicating with their health care providers. People with PNES struggle with several challenges [34]. They face the overwhelming complexity of their disorder, they do not understand the underlying causes and prognosis, they recognize the lack of education around all stakeholders, they experience lots of obstacles and barriers in the health care system, and, most

importantly, they are ill- informed right from start of their diagnosis of PNES [31,34].

Our way out of this dilemma was to produce a new communication tool in close collaboration with PNES patients: a *DEM-1-pager*. Our *DEM-1-pager* is content engineered for users—it is not written for readers.

We used a user-friendly, promise-question-answer (PQA) format as introduced in the oil and mining industry through corporate psychologists [21]; BP, one of the authors, is certified for this methodology. The PQA table is a basic framework with a heading and two columns; it consists of a *promise* presenting as the heading of the document (ie, the overriding topic the reader can expect). Organized on the left side of the document in a separate column are the most relevant *questions*. On the right side of the document are the *answers* strictly addressing the questions in simple terms.

We controlled for easy comprehension and readability by using a low Flesch-Kincaid reading level of seven [35]. The Flesch-Kincaid grade level is calculated by using a statistical program and the Flesch-Kincaid Grade Level Formula. The complex formula considers the number of words and syllables within a sentence. It measures the simplicity of writing and is widely used by teachers, librarians, educators, and others to assess the readability level of written text. We further embedded document design techniques from behavioral and Gestalt psychology [24,30]. The most important ones were limiting the questions to list to a maximum of seven items [36], implementing *cognitive linking* (ie, questions and answers containing similar wording) [29], and using behavioral enforcers [29]. We are aware that the "magic number of seven" has initiated a controversial discussion among neuropsychologists; it is also an excellent illustration for a frequent dilemma in cognitive science–based experimental findings. A rather low amount of research has followed on the numerical limit of capacity in working memory [37,38].

The outlined design techniques will enable the patients to navigate fast and efficiently through this document and quickly find answers to their pressing questions. Our tool provides the patient with the most important, essential information about PNES, including the relevant obstacles from the health care system. Our *DEM-1-pager* is not meant to replace available comprehensive and often time-consuming information either published on paper or online [39]; rather, it is meant to be complementary to these valuable resources. Ideally, it can be used in the initial communication between PNES patients and health care professionals.

We engaged a group of PNES patients and cocreated with them the *DEM-1-pager* using a design-thinking process with many iterations [31]. We subsequently tested our *DEM-1-pager* in a small focus group of PNES patients; it was found to be beneficial in several domains. It also empowered patients to make their own decisions [31]. Figure 3 [31] shows the final version of a *DEM-1-pager* for PNES. The result is a poignant *DEM-1-pager* without overwhelming and confusing information.

Textbox 1 lists a range of other, randomly chosen, frequently occurring, complex medical conditions in which a *DEM-1-pager* can be helpful and contribute to early patient engagement.

Figure 3. Document-engineering methodology (DEM)-1-pager for psychogenic nonepileptic seizures (PNES) (version 4); a tool for early communication of PNES created in a design-thinking process with patient engagement [31].

Understanding PNES, A Patient Guide

What does PNES stand for?	PNES is a medical acronym which stands for Psychogenic Non-Epileptic Seizure
What causes PNES?	The causes of PNES are multifold including psychological, social and medical causes. The causes vary from person to person and can be difficult to be identified. The condition is real, and people with PNES are not faking.
How is PNES diagnosed?	PNES is usually diagnosed by neurologists with expertise in epilepsy. PNES is diagnosed by corroborating that the clinical symptoms during a seizure are not explained by electrophysiological abnormalities on Video-EEG. There are "positive clinical signs" which are highly characteristic for PNES.
How is PNES treated?	A PNES treatment approach consists of several steps which include: • Careful explanation of the diagnosis • Exploration of medical & psychosocial factors that are predisposing and precipitating • Initiating evidence- and skills-based psychotherapy • Regular follow-ups for outcome control • PNES therapy typically involves a team of specialist clinicians who understand this disorder
What is critical to assure a successful therapy?	Several key events are critical to a successful therapy. Amongst them are: • Accept the diagnosis • Access to a health care professional with expertise in PNES treatment • Establish and maintain a trust relationship with your care team • Educate yourself about PNES – become an expert.
What improves the prognosis?	The prognosis is much better when treatment starts early and worse if delayed. Unfortunately, data from large studies is lacking, and long-term prognosis is poorly understood at this time.
What are the challenges?	The challenges for people with PNES are: • PNES occur in patients who also experience or have experienced epileptic seizures • Health professionals are still learning about PNES • Health care systems do not consistently offer the multidisciplinary & integrated care needed in PNES • The network of specialists needs to be developed • There is insufficient public awareness.
Further reading	http://www.nonepilepticseizures.com

Textbox 1. Examples of complex diseases in which a document-engineering methodology (DEM)-1-pager of information could be useful.

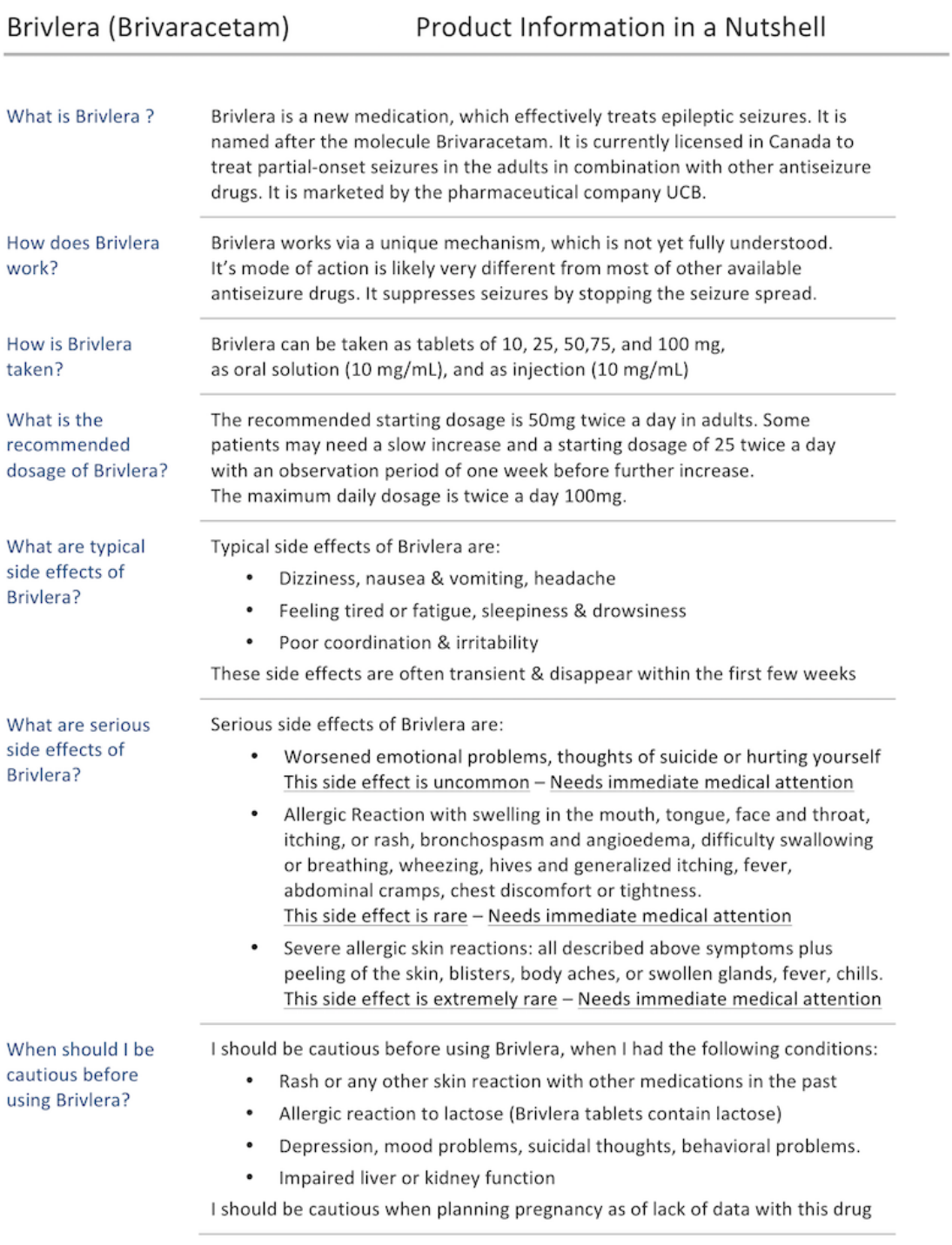
- Psychogenic nonepileptic seizures
- Autism spectrum disorder
- Bipolar disorder
- Posttraumatic stress disorder
- Attention deficit hyperactivity disorder
- Diabetes mellitus
- Colon cancer
- Parkinson disease
- Fibromyalgia
- Chronic fatigue syndrome
- Alzheimer disease
- Many more diseases

As a *second* example, we chose patient information leaflets. Information leaflets are purposefully exhaustive and detailed in order to meet all medico-legal requirements. Patients often feel overwhelmed with the extent of written medical information, find it useless, and even tend to throw it away [40]. Patient information leaflets often are extremely wordy and not well designed and patients find it hard to navigate them. The leaflets almost never have a grade 6 readability level as a basic requirement. They often do not meet patients' needs and appear ineffective [41]. Patients cannot find the information they seek or may be confronted with nonessential material, affecting patients' perceptions of the leaflets and willingness to read them [42]. Applying DEM principles to information leaflets will hopefully reduce redundant words, improve format and design, and take health literacy (ie, grade 6 readability) into account.

As stated earlier, we do not suggest replacing *patient information leaflets*—we do see the necessity to present medico-legal information in the most complete and comprehensive way. However, we believe a complementary, easy-to-read *DEM-1-pager* will enhance the willingness of the patient to consider their suggested medication, for example.

We provide an illustration of this approach. The lead author of this paper (BP) is a seizure expert and subject matter expert. He applied DEM to a comprehensive, 18-page, official US Food and Drug Administration (FDA) patient information leaflet for brivaracetam, a newly licensed medication for seizure control [43]. The result is a *DEM-1-pager* (see Figure 4) that contains all essential information. The *DEM-1-pager* can help to start an initial communication about brivaracetam. Readability of a document encourages the patient to be compliant and become an informed partner. The 18-page FDA information leaflet is a critical complementary resource at any time.

Figure 4. User-friendly, document-engineered methodology (DEM)-1-pager for the antiepileptic drug brivaracetam.



The *third* example shows a *DEM-1-pager* that we purposely developed for an extremely controversial uncharted territory: the new field of medical cannabis-based medicine (CBM). Though cannabis has been employed medicinally for more than two millennia, its recent legal prohibition, biochemical complexity and variability, quality control issues, previous dearth of appropriately powered randomized controlled trials, and lack of pertinent education have conspired to leave clinicians in the dark as to how to advise patients pursuing such treatment [44]. The use of CBM is still stigmatized, and health care providers are often reluctant to prescribe it. This is in contrast with the promising potential of CBM for multiple disorders and established clinical indications, such as epilepsy and pain [45].

The main author of this paper (BP) and other subject matter experts identified CBM as an ideal application for the use of a *DEM-1-pager*. Patients who seek treatment for chronic pain, one of the most accepted and evidence-based indications for CBM, want basic information about how CBM works. They

are often desperate and seek knowledge through dialogue with their health care providers. These patients often encounter difficulties in finding answers to their most burning questions. They are confused and need navigation. Patients want to know how CBM might help them, information about side effects, how CBM can be consumed, how CBM is prescribed, which challenges they may face in the health care system, and so on.

Figure 5 shows a proposal of an easy-to-read *DEM-1-pager* addressing this patient problem. This document was created in a design-thinking process together with subject matter experts. It aims to help patients to easily find answers for their most relevant above-mentioned questions. This *DEM-1-pager* is a perfect start for a first dialogue between health care providers and patients on the topic of CBM. It is not meant to replace other valuable comprehensive resources.

Figure 5. Proposed document-engineering methodology (DEM)-1-pager for patients interested in medical cannabis.

Medical Cannabis **First Introduction for Patients**

Can cannabis ease my symptoms?	Cannabis can ease your symptoms depending on a number of factors including your underlying medical condition. Cannabis has been used successfully in medicine since ancient times to treat a variety of symptoms. More recent studies have shown that cannabis can ease spasticity related to multiple sclerosis, chemotherapy-induced nausea and vomiting, chronic neuropathic pain and seizures in rare forms of childhood epilepsy.
How does cannabis work?	Cannabis works through multiple pathways. It has more than 500 compounds. The best studied are the cannabinoids THC (tetrahydrocannabinol) & CBD (cannabidiol). A chemical process via heating (decarboxylation) is needed to unfold the therapeutic benefits. THC & CBD modulate a complex system in the body called the "endocannabinoid system" (ECS). The ECS is found mainly in the brain and the immune system. THC & CBD work through two main "receptors", CB1 and CB2, however impact many other functions and receptors.
Which common side effects can I expect?	You can expect the following common side effects: drowsiness, dizziness, anxiety, nausea, dry mouth, euphoria (THC only), and diarrhea if taking cannabis oil. Side effects tend to be mild and dose dependent. The more you take the more likely you are to experience a side effect. Side effects are usually reversible. This is not a full list of all possible side effects. Very rarely, THC can lead to psychosis in susceptible individuals.
How can I consume medical cannabis?	You can consume medical cannabis in a variety of ways. Taking cannabis orally via an oil or a capsule has the highest dosing accuracy. You can choose between THC-dominant and CBD-dominant, or balanced products with roughly equal amounts of THC and CBD. Other, safer ways to consume cannabis include skin cream or ointment and as a suppository.
How is the dosage?	The dosage is dependent on you individually as well as the prescribed compound: • THC starting with 2.5mg on day 1 to a maximum of 20mg/day • CBD starting with 3-5mg on day 1 to a maximum of 200mg/day • The rule of thumb is to start with a low dose and slowly increase it over days and weeks to find your optimal dose.
How do I get medical cannabis?	You get medical cannabis in a relatively straight forward two-step process. • You first need to get a Medical Document (like a prescription for cannabis) from a physician or nurse practitioner • You then need to register for an account with a Licensed Producer to be enabled to order your medicine.
What are the challenges of treatment with medical cannabis?	The challenges of treatment with medical cannabis are: • Health care professionals are still learning about medical cannabis • Medical cannabis is still stigmatized and prescribers are often reluctant • Further clinical trials are needed to confirm the value of medical cannabis

There are several limitations of the three provided examples of *DEM-1-pagers*. Only the first example, dealing with psychogenic nonepileptic patients [31], actively involved patients and health care professionals. This allowed a critical design-thinking process with reiterative feedback from users. The second and third examples lacked this process and still have to undergo testing in a focus group or in specific target groups. Some of the written content could certainly be replaced by colorful images to ease reading and understanding [29]. Active involvement of patients in designing these images is another intriguing opportunity for further templates.

We also see potential risks in using the presented *DEM-1-pagers*. They will always be simplifications of complex medical information. This goes along with the risk of likely not covering all individually highly relevant aspects. The patient may not seek out the more detailed complementary information, even when encouraged. This could harm the patient. It is, therefore, critical that the health care professional always explain the limitations of this tool to the patient.

Conclusions

Our paper encourages the consideration of *DEM-1-pagers* in several health care delivery environments where written medical information is relevant, complex, and widely used (see Figure 1), such as referral documents, consent forms, and instructions for treatment procedures, to name a few.

We anticipate that *DEM-1-pagers* will help health care professionals to initiate and strengthen the dialogue between the health care professional and the patient, helping to build trust. This can lead to empowerment on both ends. A *DEM-1-pager* is conceptualized to be a first step to explain essential information, followed by a more sophisticated and detailed discussion on the subject later on. We hypothesize that *DEM-1-pagers* will help to improve patient guidance, empower the patient, and, ultimately, contribute to better outcomes.

We foresee a wide range of potential applications in the health care industry. We are fully aware of the limitations of our pilot data. Strong evidence is still lacking. Larger test studies will be needed to further validate *DEM-1-pagers* in various clinical scenarios. We, therefore, fully agree with a recent research paper mapping hypothesized impacts to suggested and assessed measures of patient, public, and stakeholder engagement. Their careful assessment confirmed lack of evidence underlying much of the impetus behind the practice of patient and stakeholder engagement in research, based on analyzing peer-reviewed literature using PubMed and PsycINFO databases from January 2005 to May 2013 [9].

We are also aware that we could not address all aspects of the impact of DEM in health care. It is, for example, beyond the scope of this paper to outline the health-economic and medico-legal aspects of patient and user empowerment by means of *DEM-1-pager*-designed documents. We also did not address the health-related preventive nature of well-written information; for example, poorly written child safety seat installation instructions have been found to be potentially harmful [46].

The main purpose of our paper is to encourage health care professionals to think in new ways about written medical documents for patients. The lessons from other industries about the usability of documents are intriguing. Cross-industry thinking carries a treasure of opportunities and will also facilitate breakthrough product innovation [47]. Safety is at stake if we do not open up to accept well-recognized and researched performance measures in these very industries. Health care is certainly still far behind in producing well-designed and user-friendly documents. DEM is a first step in this new uncharted territory.

Conflicts of Interest

None declared.

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Abbreviations

CBM: cannabis-based medicine
DEM: document-engineering methodology
FDA: Food and Drug Administration
PNES: psychogenic nonepileptic seizures
PQA: promise-question-answer

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Original Paper

Mobile App for Monitoring 3-Month Postoperative Functional Outcome After Hip Fracture: Usability Study

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Abstract

Background: As a result of an aging population, there has been an increasing incidence of hip fractures worldwide. In the Netherlands, in order to improve the quality of care for elderly patients with hip fractures, the multidisciplinary Centre for Geriatric Traumatology was established in 2008 at the Department of Trauma Surgery at Ziekenhuisgroep Twente hospital (located in Almelo and Hengelo in the Netherlands).

Objective: Though the Dutch Hip Fracture audit is used to monitor the quality of care for patients with fractures of the hip, only 30.7% of patients complete registration in the 3-month follow-up period. Mobile apps offer an opportunity for improvement in this area. The aim of this study was to investigate the usability and acceptance of a mobile app for gathering indicators of quality of care in a 3-month follow-up period after postoperative treatment of hip fracture.

Methods: From July 2017 to December 2017, patients who underwent surgical treatment for hip fracture were recruited. Patients and caregivers, who were collectively considered the participant cohort, were asked to download the app and answer a questionnaire. Participants were divided into two groups—those who downloaded the app and those who did not download the app. A telephone interview that was based upon the Unified Theory of Acceptance and Use of Technology was conducted with a subset of participants from each group (1:1 ratio). This study was designated as not being subject to the Dutch Medical Research Involving Human Subjects Act according to the appropriate medical research ethics committees.

Results: Of the patients and caregivers who participated, 26.4% (29/110) downloaded the app, whereas 73.6% (81/110) did not. Telephone interviews with the subset of participants (n=24 per group) revealed that 54.0% (13/24) of the group of participants who did not download the app had forgotten the study. Among the group who downloaded the app, 95.8% (23/24) had the intention of completing the questionnaire, but only 4.2% (1/24) did so. The reasons for not completing the questionnaire included technical problems, cognitive disorders, or patient dependency on caregivers. Most participants in the group who downloaded the app self-reported a high level of expertise in using a smartphone (22/24, 91.7%), and sufficient facilitating conditions for using a smartphone were self-reported in both groups (downloaded the app: 23/24, 95.8%; did not download the app: 21/24, 87.5%), suggesting that these factors were not barriers to completion.

Conclusions: Despite self-reported intention to use the app, smartphone expertise, and sufficient facilitating conditions for smartphone use, implementation of the mobile app was infeasible for daily practice. This was due to a combination of technical problems, factors related to the implementation process, and the population of interest having cognitive disorders or a dependency on caregivers for mobile technology.

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KEYWORDS

hip fracture; remote monitoring; elderly; telemedicine; orthogeriatric; mHealth; app

Introduction

As a result of an aging population, the global incidence of hip fractures has been increasing with an estimated 6.25 million per year expected by 2050 [1,2]. In the Netherlands, 19,000 patients with hip fractures are treated annually [3,4]. To improve the quality of care for elderly patients with fractures of the hip, the multidisciplinary Centre for Geriatric Traumatology was established in 2008 at the Department of Trauma Surgery at Ziekenhuisgroep Twente hospital (located in Almelo and Hengelo in the Netherlands). Approximately 300 hip fracture patients are treated annually in this center [4]. To improve the quality of care among patients with fractures of the hip nationwide, the Dutch Hip Fracture Audit was established in 2016. The Dutch Hip Fracture Audit [5] monitors quality of care using indicators for quality of hospital stay, 3-month functional outcome, and 1-year mortality. Some of these quality indicators have been formulated by the Health and Youth Care Inspectorate and are mandatory; living situation of the patient, prefracture mobility score, and the Katz Index of Independence in Activities of Daily Living score are currently gathered during scheduled 3-month follow-up visits to the outpatient clinic.

The proportion of patients who register to provide information regarding functional recovery is poor; only 30.7% of Dutch Hip Fracture Audit registrations are completed [5]. Due to age or health-related factors, patients do not visit the outpatient clinic for their scheduled 3-month follow-up. Poor registration may result in a suboptimal monitoring of quality of care. In contrast, the 3-month registration was completed by 89.0% of the patients in the Centre for Geriatric Traumatology. This higher percentage was achieved by using an active telephone approach for patients who missed or canceled their outpatient appointments; however, the active approach was time consuming and inefficient. Mobile apps may offer an opportunity for improvement. Mobile app use to remotely monitor patients who have a low risk of postoperative complications has been investigated in multiple studies [6-10] which have concluded that mobile apps were useful for following up with patients who had a low risk of postoperative complication and with patients from 18 to 82 years of age who had undergone day-procedures. To our knowledge, no studies have investigated the use of mobile apps for the follow-up of patients with fractures of the hip.

There has been ongoing worldwide interest in home telemonitoring to support the health and vitality of the community-dwelling elderly population which has led to promising strategies for improving health care and health management [11-13]. Despite interest in the use of home telemonitoring, the literature mostly consists of pilot or feasibility studies. Real-world use and acceptance of home telemonitoring in daily care in older patient populations have mainly been studied in patients with chronic heart failure and have shown high acceptance of the technology using a 12-month survey [14,15]. In order to further optimize mobile app use among the elderly, a supportive theoretical framework has been recommended for iterative design of app implementation and evaluation [16]. These recommendations encompass multidisciplinary approaches, focus on end-user ease of use, and suggest starting with usability and feasibility testing in simulation environments [16-18]. In addition, during implementation, variation in levels of interest and technological literacy should be taken into consideration, especially among older adults [16].

The primary goal of this study was to investigate the real-world use of a mobile app for monitoring postoperative functional recovery after hip fracture. The secondary goals were to analyze mobile app usability and acceptance among elderly patients and their caregivers. Usability and acceptance were considered to facilitate conditions for use, but were not presumed to lead automatically to use.

Methods

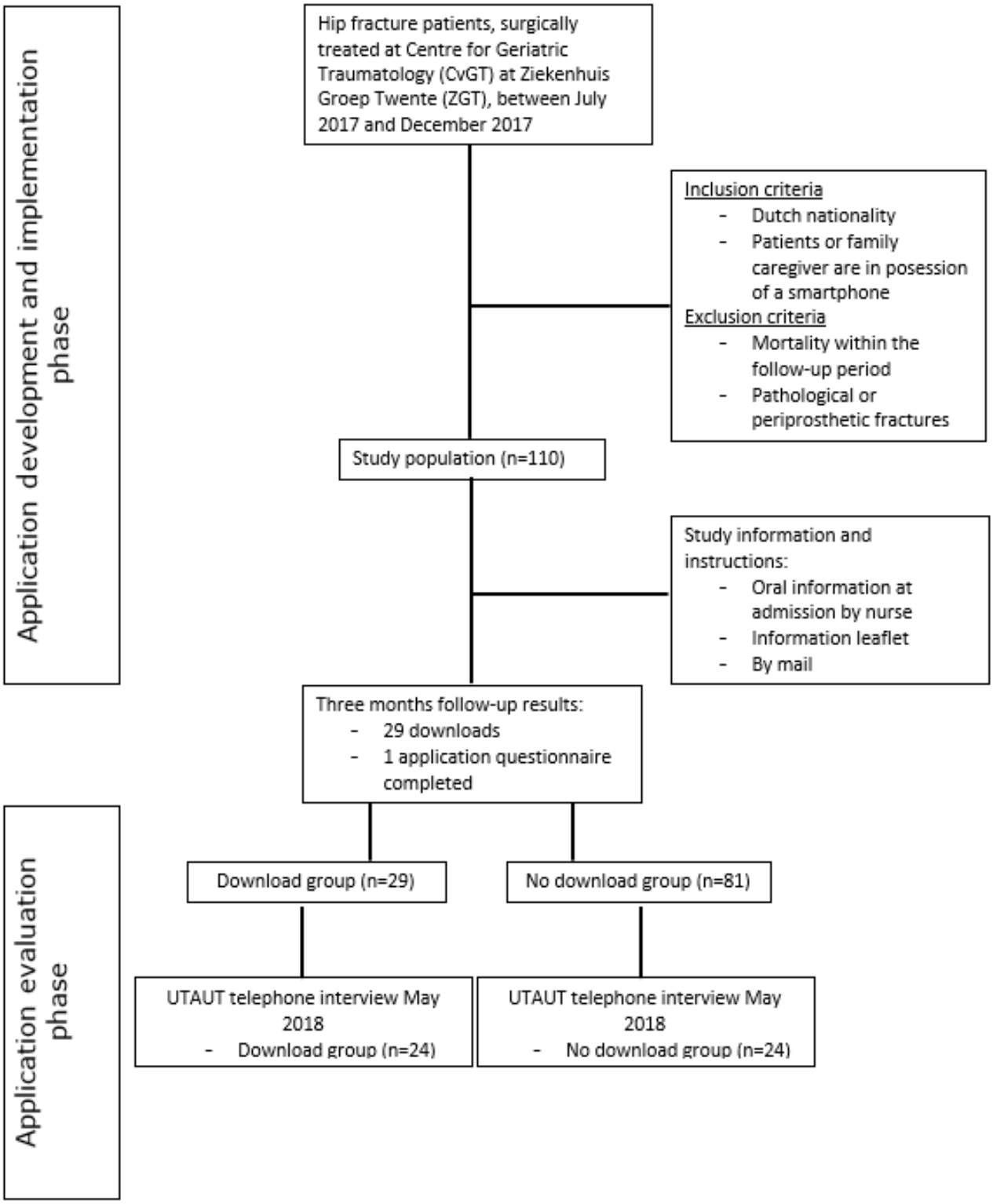
App Development and Implementation

The mobile app platform was developed by technical experts, is currently used, and has previously been used in studies of postoperative outcome with a high rate of use [1]. A multidisciplinary team of health care professionals and technical experts developed a proof-of-concept version of the app that included specific adjustments for an older population of patients. A digital questionnaire consisting of indicators of quality of care from the Dutch Hip Fracture Audit was developed to remotely monitor postoperative functional outcome at 3 months. This questionnaire was implemented in the mobile app, and the technology was pretested with 2 patients with fractures of the hip who had been chosen at random.

Participant Recruitment

Patients with a hip fracture who had undergone surgical treatment between July 2017 and December 2017 at the Centre for Geriatric Traumatology of the Department of Trauma Surgery at Ziekenhuisgroep Twente hospital were recruited to participate in the study and asked to download the app in addition to their regular 3-month outpatient visit (the recruitment process is summarized in Figure 1). The population of interest consisted of older adults, among whom information and communication technology literacy or low motivation to use technology may be factors that hinder implementation of a mobile app and which could suggest the need to focus on patient spouses in addition to the patients themselves [19]. For the purpose of this study, both patients and spouses who decided to participate were considered participants. During admission to the surgical ward of the Centre for Geriatric Traumatology, a nurse informed potential participants about the study, use of the app, and how to download instructions for using the app. After verbally providing informed consent, participants received an information leaflet and provided their email address for further information.

Figure 1. Study design flowchart.



One week later, participants received a code by mail to activate the questionnaire in the downloaded app. Completion of the questionnaire was restricted to a period between 12 weeks and 18 weeks after their operation. A push notification with a request to complete the questionnaire was sent to the participant 12 weeks after they had been discharged from the hospital. A push notification was also sent to the health care provider at 17 weeks for unfilled questionnaires.

Completed questionnaires were saved in OpenLine (a specialized health care hosting center) in accordance with Dutch legislation with respect to security standards. The local researcher applied for the data from the hosting center. Participants were anonymized and coded using a study number without any reference to patient number or date of birth. Only the local researcher had access to the participant study numbers. All data were treated confidentially and saved to the secured hospital network with a password.

Usability and Acceptance Questionnaire

To investigate usability and participant acceptance of the mobile app, an interview questionnaire was developed (Multimedia Appendix 1) based upon the Unified Theory of Acceptance and Use of Technology [20]; the model investigates user intentions and usage behavior in technology systems [20].

Two questions regarding participant recollection of the intended purpose of the study and feedback on the use of the app were added to the interview. These questions were added because we were interested in obtaining feedback on the app and on the duration of the interval from when the information was given (from July 2017 to December 2017) to when the telephone interview took place (in May 2018). A single researcher conducted all interviews. Participants were given the option to stop the telephone interview at any time.

Data Collection

Data were collected from the clinical charts of the patients who participated themselves or whose caregivers participated. Age, gender, type of fracture, American Society of Anesthesiologists physical classification status, Charlson Comorbidity Index [21], dementia, prefracture Katz Index of Independence in Activities of Daily Living score [22], prefracture mobility score, and prefracture living situation were recorded as baseline characteristics. In April 2018, the app usage data from the hosting center were collected. Participants were divided into two groups—those who downloaded the app (use group) and those who did not download the app (nonuse group). Mobile app usability and acceptance telephone interviews were conducted with participants who could be reached by telephone within 3 attempts. The number of participants in both groups was adjusted to the lowest number of participants accessible by telephone of either group (use group, n=24); therefore, in the nonuse group, 24 participants were selected randomly. Participant answers were fully transcribed in individual and anonymized Office Word (version 2007; Microsoft Inc) documents and saved on a secure hospital server.

Data Analysis

Statistical analyses were performed using SPSS software (version 22.0; IBM Corp). We used thematic analysis with a deductive theoretical approach to analyze the written answers to the recalled purpose of the study and feedback questions [23]. Identification of patterns and themes within the data was performed by one researcher, and a second researcher was consulted to reach agreement; the data were then coded by themes. Categorical data were analyzed using the chi-square test or Fisher exact test when appropriate (ie, Fisher exact test was used when frequency was less than 5). Functional outcomes were analyzed using two-tailed paired *t* tests. Continuous data were analyzed using two-tailed independent *t* tests. If significant differences were found in categorical variables with two or more subgroups, Pearson chi-square test was performed post hoc. $P<.05$ was considered statistically significant.

Ethics

This study was been designated as an observational study not subject to the Dutch Medical Research Involving Human Subjects Act by the appropriate medical research ethics committees.

Results

Patient Characteristics

Categorical variables are described as numbers with corresponding percentages. Continuous variables are described as the mean with standard deviation, or for nonparametric data, as the median with interquartile range.

Patient characteristics are shown in Table 1. Patients with fractures of the hip (N=110) were a mean age of 80.5 (SD 10.4) years and were 71.8% (79/110) female and 28.2% (31/110) male. No significant differences were found between those who downloaded the app and those who did not download the app for age ($P=.21$), gender ($P>.999$), type of fracture ($P>.999$), American Society of Anesthesiologists physical classification status ($P>.999$), Charlson Comorbidity Index ($P>.999$), dementia ($P=.05$), prefracture Katz Index of Independence in Activities of Daily Living score ($P=.10$), prefracture mobility score ($P=.10$), and prefracture living situation ($P=.73$).

Table 1. Baseline patient characteristics.

Characteristics	All (N=110)	Downloaded app (n=24)	Did not download app (n=24)	Chi-square (*df*) or *t* test (*df*)	*P* value
Age (years), mean (SD)	80.5 (10.4)	82.0 (8.7)	78.4 (10.8)	1.28 (46)	.21
Gender, n (%)				1.0 (1)	>.999
Male	31 (28.2)	7 (29.2)	7 (29.2)		
Female	79 (71.8)	17 (70.8)	17 (70.8)		
Type of fracture, n (%)				0.595 (2)	>.999
Neck of femur	64 (58.2)	13 (54.2)	14 (58.3)		
Pertrochanteric	40 (36.4)	10(41.7)	10 (41.7)		
Subtrochanteric	6 (5.5)	1 (4.2)	0 (0.0)		
ASA[a] physical status classification, n (%)				1.0 (1)	>.999
1-2	40 (36.4)	9 (37.5)	9 (37.5)		
3-4	70 (63.6)	15 (62.5)	15 (62.5)		
Charlson Comorbidity Index, n (%)				1.0 (3)	>.999
0-1	32 (29.1)	7 (29.2)	8 (33.3)		
2-3	13 (11.8)	2 (8.3)	3 (12.5)		
>4	6 (5.4)	1 (4.2)	0 (0.0)		
Unknown	59 (53.6)	14 (58.3)	13 (54.2)		
Dementia, n (%)	13 (11.8)	0 (0.0)	5 (20.8)	0.06 (1)	.05
Prefracture Katz ADL[b] score (out of 6), median (IQR)	1.0 (2.0)	1.2 (1.6)	2.2 (2.3)	—	.10
Prefracture mobility score, n (%)				0.578 (4)	.73
Freely mobile without aids	40 (36.4)	8 (33.3)	6 (25.0)		
Mobile outdoors with one aid	2 (1.8)	1 (4.2)	0 (0.0)		
Mobile outdoors with two aids or frame	30(27.3)	8 (33.3)	7 (29.2)		
Some indoor mobility but never goes outside without help	36 (32.7)	7 (29.2)	10 (41.7)		
No functional mobility (using lower limbs)	1 (0.9)	0 (0.0)	1 (4.2)		
Unknown	1 (0.9)	0 (0.0)	0 (0.0)		
Prefracture living situation, n (%)				0.327 (2)	.50
Independent	87 (79.1)	21 (87.5)	19 (79.2)		
Care home	7 (6.4)	2 (8.3)	1 (4.2)		
Nursing home	14 (12.7)	1 (4.2)	4 (16.7)		
Protected housing	2 (1.8)	0 (0.0)	0 (0.0)		

[a]ASA: American Society of Anesthesiologists.

[b]Katz ADL: Katz Index of Independence in Activities of Daily Living.

App Use

Of the participants (29/110, 26.4%) who downloaded the mobile app, only 1 (1/29, 3.4%) completed the app questionnaire.

Interviewed Participants

Characteristics

Participants characteristics of those who participated in the telephone interviews are presented in Table 2. In the use group (the subset of the group who downloaded the app), 95.8% (23/24) self-reported as expert level, and 87.5% (21/24) participants in the nonuse group (the subset of the group who did not download the app) self-reported as expert level. The groups showed significantly differences for smartphone usage of 5 to 10 years (use: 0/24, 0.0%; nonuse: 8/24, 33.3%; *P*=.004) and more than 10 years (use: 22/24, 91.7%; nonuse: 15/24, 62.5%; *P*=.02).

Table 2. Comparison of baseline characteristics between the use (participants downloaded the app) and nonuse (participants did not download the app) groups.

Variables	Both groups (n=48)	Use (n=24)	Nonuse (n=24)	Chi-square (*df*) or *t* test (*df*)	*P* value
Age (in years), mean (SD)	57.3 (10.3)	56.9 (9.8)	57.8 (10.9)	–0.279 (46)	.78
Gender, n (%)				1.0 (1)	>.999
Male	14 (29.2)	7 (29.2)	7 (29.2)		
Female	34 (70.8)	17 (70.8)	17 (70.8)		
Relation to patient, n (%)				0.133 (4)	.14
Patient self	5 (10.4)	3 (12.5)	2 (8.3)		
Partner	5 (10.4)	1 (4.2)	4 (16.7)		
First-degree relative	34 (70.8)	20 (83.3)	14 (58.3)		
Second-degree relative	3 (6.3)	0 (0.0)	3 (12.5)		
Other	1 (2.1)	0 (0.0)	1(4.2)		
Smartphone experience (years), n (%)				0.008 (2)	.004
<5	3 (6.3)	2 (8.3)	1 (4.2)	0.551 (1)	>.999
5-10	8 (16.7)	0 (0.0)	8 (33.3)	0.002 (1)	.004
>10	37 (77.1)	22 (91.7)	15 (62.5)	0.016 (1)	.04
Use of apps on a smartphone, n (%)	48 (100)	24 (100)	24 (100)	—	>.999
Self-registered expert level, n (%)	44 (91.7)	23 (95.8)	21 (87.5)	0.296(1)	.61

Questionnaire Results

Questionnaire results are presented in Multimedia Appendix 2. Among the use group, 95.8% (23/24) of participants had the intention of completing the app questionnaire; 41.7% (10/24) of the nonuse group had the intention of downloading the mobile app. In the nonuse group, 54.2% (13/24) stated that they were not informed during admission at the hospital or by mail of the app; 4% (1/24) had no intention of downloading the app. Therefore, no difference in expectancy determinants were calculated between the groups, and no answers were considered as blank.

Thematic Analysis

A thematic analysis was conducted to evaluate patient recollection of the study's purpose. Participant responses (transcribed excerpts are presented in Multimedia Appendix 3) resulted in five themes: functional monitoring, replacement of the outpatient appointment, evaluation of participant satisfaction, no idea or not sure, and other. Correct answers for patient recollection of the study's purpose were defined as those classified within the themes of functional monitoring and future replacement of the outpatient appointment.

The study purpose was correctly remembered by 62.5% (15/24) of the use group participants compared to only 20.8% (5/24) in the nonuse group; 50% (12/24) of the participants in the use group said that they did not receive a smart phone notification with the request to complete the questionnaire which suggested a suboptimal implementation process.

Discussion

Principal Findings

Completion of 3-month mandatory functional monitoring is poor among patients with fractures of the hip, which may result in a suboptimal monitoring of quality of care. This single-center pilot study to investigate the use and to analyze the usability and acceptance of a mobile app for monitoring postoperative functional recovery after hip fracture revealed poor results for actual use of the mobile app despite high self-reported intention to use the mobile app, high self-reported expertise in using mobile apps, and conditions that facilitated the use of mobile apps. This suggests that participants had the goal of using the mobile app, but that better support was needed to properly implement the technology in health care.

For many years, apps have been regarded as an alternative to paper questionnaires, but the use of apps may have difficulties as well, especially when implemented in a population of community-dwelling older patients [16]. This study demonstrated implementation difficulties; only 26.4% (29/110) participants downloaded the mobile app. This demonstrated that implementation of the app may have required that sufficient attention be given to education of the community-dwelling older patient users.

The low percentage of app downloads could partially be explained by an inability of the patients or caregivers to correctly remember the information that was provided to them in the hospital possibly as a result of stress [24]. Receiving information in a state of stress has been associated with suboptimal information processing and reduced cognitive efficiency [25,26]; therefore, correct timing of information provision is essential.

This study provided both oral and written information, but more emphasis should be given to written information or video instructions, as this has been shown to lead to better information retention [27]. Among participants who are elderly, an inverse correlation has been reported between age and recall of medical information which could also have influenced the findings of this study [24,28]. The 3-month time period between when the information was provided and when the questionnaire was to be completed which also could have negatively affected information recall and recollection of the study's purpose.

One participant completed the app questionnaire after downloading the app. This participant showed an active approach by contacting the app developers and completed the questionnaire with assistance from the developers.

A high percentage of the participants (34/48, 70.8%) who were interviewed were caregivers who were first-degree relatives of the patient. Study information was provided independently of whether a caregiver was present at the time of information provision; therefore, it is possible that some first-degree relatives were not provided with the study information if they were absent during recruitment.

The telephone interview findings demonstrated that many in the use group had the intention of completing the questionnaire. This indicates that those participants were motivated to complete the app questionnaire. In the nonuse group (11/24, 45.8%), participants remembered the study, and 10 out of the 11 intended to download the app. Given this result, there seems to be a good level of intention in both groups. Facilitating conditions, such as facilitated help, were high in both groups and were not a restrictive factor for app usage [29]. Some participants in the nonuse group (13/24, 54.2%) were unable to remember the study, and they could not complete the interview. Difficulties in patients or caregiver recollection of study information may have been influenced by the previously noted patient-related factors such as cognitive impairment, anxiety, or stress [24]. Approaching multiple caregivers when providing information and conducting the telephone interview may also be a reason for some participants reporting that they did not remember the study. Respondents (18/48, 41.6%) also reported technical problems. The app developers suggested the start-up phase of the app as a possible explanation for the technical problems. The developers also suggested that a lack of received notifications could have been as a result of participants not enabling the appropriate permissions for notifications when downloading the app. Providing help in the hospital with downloading of the app could assist with this issue. Another way to decrease the frequency of technical problems while also optimizing usability and acceptance would be to frequently evaluate the mobile app during the implementation process [16].

Recommendations

Findings revealed intention to use the mobile app, but very low actual usage. The use of a mobile app as it was implemented in this study was not feasible, but the study findings suggested a potential for use if implemented properly. First, technical issues should be solved, and a helpdesk should be made available. Second, it is recommended to involve participants in the development and implementation phases—doing so can optimize ease of use and acquiring feedback during implementation is a feasible goal. Third, information provision needs to be optimized in terms of timing and method of dissemination. It is important to supply additional information after discharge in order to prevent low download rates as a result of patient or caregiver stress during admission [27]. Written information, video instructions, or fact sheets are preferred to oral information [2,3]. Fourth, in studies involving caregivers, a single contact person is recommended.

Limitations

Selection bias in the downloading group represents a threat to validity, as patients or caregivers already intended to participate in the study by downloading the app.

Conclusions

The use of a mobile app to monitor 3-month postoperative functional outcome of hip fracture was low. Despite intention, expertise, and sufficient facilitating conditions for using smartphones, the implementation of the mobile app in this study was demonstrated to be infeasible. Reasons for this included a technical problem, the implementation process, and population of interest having cognitive disorders or a dependency on caregivers for mobile technology.

Conflicts of Interest

None declared.

Multimedia Appendix 1
Telephone interview questionnaire.
[DOCX File , 14 KB - humanfactors_v7i3e16989_app1.docx]

Multimedia Appendix 2
Questionnaire results.
[DOCX File , 21 KB - humanfactors_v7i3e16989_app2.docx]

Multimedia Appendix 3
Excerpts from participant responses.
[DOCX File , 14 KB - humanfactors_v7i3e16989_app3.docx]

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Original Paper

Integration of Conversion Factors for the Development of an Inclusive eHealth Tool With Caregivers of Functionally Dependent Older Persons: Social Justice Design

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Abstract

Background: eHealth can help reduce social health inequalities (SHIs); at the same time, it also has the potential to increase them. Several conversion factors can be integrated into the development of an eHealth tool to make it inclusive: (1) providing physical, technical, and financial access to eHealth; (2) enabling the integration of people at risk of SHIs into the research and development of digital projects targeting such populations (co-design or participatory research); (3) promoting consistency between the digital health literacy level of future users (FUs) and the eHealth tool; (4) developing an eHealth tool that is consistent with the technological skills of FUs; (5) ensuring that the eHealth tool is consistent with the help-seeking process of FUs; (6) respecting the learning capacities of FUs; and (7) being sensitive to FUs' cultural context. However, only little empirical evidence pointing out how these conversion factors can be integrated into an effective eHealth tool is available.

Objective: On the basis of Amartya Sen's theoretical framework of social justice, the objective of this study was to explore how these 7 conversion factors can be integrated into an eHealth tool for caregivers of functionally dependent older persons.

Methods: This study was based on a social justice design and participant observation as part of a large-scale research project funded by the Ministère de la Famille through the Quebec Ami des Aînés Program. Data were collected by recording the preparation sessions, the co-design and advisory committee sessions, as well as the debriefing sessions. The results were analyzed using Miles and Huberman's method.

Results: A total of 78 co-designers participated in 11 co-design sessions, 24 preparation sessions, and 11 debriefing sessions. Of the 7 conversion factors, 5 could be explored in this experiment. The integration of conversion factors has been uneven. The participation of FUs in the development of the tool supports other conversion factors. Respecting the eHealth literacy level of FUs means that their learning abilities and technological skills are also respected because they are closely related to one another and are therefore practically difficult to be distinguished.

Conclusions: Conversion factors can be integrated into the development of eHealth tools that are intended to be inclusive and contribute to curbing SHIs by integrating FU participation into the tool design process.

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KEYWORDS

caregivers; aged; help-seeking behavior; community-based participatory research; eHealth; telemedicine; mobile phone

Introduction

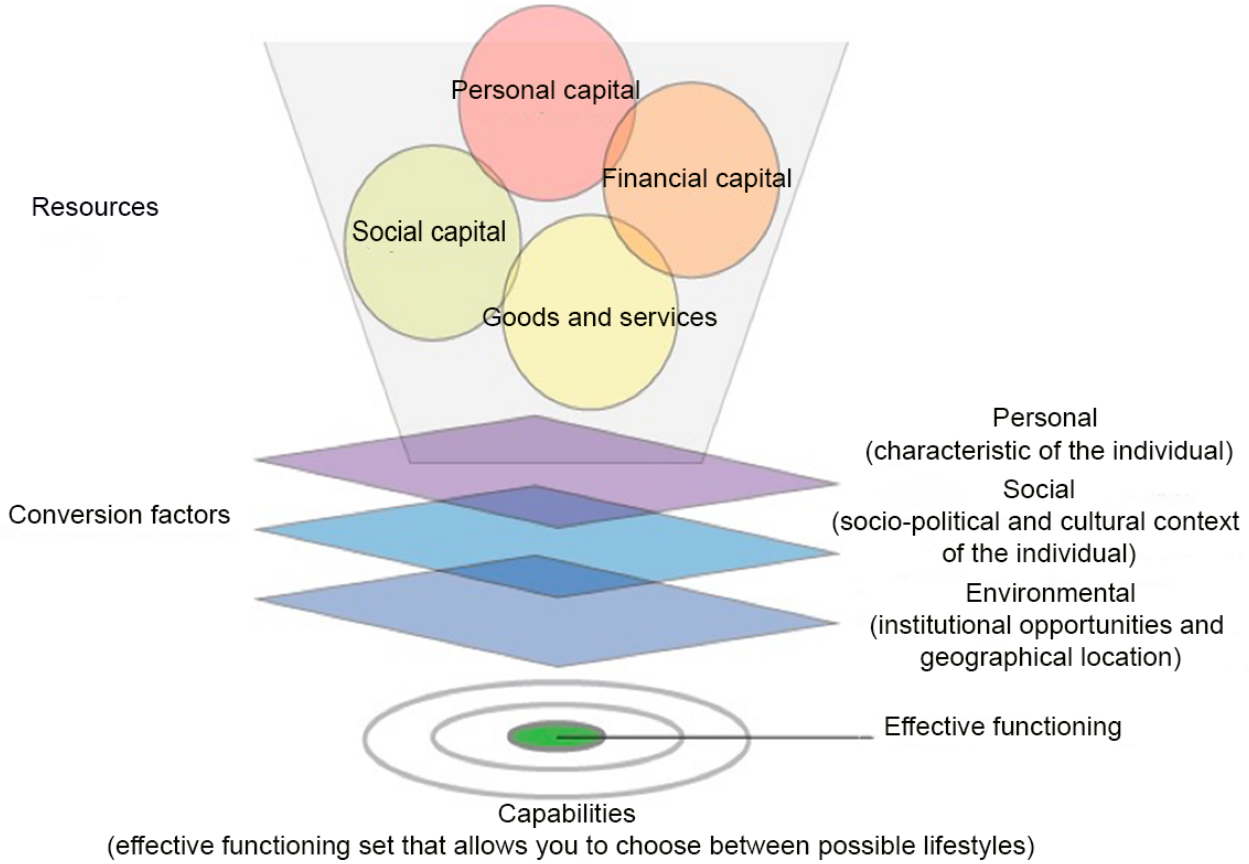
Background

Do you have access to your digital health record? What mobile apps do you use? eHealth, or any other digital tool used to take care of our health, is an integral part of our lives. However, a segment of the population cannot use these means to take care of their health, which leads to social health inequalities (SHIs). SHIs represent, for groups of people, the difference in the prevalence of disease and mortality rates due to unfair and modifiable social factors [1]. eHealth can exacerbate SHIs due to the digital divide [2]. The term *digital divide* evokes the separation between those who have access to technologies, such as computers, mobile phones, or the internet, and those with no such access, especially low-income individuals [3-5]. This concept also highlights the knowledge gap between users. Furthermore, this term refers to the notion of significant (or universal) access, which includes equipment, internet connection, skills development, technical assistance, and appropriate content, meaning health information that is comprehensible and useful for disadvantaged populations. The concept of digital divide also includes geographical location, behavior for searching information, confidence about private life and institutional policies, language, incapacity, and the lack of cultural sensitivity [3,5-7]. People who are in poor health condition and hence at higher risk of SHIs are also more likely to experience this digital divide [2]. eHealth makes a genuinely positive contribution to reducing SHIs by providing effective access to health services [8] anytime and anywhere while reducing stigma [9], which has led to a health justice issue.

Conceptual Framework

The capability approach proposed by Amartya Sen provides an interesting theoretical framework for addressing SHIs in eHealth [10]. His approach is different from the more classical school of thought regarding the notion of equality (utilitarianism vs egalitarianism), understood as an individual's freedom to choose a course of life that he or she has good reasons to value (ie, their capabilities) [11]. It is, therefore, an opportunity for individuals to perform an activity that makes sense to them. They must be able to convert their resources and formal rights into effective functioning. Subsequently, they can choose whether or not to engage in activities that are conducive to achieving the lifestyle that they have chosen (capability). The capability approach is illustrated in Figure 1.

Figure 1. Representation of the Capability Approach.



Resources that can be mobilized refer to personal, social, and financial capital as well as goods and services [11]. However, even if all individuals had the same resources, human diversity, recognized by Sen as being ubiquitous, means that the mobilization of these resources would vary from one individual to another and would not necessarily lead to effective functioning [10]. Conversion factors are the different personal, social, and environmental characteristics of a person that positively or negatively affect their ability to convert their resources and formal rights into effective functioning [12]. Differences in conversion factors lead to different (or unequal) degrees of freedom in achieving capabilities [12]. In other

words, conversion factors can be viewed as intervening variables or categories of intervening variables that may support or hinder effective functioning. Effective functioning represents the accomplishments or achievements of an individual [13].

There is a significant consistency between the concepts of SHIs and the capability approach. SHIs can result in a limited ability to take care of one's health. Although Sen refuses to establish a list of capabilities, this was done by Nussbaum [14], who identified a list of 10 basic human abilities, one of which, labeled *life*, refers to being able to live a *normal* life and avoiding premature death [15]. This is fully in line with the idea of combating SHIs. In individuals at risk of SHIs, one or more characteristics are associated with variations in resources such as low income, living alone or in a single-parent situation, precarious occupational status, belonging to an ethnic minority, and poor health literacy or education level [2]. Health services and eHealth can also fall within the resources category that Sen refers to. Although access to health services must be free and universal (formal rights), many negative conversion factors can hinder the mobilization of resources, already marked by vulnerabilities. The digital divide potentially associated with the use of eHealth is an example of a negative conversion factor that can be broken down into more detailed ones, namely, difficulty in initiating and completing the process of help-seeking, difficulty in accessing eHealth, limited ability to use technology, limited ability to fully understand what is said and written about health, and learning difficulties [2,16]. Promising strategies for the development of an eHealth tool that takes into consideration SHIs are potentially positive conversion factors.

Conversion Factors

On the basis of this conceptual framework of social justice [10], the following 7 conversion factors conducive to curbing SHIs in eHealth projects have been identified: (1) providing physical, technical, and financial access to eHealth; (2) enabling the involvement of people at risk of SHIs in the research and development of digital projects that concern them (co-design or participatory research); (3) promoting consistency between the level of digital health literacy of future users (FUs) and the eHealth tool; (4) developing an eHealth tool that is consistent with the technological skills of FUs; (5) ensuring that the eHealth tool is consistent with the help-seeking process of FUs; (6) respecting the learning capacities of FUs; and (7) being sensitive to FUs' cultural context [2].

Providing Physical, Technical, and Financial Access to eHealth

In Quebec, in 2018, 95% of adults had at least one electronic device (computer, smartphone, tablet, connected exercise bracelet, or smartwatch) [17], and 92% of them had internet access at home [17]. In Canada, almost all Canadians aged under 45 years use the internet daily [18]. This decreases to 35% as Canadians advance in age, that is, 75 years and above [18]. In addition, education and income are important indicators of internet use among older persons. Globally, North America and Europe are the continents where the internet penetration rate exceeds 85%, followed by Latin America, Australia, and the Middle East with rates ranging from 65% to 70% [19]. Asia and Africa have a penetration rate of 54% and 40%, respectively [19]. Although inequalities are present around the world, they seem to be less with regard to access in Quebec. However, these data should be used with caution. In a 2018 research project on the use of the tablet computer to prepare for hospital discharge, one patient was unable to participate in the research project because the internet and a cellular network were not available in her municipality (paper in preparation). A Quebec project called *Régions branchées* aims to provide complete internet access in Quebec [20]. However, this objective appears ambitious considering the vastness of the province. In addition, the costs associated with internet connection or technical assistance, which may sometimes be necessary, can force families and people experiencing poverty to make difficult choices in their budget management. More and more public establishments (shopping centers, hospitals, libraries, etc) offer free internet access. However, this can lead to confidentiality issues, especially when the search subject is related to health [21]. A Canadian program called Connected Families attempts to address this problem by providing Canadian families living in poverty with access to high-speed internet packages at a cost of Can $10 (US $7.47) per month [22]. It is not known at this time whether low-income families are using this program.

Enabling the Involvement of People at Risk of SHIs in the Development of Digital Projects That Concern Them (Co-Design or Participatory Research)

Involving FUs and a diversity of perspectives, circumstances, capacities, and experiences in the design process increases the likelihood that the tool will meet their needs and preferences [23]. Similar to many participatory methodologies, such as participatory action research, patient-partner approach, community-based research, or co-design, the objective of this study was to involve the people targeted by the research project in the process as early as possible in the hope of obtaining better results for them, including people at risk of SHIs. From Sen's perspective, any way of looking at a problem (and its solutions) is a social construction that implies the need to include the people concerned [13].

Promoting Consistency Between the Level of Digital Health Literacy of FUs and the eHealth Tool

eHealth literacy was defined as "the ability to seek, find, understand, and appraise health information from electronic sources and apply the knowledge gained to addressing or solving a health problem" [24]. It is very important to present information that can be understood by patients and users of eHealth tools to help them make decisions about their health and benefit from remote intervention programs [25]. People with poor literacy skills are less likely to use health information technologies and have a poorer overall health status and an increased risk of death [26].

Developing an eHealth Tool That Values Technological Skills of FUs

Technological skills or abilities refer to the use of various software, digital platforms, and apps in educational, professional, or everyday life activities [27]. This may also include activities such as securing personal data and appropriating new

technologies [27]. In Quebec, 19% of adults believe that they have poor skills, or they do not use the internet [28]. Age also seems to affect the sense of competence [29]. However, in recent years, internet use doubled from 32% to 68% among Canadians aged 65 years and above [29]. Bowen et al [30] have argued that low technological skills are as important a reason as the cost for not adopting the internet.

Ensuring That the eHealth Tool is Consistent With the Help-Seeking Process of FUs

The number of people who look for web-based information about their health problems and available services has increased; however, the need to interact with health professionals remains important [31]. In their study, Lin et al [31] argued that people seek information that was put out, among others, by people who are in the same situation as them; in other words, perceived similarity appears to be more influential than perceived expertise. It is important for FUs to identify the eHealth tools that not only can help them take care of their health but also guide them through their process of seeking formal help.

Respecting the Learning Capacities of FUs

Many eHealth tools are intended to offer some form of health education. However, studies show that some of them are less effective because they were not designed on the basis of learning theories [32]. eHealth tools would benefit from including key principles related to effective learning environments to allow FUs to get the most out of the tool to improve their health. These include, among others, fostering positive emotions and motivation by ensuring that FUs feel able to achieve what is expected of them, that they are able to perceive a stable link between their actions and results, that they have a clear vision of the objective, that they feel positive emotions toward the learning activities, and that they give relevance to the task [33]. In addition, it seems important to aim for easy knowledge acquisition by focusing on understanding topics rather than memorization, thereby allowing learners to understand when, where, and why to use information. It also seems important to enhance the adaptive skills of the learners, that is, the ability to creatively use the topic mastered in contrast to simply applying the subject matter effectively by supporting metacognition and a reflective view of learning [34]. More specifically, with regard to the use of digital technology, active cognitive processing must be supported without overloading the learner's cognitive abilities with computer technology [35].

Being Sensitive to the FUs' Cultural Context

People may not feel attracted to the eHealth tool if it does not match their beliefs, values, and habits. The use of photographs representing FUs and a variety of testimonies can support the cultural aspect of the tool [36,37].

Objectives

On the basis of Amartya Sen's theoretical framework of social justice, the objective of this paper was to explore how conversion factors can be integrated into an eHealth tool through a co-design project for caregivers of functionally dependent older persons.

Methods

Study Design

To attain this goal, the exploration of conversion factors will be carried out through a field project titled "Better meeting the needs of caregivers in providing safe home care for the functionally impaired older persons," which the research team informally refers to as *the QADA project* in recognition of the fact that it is funded by the Ministry of Families as part of the Age-Friendly Quebec Program (QADA). The project is led by a group of researchers whose intention is to include the social justice perspective in their project (see the protocol of this project for more details) [38]. The purpose of the QADA project is to develop an eHealth tool that facilitates the process of help-seeking for caregivers of functionally dependent older persons. The QADA project is based on a participatory design, more specifically, a co-design approach, and therefore meets the conversion factor that involves the participation of FUs in the development of the eHealth tool.

This study is qualitative in nature, with what can be described as a social justice design as the concept of social justice, based on the capabilities approach, is involved in all phases of the study [39]. It, therefore, aims to determine ways to integrate conversion factors in the development of the eHealth tool to make it inclusive for all caregivers of functionally impaired older persons.

Epistemological Posture

The epistemology of this study concurs with that of Miles and Huberman [40] in recognizing that social phenomena exist in a real world where regularities are observed and connections between them are established. Some of these observations, however, are based on human subjective experience. It also relates to the desire for social justice and the restoration of power among individuals. Finally, it supports the idea that knowledge develops in action, and as the purpose of this study was to obtain a solution to the problem, any potentially useful methods have their rightful place in it [41]. Thus, it could be said that this study is rooted in the pragmatic paradigm [42].

Research Sites

This study was conducted in 11 Quebec regions (Côte-Nord, Mauricie, Centre-du-Québec, Capitale-Nationale, Chaudière-Appalaches, Montérégie, Bas St-Laurent, Gaspésie, Outaouais, Montréal, and Laval). The locations of co-design sessions vary, depending on their availability (eg, municipal or community). The work sessions of the research team were held at the research center, sometimes in person and sometimes via Skype.

Population, Participants, and Selection Criteria

In this study, all QADA project co-designers were participants and were divided into 4 categories: caregivers, community workers, health and social service professionals (HSSPs), and research team members.

Caregivers

The population of caregivers of functionally impaired older persons is particularly interesting as it is a very diversified group of people (ie, rich, poor, young, not so young, having a variety of skills, etc) having in common the role of providing care to another person. In this study, caregivers of a functionally impaired older person are those who provide regular, unpaid assistance to a person aged 65 years and above and are a population group at risk of SHIs. Owing to the nature of their tasks, caregivers are more likely to develop physical and mental health problems [43-45]. Some of them are already at risk for SHIs (eg, low income, mental health issues, immigrant status, etc). Bucki [43] argued that caregivers with the lowest incomes had poorer health (ie, psychological and physical functioning, self-efficacy, lifestyle, family support, social capital, and physical and financial security). In addition, lack of resources, limited access to information, social exclusion, and exposure to harmful environments also affect both the caregivers and the elderly person they support and represent factors that create important SHIs [46]. Factors that increase the risk of burnout among caregivers (ie, ethnicity, language, gender, socioeconomic status, health literacy, age, poor education, history of depression, and high time consumption for care) are virtually the same factors that increase the risk of experiencing SHIs [47-49]. This means that caregivers at risk of burnout who need help are also those who are likely to experience SHIs and to be excluded from eHealth interventions. This has a double impact on social justice by dint of the caregivers' limited ability to take care of their own health, on the one hand, and to take care of the sick person, on the other hand. The latter is, therefore, also in a situation of injustice. Bucki [15] highlighted, in her study, the importance of continuing the fight against SHIs for caregivers.

Community Workers and HSSPs

Given their proximity to caregivers, the possibility of obtaining an additional perspective, and the desire that the tool developed be complementary to what already exists, the choice to integrate community workers and health and social services professionals as co-designers was relevant to the QADA project. Their participation in this study allows us to understand how professionals perceive conversion factors and wish to integrate them into the co-design process.

Research Team

The members of the research team are participants, and this is of key importance in this study insofar as the integration of conversion factors must rest on an epistemological and methodological choice made by researchers or designers that must be applied in a realistic and concrete way. Their point of view, which will be largely experiential within the QADA project, is therefore crucial for the implementation of the recommendations resulting from this study.

Number of Participants and Selection Criteria

A total of 78 co-designers participated in this project and are detailed as follows:

1. *Caregivers:* 30 caregivers participated in this project. In the context of this project, any person providing unpaid assistance on a sustained (weekly) basis to a functionally impaired older person was considered a caregiver.
2. *Community workers*: 26 community workers participated in this project. They had to provide services or interact directly with caregivers of functionally impaired older persons.
3. *HSSPs*: 18 HSSPs participated in this project. Similar to the community workers, the HSSPs had to provide services or interact directly with the caregivers of functionally impaired older persons. These professionals included nurses, nursing assistants, client care attendants, home care workers, occupational therapists, physiotherapists, physicians, social workers, and psychologists.
4. *Research team members*: The research team of the QADA project initially consisted of 8 coresearchers, whose participation varied based on their availability and their expertise. The members of the research team were involved in all phases of the project, and they included the QADA project director, an anthropologist and professional researcher, a user experience designer, and the author of this paper—a doctoral candidate in educational technology.

In line with the epistemological view of the author of this paper, she was involved in the study as a participant-observer [50]. That is, the author took part in the preparation of the co-design sessions by ensuring the participation of FUs and by exploring different ways of integrating conversion factors, facilitating the co-design sessions, debriefing co-design sessions, and developing the prototype from the results of the co-design sessions. In addition, once the co-design phase was completed, she listened to all the recordings of the preparation sessions, co-design sessions, and debriefings; condensed the data; and analyzed the results.

Recruitment

A secondary data analysis had been planned for and included in the QADA project protocol. As data collection for this study was based on the research team's work sessions and co-design sessions, no additional recruitment was expected. The researchers adopted a purposive sampling strategy. Community workers were recruited directly. For HSSPs, an email was sent to managers of the participating institutions, who put the team in contact with interested professionals. Caregivers were recruited through community workers and HSSPs. See the paper on the results of the project for more details [51].

Data Collection

To achieve the targeted goal, the review of conversion factors stretched over several stages of the QADA project:

1. Preparatory meetings for the co-design sessions (including the advisory committee) by the research team (n=24). These meetings provided information regarding the efforts made to ensure optimal mobilization of participants, obtain consensual decision making, and choose the information to be presented to take account of conversion factors. The resulting documents (co-design session planning) and the audio recording of these meetings were used as raw data for the analysis.

Table 1 presents the number of preparation sessions required for each of the co-design meetings.

2. Co-design sessions (n=8 co-design sessions and *n*=3 working sessions of the advisory committee). In these sessions, information relating to conversion factors was produced to support the effective utilization of the eHealth tool. The sociodemographic data of the participants (provided by them), the resulting documents (artifacts), the audio recordings (of subgroup activities), and the videos of these meetings served as raw data for the analysis. Details of each of the co-design sessions, also presented in a paper on the QADA project [51], are summarized in Table 1.
3. Co-design postsession debriefing meetings (n=11). These meetings helped *us* to quickly identify the perception of the researchers regarding the process and the conversion factors. Note-taking during debriefing and audio recordings also served as raw data for *the* analysis. These meetings took place immediately after each co-design session.

Figure 2 illustrates where this paper fits into the overall QADA project process (in italics).

Table 1. Content covered in the co-design sessions and the number of preparation sessions required.

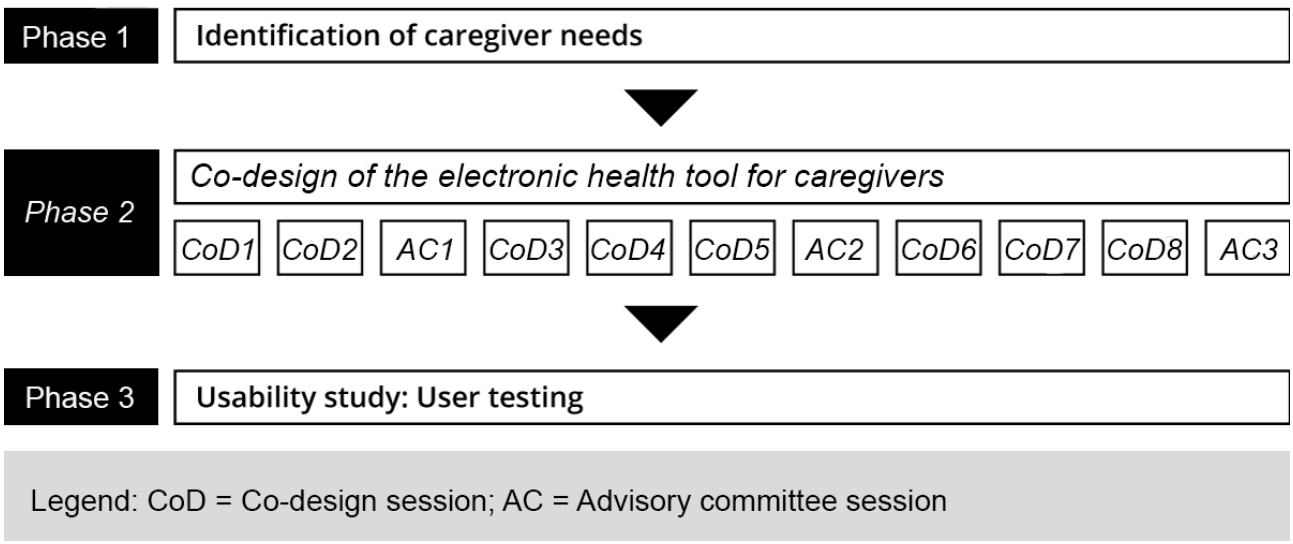
Working sessions	Number of preparation sessions that were required[a] (n=24)	Content of the co-design or advisory committee session
CoD1[b]	2	Identification of the needs that the tool must address
CoD2	1	Idem
AC1[c]	1	Final choice of needs and recommendations for further co-design
CoD3	1	Exploring existing functionalities that meet needs and identifying gaps between what exists and previously identified needs
CoD4	2	Brainstorming on the functionalities to address the needs that former attempts failed to meet
CoD5	3	Choice of functionalities to be integrated into the tool and development of the site architecture
AC2	1	Choice of functionalities that failed to draw a consensus
CoD6	3	Functionalities and content development
CoD7	5	Functionalities and content development
CoD8	3	Functionalities, content development, and pretest
AC3	2	Exploration of the prototype, choice of more or less realistic functionalities, and discussion on the content

[a]The number of preparation sessions was not defined in advance, but rather defined on an as-needed basis depending on the evolution of the prototype and the complexity of the analysis of the results.

[b]CoD: co-design sessions.

[c]AC: advisory committee.

Figure 2. Design Phase of the overall project.



Data Analysis

The analysis plan followed the method proposed by Miles and Huberman in 3 convergent analysis activities: data condensation, data presentation, and conclusions development or verification [52].

The purpose of data condensation is to "sort, distinguish, reject and organize data so that final conclusions can be drawn and verified" [52]. In this study, data condensation resulted in a written summary of each document and audio or video recording concerning the preparation of the co-design sessions, the co-design sessions themselves, and the debriefing. Consequently, an initial analysis was carried out to determine what will be reported in the summary document. This choice was made on the basis of the following question: Does what is said in the recording provide relevant information about one of the conversion factors? If so, then the extract was transcribed into a Word document. The reflections emerging in the process of drafting the summary were written in commentary mode. The documents were then imported into MAXQDA software (VERBI GmbH) [53]. MAXQDA is a qualitative analysis software that allows to analyze written documents as well as audio, photos, and videos. A deductive coding was performed to associate the content of the summary documents with the 7 conversion factors. The same extract can be coded with 2 factors. These conversion factors, although independently presented, have several areas of convergence. They were analyzed separately first to see how they will be operationally integrated into the development of the tool and subsequently for their co-occurrence.

Data presentation is an organized collection of information that also aims to draw conclusions. It is presented in the form of tables, cognitive maps, and matrices [52]. In this study, cognitive maps were used to understand how the conversion factors could be considered in the tool as well as the relationships among them. The data were presented in a tabular form to examine the flow of events, the importance given to the conversion factors according to the moment, and progression of the prototype [52].

The development and verification of conclusions occurs when the researcher makes sense of things [40]. These findings, however, need to be rigorously verified by peer review (intersubjective consensus) or by replicating one result into another set of data (triangulation) [40]. As the latter was difficult to produce in this study, the summary documents, cognitive maps, and tables were presented and discussed with the author's two thesis supervisors. In addition, the accuracy of the summary documents was verified by the other member of the research team (an anthropologist and research professional) who participated in the working sessions, co-design, and debriefing. Considering the large amount of raw data, she checked the accuracy of 10% (1/10) of the documents, at random. She also checked whether the content of the documents was consistent with her perception of the sessions. This study is the subject of a thesis, and it is, therefore, supervised by a thesis committee comprising 4 university researchers in the fields of education and health.

Ethical Considerations

This project was approved by the *Comité d'éthique de la recherche des Centres de santé et de services sociaux de la Vieille-Capitale* (Research Ethics Committee of the Health and Social Service Centers of the Old Capital). A monetary compensation of Can $20 (US $14.98) was given to each co-designer through the QADA project. The informed consent of each co-designer was obtained in writing.

Confidentiality of Data and Anonymity

The data were anonymized from the first level of analysis. All the study materials, including information, consent forms, and recordings, were kept in a locked filing cabinet in a locked room at the research center. The digital data were saved in encrypted files, on a secure server of Laval University, and access to it was protected by the use of a password available only to the members of the research team. Finally, all the materials and data will be kept for 5 years and then destroyed.

Results

Co-Designer Characteristics

A total of 78 co-designers participated in co-design sessions or advisory committee sessions. Table 2 presents the characteristics of the people who contributed to this study.

Table 2. Description of co-designers.

Sociodemographic characteristics	Caregivers (n=30)	Community workers (n=26)	Health professionals (n=18)	Research team (n=4)
Sex, n (%)				
Women	26 (87)	20 (77)	18 (100)	4 (100)
Men	4 (13)	(23)	0 (0)	0 (0)
Age (years), mean (SD)				
42-88	77.9 (11.0)	N/A[a]	N/A	N/A
24-66	N/A	44.8 (12.3)	N/A	N/A
29-53	N/A	N/A	39.6 (7.9)	N/A
33-45	N/A	N/A	N/A	40.7 (5.4)
Education level, n				
Elementary school	1	0	0	0
High school	10	1	0	0
College	4	4	6	0
Vocational studies	1	0	3	0
University	12	21	9	4
None	1	0	0	0
Not mentioned	1	0	0	0
Age of the relative (years), mean (SD)				
61-96	78.2 (9.9)	N/A	N/A	N/A
Relationship with the person cared for, n				
Children	8	N/A	N/A	N/A
Sibling	3	N/A	N/A	N/A
Spouse	17	N/A	N/A	N/A
Friend	2	N/A	N/A	N/A

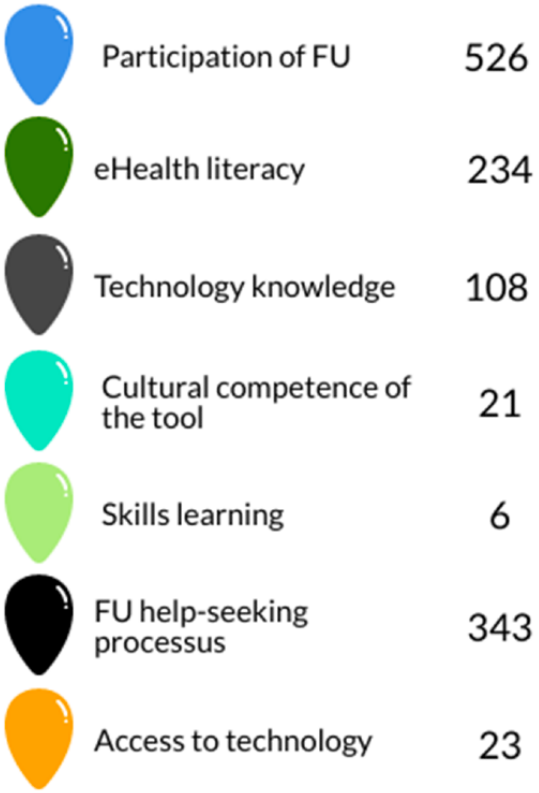
[a]N/A: not applicable.

Overview of the Presence of Conversion Factors in the Co-Design Phase

The initial segmentation generated 1257 analytical units. It can be seen that the conversion factors did not have the same occurrence in the development of the tool (Figure 3). Conversion factors were also represented unevenly over time (Multimedia Appendix 1).

The conversion factors, that is, FU participation, eHealth literacy, and the process of seeking help from the FU, were the most discussed in the co-design sessions. Each of these will be the subject of a full paper to reflect the wealth of knowledge resulting from this project. However, we will outline the impact of their integration into the eHealth tool.

Figure 3. Code list. FU: Future users.



FU Participation

FU participation in the design of the tool was the conversion factor that was present at all stages in a prominent way. This is partly explained by the team's concern not only by optimizing co-designers' participation during session preparations but also by respecting the choices they made during sessions. Decision making was coded under this conversion factor. A reflection on this participation and its effect was also the subject of discussion during the debriefing sessions. Co-designers (caregivers, HSSPs, and community workers) were offered the choice to work in large groups or small subgroups and in mixed groups or nonmixed groups (caregivers only, HSSP only, etc) and thus given equal opportunities for expression:

> *Small groups encourage discussion.* [Research team, preparation of CoD1]
>
> *In small groups, all participants spoke; this was not the case during the plenary session, where one participant did not speak at all.* [Research team, debriefing CoD3]
>
> *Caregiver who did not speak at all during the plenary session but who spoke +++ in small groups with other caregivers.* [Research team, debriefing CoD4]
>
> *We limit the workshops to 60 minutes and we do a plenary session to bring together what was covered in the workshops. We don't have to, but it's valuable to see the work of others. One person mentioned that there is no point in a plenary session where no decisions are made. We can hold a plenary session to make group decisions such as choosing the angle to use for the caregiver in the algorithm and let co-designers pick the workshop that most interests them. This way, many people participate in making choices on certain aspects and each person gets to work on what they are most interested in. This is valuable insofar as the groups are fairly balanced. We can add a representativeness criterion (caregiver, community worker, HSSP). We must therefore explain the workshops beforehand.* [Research team, preparation of CoD6]

eHealth Literacy

eHealth literacy was addressed at all stages of the co-design phase, but even more extensively in co-design sessions 6 to 8. This is due to the fact that several content creations were developed at these stages. The creation of content (including word choice and sentence constructions) and also the use of videos, what co-designers see when they look at the prototype, and the concern to have as little text as possible in the tool are manifestations of this conversion factor. There were also interesting discussions on the choice of common words (used by caregivers) versus the new terminology desired for certain diseases (eg, dementia vs neurodegenerative diseases):

> *The text is very heavy. The first thing I would do is click on the video.* [Caregiver CoD7]
>
> *I am insistent, but I would like "neuro-cognitive disorder" to appear (HSSP). Yes, but you're going to be the only one who knows what it means (caregiver). Caregivers will not know what it is.* [Can we put it in parentheses? (HSSP) CoD5]
>
> *HSSP: what do you mean by category of organization? Team member: it's a community*

> *organization, CLSC... Caregiver: you are academics. You have to speak in layman's terms.* [Team member: yes, it's literacy, the other group talks about that. CoD7]
>
> *Everything on the right has been omitted. We're talking about someone with technological skills. She eliminated what was placed on the right.* [Research team, debriefing CoD8]

Help-Seeking Process

The conversion factor related to help-seeking was significantly addressed in all co-design sessions. This is not surprising considering the nature of the tool that directly addressed this subject, the tool developed in the QADA project to support the process of help-seeking from caregivers. The co-designers provided input on this process at each phase during tool development, especially on the link between the process and the tool. For example, it was discussed that caregivers often sought formal services in a state of extreme emotional exhaustion. The co-designers, therefore, established as a guideline that the tool should provide targeted and complete results (with a brief description and telephone number) in 2 clicks. Consequently, the QADA tool was centered around the search box in the center of the home page:

> *I did a search on the X website. But sometimes it takes too long. We do it in the evening, we're already tired, it's too taxing. I think the project must ensure that we can get to the information rapidly and that we can take action rapidly.* [Caregiver CoD7]

Access (physical, technical, and financial) to eHealth, learning capabilities, technological skills, and cultural context were the conversion factors that were least addressed during the co-design phase of the tool. The results related to these conversion factors are presented in the following sections.

Providing Physical, Technical, and Financial Access to eHealth

Access to the tool, although less extensively addressed across sessions compared with other themes, remained a concern throughout the process for both the research team members and the co-designers. The access problems mentioned were based on the assumption that older persons may use technology less, that some people may not have the required skills to use it, or that people in vulnerable situations do not use the internet. Therefore, co-designers feel that the issue of access is linked to the eHealth literacy and technological skills conversion factors. We will return to the relationship between age and technological skills when we discuss this conversion factor:

> *Some people don't have access to the Internet. The fact that some people are not comfortable with the Internet has nothing to do with age. Of course, making a digital tool excludes people. We can't expect to reach everyone with this. Older adults include three generations.* [Researcher AC1]
>
> *Challenge to create a tool that responds to different people's skills and is interactive.* [Caregiver AC1]
>
> *Team member: You have to think of the isolated and vulnerable person, it has to be simple for them.*
>
> *Community worker: Well, if you think of the isolated and vulnerable person, well, they don't have the Internet. This doesn't make sense.* [CoD6]

The majority of the co-designers mentioned that alternatives to the eHealth tool should be provided for caregivers who do not have access to the internet or technology. Bookmarks with telephone numbers, advertisements, announcements, and posters were proposed to make the tool known to those who do not spontaneously search the internet or to contact someone directly to obtain answers about services for caregivers. Third-party intervention was also identified as a solution to accompany a person who would have an access problem such as a friend, neighbor, or pharmacist:

> *Caregiver 1: In the other advisory committee, it was said that we need a paper version. Caregiver 2: People can go to the library. Caregiver 1: People who provide home care will not take the time to do this.* [AC2]
>
> *It reminds me of a client who never uses the Web. For this person, it takes a third party, another person who will go online for him.* [Community worker CoD1]
>
> *It takes someone from his circle, a friend, for example, to help him with this.* [Caregiver CoD1]
>
> *You need someone who's close to him to help with this. The third party will use the tool.* [Caregiver CoD1]

In addition, co-designers mentioned that mobile technologies may be more accessible today and that the tool must be available for use with an electronic tablet and a smartphone:

> *It's useful. I did a lot of research on my tablet to find a neurologist and find out how to get my husband evaluated. It's useful because you group everything together. I would like it to be adapted for tablets.* [Caregiver CoD8]

To date, there is no alternative to the digital tool simply because it is not implemented yet and a transposition into a nondigital format would be hasty. However, it was designed to be used with an electronic tablet and a smartphone:

> *The alternative will depend on the type of tool developed, so we should wait until we have this information.* [Research team CoD3]

Respecting the Learning Capacities of FUs

Learning capacities were not addressed much for 2 reasons. The first reason is that the tool developed in the QADA project aims to support caregivers in their help-seeking process by helping them find services and by trying to establish contact with organizations. In this sense, eHealth is more of a search help tool than a learning process (even if it requires putting some effort into learning how to browse it). Besides becoming familiar with a new resource, few real-life learning situations are also presented in the tool. The second reason is that tool usability concerns have been further categorized into conversion factors related to digital literacy or technological skills. The motivation

and emotions to be considered in the learning process may have been included in the conversion factor related to the help-seeking process given the nature of the tool.

Being Sensitive to the FU's Cultural Context

The conversion factor related to the cultural context of the tool was explicitly expressed in one way. All co-designers mentioned the importance of making the tool available in several languages:

> *There are Anglophones in Quebec. The site will also be in English, right?* [Caregiver CoD5]
>
> *Will the tool be translated into several languages? Being able to use one's language is important to identify with the tool.* [Community worker CoD6]
>
> *Several languages: English, Innu, French. It's important.* [Community worker CoD1]

Among other things, the importance of having a tool in one's primary language was observed in a co-designing session where co-designers tended to reject sites that were in English because they could not understand them:

> *As soon as we see that it's in English, bye! We drop them right away.* [Community worker CoD3]
>
> *But in English, I won't read. I would just like some French.* [Community worker CoD3]

Developing an eHealth Tool that Values the Technological Skills of FUs

According to a number of co-designers, age appears to be the main factor explaining poorer technology skills:

> *The homepage needs to be simplified because caregivers who are seniors themselves are less familiar with technology and they may need to be able to get the information without registering. Many of them do not have an email address.* [Community worker CoD5]
>
> *Have you thought about the fact that older persons are not familiar with technologies? This is very important. I have met some people who are not at all skilled with computers.* [Caregiver CoD7]
>
> *Most caregivers are aged between 40 and 50. I'm my spouse's caregiver. Even people aged 65 and over are comfortable with the Internet. We must not be ageist. Yes, but there are caregivers who are 80 years old and who do not use the Internet at all. Yes, but these people are supervised, they can go to the library. There are numbers they can call to get help.* [Community worker CoD6]
>
> *The older persons we deal with are not tech-savvy. Forget social media such as Facebook, or email. We have to go to their homes. Phone is okay.* [Community worker CoD3]

As the participating caregivers of older persons were themselves seniors, there was a concern to make the tool as user-friendly as possible. This appeared prominently in discussions of co-design sessions 3 and 5, where the objective was to identify and choose functionalities for the QADA project tool. Some features have been discarded due to their perceived complexity:

> *I think most people will go on there and look for information without creating a profile. I'm not attracted to webinars. It's not something I'd do automatically. I am not part of this generation that watches webinars.* [Caregiver CoD5]
>
> *Wanting is not enough. A person in their fifties, who's used to the Internet, won't be scared; they'll be able to answer the questions and they'll get it. For someone who doesn't use computers, it must be as simple as possible.* [Community worker CoD5]
>
> *HSSP asked a caregiver if she would be comfortable with writing Caregiver: No, I would call. HSSP: Chatting and BOTS are excluded.* [CoD5]

Other features were chosen specifically to accommodate users with poorer technological skills:

> *I think of my elderly people who end up creating plenty of profiles because they get all mixed up. The tool must have a message that tells the user that their email address is already in the database but the password is incorrect, or that the email is not in the database so they don't create a new profile every time.* [Team member preparation CoD7]
>
> *Make clickable images and buttons obvious by putting them in 3D effect because clickable images are not used by older persons.* [Team member preparation CoD7]

Some members of the research team wanted to make sure that the tool would be useful both to people who feel at ease with technologies and to people who do not. Till now, they had the impression that participating co-designers had poor skills. Other team members saw this as an advantage because it allowed them to choose features that increased the chances of designing an inclusive tool:

> *It won't help us to have only caregivers who are not familiar with technologies. But it helps us to simplify as much as possible.* [Team members Debriefing CoD4]
>
> *To date, in our co-designs, it is still caregivers who make little use of the technology and will not use it in the process of help-seeking. This is the reality right now. This is the reality for the spouses, perhaps not the children.* [Team member Debriefing CoD4]

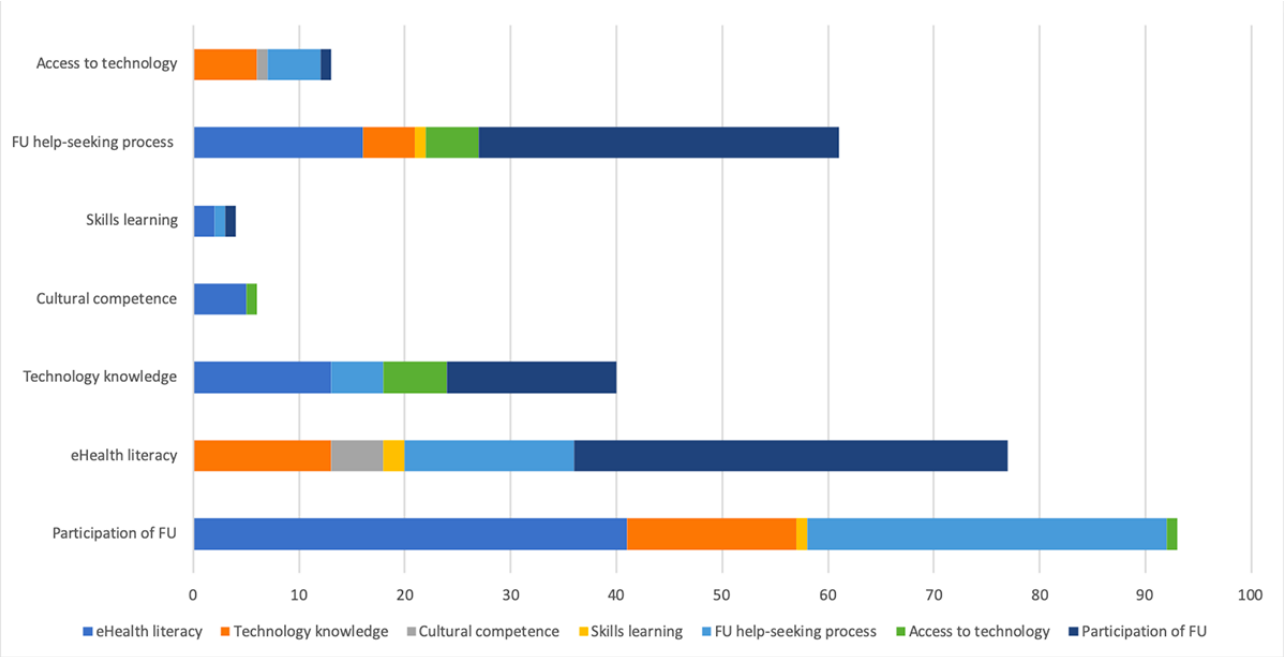
This concern is all the more relevant given that the profile of caregivers who use the internet is likely to change in the coming years:

> *[Speaking of BOT] Fifteen years from now, people will be more empowered and may be interested in this feature.* [HSSP CA2]
>
> *I don't know many caregivers who have iPads and who manage well with them. There are a few, but not many. Of course, caregivers today and caregivers in 20 years' time will not be the same.* [Community worker CoD8]

Convergence and Linkage Between Conversion Factors

Several verbatim extracts support more than one conversion factor. Figure 4 shows the co-occurrences between the themes.

Figure 4. Co-occurence between codes. FU: Future users.



As discussed earlier, less tech-savvy people may have difficulty using a digital tool. In this sense, several verbatim extracts have been categorized into these 2 conversion factors. The same applies to the process of help-seeking, which may be hampered by limited access to technology and poor technological skills. eHealth literacy is defined as the degree to which individuals have the capacity to obtain, process, and understand basic health information and services needed to make appropriate health decisions. Therefore, technological competence and the help-seeking process should be considered as literacy skills, as reflected in the categorization of verbatim extracts.

It should be noted that there is a co-occurrence of the conversion factor related to FU participation with the other conversion factors. It appears that understanding conversion factors such as eHealth literacy, technological skills, and the help-seeking process requires FU participation in the development of the tool.

Discussion

Principal Findings

The objective of this study was to explore how 7 conversion factors can be integrated into the design of an eHealth tool.

The results suggest that conversion factors can be integrated into the development of an eHealth tool at different levels. The technological skills of FUs can be taken into account when choosing the functionalities to be integrated into the tool and the format of the technology used (computer vs tablet). However, these decisions are not easy to make. In this project, the technological skills of caregivers ranged from poor to advanced. Some co-designers did not use technologies because they said they lacked the skills, whereas others indicated that they mastered them very well. One might think that co-designers' perception was biased by stereotypes related to poor technological competence among older persons. However, statistics show that 19% of adults believe that they have poor skills and they do not use the internet, suggesting that 81% of adults feel that they have moderate to good skills [28]. In addition, individuals' sense of competence tends to decline with age [28]. As designers, we must, therefore, juggle with heterogeneity in the FU's skills, while the eHealth tool is intended for the general public or, in this case, for caregivers. This leads to a dilemma faced by the co-designers about the exclusion of features that might have been useful for experienced users but prove to be too complex for neophytes, and also the expected evolution of individuals' technological skills in the years to come. Indeed, internet use by older persons in Canada has steadily increased between 2007 and 2016 [29]. The presence of more tech-savvy caregivers would have undoubtedly allowed us to discuss this dilemma with them. It would have been appropriate to evaluate the effect of the decisions made on the caregivers' perception regarding their technological skills during usability tests. Would the complex functionalities that were excluded in favor of more basic ones have allowed caregivers who felt they had poor to moderate technological skills to effectively use the tool? Could we have kept the tool very simple and user-friendly and still included more advanced features accessible to people willing to use them?

The conversion factor related to eHealth access was not addressed by co-designers in terms of access to efficient bandwidth, for example, in rural areas, or in financial terms, but rather from the angle of technological competence and eHealth literacy level. This may reflect the fact that in Quebec, financial or material access to eHealth is not perceived as a major problem. Nevertheless, we must remain cautious and vigilant to ensure that access to eHealth becomes universal because there is concrete evidence that internet access is not

globally available (especially in rural areas). Discussions with co-designers led to the exclusion of the use of technology for the so-called less competent individuals rather than adapting the eHealth tool or training them to use it. There seems to be a consensus among caregivers that they are not interested in using technology and that it will be necessary to supplement the tool to support them in their help-seeking process. One of the avenues discussed in this study is to have a third party use the eHealth tool to search for services. This possibility is of particular interest in the context of caregiving because one of the triggers for seeking formal services is also the intervention of a third party (paper in preparation). The third party would act as a mobilizer both to identify the services available through the eHealth tool and to encourage the use of formal services. The inclusiveness of the tool would be further enhanced by its availability to third parties, who can be friends, neighbors, pharmacists, and so on. Instead of referring to access, this conversion factor could be renamed *third-party assistance*.

The conversion factor related to the cultural context was minimally integrated by explicitly addressing the language. The integration of this factor goes further than simply making the tool available in several languages. Can it be argued that this conversion factor was implicitly integrated by involving the FU? Can we assume that the choices made by co-designers were necessarily in accordance with their beliefs, values, and habits? In the case of this experiment, there was little cultural variation among the co-designers as the majority were French Canadian, although this was not what was initially desired. The only variabilities present were related to the particularities of each region, which were integrated by selecting services by sector rather than by region, for example. However, as help-seeking is a process that varies from one cultural community to another, caregivers from an ethnic minority may not feel concerned by the tool [54]. Sen argued that the cultural dimension can only be respected by allowing for debate between users because individual cultural differences persist within the same cultural community [10]. Only the mediation between individual and collective preferences through debate can reconcile differences. The participation of the FU appears to be the way to integrate cultural context into the eHealth tool insofar as co-designers represent cultural diversity.

Similar to the cultural context, knowledge of the caregivers' help-seeking process was also made possible through the discourses of the co-designers, especially the caregivers themselves. Unlike other design methodologies where the FU is questioned punctually, co-design has allowed us to reflect on the process of help-seeking, which we may not have thought to address in an interview or questionnaire. Co-design allowed the tool to ensure that each of its development stages was consistent and adapted to the caregivers' help-seeking process.

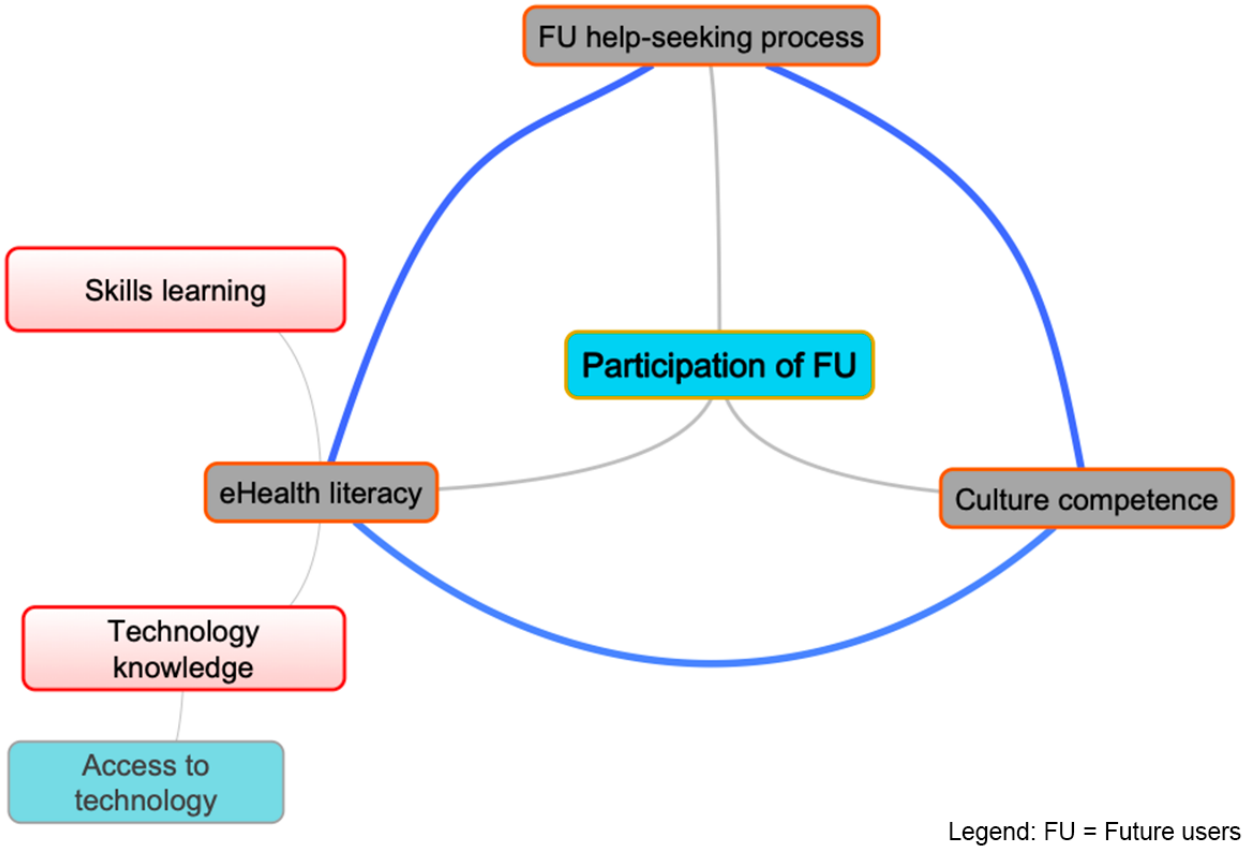
For eHealth literacy, the team used literature to help developers ensure that their tool would require no more than basic literacy. Elements include language, cognitive overload, and visual exploration by people with low literacy skills, among others, with cross-references to conversion factors such as technological skills and learning abilities. In concrete terms, it is through the content of the site (the choice of words and sentences) that we were able to keep the literacy level requirement to a specific level. However, the simple and refined nature of the tool intended by co-designers, especially in relation to the conversion factor related to technological skills, is also consistent with the principles found in the reference documents related to literacy.

In summary, conversion factors, particularly compliance with the desired eHealth literacy level, the help-seeking process, and cultural context, were integrated into the eHealth tool by the co-designers' discourse and, more importantly, by the caregivers themselves.

In future research on conversion factors, it does not seem useful to continue to focus on the 7 factors. A range of population-based measures are underway to ensure physical and financial access to technology, and a number of alternatives (eg, free access in shopping malls), although imperfect, are now available. Efforts should be streamlined to pressuring governments to guarantee access to technologies for all citizens in the same way that it ensures access to hydroelectricity, for example. However, it seems essential to continue to look for solutions to the access problems related to technological skills. Nevertheless, this issue can be addressed under the conversion factor related to eHealth literacy. According to some authors, eHealth literacy is composed of 2 types of skills: general skills that include traditional literacy (reading, writing, and numeracy), media literacy (media analysis skills), and information literacy (information seeking and understanding) as well as specific skills that include computer literacy (IT skills), health literacy (health knowledge comprehension), and science literacy (scientific processes and outcomes) [26,55]. Learning abilities, eHealth literacy level, and technological skills of FUs are closely related; it is, therefore, difficult to distinguish the respect of each separate element. From an operational perspective, eHealth literacy assessment could include technological skills as well as, perhaps, learning abilities.

If we had to map the conversion factors to be considered in the development of an eHealth tool to date, here is what it would look like (Figure 5).

Figure 5. Relationship between conversion factors.



The participation of the FU would be the central conversion factor that allows the integration of the other conversion factors. Learning abilities would likely be an integral part of the concept of eHealth literacy. However, the risk associated with this integration would be to leave out the findings generated by the project from the perspective of education and cognitive science about learning in the digital context. The interconnectedness of access to technology, technological skills, and eHealth literacy may raise questions about whether these conversion factors are all necessary or whether they could be functionally grouped under a single concept. However, similar to learning abilities, there would be a risk of losing all the knowledge related to these concepts, each of which could be the subject of future research.

Scientific Quality of the Study

The rigorous approach of this study is based on the scientific quality criteria identified by Guba and Lincoln [56] for the field of qualitative studies.

Credibility and Dependability

To ensure the credibility and dependability of the study, data collection was spread over a period of 1.5 years and it involved a variety of participants (caregivers, community workers, HSSPs, and research team members) having various profiles (gender, age, comfort level with technology, etc). In addition, various data were collected from the recordings of the preparation, co-design, and debriefing sessions. The consistency between data and results is supported by the supervision of 2 researchers (the author's thesis supervisors), one of whom was not involved with the project. The reader was invited to judge the consistency between the verbatim excerpts and the results presented. In addition, the links between the data (synthesis documents) and the coding (deductive and inductive) were also made available to the supervisors. Finally, the synthesis documents were verified by theoretical triangulation and by researchers (KL and MC).

Transferability

Transferability was ensured by producing as complete a description as possible of the contexts related to the research process, including the profile of the participants. The reader will, thus, be able to determine the degree of transferability of the results of this research in other contexts.

Dependability and Confirmability

The first author (KL) used a reflective approach by highlighting her preconceived ideas, participating in each debriefing meeting, and adding comments to the documents.

Limitations

This study has some limitations. As already mentioned, cultural diversity could not be represented through co-designers, which limited the possibility of studying the conversion factor in relation to the cultural context. In addition, the caregivers who participated as co-designers were mostly retirees and hence not representative of caregivers among the active population. These caregivers could have influenced the study of conversion factors related to the help-seeking process, technological competence,

and eHealth literacy. Similarly, most of the caregivers recruited were already service users. Caregivers at the beginning of the help-seeking process could also have contributed to the study of the process-related conversion factor. Although in line with Quebec statistics, where the majority of caregivers are women (approximately 58%) [57], as is the case for community workers (approximately 80%) [58] and health service providers (approximately 64%) [59], there was no variability regarding gender in our sample. It is possible that greater gender diversity could have influenced the occurrence of conversion factors. Another limitation, and recommendation, for those who wish to develop an eHealth tool with conversion factors is the participation of information technology resources, programmers, and so on as co-designers and team members. This would help them to become familiar with the viewpoint of other co-designers such as caregivers. It would also allow co-designers to better explore the various possibilities offered by functionalities to meet the needs of the caregivers. However, the sharing of decision-making power in such a context will need to be rigorously monitored.

Finally, the evolving nature of the project related to the development of an eHealth tool and the inherent chronology meant that data saturation was not obtained for each of the conversion factors. However, this was anticipated given the exploratory nature of this project.

Benefits of the Project

This project contributed to the empirical exploration of 7 conversion factors and to the modeling of the relationship among them. Bonvin and Farvaque [13] argued that the link between resources (capital) and capabilities (ie, conversion factors and free choice) is poorly developed by Sen and requires more empirical exploration. Thus, although the strength of the capability approach is to capture social injustice, it provides little evidence as to how to practically address social injustice in communities [60]. This point is also supported by Lorgelly [61], Bonvin [62], and Kleine [63], who pointed out the absence of a modus operandi (planning, implementation, and evaluation). Thus, this project has contributed to operationalizing Sen's theoretical framework of social justice in a digital context and further developing the concept of conversion factors.

Conclusions

Conversion factors can be integrated into the development of eHealth tools that are intended to be inclusive and contribute to the reduction of SHIs by integrating the participation of FUs into the design of the tool. However, there is currently no way for the developers of the eHealth tool to rapidly and effectively ascertain whether these conversion factors are well integrated into the development of their tool. The growing development of eHealth around the world, especially in this time of a pandemic, and the governments' commitment to combating SHIs provide a unique opportunity to reflect on good practices for an inclusive and healthy digital society. To pursue this reflection, it will be important to identify empirical indicators that can measure these integration factors during and after eHealth tool development and guide developers in the designing of inclusive eHealth tools and educational technology that genuinely contribute to reducing SHIs.

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Conflicts of Interest

None declared.

Multimedia Appendix 1
Conversion factors over time.
[PNG File , 121 KB - humanfactors_v7i3e18120_app1.png]

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Abbreviations

FU: future user
HSSP: health and social service professional
QADA: Québec ami des aînés (Age-Friendly Quebec Program).
SHI: social health inequality

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Review

Novel Interface Designs for Patient Monitoring Applications in Critical Care Medicine: Human Factors Review

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Abstract

Background: The patient monitor (PM) is one of the most commonly used medical devices in hospitals worldwide. PMs are used to monitor patients' vital signs in a wide variety of patient care settings, especially in critical care settings, such as intensive care units. An interesting observation is that the design of PMs has not significantly changed over the past 2 decades, with the layout and structure of PMs more or less unchanged, with incremental changes in design being made rather than transformational changes. Thus, we believe it well-timed to review the design of novel PM interfaces, with particular reference to usability and human factors.

Objective: This paper aims to review innovations in PM design proposed by researchers and explore how clinicians responded to these design changes.

Methods: A literature search of relevant databases, following the Preferred Reporting Items for Systematic Reviews and Meta-Analyses guidelines, identified 16 related studies. A detailed description of the interface design and an analysis of each novel PM were carried out, including a detailed analysis of the structure of the different user interfaces, to inform future PM design. The test methodologies used to evaluate the different designs are also presented.

Results: Most of the studies included in this review identified some level of improvement in the clinician's performance when using a novel display in comparison with the traditional PM. For instance, from the 16 reviewed studies, 12 studies identified an

improvement in the detection and response times, and 10 studies identified an improvement in the accuracy or treatment efficiency. This indicates that novel displays have the potential to improve the clinical performance of nurses and doctors. However, the outcomes of some of these studies are weakened because of methodological deficiencies. These deficiencies are discussed in detail in this study.

Conclusions: More careful study design is warranted to investigate the user experience and usability of future novel PMs for real time vital sign monitoring, to establish whether or not they could be used successfully in critical care. A series of recommendations on how future novel PM designs and evaluations can be enhanced are provided.

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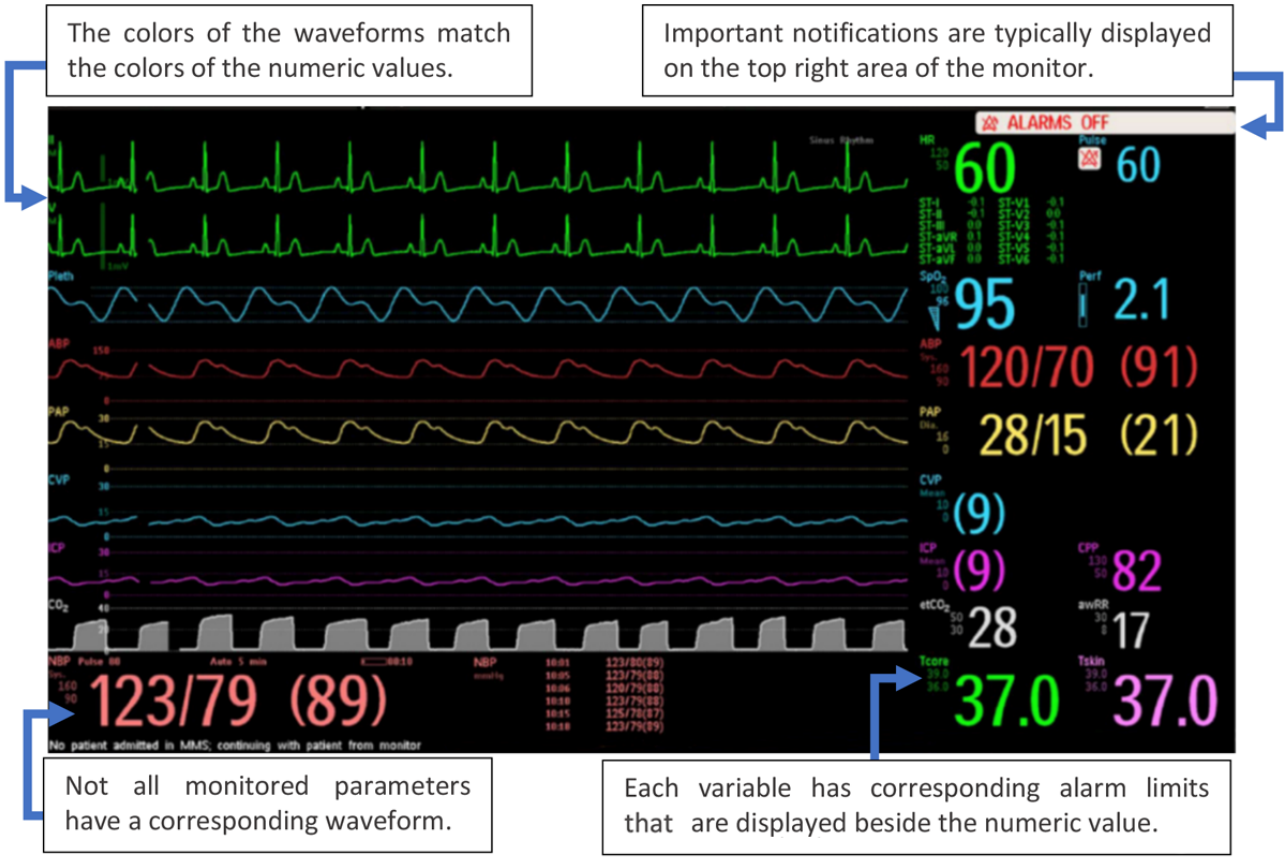
KEYWORDS

interface design; usability; situation awareness; graphical display; satisfaction; response time; accuracy; anesthesiology; critical care; performance; ecological display

Introduction

The patient monitor (PM) is one of the most commonly used medical devices in hospitals. It is used to monitor patients' vital signs in a wide range of patient care environments. A typical PM interface is composed of two main elements: the waveform and the numerical values of the monitored parameters (Figure 1). The waveform element displays the analog signals for each parameter for a few seconds in a line graph. The numerical values element, on the other hand, represents the calculated value for each parameter in a numeric format and these values are continuously updated every few seconds or milliseconds, depending on the parameter. However, not all monitored parameters are displayed in both waveform and numeric form. For instance, noninvasive blood pressure (NIBP) is not continuously measured; hence, only the numerical value is presented, and this reading is updated every time this vital sign is measured according to clinical requirements.

Figure 1. Example of a commercial patient monitor interface (Philips IntelliVue MX series). Each vital sign is color-coded (waveforms and numerical values). Depending on the make and model, additional information might also be displayed alongside the numerical values (eg, configured alarm limits and previous values for noninvasive blood pressure as seen in the image). The image was added with the permission of Philips. ABP: arterial blood pressure; awRR: airway respiratory rate; CPP: cerebral perfusion pressure; CVP: central venous pressure; $etCO_2$: end-tidal carbon dioxide; HR: heart rate; ICP: intracranial pressure; NBP: noninvasive blood pressure; PAP: pulmonary artery pressure; SpO_2: blood oxygen saturation; Tcore: core temperature; Tskin: skin temperature.

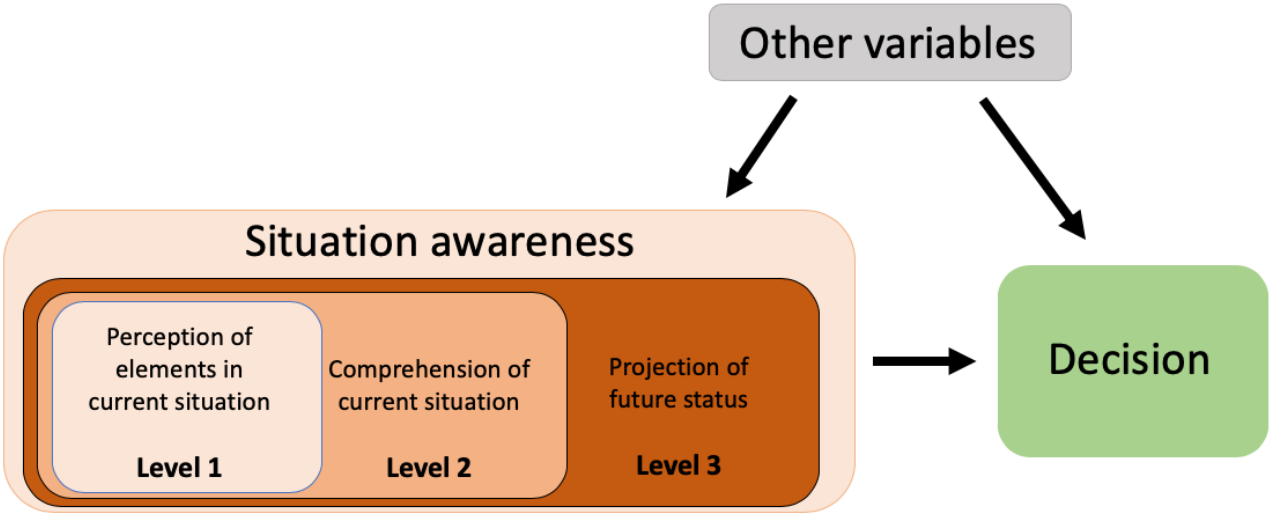


The context in which PMs are used includes any clinical environment in which clinical caregivers provide critical care to patients. Such environments include the intensive care unit (ICU), emergency department, operating room (OR), cardiology unit, and during the transportation of a patient. Within these contexts of use, regular assessment of vital signs is crucial to identify patients at risk of serious adverse events as early as possible. During an anesthesia procedure, for example, the anesthesiologist needs to be able to quickly identify the changes in vital signs, whereas, in the ICU, if any of the vital signs become abnormal, nurses need to be immediately warned. In both cases, any delay in providing appropriate care or in making a clinical decision might result in severe consequences for the patient.

In such contexts of use, it is not uncommon for the primary users of a PM (nurses and doctors) to be under extreme pressure in terms of time, cognitive workload, and stress [1,2]. Correct decisions related to patient care based on information provided by the PM may need to be made in a short time. Coupled with this is the prevalence of work-related fatigue in these environments, which may increase the risk of use error when interacting with the PM [3]. For this reason, novel PMs need to reach the highest standards in usability and human factors, thereby facilitating enhanced user interaction and preventing potential risks related to use error. Good usability in medical device design is essential in avoiding potential risks associated with use error, as evidenced by the publication of standards documents such as IEC 62366-1/2, ANSI/AAMI HE75 and ISO 9241-210 210 [4-6]. HE75 makes frequent reference to the importance of usability engineering in the design of PMs. Usability is defined in ISO 9241-210 (section 2.13) as the "extent to which a system, product or service can be used by specified users to achieve specified goals with effectiveness, efficiency and satisfaction in a specified context of use" [6]. The study of human factors (section 2.5) is defined as "the scientific discipline concerned with the understanding of interactions among human and other elements of a system, and the profession that applies theory, principles, data and methods to design to optimize human well-being and overall system performance" [6].

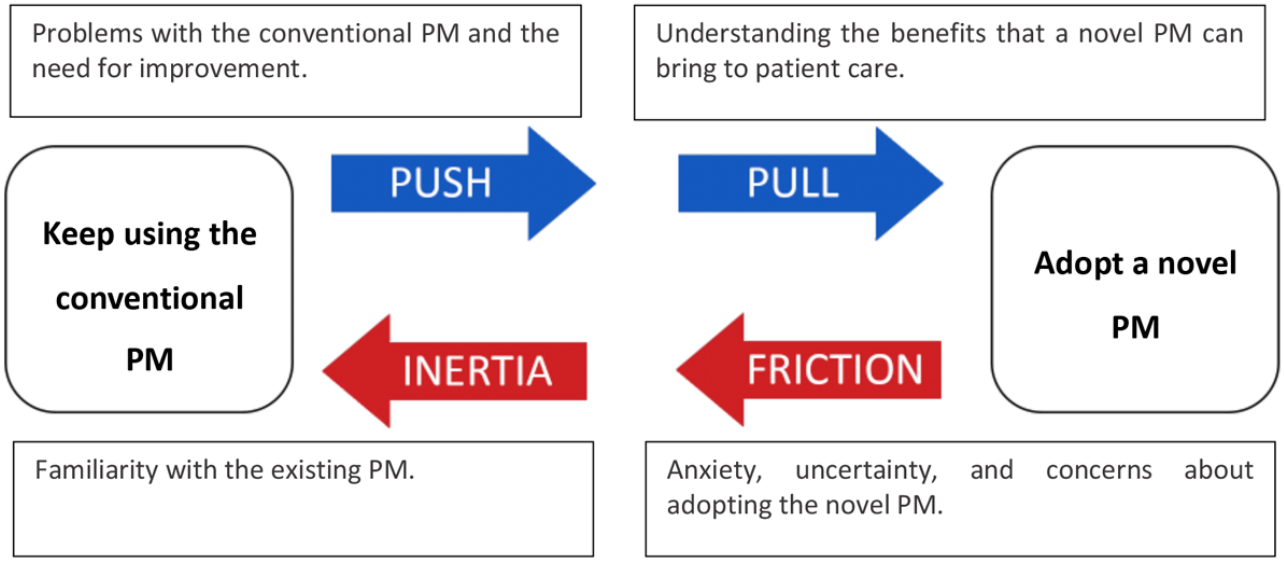
Given the importance of the decisions made in the critical care environment in response to displayed vital signs, it is imperative that PMs display the required information in a user-friendly manner to enable clinicians to fully comprehend the patient's status. This level of comprehension will be referred to in this work as situation awareness (SA). According to Endsley [7], "Situation awareness is the perception of the elements in the environment within a volume of time and space, the comprehension of their meaning, and the projection of their status in the near future." The concept of SA applies to many mission-critical tasks in various fields (eg, aviation, nuclear power plants, military combat systems, etc). In the context of using PMs in critical care medicine, SA level 1 (perception) is associated with the ability of the user to perceive the changes in vital signs; SA level 2 (comprehension) is associated with the ability of the user to understand the patient's state based on the vital signs; and SA level 3 (projection) is associated with the ability of the user to predict the patient's future state based on the current state. The flow of the SA process is illustrated in Figure 2.

Figure 2. Part of the situation awareness model in dynamic decision making presented by Endsley (1995). This reflects how situation awareness influences decision making.



By fulfilling user requirements related to usability and SA, designers can significantly increase the chances of a novel PM being adopted by end users. However, there are natural barriers to the adoption of new technologies that need to be considered. For instance, familiarity with conventional monitoring tools and uncertainty about the novel PM are forces that contribute to the reluctance of clinicians to adopt a new approach. Therefore, for a new PM to be adopted, end users need to identify considerable benefits that the PM can deliver, in conjunction with a low burden of adoption [8]. Inherent in critical care medicine and PM design, in particular, is a high resistance to design changes by clinicians. This reluctance is based on their concern that changes to the status quo in terms of PM design can result in an increased risk of clinical errors [8]. This balance of forces, involved in the adoption of a new PM, is illustrated in Figure 3, which is adapted from a concept presented by Maurya (2017) in *The Science of How Customers Buy Anything* [9].

Figure 3. Balance of forces acting on the decision making of the clinicians when deciding whether to adopt a novel patient monitor for critical care or continue using the conventional patient monitor .



The specific aims of this paper are to review innovations in PM design proposed by researchers and to explore how clinicians responded to these new designs with a focus on usability and SA. The ultimate goal of this review was to review the design of new PM devices, designed to deliver improved usability and SA for nurses and doctors and hence the reduced likelihood of use error–induced risks to patients [10].

Methods

Article Selection

The literature search included data up to June 2019 with no cutoff on the start date. Search terms were chosen to reflect the review focus. The article selection was conducted in 2 phases: an initial search based on the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) guidelines, followed by a search of the references within each of the previously identified papers. The PRISMA guidelines were used to identify relevant studies. The search was conducted with 7 relevant databases (Scopus, IEEE Xplore, PubMed, Science Direct, CINAHL, Cochrane Library, and Engineering Village) using the search terms presented in Textbox 1. Articles were further excluded after title, abstract, and full paper analysis by members of the multidisciplinary team. The papers included in this review were analyzed using a narrative synthesis approach.

Textbox 1. Search terms used in the database search. The search terms are grouped into 3 categories: patient monitor, usability, and hospital settings.

Patient_Monitor: “patient monitor” OR “patient display” OR “vital sign* monitor” OR “vital sign* display” OR “monitor* display” OR “physiologic* monitor*” OR “physiologic* display”

AND

Usability: “human factor*” OR “usability” OR “ergonomic*” OR “human error” OR “UX” OR “user experience” OR “interaction design” OR “interface design”

AND

Hospital_Setting: “hospital” OR “intensive care” OR “ICU” OR “critical care” OR “operating room” OR “emergency department” OR “cardiology” OR “neurology” OR “oncology” OR “obstetrics”

Inclusion and Exclusion Criteria

This review focused on the design and usability of prototype devices from research laboratories that were designed to overcome identified problems with commercial PMs. In this regard, the inclusion and exclusion criteria for this review were as follows:

- Studies published in English appearing in peer-reviewed academic sources.
- Studies that include user testing, comparing the performance and user experience of participants when using the novel prototype display and the traditional monitoring equipment. Studies that merely described the design of the prototype were not included in the review.
- The subjects participating in the experiment must be the intended users of the device (eg, ICU nurses or anesthesiologists). Studies in which participants were not the intended users (eg, undergraduate students) were not included in this review.
- The prototype display and the devices used as controls must be designed for real-time physiological monitoring. Therefore, novel prototypes that were designed specifically for trend and medical record analysis were not included.
- The prototype display must be a visual display designed for critical care use. Novel wearable prototypes such as

tactile, head-mounted, and smartwatch displays were not included because this category of PM warrants a separate literature review focusing on wearable PMs. In addition, studies in which the focus was to test an enhanced algorithm with no meaningful enhancement on the user interface were not included.

The summary of the studies reviewed is presented in Multimedia Appendix 1. The selected studies were assessed regarding bias risk using an adaptation of the well-established Cochrane Collaboration tool for randomized controlled trials and crossover trials [11]. The results from the quality assessment are presented in Multimedia Appendix 2.

Results

Table 1 provides a breakdown of the article search. The initial database search (including title, abstract, and keywords) yielded 136 articles. After the removal of duplicates and filtering by title, abstract, and full-text review, 10 items were included from the PRISMA search, and 5 additional items were identified during the reference search. Therefore, the final number of publications incorporated for review was 16. A summary of these publications is presented in Multimedia Appendix 1.

Table 1. Demographic characteristics of SEM survey respondents.

Database	Patient_Monitor search results	(Patient_Monitor search results) AND (Usability search results)	(Patient_Monitor search results) AND (Usability search results) AND (Hospital_Setting search results)
Scopus	11,720	249	69
PubMed	32,029	190	62
IEEE Xplore	131	4	1
Science Direct	3396	123	8
Cumulative Index to Nursing & Allied Health Literature	333	8	3
Cochrane Library	2928	14	8
Engineering Village	308	12	5
Number of publications identified	50,714	596	156
Remaining publications after removing duplicates	N/A[a]	N/A	136
Remaining publications after title assessment	N/A	N/A	83
Remaining publications after abstracts assessment	N/A	N/A	61
Remaining publications after full-text assessment	N/A	N/A	10
Additional publications found by references assessment	N/A	N/A	6
Publications included	N/A	N/A	16

[a]Not applicable.

Graphical and Integrated Displays

Graphical displays (GDs) are designed to integrate the discrete vital signs from the PM into one or more multidimensional objects to facilitate improved assimilation by the clinician of the patient's current state [12]. The concept seeks to take advantage of the natural human perception capability to detect changes in shape and color and use this capability as a means to convey relevant information effectively and efficiently. GDs and ecological displays (EDs) have been studied for complex, high risk, and data-rich environments such as commercial aviation control and power plant management [13,14] before the investigation of their use in health care.

Gurushanthaiah et al [15] performed one of the first studies to analyze the effect of GDs on patient monitoring performance. They did not develop a novel interface to enhance patient monitoring; rather, the authors tested 3 different displays that were available on a commercial anesthesia machine, the Ohmeda Modulus CD. The purpose of the study was to investigate with which display format anesthesiologists would perform better in terms of response time and accuracy. The displays tested were the numeric, histogram, and polygon displays. In each case, the displays monitored variables such as heart rate (HR), arterial blood pressure (Art), NIBP, blood oxygen saturation (SpO_2), expired (end-tidal) partial pressure of carbon dioxide (CO_2), and the percentage of inspired oxygen (O_2).

The numeric display (Figure 4) is considered a conventional display because each variable is presented in a numeric form using the single-variable-single-indicator approach, as used in

a traditional PM. The main differences between this numeric display and the traditional PM are the arrangement of the variables, the presence of waveforms, and the lack of color-coding. Therefore, the user had to rely solely on the numbers and labels to assimilate the information. The histogram display also displayed the numeric values of the variables as in the numeric display; however, it also graphically presented the variables in the form of a *bobbin* sliding up and down on a linear scale as the value of the variable changed (Figure 5).

The histogram display depicted 7 variables in the form of scaled linear *tapes*, where a *bobbin* indicated the value of each variable on the vertical scale. The *bobbin* moved up and down proportionally on the linear scale as the value of the variable changed. The numeric value for each variable was also displayed directly below the linear scale (Figure 5). In addition, the normal range for each variable was represented by the dark region inside the graph. The polygonal display integrated 6 of the 7 variables (excluding O_2), with each of the 6 variables forming a vertex of a hexagonal-type figure, occupying less space than the histogram graph. At each vertex of the hexagon, a bar indicated the maximum and minimum values reached by the parameter. As the variable changed value, the vertex moved along this bar. The dotted line indicated the *ideal* value for the variables; if the variable exceeded or was less than this value, then the vertex moved to a position where the resulting shape was a distorted hexagon (Figure 6).

Figure 4. Numeric display (a model of the concept presented in the paper).

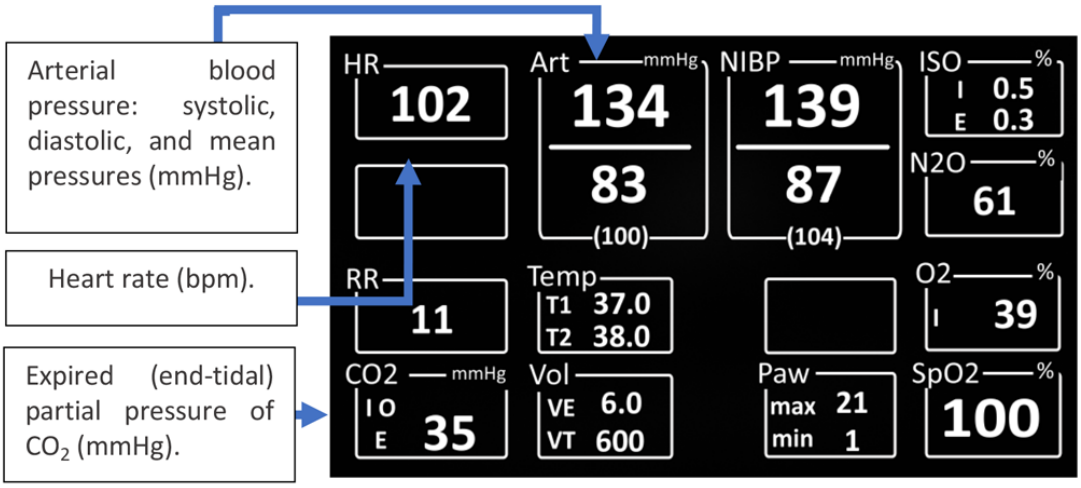


Figure 5. Histogram display (a model of the concept presented in the paper).

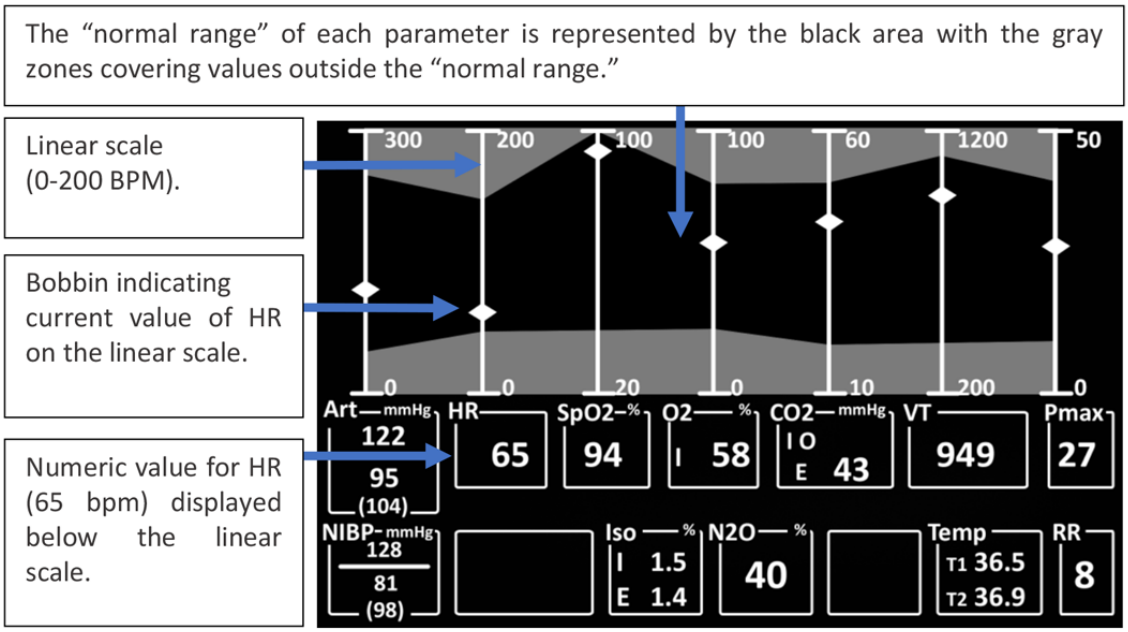
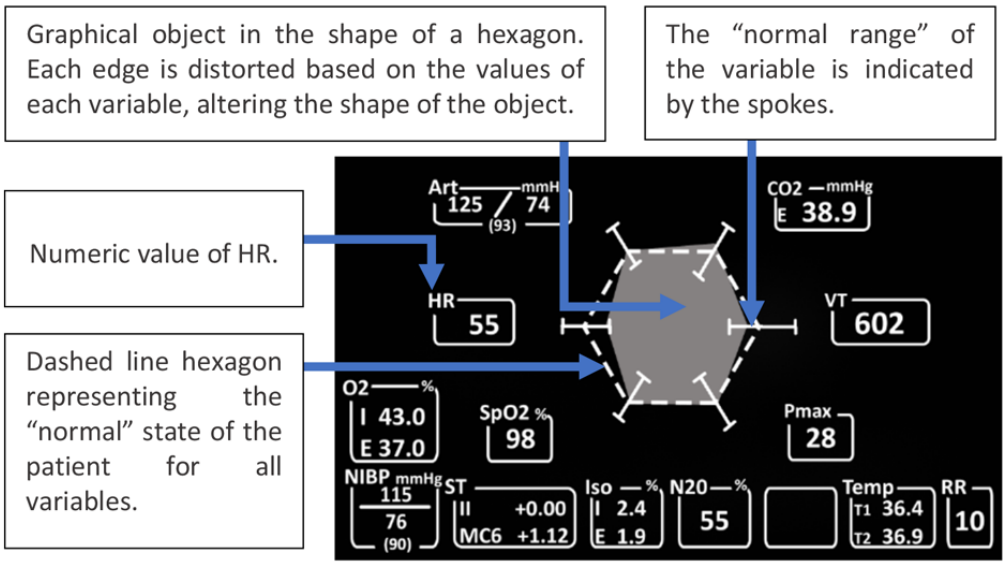


Figure 6. Polygon display (a model of the concept presented in the paper).



Thus, the shape of the gray element in the display was indicative of the patient's current state, and the users of the interface would be able to perceive the patient's state based on the amount of deviation of the gray hexagon shape from the dashed line hexagon.

A total of 13 anesthesia residents were trained to use the displays and were asked to test the 3 different simulated data visualization formats. Participants were asked to indicate when they noticed a change in the variables and if the change was an increase or decrease in the variable value. It was observed that the response time and accuracy were significantly higher when the anesthesia residents used the graphic displays (histogram and polygon) in comparison with the numeric format. Although the order in which the displays were exposed to each participant was randomized, the randomization method was not detailed. This makes it difficult to judge whether the results were biased by carryover effects.

These positive results supported the use of GDs by anesthesiologists. However, within a few years, the polygon display option was removed from the next-generation Ohmeda Modulus CD anesthesia machine, as only a very small number of their customers used it. This finding motivated researchers to query the reason for the reluctance of clinicians to adopt this new approach. According to Drews and Westenskow [12], the difficulty of new displays in having to overcome user inertia could have contributed to the failure of the polygon display. This kind of inertia is a natural barrier to the adoption of new technology in critical care, where lives are at stake and users are more comfortable working with tried and tested interfaces. Another contributing factor may have been related to data visualization difficulties. To create a regularly shaped polygon when the patient's state was normal, the spokes for each monitored variable had to be scaled at equal lengths. With this scaling, a significant change in one variable could be less perceptible than a significant change in another variable, thereby creating a risk of an anesthesiologist missing a critical event and putting the patient in danger [12]. This obvious usability problem highlights the importance of user testing with experienced end users who have a greater chance of flagging such problems before a device is released in the market.

Michels et al [16] evaluated a custom-designed integrated GD (IGD), designed for anesthesia monitoring. The IGD (depicted in Figure 7) integrated not only the related variables from the same device but also data from different devices such as a PM, mechanical ventilator, and infusion pumps in a graphical manner.

On first exposure, this display may look overwhelming to the user because of the high number of variables presented on the display. To allow the user to interpret the display more efficiently, Michel et al [16] arranged the display elements from left to right based on the flow of gases and drugs through the body. The idea behind this strategy was to provide the clinician with an intuitive visualization that mapped the display element to the relevant human body system. The variables related to the respiratory system, such as inspired and expired tidal volumes, peak airway pressure, positive end–expiratory pressure (PEEP), and respiratory rate, were displayed on the left side, followed by cardiovascular, drug delivery, and fluid management variables toward the right of the display (Figures 8 and 9, respectively). In addition, color-coding was used for related variables, as shown in Figure 9.

The displays depicted in Figures 7 and 8 illustrate a patient in a healthy state. However, the levels of some variables could decrease or increase and exceed the threshold (vertically or horizontally). The anesthesiologist was able to detect the changes and abnormality of the parameters based on the distance of the actual levels of the variables from the threshold lines. The representation of the display by Michel et al [16] monitoring abnormal values is shown in Figure 10.

Figure 7. Michels et al (1997) display used to monitor 30 variables from a range of monitoring devices (a model of the concept presented in the paper). This display represented a patient in a normal state with all variables in acceptable levels including all labels, scales and units.

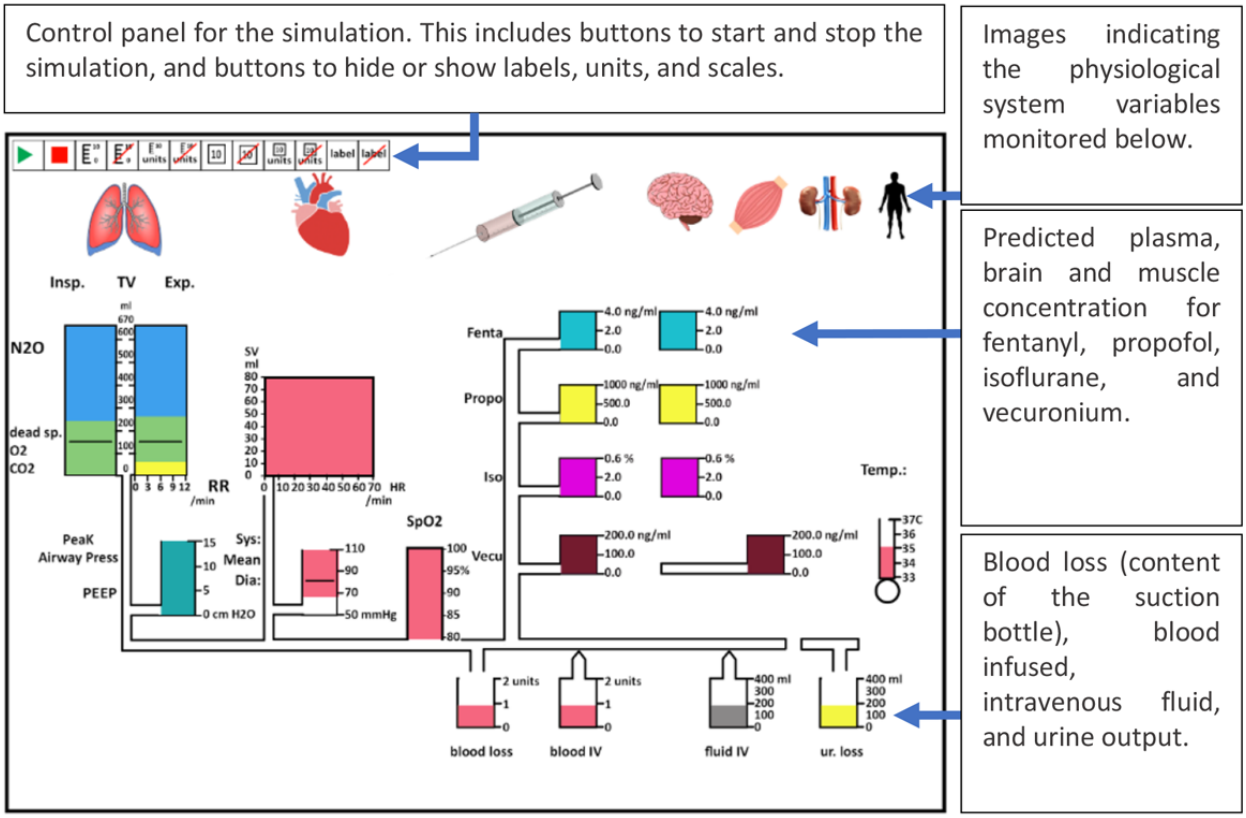


Figure 8. Respiratory system variables. The thresholds (represented by the black lines) for the vital signs and drug delivery indicating the acceptable levels for these variables.

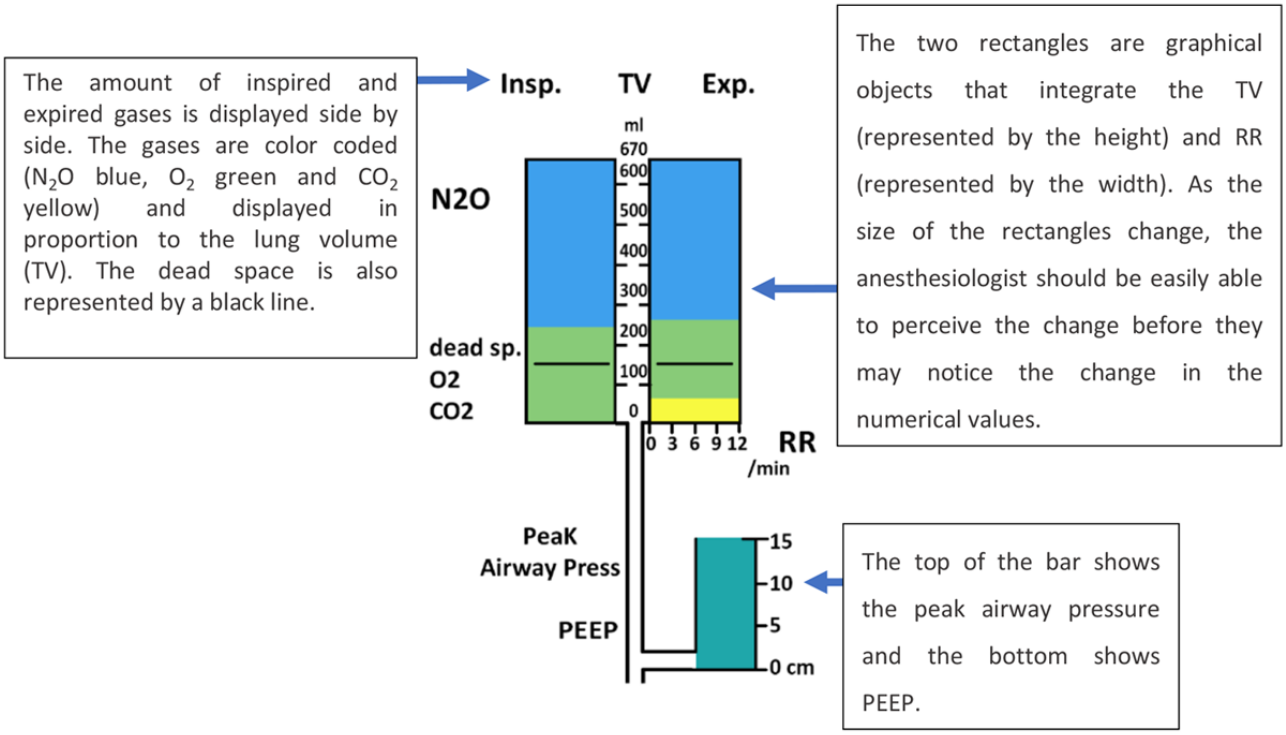


Figure 9. The cardiovascular system variables had the same colors.

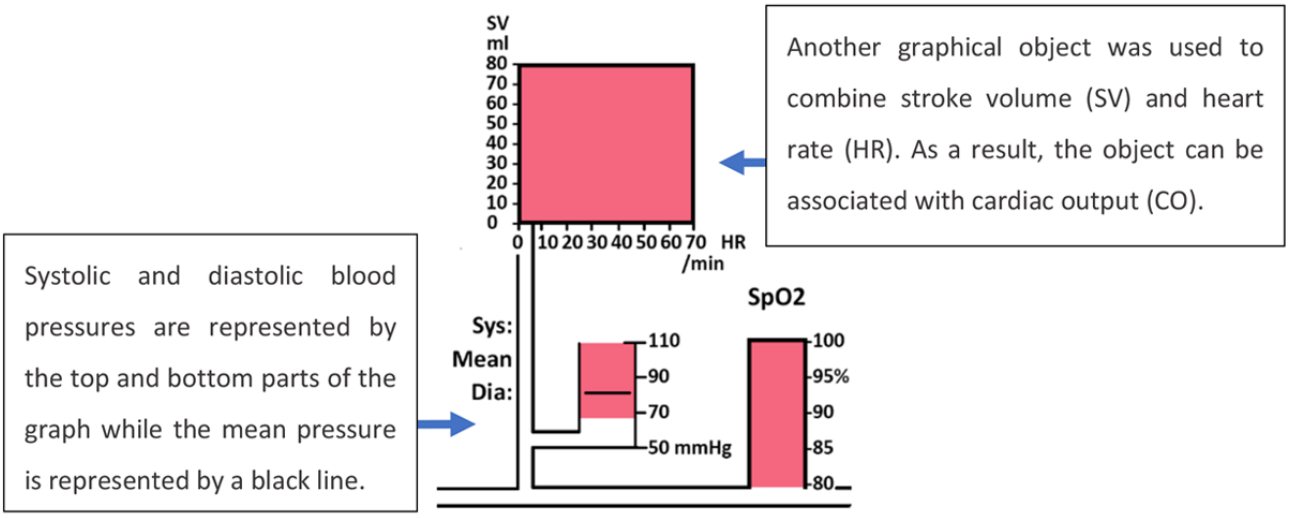
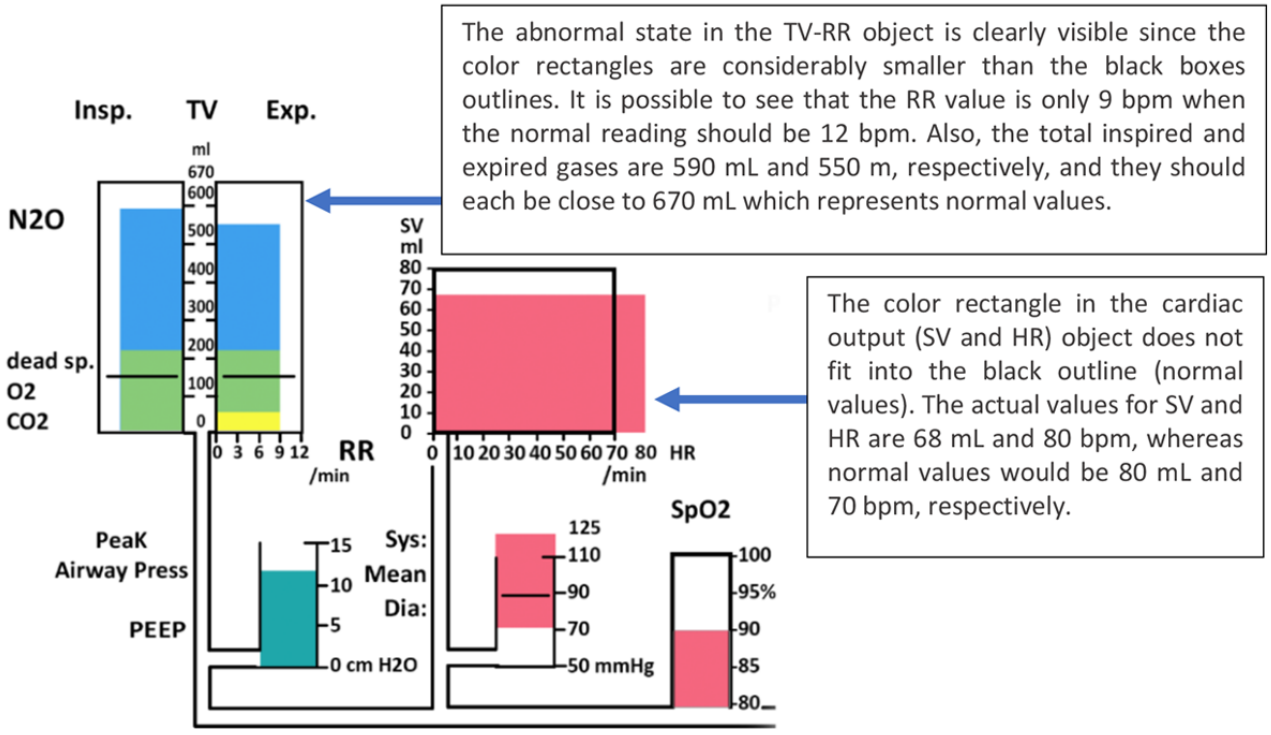


Figure 10. The display by Michels et al showing abnormal monitoring values in the respiratory and cardiovascular systems (a model of his concept).



Ten anesthesiologists were asked to monitor a simulated patient in 4 different scenarios (blood loss, inadequate paralysis with spontaneous ventilation, cuff leak, and depletion of soda lime). Five anesthesiologists were asked to use the display by Michel et al [16], and 5 anesthesiologists used an anesthesia simulator (Body Simulation, Advanced Simulation Corporation) simulating a traditional PM. The results of the testing varied depending on the scenario used. For example, when participants used the IGD, the detection time was significantly shorter only for 2 scenarios (inadequate paralysis and cuff leak) and accurate event identification occurred significantly sooner only in 3 scenarios (blood loss, inadequate paralysis, and cuff leak).

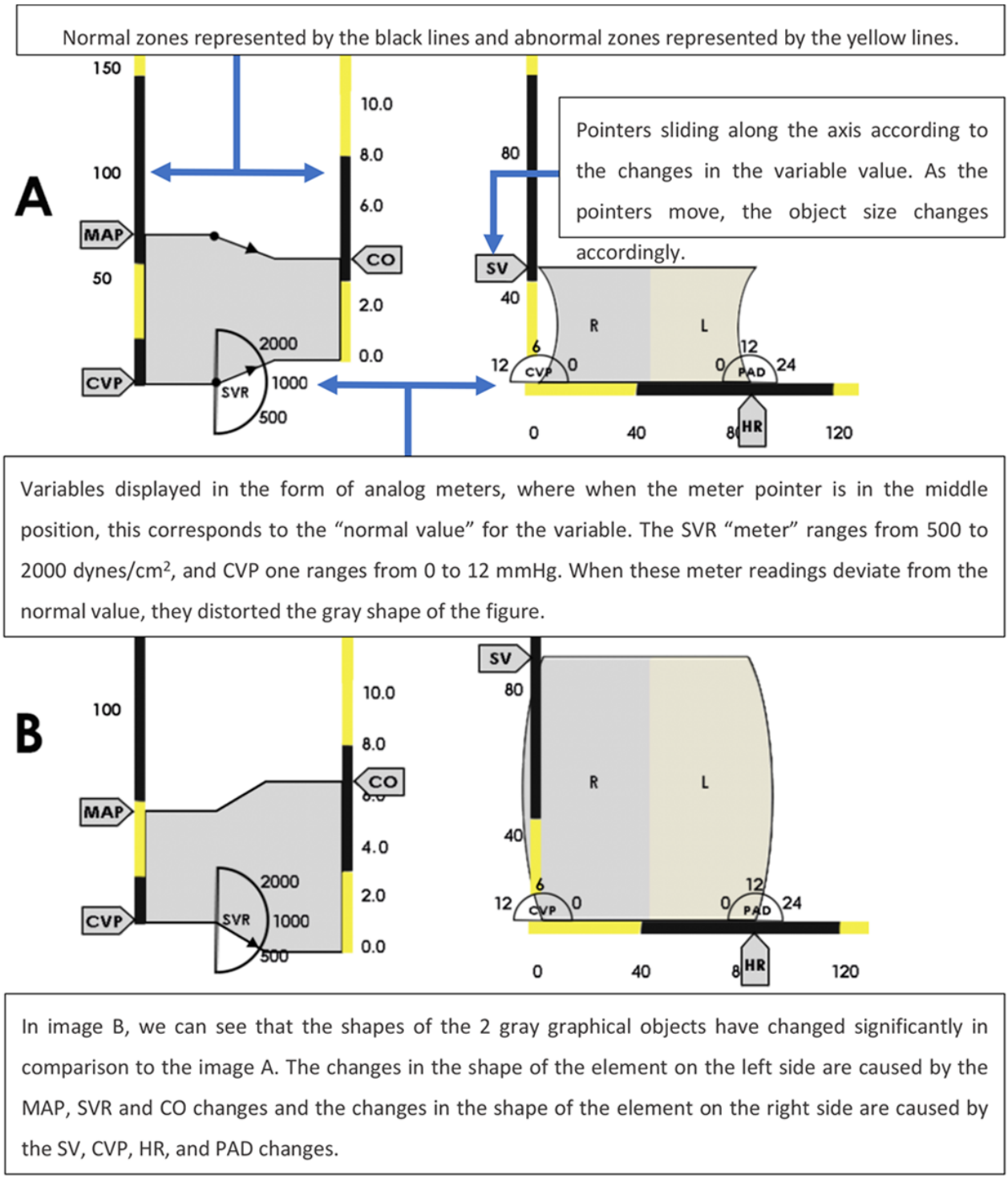
This study demonstrated that IGDs have the potential to enhance the response time of anesthesiologists. The IGD presented in this study displayed all the information required by the anesthesiologists on a single screen, giving it an obvious advantage over conventional PMs under real-world conditions, where anesthesiologists would need to acquire information from multiple sources. For example, the anesthesiologist may have to ask the nurse to read the quantity of the blood collection bottle and measure the urine output.

The experimental design may have favored the IGD in this study as participants using the simulator in the experiment had to toggle through 4 screens on a single monitor to obtain the full range of clinical information, thereby influencing their response time with the simulator. This does not reflect the real-world conditions that the anesthesiologists would encounter, where all information would be simultaneously available on separate displays.

Another factor that might have affected the experiment was that participants from both groups were given a short introduction training session on the relevant display before the experiment commenced for approximately 15 min. Although all the questions were answered after the introduction, a short training session may not be sufficient to acclimatize clinicians to a completely new display, especially considering that the participants had never seen the IGD or used the body simulation system before.

Blike et al [17] developed and evaluated a cardiovascular GD designed to support anesthesiologists to perform a diagnostic task rapidly and correctly. Before the development of the display, the authors interviewed cardiac anesthesiologists to generate a decision model of how experts diagnose cardiac shock and determine its cause. Designers then developed the GD presented in Figure 11 based on the decision model created.

Figure 11. The graphical display by Blike et al contained 2 graphic objects that change shape and size depending on the changes in the values of the variables (a model of the concept presented in the paper).



Blike et al [17] sought to improve the usability of their novel interface by arranging the elements on the screen in a meaningful manner. The GD was composed of 2 graphical objects, as shown in Figure 11. A new concept introduced by Blike et al [17] was the use of meters (gauge icons). In this concept, variables such as systemic vascular resistance (SVR), CVP, and diastolic pulmonary artery pressure (PAD) were presented in the form of meters with arrows indicating the values of these variables, with an arrow position at 12 o'clock, representing a normal value. Blike et al [17] compared the performance of this GD to an alpha-numeric display showing only the numeric values for blood pressure (BP), HR, CVP, PAD, and cardiac output (CO).

Using a between-subjects design, 11 anesthesiologists were presented with 10 scenarios (5 without cardiac shock and 5 with cardiac shock). Participants committed fewer diagnostic errors when using the GD in comparison with the alpha-numeric control display. The recognition of the patient's condition was also completed faster when using the GD. However, the authors reported that all participants used the control display first followed by the GD. This indicated a high risk of carryover effects, which could have contributed to biased results.

Interestingly, the authors reported that after a brief initial exposure to the GD, most participants expressed confusion regarding the display and “found it to be too complicated” [17]. Considering that Blike et al [17] brought new concepts to the display, such as the meters and graphical objects, it is therefore natural that such an innovative display would cause some level of discomfort for users on first exposure. As the use of the GD resulted in improved performance metrics according to the study, it would be interesting to know if extended exposure to this interface would be sufficient to overcome the reported negative initial impressions.

In a follow-up study, Zhang et al [18] compared the GD developed by Blike et al [17] with a commercial PM display. The study sought to investigate whether the use of the GD by Blike et al [17] could enhance the accuracy and response time of clinicians and whether it could also increase clinicians’ SA during the type of dynamic situation occurring in real practice. Zhang et al [18] developed 4 scenarios for the experiment: hypovolemia, arrhythmia, ischemia, and bronchospasm. Overall, 12 anesthesiologists (residents and faculty members) were asked to use the display by Blike et al [17] as the experimental display and a commercial PM (Datex AS/3 anesthesia monitor) as the control display. Participants were introduced to the new GD during the training phase. SA level 1 (related to the perception of the patient’s current state) and SA level 2 (comprehension of patient’s current state) were measured by routinely pausing the simulation and administering a questionnaire to the participant about the status of the variables displayed on the monitor. A higher number of correct answers indicated a higher level of SA.

The results showed that the anesthesiologists improved their detection time for the bronchospasm scenario, but no significant differences were found for scenario recognition time between the control and experimental displays. Level 1 SA was higher in the control condition during the arrhythmia, hypovolemia, and bronchospasm. Level 2 SA was higher for GD during the hypovolemia scenario. It is not clear whether the order of displays tested was randomized; therefore, it is not possible to confirm whether the results were affected by the carryover effect. In the same article, Zhang et al [18] presented the results from a second experiment involving a 3D IGD. However, insufficient information was provided in the study to fully understand the operation of this 3D GD, and the participants who tested the interface were not anesthesiologists; therefore, it was not discussed in this review.

Agutter et al [19] developed a display designed for cardiology monitoring. The GD had the format of a 3D pipe, used as a metaphor for a blood vessel, as presented in Figures 12 and 13. Similar to the IGD by Michel et al [16], this GD also arranged the variables in a metaphorical manner to diagrammatically mimic physiological blood flow through the circulatory system. For example, central venous pressure (CVP) is the first element displayed as the deoxygenated blood flows to the vena cava. This blood flows through the pulmonary arteries to the lungs. Hence, the pulmonary artery pressure is displayed next in the sequence. After oxygenation, the blood flows to the left side of the heart and is then pumped into the aorta. Therefore, left atrial pressure (LAP) and mean arterial blood pressure (MAP) are the elements in the sequence. Other variables monitored by the display include pulmonary vascular resistance (PVR), HR, stroke volume (SV), CO, SVR, and arterial blood oxygen saturation (SaO_2).

Figure 12. The cardiovascular graphical display by Agutter et al (2003) showing the vital signs of a patient in a normal state (a model of the concept presented in the paper).

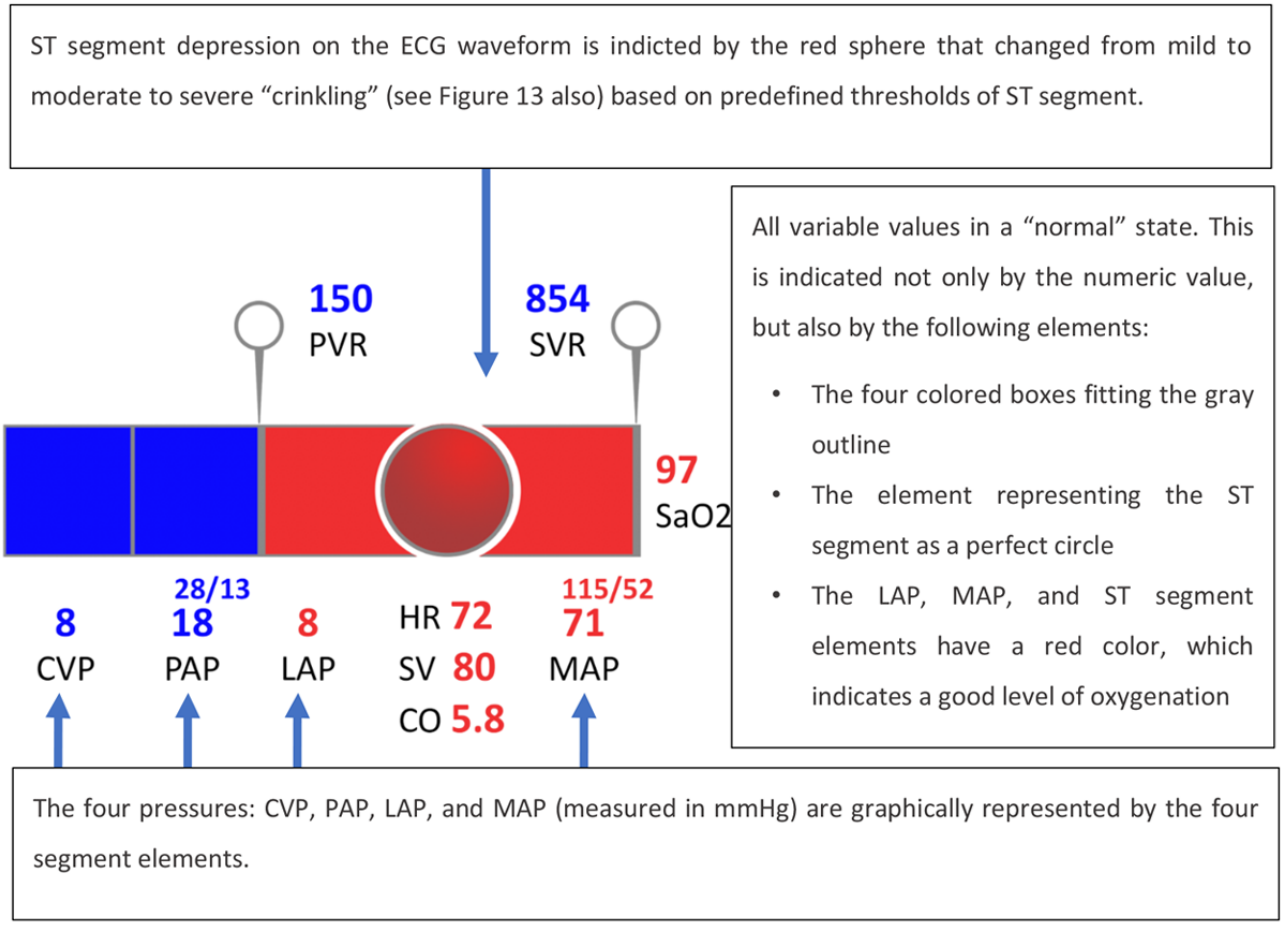
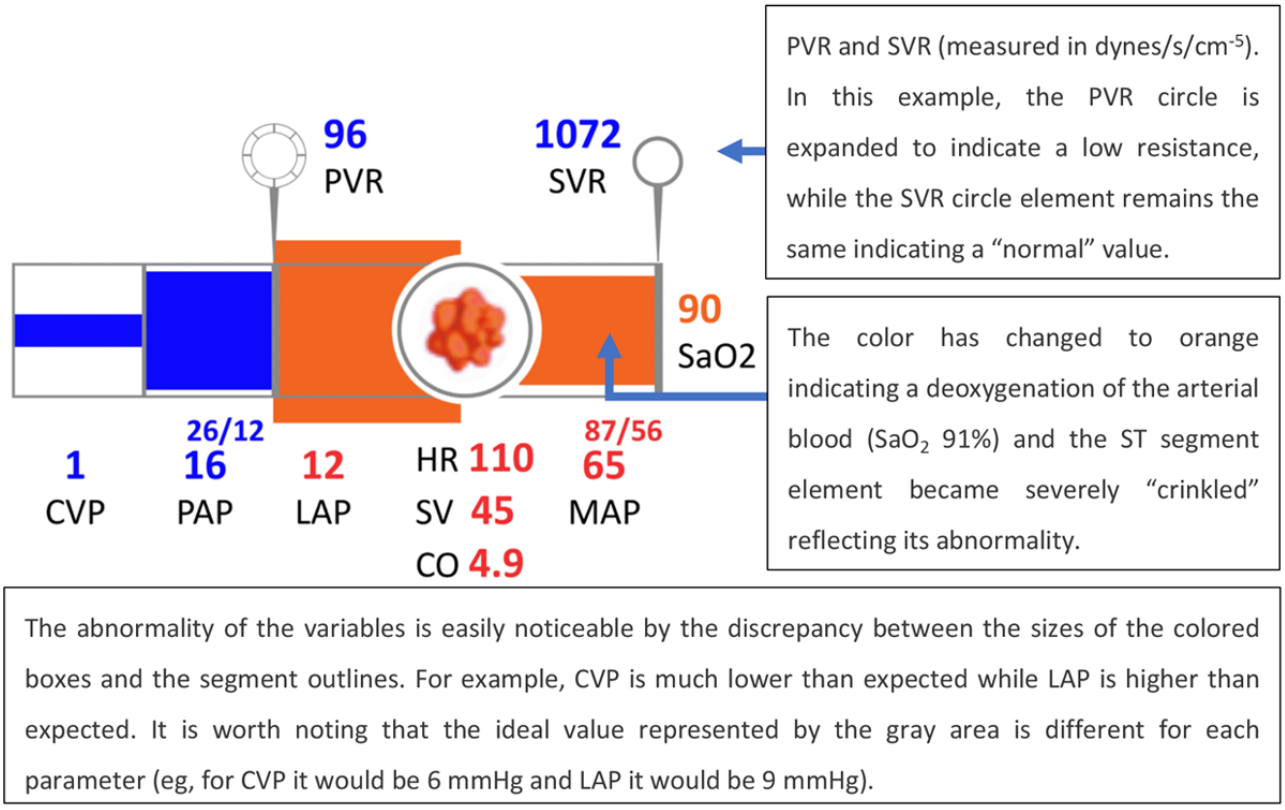


Figure 13. The cardiovascular integrated graphical display by Agutter et al (2003) showing the vital signs of a patient during myocardial ischemia (a model of the concept presented in the paper).



Numeric values for each variable were presented directly below their respective segment, and the height of each segment was directly related to its value. The oxygenation level (SaO_2) was indicated by the color change from deoxygenated (blue) to oxygenated (red) after passing through the lungs.

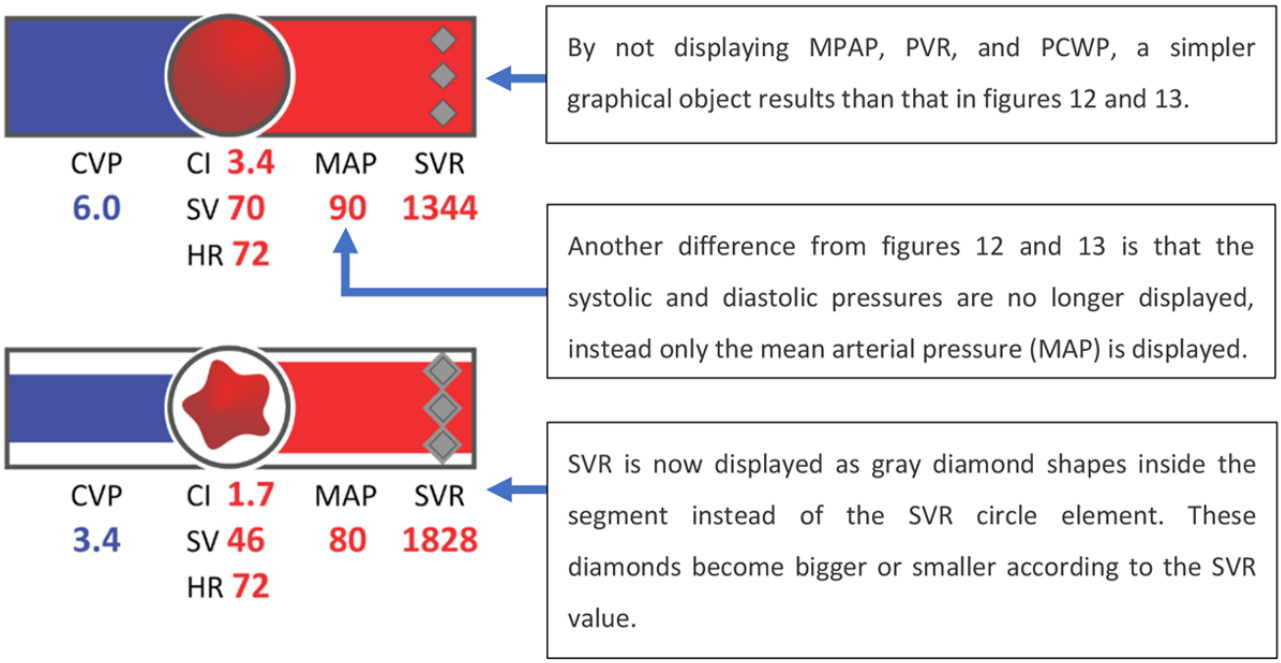
A total of 20 anesthesiologists were invited to participate in the testing and were asked to assume care of a simulated patient (an instrumented mannequin connected to the monitor) in a high-fidelity simulation. Of them, 10 participants used GD as the experimental display and 10 participants used a numeric monitor, showing real-time values for the same variables appearing on the GD, as the control display. In addition, both groups used a commercial PM (Datex AS/3 monitor) in its full operating mode. Two scenarios were developed for the experiment: (1) total hip replacement with a transfusion reaction to mismatched blood and (2) a radical prostatectomy with 1.5 liters of blood loss and myocardial ischemia. The results show that participants using the GD could detect and treat ischemia faster than participants using the control display in the second scenario. It was also observed, for each scenario, that participants who used the GD finished the scenario with CVP and SaO_2 values closer to the baseline values than participants using the control display. In the first scenario, participants did not detect the anaphylaxis faster, as expected, with the authors observing that changes in SVR and PVR could have helped in making this diagnosis. However, the changes in these display elements were not noted by the participants. This led to a redesign of these elements to improve their salience (as presented in Figure 14). In this study, the authors commendably strived to create an environment and context of use as close to real-world conditions as possible, in contrast to some of the other studies reviewed in this study. This led to important problems with the display being uncovered, allowing designers to solve the interface deficiencies that led to use errors.

As this GD was designed to be used in conjunction with a commercial PM, as an additional screen in the OR, it was important to investigate whether this new information source could affect the clinician's workload and mental demand. Participants were asked to answer a NASA Task Load Index (NASA-TLX) questionnaire, which is used to evaluate the self-perceived workload. Although participants had only a brief introduction to the GD before the experiment (approximately 15 min), the authors did not report significant differences in the workload ratings between the GD and control displays. This indicates that the novel display was successful in conveying information without imposing additional physical or mental demands on the clinician.

As a follow-up, Albert et al [20], from the same research group, evaluated the display developed by Agutter et al [19]. The rationale for this experiment was that, despite the positive results in the experiment by Agutter et al [19], regarding the time to diagnose and treat myocardial ischemia, Albert et al [20] identified some limitations in the experiment by Agutter et al [19]: (1) the IGD was evaluated in only 2 scenarios, (2) investigators recording the participants' actions were not blinded to the presence or absence of the IGD, and (3) the display by Agutter et al [19] required the use of a pulmonary artery catheter (PAC) to obtain the CVP, pulmonary capillary wedge pressure, cardiac index, and SVR values, when it is not a part of routine monitoring for most anesthesiologists. The purpose of this new

study was to address these limitations and broaden the applicability of the display, presenting it in 2 formats: with and without PAC-derived data. The representation of IGD without PAC-derived data is shown in Figure 14.

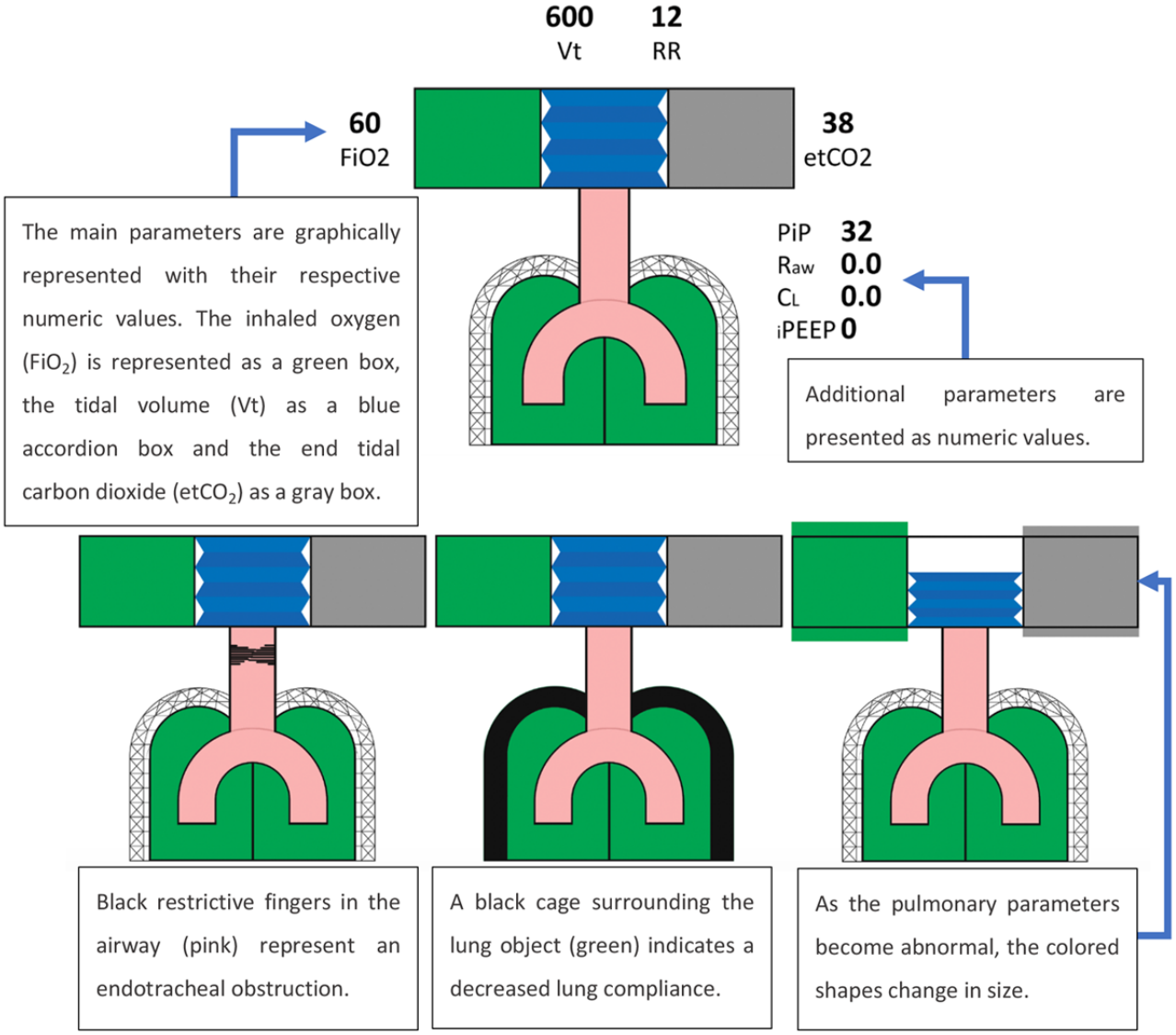
Figure 14. The integrated graphical display by Albert et al (2007) without pulmonary artery catheter data (a model of the concept presented in the paper) displaying the patient in a normal state and during myocardial ischemia.



A total of 16 anesthesiologists and anesthesia residents participated in the new evaluation, 8 participants in the intervention group (using a commercial PM and the GD) and 8 in the control group (using a commercial PM and only the numeric values from the GD). Six scenarios were developed for the experiment: 3 without PAC-derived data (hypertension because of inadequate analgesia, myocardial ischemia, and hemorrhagic hypovolemia) and 3 with PAC-derived data (left ventricular failure, septic shock, acute respiratory distress syndrome, and myocardial ischemia). Two experts were invited to rate the participants' performance from best (rank 1) to worst (rank 16) in terms of accuracy, timeliness, and quality. Unlike in the experiment by Agutter et al in 2003 [19], in this case, the experts were blinded to the display used by the participant, which reduced the risk of detection bias.

Wachter et al [21] developed a GD that presented the respiratory parameters for patients who were intubated and mechanically ventilated. The pulmonary GD displayed the parameters by making use of the anatomical shape of the lung (Figure 15). A total of 19 anesthesiologists, split into control and intervention groups, were asked to assume care of a simulated patient midway through a surgical procedure in a simulated OR. The simulation was composed of conventional monitoring equipment (a traditional PM), an anesthesia machine, and a cart containing airway management equipment. Both groups had access to the standard displays, but the intervention group also had access to the pulmonary GD on a 17-inch monitor.

Figure 15. The figure at the top depicted pulmonary graphical display in which pulmonary variables are within the normal range. The design included a graphical display and numeric values. Examples of abnormal pulmonary variables are represented at the bottom (a model of the concept presented in the paper).

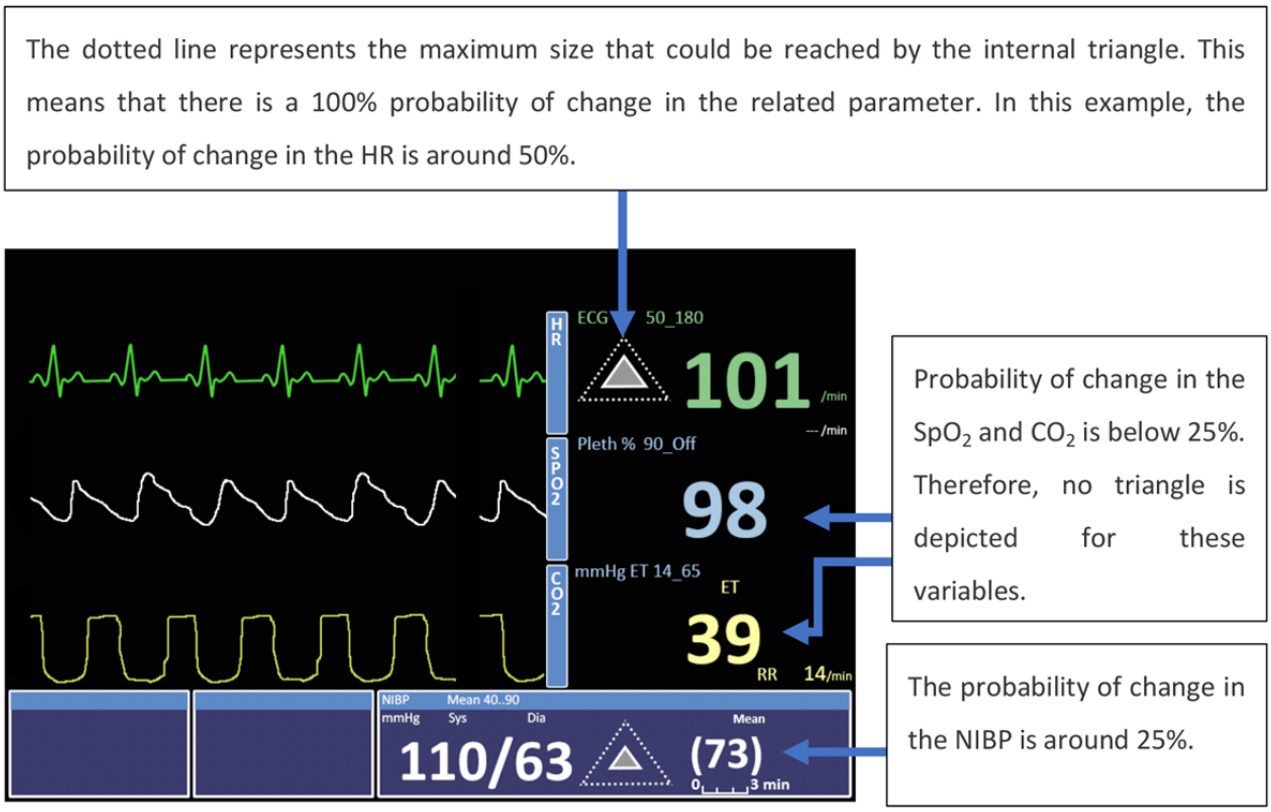


Two expert anesthesiologists assessed participant performance. It was found that when using the pulmonary GD, participants detected and treated 2 out of 5 scenarios (obstructed endotracheal tube and intrinsic PEEP) significantly faster and reported lower subjective workload than when using the conventional monitoring setup. In addition, the accuracy of the participants was significantly higher in the intrinsic PEEP scenario when using the GD. However, in 2 scenarios (endobronchial intubation and hypoventilation), the number of incorrect diagnoses was higher (not significantly) with participants using the pulmonary GD.

Participants using GD in scenarios involving mild pain, myocardial infarction, and left ventricular failure were rated higher in performance than participants in the control group. In addition, participants using the GD detected and treated myocardial ischemia faster than those who did not use the GD. Once again, there was no statistically significant effect of the GD on the self-assessed workload as measured by the NASA-TLX.

Tappan et al [22] explored the hypothesis that the simple addition of a graphical visual cue to an existing traditional PM (rather than a complete redesign) would be sufficient to improve the detection ability and response time of a clinician to a change in a patient variable. The display tested was almost identical to a traditional PM, with the only difference being the incorporation of a triangle between the waveforms and the numerical values (Figure 16). The size of the triangle would change according to the probability of change (increasing or decreasing) for each variable. When the probability of a change in the variable was below 25%, no triangle was displayed. If it was above 25%, the triangle was displayed to attract the attention of the observer. If the probability of change went beyond 25%, the triangle became proportionally larger. Along with the triangle, an outline of the maximum possible size of the triangle was also displayed as a reference. The display was compared with a simulated PM in terms of detection time and the number of events missed.

Figure 16. The enhanced display (a model of the concept presented in the paper) by Tappan et al (2009). The visual cue was a triangle object placed between the waveform and numerical values, which were displayed as in a traditional patient monitor. The size of the triangle changed according to the probability of change for each variable.



A total of 22 participants (anesthesiologists and anesthesia residents) were asked to identify when a change occurred in the monitored variables using the enhanced display and the control display, which consisted of the same display without the graphical visual cue. The detection time was reduced on average by 14.4 (SD 12) seconds when using the PM with the graphical visual cues when compared with the traditional PM. The percentage of missed events was 11.2% when using the PM with the graphical visual cues and 18.8% when using the traditional PM. A usability questionnaire was applied, but no significant differences were found regarding satisfaction between the 2 displays. These results show that to improve the performance of PM users, a complete redesign of a commercial PM is not always necessary. However, it is important to keep in mind that the usefulness of the display is dependent on the accuracy of the algorithm that calculates the variable change. If the algorithm is not accurate or is not perceived as accurate by the PM users, this change in the PM may generate frustration, leading to a negative impact on patient care.

The GDs described so far in this review were designed to support the needs of anesthesiologists in the OR, taking into account their decision-making process [17,18] or the biological mapping of vital signs [16,19,20]. However, another important user of PMs that must be taken into account when designing a new PM is the nurse, as *clinical monitoring by a vigilant nurse is the basis of intensive patient care* [23].

Görges et al [24,25] described 2 integrated displays where they combined numeric values, trends, alarm status of vital signs, infusion pump information, and therapy support indicators into 1 screen. The displays were designed to support ICU nurses and doctors when they have to quickly choose which patient to treat first from a distance of 3 to 5 m. For this reason, these displays were referred to as far-view displays.

On the left side of the display, the displayed images of syringes indicated which medicine the patient was currently receiving and how long it would take for full delivery of the medication to be completed as illustrated in Figure 17. The display presented in Figure 18 is referred to as a far-view bar display. On the middle and right sides of the display, 5 variables were monitored using trends: HR, MAP, CO, SpO_2, and ventilation minute volume (MV). Each graph was composed of a 12-hour trend highlighting the target zone for the variable and a numeric element depicting the current value of the monitored variable. The trend element in this display is shown in Figure 19 [24,25].

Figure 17. Four stages of drug delivery represented by the syringe by Görges et al (2011, 2012).

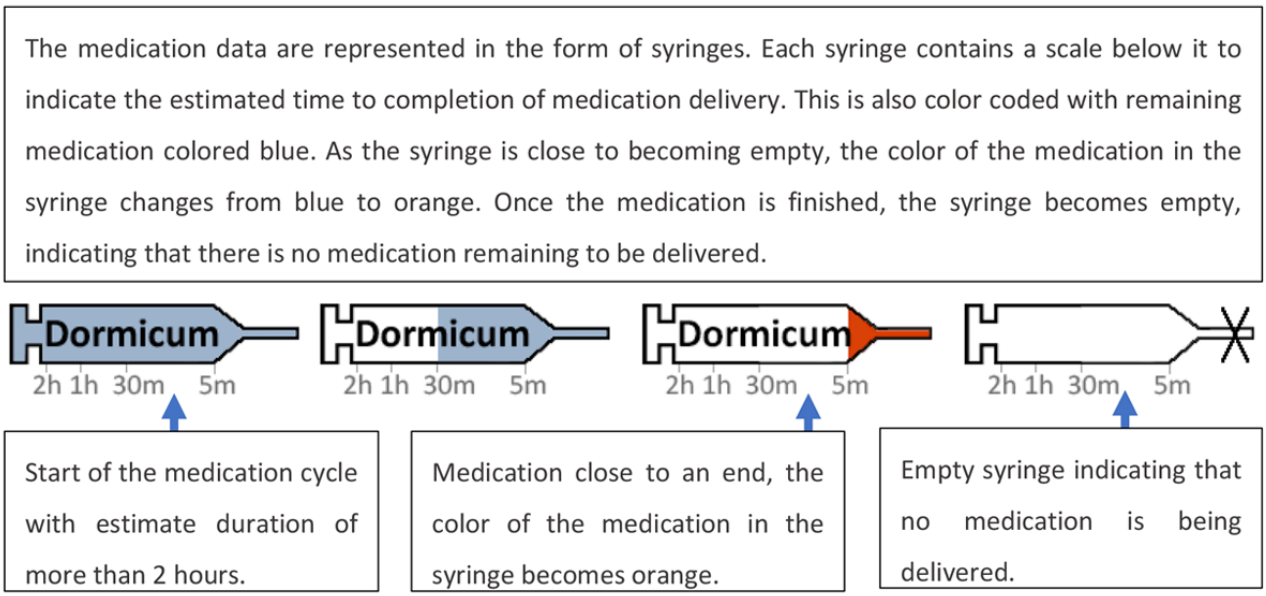


Figure 18. Integrated trend display tested by Görges et al (2011, 2012).

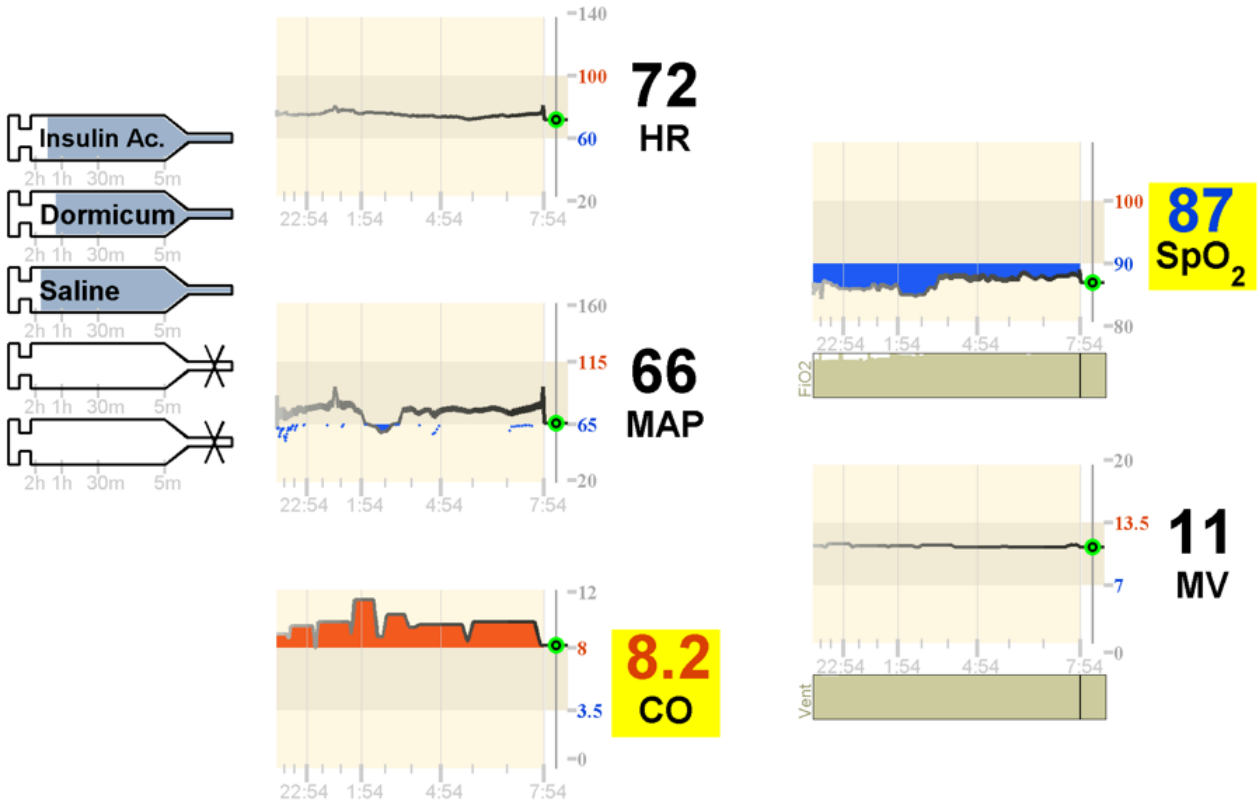
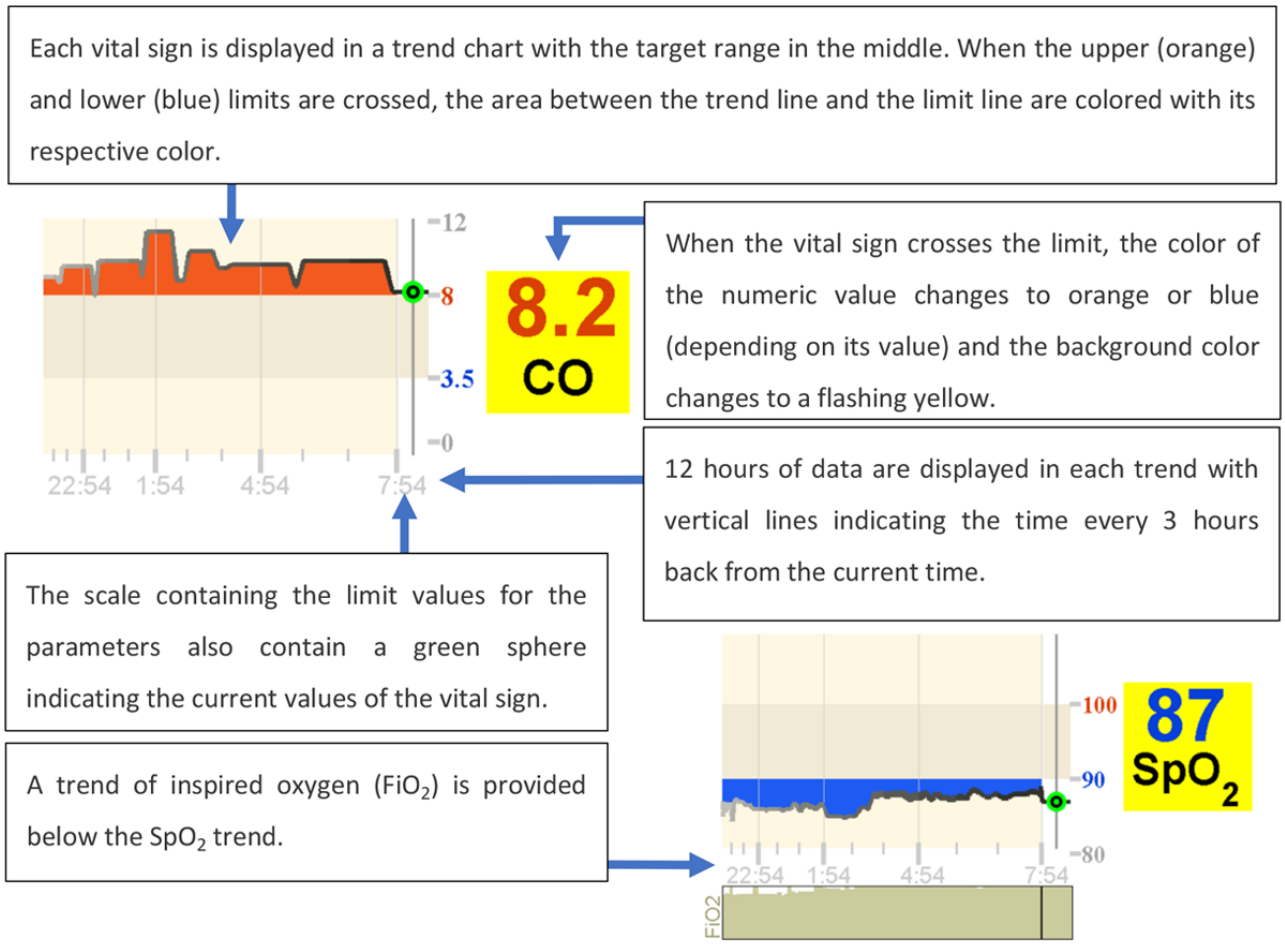


Figure 19. The trend element in Görges et al (2011, 2012) far-view bar display.



The display presented in Figure 20 is referred to as a far-view clock display. It displays the same data as the bar display in a circle that looks like a clock in which the new variable values overwrite the old ones after 12 hours. The clock element in this display is explained in detail in Figure 21. The values for inspired oxygen (FIO_2) and MV were presented within the circle using 12 circles (1 for each hour) instead of trends, with the current values being the background for the SpO_2 and MV, respectively.

In both the studies (2011 and 2012) [24,25], participants were asked to take care of 2 patients simultaneously and decide which of the 2 patients required attention first, based on the information provided on the display. In the intervention condition, participants were using the integrated displays, and in the control condition, participants were using a commercial PM (Draeger Kappa XLT PM) and 4 commercial infusion pumps. In the first experiment, involving 16 ICU nurses, it was found that the decision time was shorter and the accuracy was higher when using the 2 novel displays. The results from the NASA-TLX questionnaire indicated that both far-view displays performed statistically significantly better than the control PM in terms of self-perceived frustration. Interestingly, more than half of the participants (n=9) preferred conventional displays. Unfortunately, these participants were not asked why they preferred the conventional displays. A particular feature that all nurses liked from the integrated display was the addition of the syringe functionality.

In the second experiment, 15 ICU physicians performed the same task. The physicians made more appropriate decisions and took less time in deciding which patient required attention first, when using the 2 novel displays. No statistically significant differences were found in the clinician workload when using the 3 displays. Regarding preferences, 1 physician preferred the control display, whereas 10 preferred the bar display and 4 preferred the clock display. Once again, participants were not asked the reason behind their preference, which makes it difficult to understand why nurses and doctors differed in their preferences.

Koch et al [26] conducted a thorough investigation of the tasks performed by ICU nurses, intending to provide recommendations for the design of integrated PMs, which could enhance the SA of nurses. In this study, 19 ICU nurses were observed for 38 hours in 3 clinical practice settings. The team wrote extensive field notes that were classified into 46 distinct tasks. These tasks were then grouped into categories for communication, medication management, patient awareness, organization, and direct patient care.

Figure 20. Integrated clock display tested by Görges et al (2011, 2012).

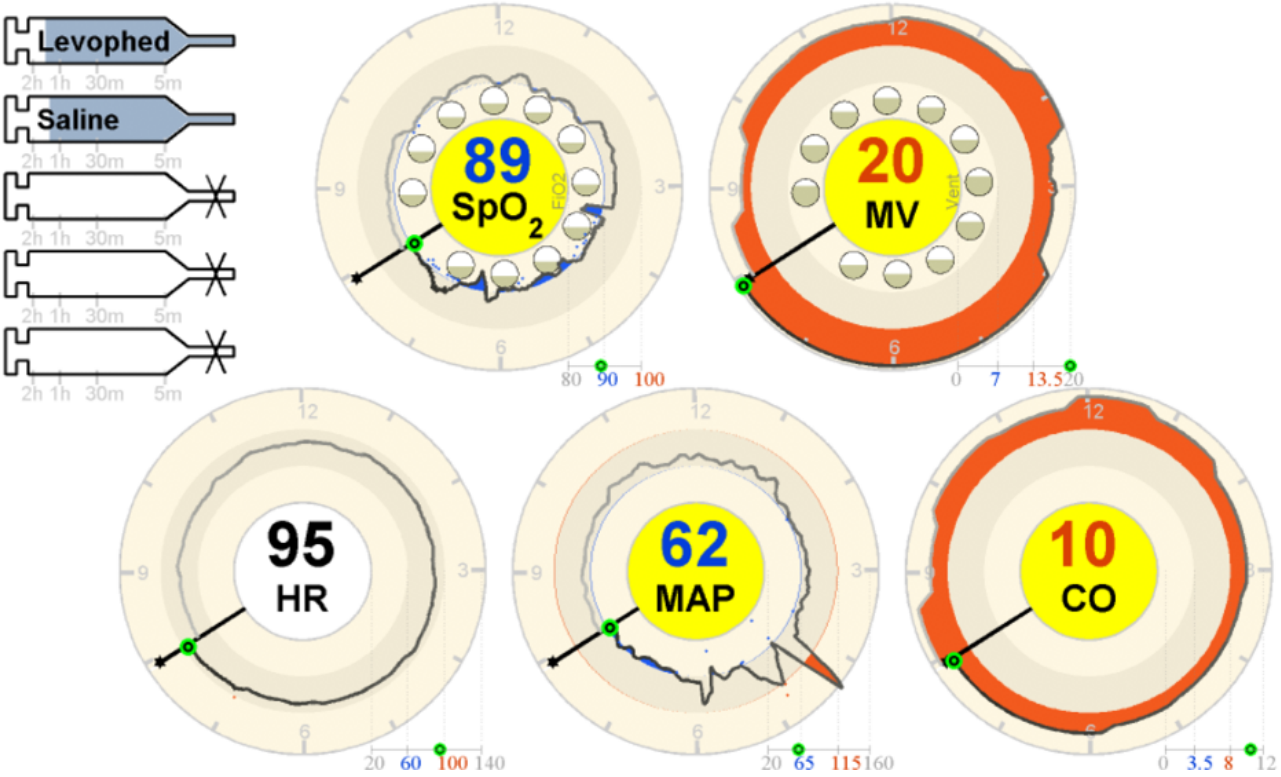
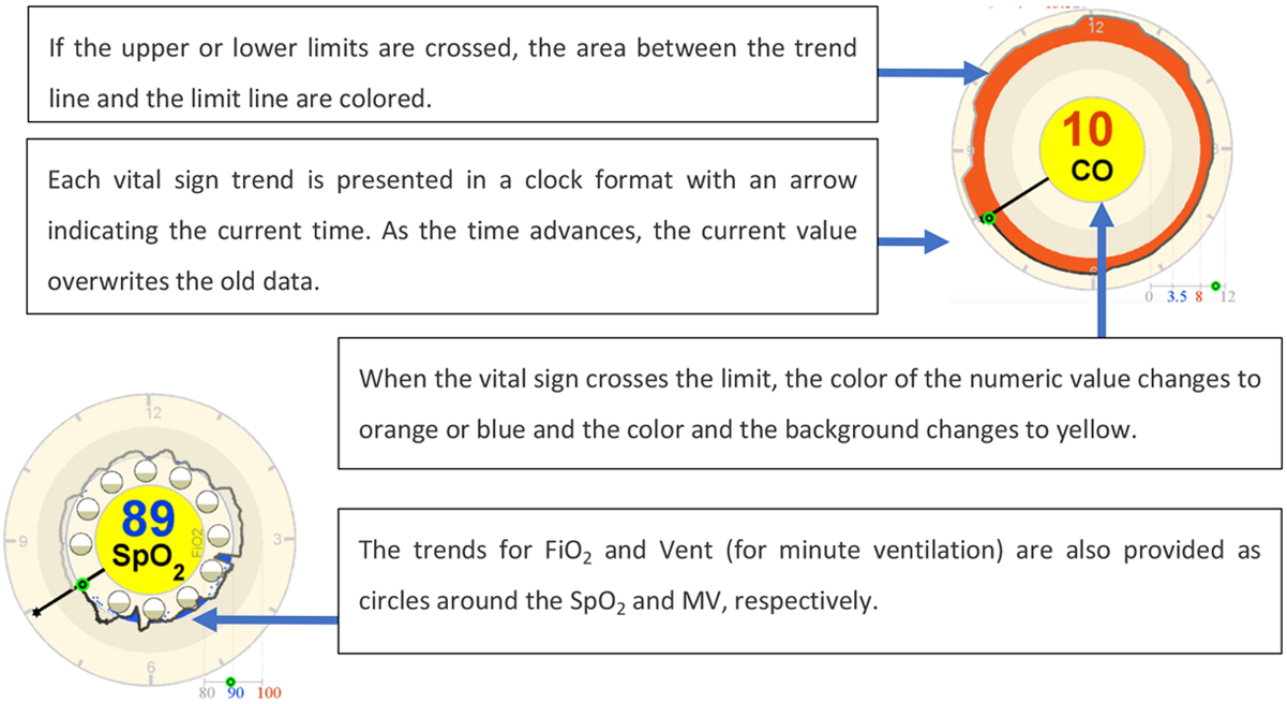


Figure 21. The clock element in Görges et al (2011, 2012) far-view clock display (a model of the concept presented in the paper).

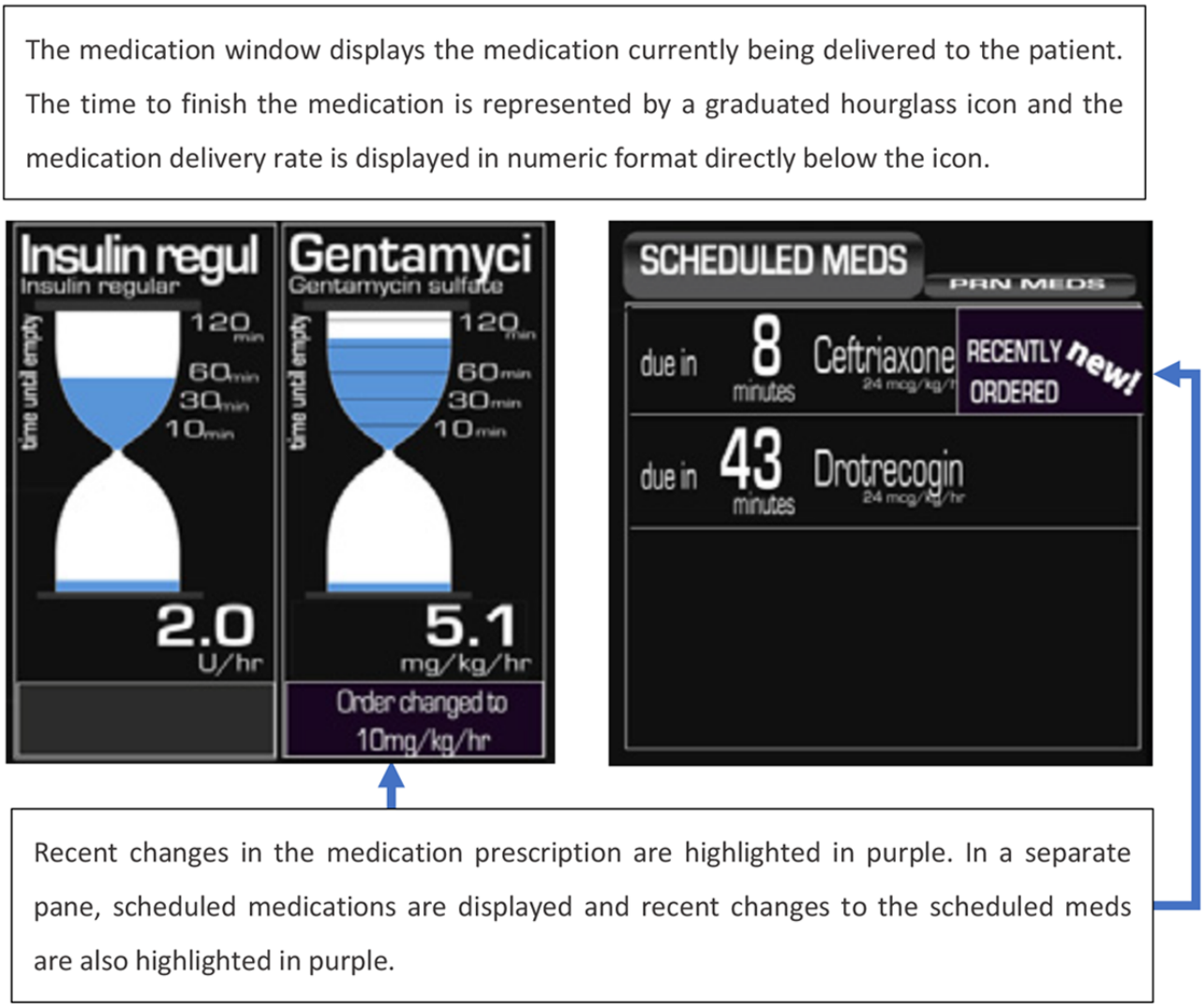


Koch et al [26] identified that essential information was deemed to be missing at the bedside, and even when the information was present, it was not integrated at the task level. Using the concepts presented by Endsley [7], Koch et al [26] classified the challenges arising from this lack of integration as perception, comprehension, and projection challenges. On the basis of the identified information gaps, Koch et al [26] provided recommendations for enhancing SA for frequently carried out tasks. These recommendations included (1) establishing methods of information sharing from any location, (2) an integrated display inside the patient's room containing all the information necessary on 1 screen, and (3) making the relevant information visible and readable from the doorway.

As a follow-up to this investigation, Koch et al [27] developed a paper prototype of a new integrated display. In contrast to the displays by Görges et al [24,25], the display by Koch et al [27]

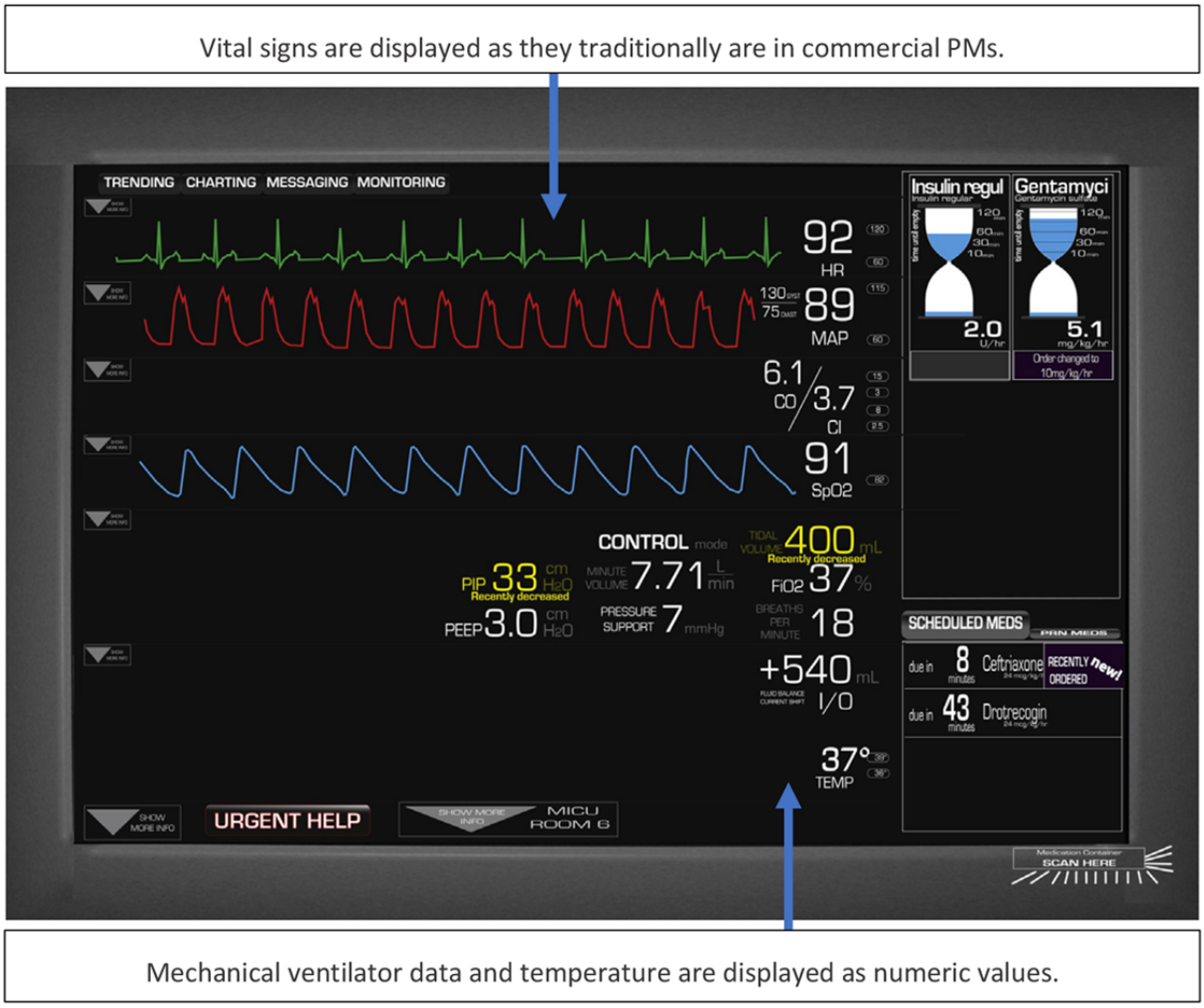
did not make significant changes to the look and feel of the display, when compared with a traditional PM. The waveforms and numerical values were displayed as in a traditional PM, but some elements from an even wider range of medical devices were added to the screen. For instance, ventilator settings, fluid balance, and temperature data were also included as numeric values below the vital signs, and the scheduled and current medications were displayed on the right side of the display. The medication windows are shown in Figure 22.

Figure 22. Koch et al (2013) medication windows added to the integrated display.



In the study by Koch et al [26], it was established that most tasks performed by nurses relate to medication management, patient awareness, or team communication. Therefore, 3 common scenarios for nurses interacting with information systems were developed to cover each of these 3 aspects. A total of 12 nurses from a burn trauma ICU were asked to use 2 paper-based prototypes (the order of the displays was randomly assigned): (1) the new experimental integrated display (Figure 23) and (2) the screens from each device separately (not integrated). It was found that the SA (represented by the accuracy of the participants' answers to questions asked during the testing) was higher, and the task completion time was shorter when using the integrated display.

Figure 23. Koch et al (2013) prototype of an integrated display. The display shows scheduled and current medication, vital signs, ventilator settings, fluid balance and temperature.



This study demonstrates that the integration of data from multiple devices does not always require a radical change in the look and feel of the conventional PM. In a number of the studies reviewed thus far, we have seen that complete PM interface redesigns can lead to resistance from clinicians for reasons already discussed. Nonetheless, additional experiments using high-fidelity prototypes are required to ensure that the new design is useful and would be adopted by the users in critical care.

Drews and Doig [28] developed a GD to support rapid detection and identification of physiological deterioration in patients by ICU nurses. This display was developed with a focus on ICU nurses' needs and to address areas of improvement in commercial PMs identified in previous studies [29,30]. The interface was developed using an iterative design process with 3 experienced ICU nurses evaluating the display after each iteration. As shown in Figure 24, the GD monitored HR, SpO_2, and BP. It was composed of 3 main components: trend data, numerical data, and a graphical object.

For each variable, the trends displayed the values from the previous 8 hours on a line graph. The line graph contained a gray area representing the normal range of the values. The numerical data corresponded to the current values of the variables. The current state object (CSO), explained in detail in Figure 25, combined HR (in the X-axis) and BP (in the Y-axis). The white rectangle represented the variability of BP and HR in the last hour, where the upper boundary of the box represented the maximum systolic BP, the lower boundary represented the minimum diastolic BP, the leftmost boundary represented the lowest HR, and the rightmost boundary represented the highest HR value. The gray rectangle represented the normal or customizable thresholds, and the colored element inside (or outside) the white rectangle represented the current patient vital sign measurements. The color reflected the SpO_2 level, which could be red (93%-100%), orange (91%-92%), pink (89%-90%), purple (87%-88%), or blue (<87%).

Figure 24. Drews and Doig's graphical display. On the left side, data were presented in a similar manner to a traditional patient monitor, but with trends instead of waveforms of the vital signs.

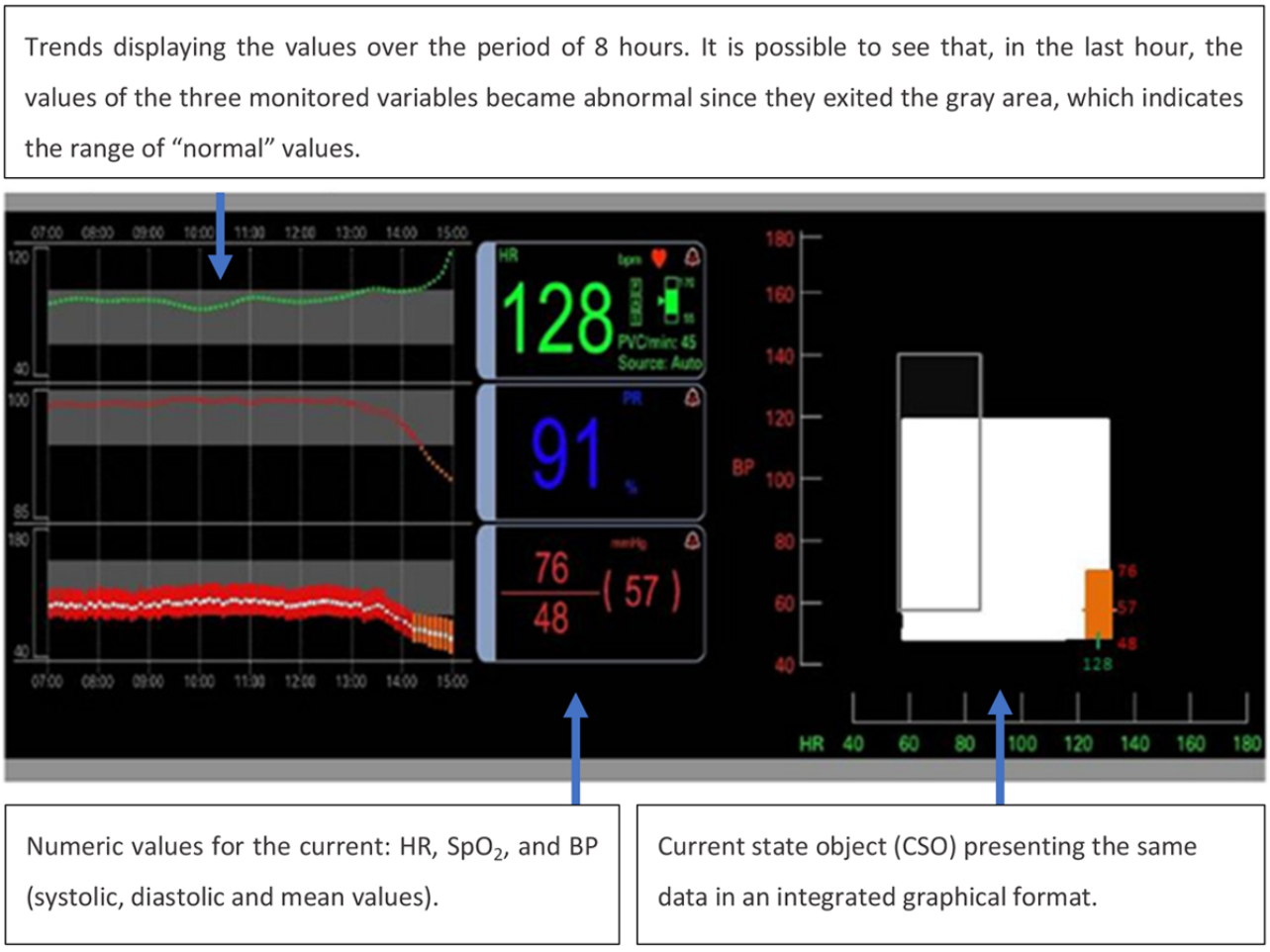
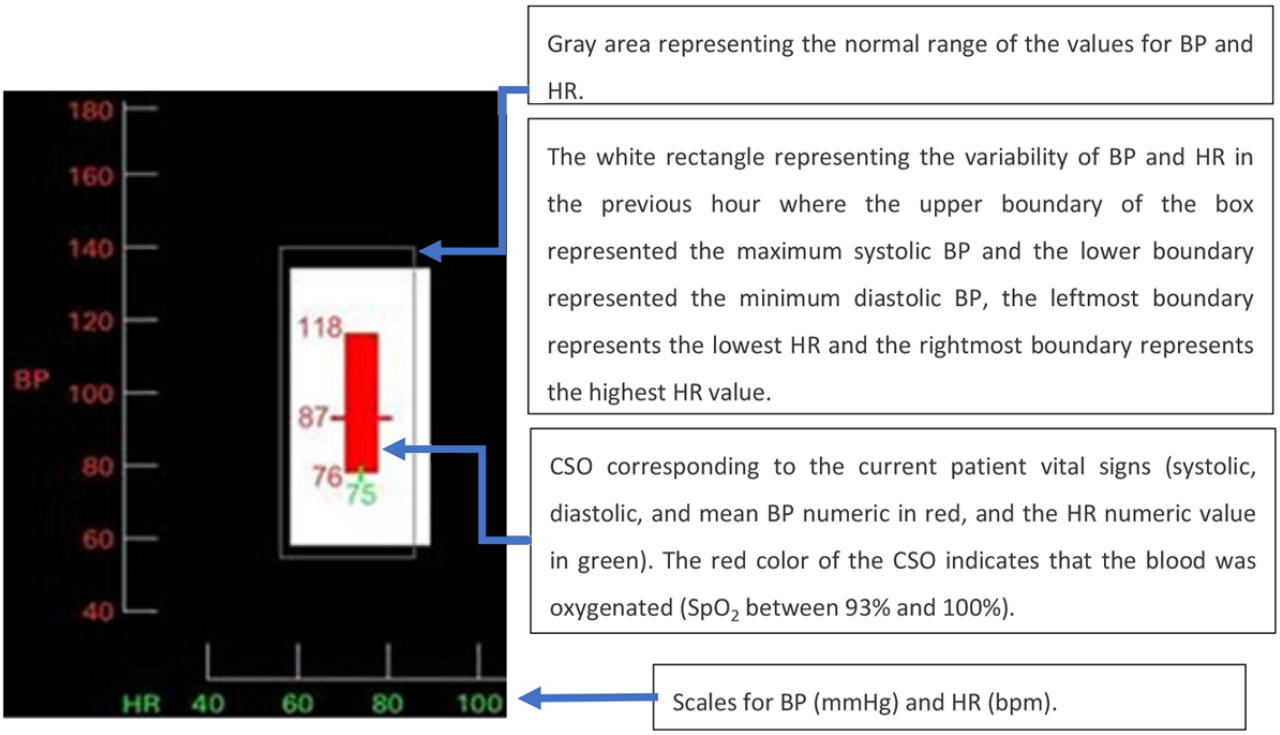


Figure 25. The graphic object combined the blood pressure and heart rate values to create an object that depicts the current state of a patient.



The GD was compared with a simplified version of a PM (control) in terms of response time and accuracy of data interpretation. The simplified version of the PM contained only a numerical display, as presented in Figure 24, without trends or CSO. In both conditions (intervention and control), the vital signs were also displayed on a desktop computer along with the display being tested. Four scenarios were developed for this experiment: early sepsis, septic shock, pulmonary embolus, and a stable scenario. On the basis of the provided display and context information, 42 ICU nurses (21 using the novel display and 21 using the control display) were asked to evaluate and interpret the data and recommend appropriate interventions as quickly and as accurately as possible.

Overall, the participants using the GD were 30% faster than participants using the simplified traditional display, with statistically significant differences for septic shock, pulmonary embolus, and stable vital sign scenarios. In terms of accuracy, participants correctly identified the condition of the patient with statistically significant differences in septic shock and pulmonary embolism scenarios. A NASA-TLX questionnaire distributed after the test revealed a statistically significant difference in the mental demand, with lower mental demand reported by nurses using the GD.

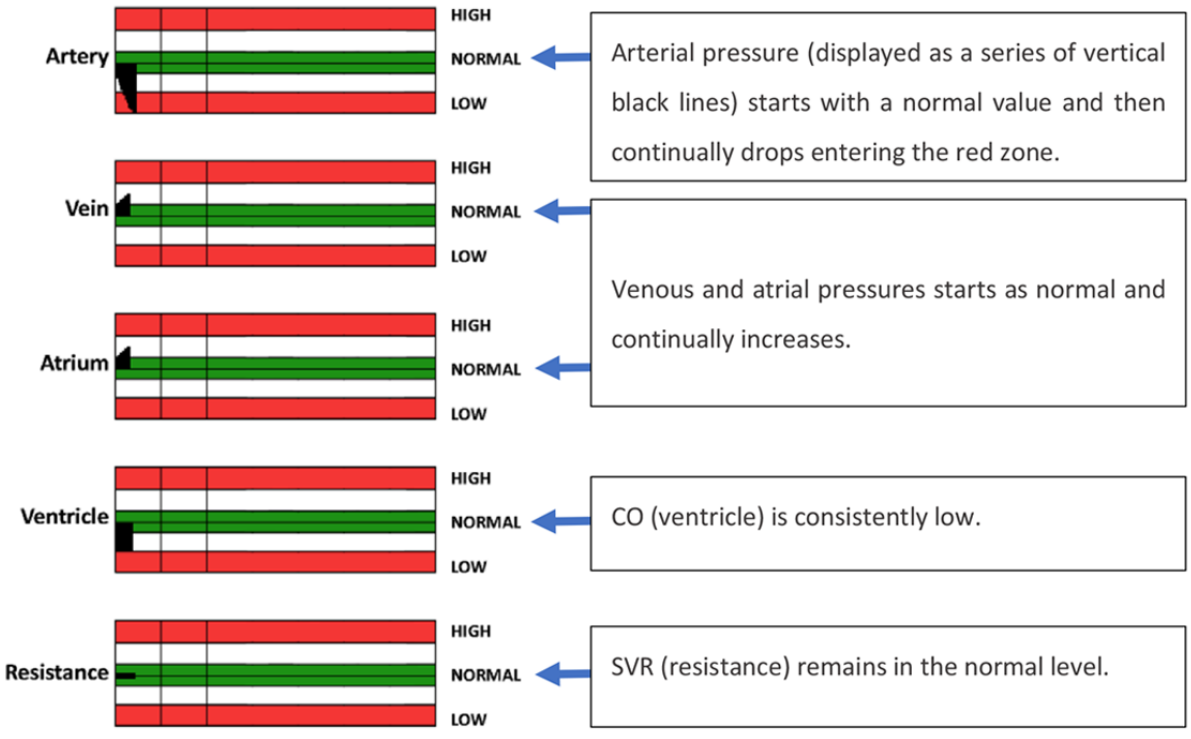
The purpose of this experiment was to measure the performance of the nurses when using a single-sensor-single-indicator display compared with a graphical or object display. In this sense, it is understandable that the presence of waveforms on the control display was not essential. However, because the novel display was designed to replace the conventional PM display, it is unusual that the control display did not adopt the full PM interface in daily use by the end user. This theme of so-called control displays not truly representing the display used by users in their everyday work, recurs throughout some of the studies presented in this review.

Ecological Displays for Patient Monitoring

Some authors have used a framework for interface development called ecological interface design (EID). EDs attempt to minimize the cognitive load on the user by presenting data in a meaningful way, depicting the relationship between data elements and making the constraints of the monitored system visible to the operator [31,32]. Constraints refer to the task- and goal-relevant information (eg, how far is the patient's BP from optimal values? Are the patient's hemodynamic parameters changing as expected?). In most cases, EDs are GDs in the sense that they typically also use shapes and colors to facilitate improved assimilation of the patient's current state by the clinician, but a GD cannot always be classified as an ED.

Effken et al [32] developed 2 EDs for hemodynamic data visualization, namely an integrated balloon display (IBD) and an etiological potential display (EPD). The 2 EDs were compared with a traditional strip chart display (TSD), which displayed the data using the single-sensor-single-indicator model and was considered by the authors the traditional display (Figure 26). The TSD displayed trends for the arterial, venous, and atrial pressures; CO; and SVR. The terms used for the variables in the 3 displays differed somewhat from the terms used in critical care. For example, *SVR* was replaced by *resistance* and *CO* was replaced by *ventricle*. The rationale for more generic physiological labels instead of the conventional ones was that the authors wanted to investigate the utility of the display by students with no clinical experience as well as by experienced participants.

Figure 26. The strip-chart display displayed the 5 variables separately using 55 × 660-pixel bar graphs. Every second, the graphs were updated, and a new bar was added to the graph. In this scenario, the strip-chart display started with all variables in the normal condition and quickly evolved to a low heart strength state. This image is a model of the concept presented in this paper.



The IBD (Figure 27) represents each system in the form of balloons that expanded or shrunk according to the value of the variable. Colored regions around the balloons represent different states: good (green), warning (white), and danger (red). The IBD also contains a strip chart element at the bottom to indicate the overall status of the patient. In the EPD (Figure 28), the vertical axis represented heart strength and the horizontal axis represented resistance. Fluid changes were shown as a shrinking or expanding square. The central crossing point for each bar (axis) represented the optimal value for each. Figure 28 presents the patient data in a *normal* state (top left image) and in a low heart strength state (bottom right image), where the values of pressure and flow have moved away from the targeted state, deforming the 4-sided object and moving it away from the central crossing point of the resistance and heart strength axes.

An experiment was carried out with 6 experienced nurses and 6 student nurses. Participants were asked to treat a simulated patient using simulated drugs, based on a clinical assessment of the data presented on the monitor, to get their patients' vital signs into the normal range as quickly as possible. It was observed that both groups of nurses initiated the treatment faster, used fewer drugs, and were able to maintain the vital signs within the target range for longer when using the ED in comparison with the TSD. In addition, the student nurses using the EDs were able to match the performance of experienced nurses using the traditional display.

Figure 27. Hemodynamic variables presented using an integrated balloon display, where each system was presented in the form of balloons that can be expanded or shrieked according to the value of the variable. This image is a model of the concept presented in this paper.

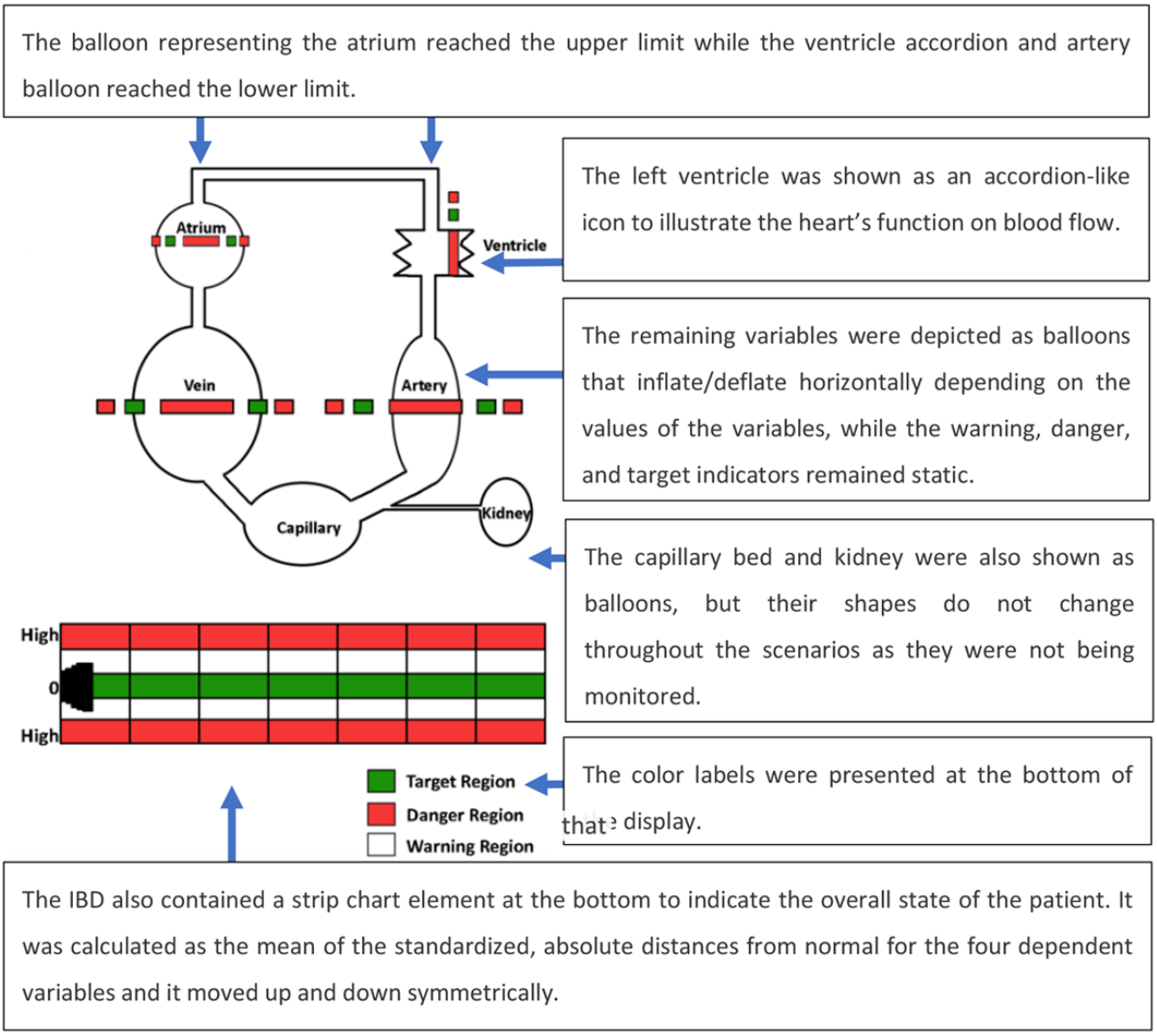
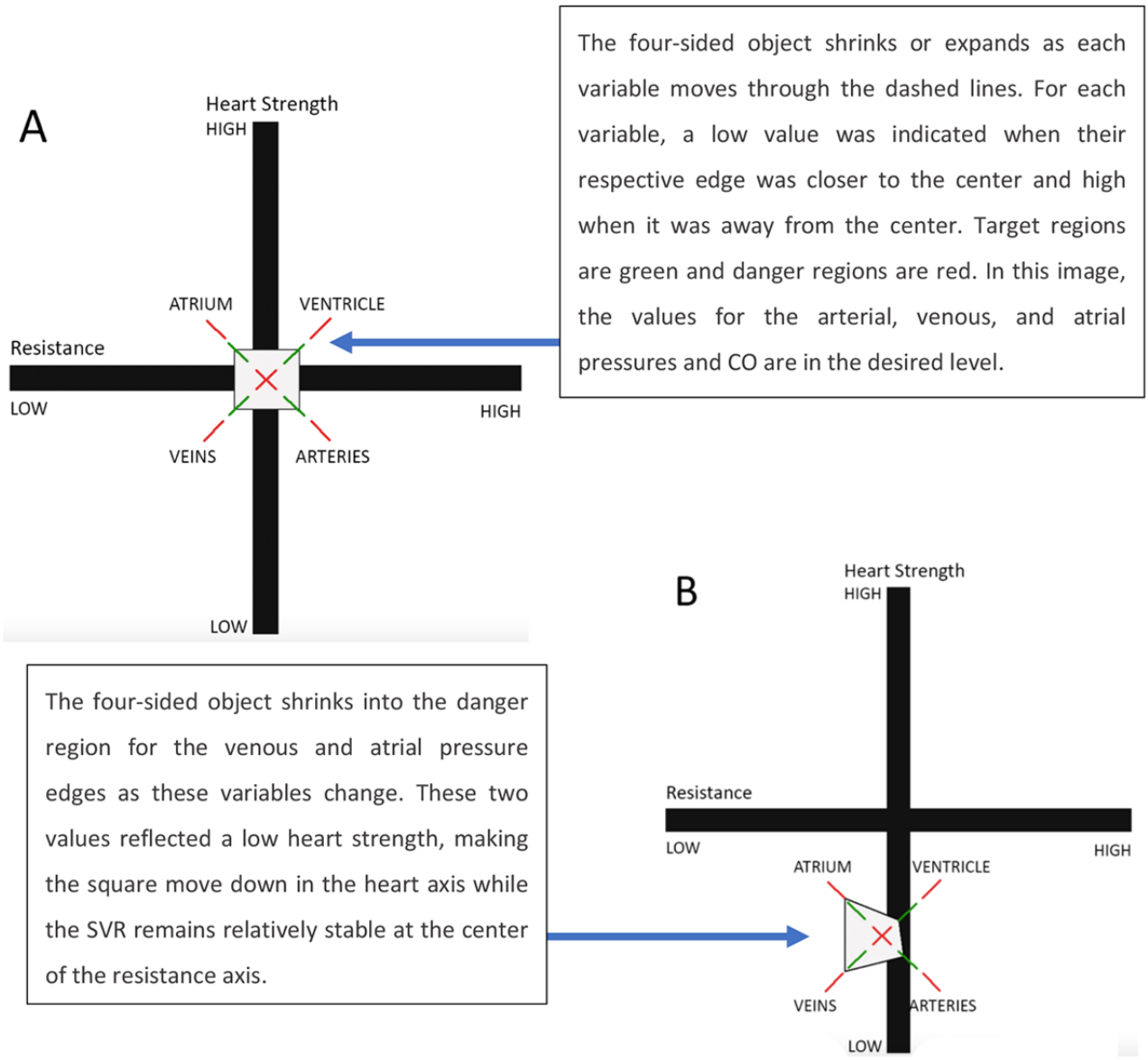


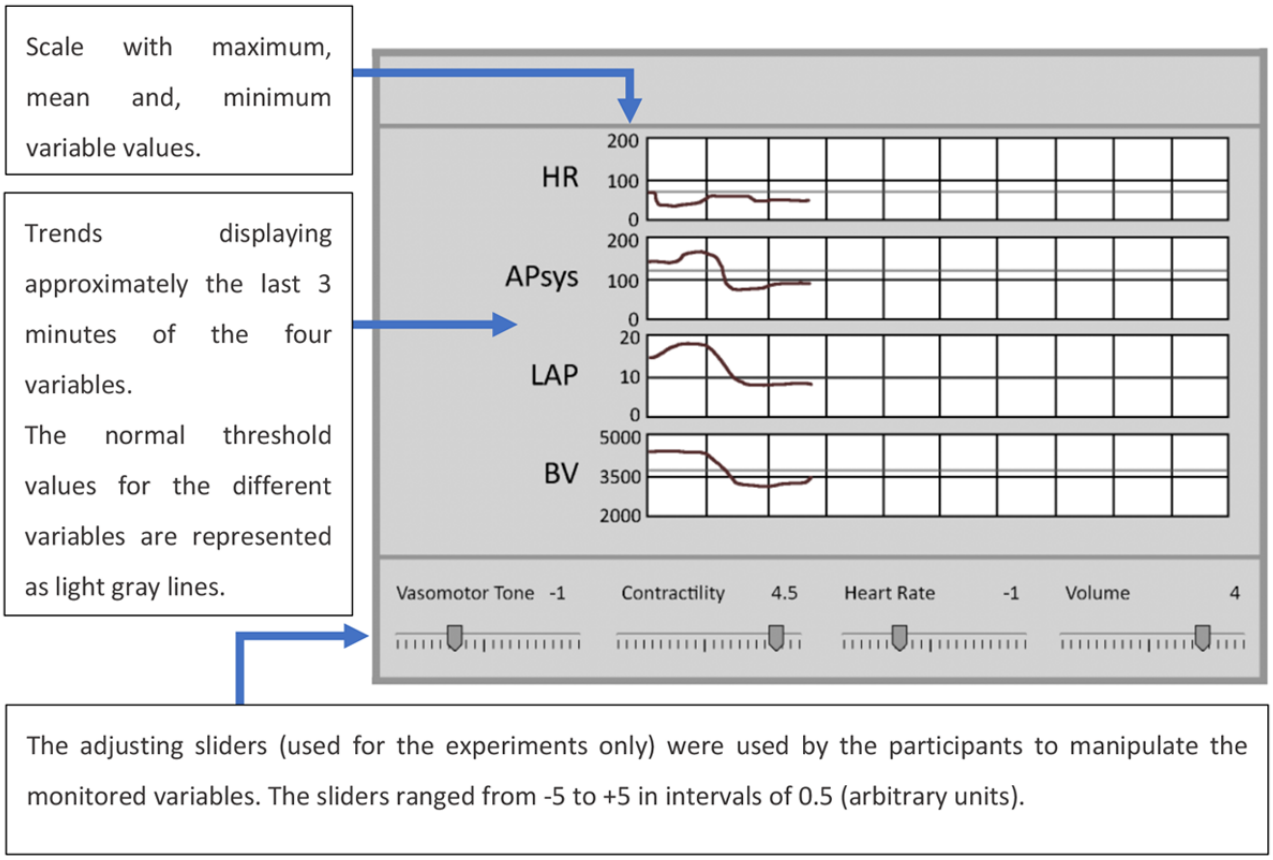
Figure 28. Hemodynamic data are presented using the etiological potential display in a normal state (A) and in an abnormal state (B). The vertical axis represented heart strength and the horizontal axis represented systemic vascular resistance. Fluid changes were shown as a shrinking or expanding square. The central crossing point for each bar (axis) represented the optimal value for each. This image is a model of the concept presented in this paper.



The novel concepts presented by Effken et al [32] are quite innovative, and the study demonstrated the potential to enhance nurses' performance in critical care. However, there were some issues with the experimental design that could have biased the results. For example, considering that the TSD does not resemble a typical PM, as presented in Figure 1, it is not clear that the TSD was a valid control display. In addition, while the experienced clinicians were instructed regarding the terminology changes so that they could relate the new terms to the ones actually used in clinical practice; however, it is unclear what impact these changes in the mental model had on the experienced clinicians. This may help explain why student nurses using the EDs were able to match the performance of more experienced clinicians.

Jungk et al [33] developed a profilogram display and an ED and compared these 2 novel displays to a trend display. Similar to the main interface of the traditional PM, the trend display, presented data using the single-sensor-single-indicator approach. It is possible to configure most commercial PMs to present data using the trends format, but it was reported that this functionality of the PM was infrequently used in critical care [30]. The trend display was used to monitor HR, systolic arterial pressure (APsys), LAP, and blood volume (BV). As the data were presented using the trends format only, to know current values for each variable, the user had to interpolate the values visually with the aid of the trend display scales. The time axis range for each variable was between 0 and 10 min (Figure 29).

Figure 29. Trend display used by Jungk et al as a control display (a model of the concept presented in the paper). The trend display presented the heart rate (bpm), systolic arterial pressure (mmHg), left atrial pressure (mmHg), and blood volume (mL).

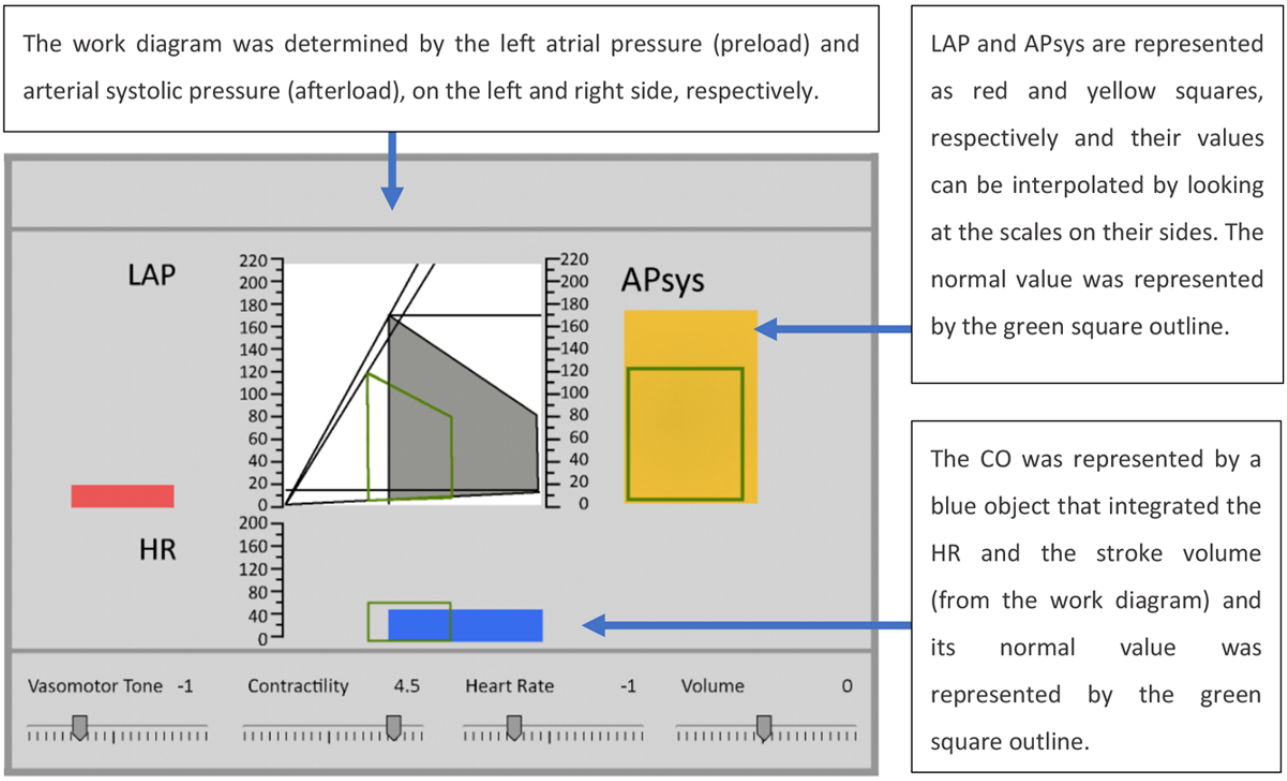


As a part of the experiment, at the bottom of the 3 displays, the researchers added a control panel that was used to manipulate 4 functional parameters: HR, vasomotor tone, contractility, and circulating BV. The profilogram display was developed based on the principle of intelligent alarms. This system combined the relevant data needed by the physician to make decisions (eg, each monitored variable, physiological background knowledge, and patient-specific knowledge). The system used fuzzy logic to generate color-coded profilograms (Figure 30) [34]. Each profilogram presented the amount of a variable's deviation in a positive or negative range for its related variable (HR, APsys, LAP, BV, and CO). Normal values for the variables were represented as a line in the middle of each profilogram. Bars to the left side of this line indicated a state variable becoming *too low* and bars to the right side of this green line indicated a state variable becoming *too high*. The amount of deviation was indicated by the length and the color of the bar (green for normal values, yellow for small deviations, and red for excessive deviations), which was intended to support rapid perception of the patient's state.

The third display evaluated by Jungk et al [33] was a simplified ED for hemodynamic monitoring that integrated the necessary components for decision making (Figure 31). The LAP, APsys, and HR were displayed according to their physical location in the heart and corresponding to the schematic work diagram of the heart, which was displayed in the center of the display. Some of these variables were displayed using the graphical object concept typically used by GDs [15-18].

Figure 30. Profilogram display used by Jungk (a model of the concept presented in the paper). Profilograms for HR (too low), CO (a little low), LAP (too high), APsys and BV (good) were displayed.

Figure 31. Jungk's (1999) ecological displays (a model of the concept presented in the paper).



A total of 20 anesthesiologists, with no previous experience with an ED or profilogram display, carried out a prescribed task on the 3 displays separately. They were required to observe the data presented on the screen and maintain the vital signs within the desired range by adjusting the sliders located at the bottom of the interface. The sliders corresponded to vasomotor tone, contractility, HR, and volume.

It was observed that participants finished the task with the monitored variables within the acceptable range more often when using the ecological interface than when using the other 2 displays. However, the performance of the participants in terms of time to complete the task, number of slider interactions, and time to find relevant information was found to be much quicker with the trend display than when using the ED or profilogram display. On the basis of these results, the authors concluded that participants performed better with the trend display. Jungk et al [33] hypothesized that the difference in the performance of the 3 displays was attributed to the years of experience anesthesiologists had with the trends display and suggested that the future ED designs should not differ too much from the traditional PM displays.

One year later, Jungk et al [35] developed an ED that presented 35 monitored variables, intending to support anesthesiologists during anesthesia monitoring. The reason for such a large number of monitored variables is that this ED (Figure 32) integrated data from different devices, such as a PM, a mechanical ventilator, and infusion pumps. This display made extensive use of graphical objects such as those presented in Figure 33.

Figure 32. Jungk's ecological displays (first approach).

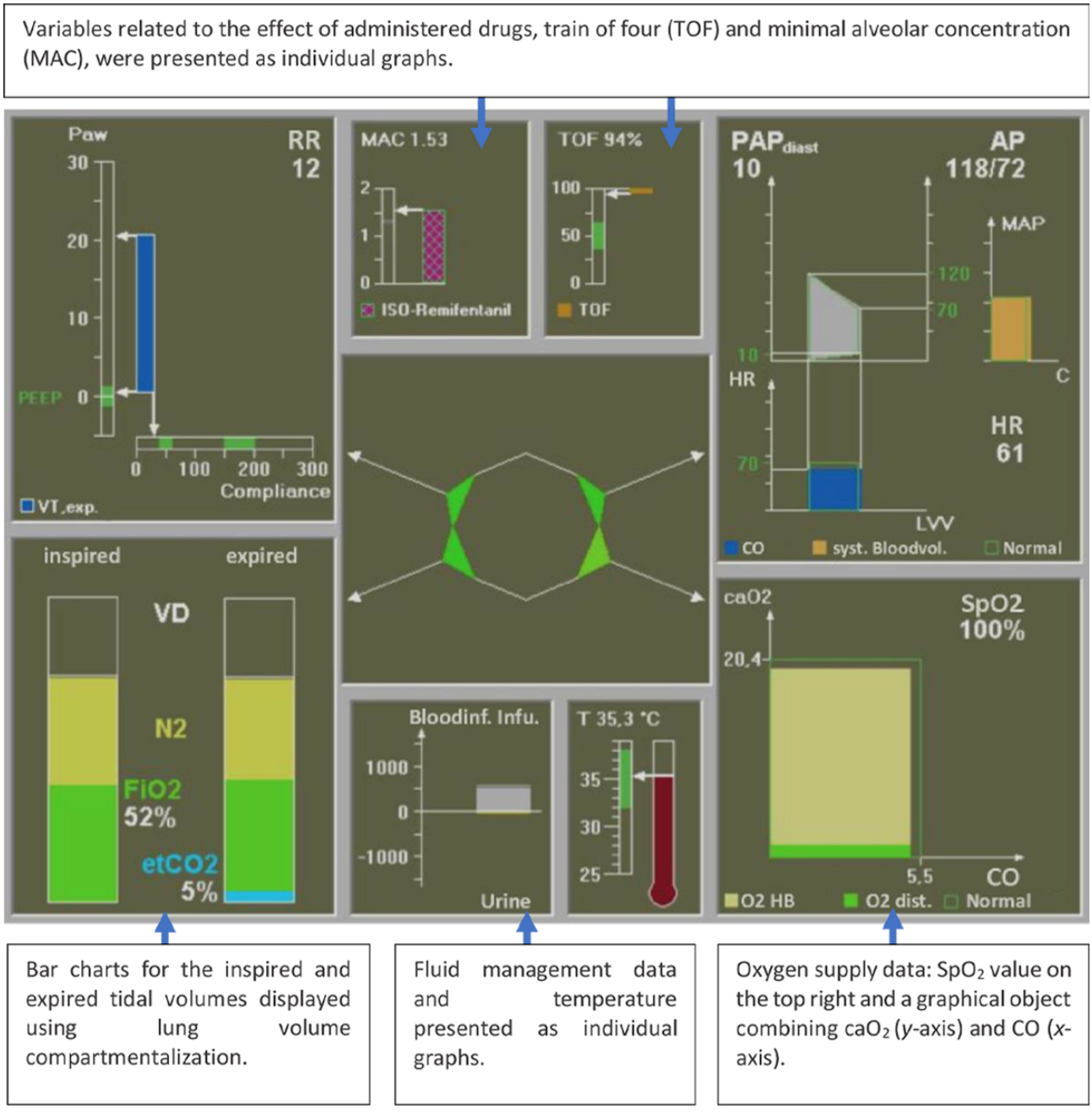
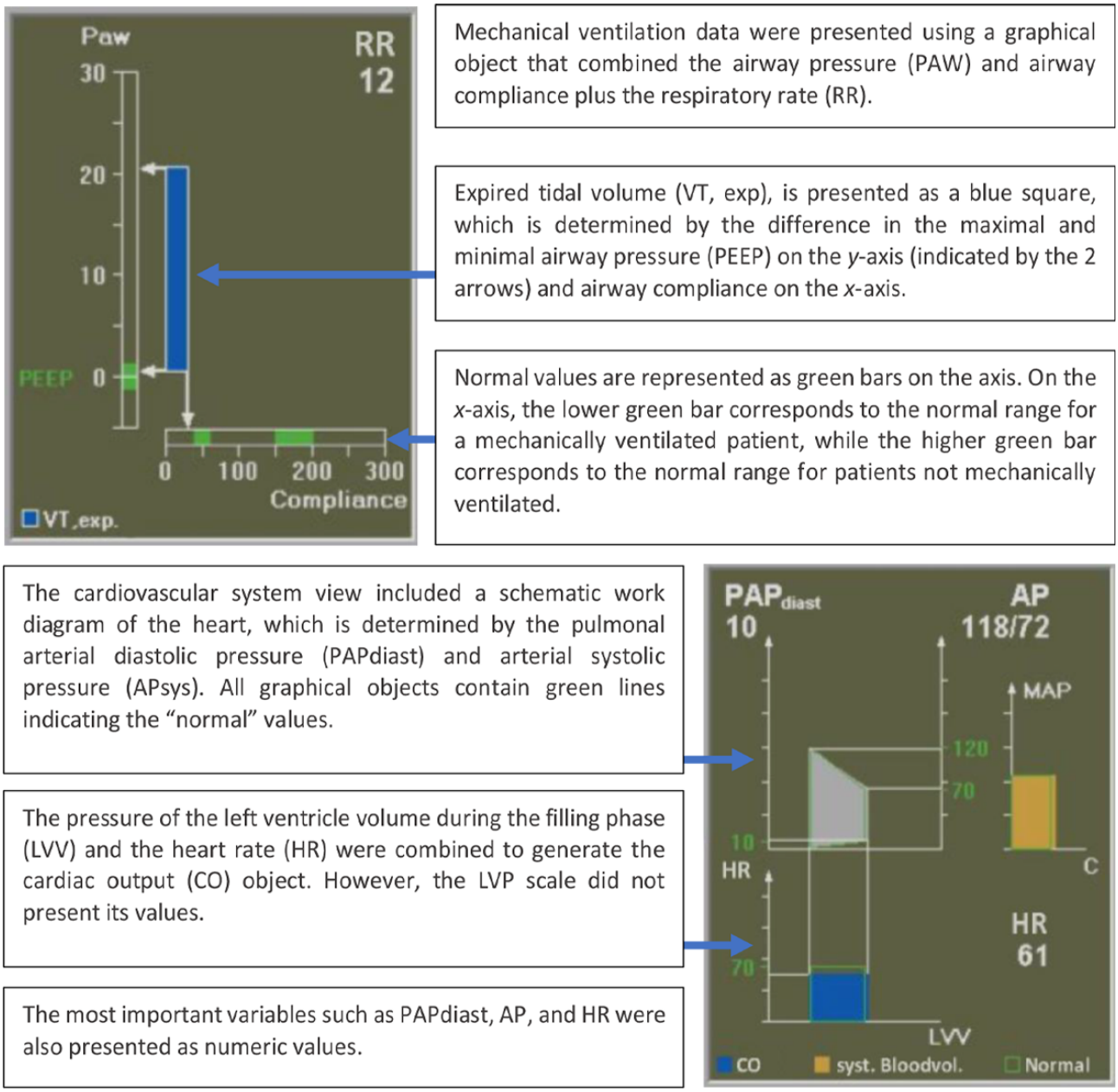


Figure 33. Respiratory and cardiovascular views used in experiment 1 on the Jungk et al (2000) study.



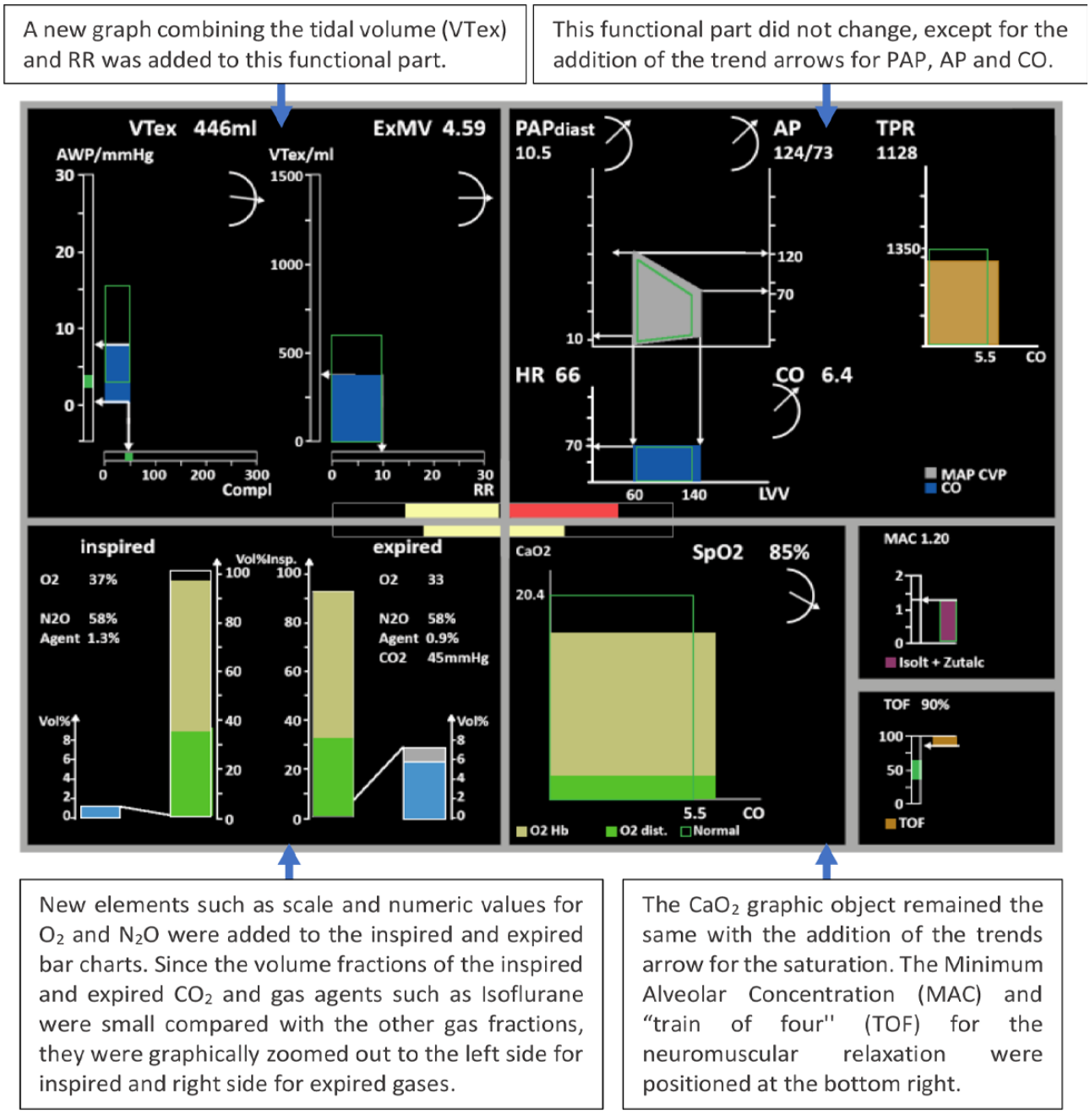
The display was composed of 7 sections in which related variables were grouped, with a star in the middle, which represented an assessment of respiratory mechanics, respiratory volumes, oxygen supply, and the cardiovascular system. The star was color-coded based on the assessment of parameter constellations with the help of fuzzy sets and fuzzy rules. Jungk et al [35] intended to evaluate whether the performance of anesthesiologists would improve with the addition of an ED. The performance was assessed based on trial time, number of successful trials, and on some strategic behavior parameters (region-of-interest, related metrics, and think-aloud protocol). Of which, 16 anesthesiologists were asked to anesthetize a simulated patient under intervention conditions (the ED in conjunction with a simulated gas monitor and a simulated commercial PM) and control conditions (a simulated gas monitor and a simulated commercial PM only).

It was found that participants using the ED had poorer performance than the control group. For example, all participants correctly identified the blood loss scenario in the control group, while 3 participants failed in the intervention group. The eye-tracking analysis revealed that in the intervention group, almost half of the time, the ED was used as the main source of information and was frequently favored when identifying an evolving critical incident. It was also noticed that some of the elements in the ED, such as temperature and fluid management, were of little interest to the participants. Interestingly, 8 participants did not use the traditional PM when the ED was available.

With the knowledge gained from this first experiment and following several interviews with anesthesiologists, Jungk et al [35] redesigned the ED to improve its usability (Figure 34). The data were rearranged on-screen to prioritize elements of most interest to the participants based on the eye-tracking analysis. In addition, this new display incorporated elements that had been used in other studies, such as the meters (gauge icons) and profilograms (Figure 34). Four color-coded

profilograms were added to the center of the display representing groups of variables (respiratory mechanics, respiratory volumes, oxygen supply, and the cardiovascular system). The star in the middle was removed, as well as the temperature and fluid management variables, and the positions of the graphs were changed.

Figure 34. Jungk et al ecological displays (second approach). Profilogram bars based on the fuzzy logic approach for intelligent alarms were displayed at the center of the ecological displays, providing an overall state for each functional part of the display.



Jungk et al [35] repeated the same experiment with 8 different anesthesiologists using only an intervention group (no control). All participants identified the blood loss incident in this second test, but 1 participant did not identify the cuff leakage incident. The identification time was significantly shorter for both scenarios compared with the control test in experiment 1. This study exemplifies the importance of an iterative design process in which end users test the device in simulations.

A total of 11 years after the first experiment with an ED for patient monitoring, Effken et al [36] developed and evaluated an ED specifically designed for oxygen management. The development of the ED started with a cognitive work analysis (CWA) aimed to identify the work domain constraints and the cognitive tasks performed by ICU nurses. This helped the designers in arranging the elements on the screen to optimize the cognitive performance of the nurses. As a result, an interesting concept was developed. Figure 35 presents the clinical data structure at 4 levels: purpose, balance, processes, and physiology. The main goal of the system was cellular oxygenation, which was the *purpose*; therefore, it was placed on the top of the screen. If oxygenation was inadequate, the clinician then evaluated the *balance* between the variables related to oxygen demand and delivery, such as oxygen delivery

(DO_2), arterial blood oxygen content (CaO_2), and oxygen consumption (VO_2), which were presented in the form of bar charts directly below cellular oxygenation.

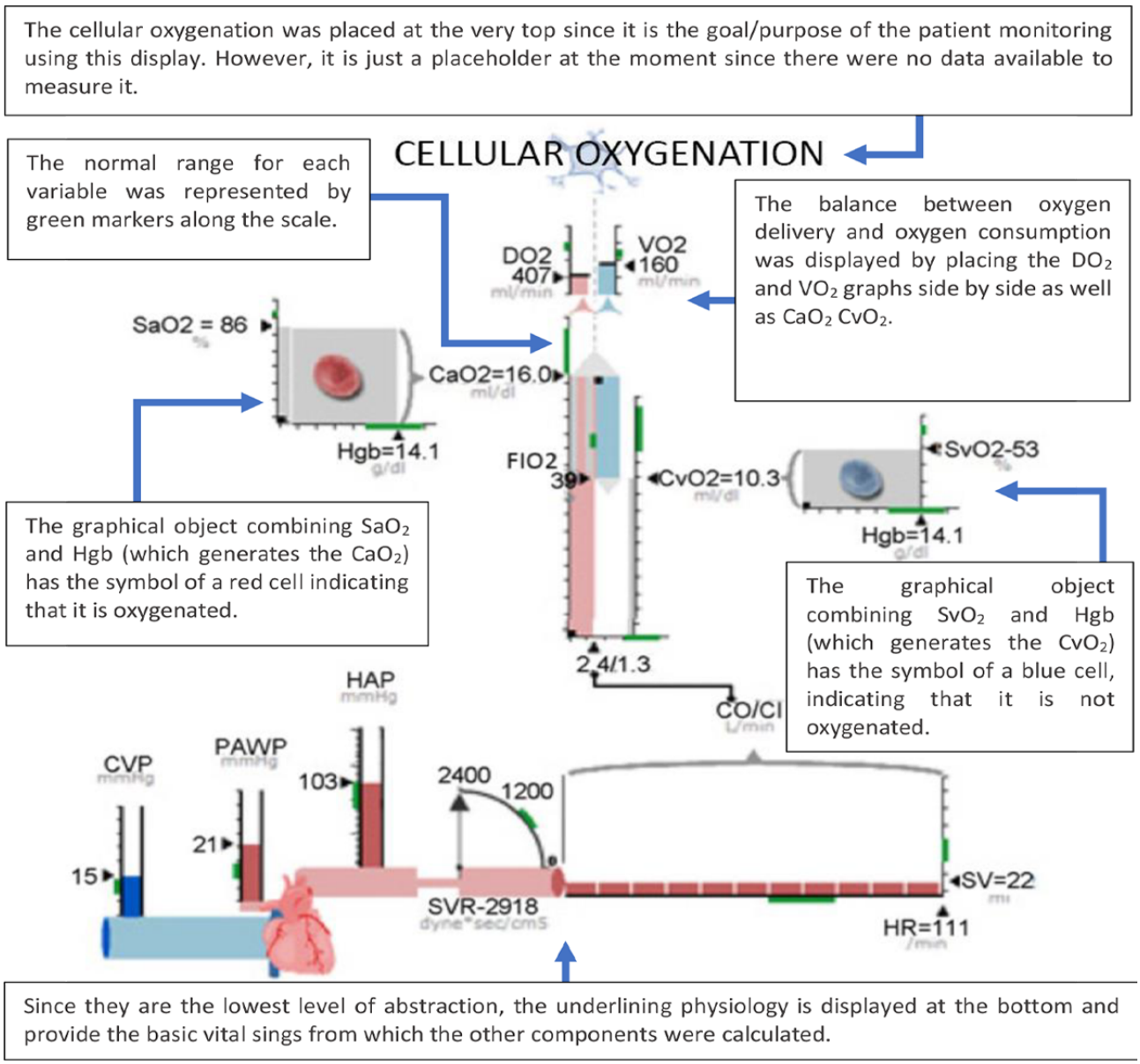
Depending on which side was out of balance, the clinician could identify the cause of the problem in either DO_2 or metabolic *processes* (SaO_2, Hgb, and CO), which were presented as graphical objects. Their underlying *physiology* (CVP, pulmonary artery wedge pressure, MAP, SVR, SV, and HR were presented as bar charts [37].

The ED was compared with a bar graph display (BGD) in terms of clinical event recognition, treatment efficiency, and usability. The BGD presented the monitored values as bar charts using the single-sensor-single-indicator model. In both displays (ED and BGD), the patient history was provided at the bottom of the display and the treatment options (clickable buttons) were presented on the right side of the display. In the experiment, 32 ICU nurses were asked to identify changes in the patient's variables and use the available *treatments* to maintain these variables within the desired ranges.

The results showed no significant differences in the time to initiate the treatment between the ED and BGD. The mean percentage time in the target range varied for each display depending on the number of variables being presented simultaneously and the order of the experiment. Perceived workload (measured by the NASA-TLX questionnaire) was not statistically significantly different across displays.

As in the previous experiment by Effken et al (Effken et al, 1997) [32] there was no indication that the control display (BGD) was clinically used, which makes it impossible to draw meaningful comparisons between the novel display and the conventional PM.

Figure 35. The Effken et al ecological display presented clinical data structured at 4 levels: purpose, balance, processes, and physiology.



Discussion

Principal Findings

This review aimed to critically review and examine the innovations in PM design proposed by researchers and to explore how clinicians responded to these novel design approaches. These proposed innovations are fully described in the Results section of this review. Having analyzed the methodologies used to develop and test these displays, as well as the results of these tests, a few topics have emerged for discussion.

Most novel displays described in this review were developed to promote rapid detection and interpretation of changes in patient vital signs, provide a *bigger picture* of the patient state, and reduce the physical and cognitive load of users and increase the SA for nurses and doctors. For example, GDs and object displays were developed by utilizing shapes and colors to represent changing vital signs. It was expected that these displays would better support nurses and doctors by reducing their detection and decision times and by improving diagnostic accuracy. However, in most cases, the performance of the participants when using the novel displays varied according to the test scenario. Statistically significant improvements in performance metrics were found when using a GD over a traditional PM for some scenarios, but not all of them [18-20,28,33,36]. Only three studies that evaluated a GD observed significant improvement for all tested scenarios [15,17,32], although it is important to mention that in these cases, a conventional PM was not used as a control. For example, one of these studies used as a control display not commonly used in real practice [32] while the other two used alpha-numeric displays as a control, which only presented the numeric values of vital signs without waveforms [15,17]. A traditional PM display in critical care will typically be composed of numeric values and waveforms. Therefore, it is not possible to determine if the outcomes would be the same if a traditional PM was used as a control in these cases.

In the studies where a novel PM was developed with the intention to improve the performance of clinicians by integrating information from several devices into a single screen, participants performed better when the volume of information presented simultaneously on-screen was not overwhelming [24,25] and when the *look and feel* of the traditional PM was not radically changed to accommodate the data integration [27]. When the number of variables presented on a single screen was excessive (eg, more than 30 variables), the cognitive load created for the user was too high, and the designers decided to make use of graphical and object elements to facilitate the assimilation of the patient's state by the clinician [16,35]. Once again, it was verified that statistically significant improvements in the users' performance were found in some scenarios, but not for all scenarios. Therefore, when integrating data from multiple devices, it is important to display only those variables that are essential for the task at hand. This saves the user from feeling overwhelmed by the volume of information presented. Furthermore, challenges of data integration from multiple devices onto one screen go beyond usability and data visualization challenges, as medical devices might not always provide the technological means of integration.

User Involvement in the Design Process

Before 2010, most studies did not mention end-user involvement during the design process. Some of these studies based the design of their interfaces on frameworks, such as EID [32,35,36] and CWA [17] or did not describe the design process used at all [16,19,33]. Other studies did not develop the interface from scratch, instead they tested previously developed displays [15,18] or presented adaptations of existing displays [20,35]. The majority of these studies had inconclusive results when they compared the performance and user satisfaction between the experimental and the conventional displays. On the other hand, generally, studies that used user-centered design (UCD) or participatory design approaches [24,25,27,28] had more satisfactory results regarding usability. One compelling case of how the interface design benefitted from user involvement in the design process can be seen in Jungk et al [35]. The authors conducted an initial study with an experimental display designed based on EID [17]. The results of this first attempt were not satisfactory, and the display was adjusted based on the results of the first experiment and several interviews with the end users. After making adjustments to the design following this feedback, the second experiment had superior results compared with the first experiment. It is worth noting that although the nurses and doctors are the end users of the PM and that design changes in this device will directly influence their user experience, the patient is the one who will ultimately benefit or be affected by the design of the PM.

Study Design Considerations When Testing a Novel Patient Monitor

An essential usability attribute that is not given proper attention in the reviewed studies is safety, and the authors of the studies reviewed did not make references to how they addressed error prevention or error recovery in their displays. As seen with the polygonal display by Gurushanthaiah et al [15], it is possible for a novel display to be seen to enhance a clinician's performance and to elicit a positive user experience, while also being likely to result in inadvertent use errors due to design limitations. Therefore, it is imperative that testing of novel displays also targets the identification of sources of use errors in the design. As a result, it is highly recommended that researchers conduct usability inspections on novel devices before user testing. One way to achieve this is through a heuristic analysis of the display in which clinical or human factors experts evaluate the device or system by assessing how it conforms to well-established user-interface design rules or heuristic guidelines, such as the usability heuristics proposed by Jackob Nielsen [5,38]. A review using the heuristics by Neilsen will not only highlight safety issues but will also identify if usability best practice is adopted in the display design around issues such as the visibility of system status, user control and freedom etc. None of the studies reviewed made reference to carrying out a heuristic analysis.

It should be made clear in a study design if the novel display is intended to replace or to augment a traditional PM. This consideration will heavily influence the introduction of a novel

PM in a clinical context. For instance, clinicians might be willing to introduce a novel PM in their workflow as long as conventional equipment is not being removed. In cases where the novel PM is designed to fully replace a traditional PM and, if the novel PM's interface differs significantly from that of a traditional PM, a more effective approach could be having the novel PM augment the traditional PM and not replace it. Once it is confirmed whether or not the users have fully adapted to the novel PM, further actions can be decided.

Devices are designed to be used in specific contexts of use; therefore, when evaluating a novel PM, researchers should design experiments in which the user interacts with the device in a setting and under circumstances similar to those expected in the intended context of use. However, most of the novel PMs described in this review were tested in a context of use that did not match the expected real-world conditions (eg, laboratories and work offices instead of quasi-clinical settings). The outcomes of an experiment will be weakened if the experiment fails to replicate the expected context of use.

In addition, the control devices used during the testing should be as close as possible to the devices typically used by the users for this application. Some experiments have used an unrepresentative control display as a control for the novel PM [17,19,28,32,35,36]. In such cases, it is impossible to draw conclusions on how the novel PM may impact patient care in comparison with the current standard of clinical care and use.

If at all possible, researchers should provide a comprehensive program of training on the novel interface to participants before carrying out testing. The purpose here is to achieve as a high level of familiarization with the novel display, before testing, as is feasible. Essentially, one should try to eliminate lack of familiarity with the display as a *confounding factor* in the testing, as it is expected that the control display (typically the PM in regular use) will be very familiar to the participants.

This training should ideally include not only an introduction to the new display but also feature demonstrations, simulations, and competency tests.

Providing robust training on a new interface as part of a research study requires a considerable amount of effort and time and, in many cases, this can be very challenging. Nearly all studies reviewed did not exceed 45 min of training. Researchers must keep in mind that although a short training session may be sufficient to allow the participant to understand how the device works, it may not be enough to achieve the same level of familiarity as exists with the control device. In these circumstances, when a novel interface is compared with the standard approach, the standard approach likely achieves much higher preference and, therefore, distorted preference data can result.

Some studies evaluated novel PMs using research participants with no (or very little) medical background and the results of these studies were not presented in this review. The reason for this is that, although it is possible to introduce nonmedical participants to a display to be tested, participants who are not the intended users of a device will have completely different perceptions of the device and will likely use different cognitive strategies to interact with it. These differences produce inaccurate outcomes, as demonstrated by Gurushanthaiah et al [15]. Therefore, we recommend that only samples of the intended users of a device should be used as test participants.

Usability is defined by the ISO 9241-210 (section 2.13) as "the extent to which a system, product or service can be used by specified users to achieve specified goals with effectiveness, efficiency and satisfaction in a specified context of use." Therefore, for good usability, a device must not only improve effectiveness and efficiency (eg, detection/response/trial times, treatment efficiency, accuracy, etc.) but also provide a positive experience for the user. Up to the early 2000s, most studies solely focused on performance metrics and neglected the effects of the design on the user's experience, such as cognitive workload, comfort, and preference. However, since 2003, almost all studies have evaluated the effects of the design on the user during their experiments using questionnaires. For example, studies used either the NASA-TLX questionnaire to measure self-reported perceived workload [19-21,28] or Likert scales to measure participants' preference or satisfaction [22] or both [10,11,36]. The addition of such questionnaires as a part of the experimental methodology indicates a positive paradigm shift in which positive user experience and device satisfaction are also perceived as essential qualities to be considered in the design of a novel PM.

On the basis of our experience with reviewing these studies, we would propose the following recommendations for researchers designing and evaluating new PM interface designs:

1. To identify any usability problems associated with the design of user interfaces and to mitigate error risks before user testing, researchers should consider conducting a heuristic analysis of the displays.
2. During the user testing, the purpose of the novel PM should be made clear to the participants, including specifying whether the purpose of the novel PM is to augment or replace a conventional PM or not. This is important because this information will have an impact on users' perceptions of the device during testing.
3. In all development stages of a novel PM, targeted end users (eg, ICU nurses and anesthesiologists) must be involved in the design and evaluation processes through a UCD methodology.
4. Researchers should strive to design a test protocol that accurately reflects the expected context of the use of the display.
5. To achieve meaningful results and a fair comparison, when testing a novel PM against a conventional PM, the control device (representing a conventional PM) must match the characteristics of the conventional PM as closely as possible.
6. Attempt to eliminate the participant's lack of familiarity with the novel display (relative to their familiarity with the conventional PM) as a confounding factor in testing. Before testing a novel PM with potential end users, researchers should provide extensive training to the participants on the novel PM (preferably involving multiple training sessions) to acclimatize the participants to the use of the novel display and ideally achieve a high level of familiarity with it.

7. As user satisfaction is a key component of usability, more comprehensive assessments of user satisfaction should be carried out using both quantitative and qualitative analyses.

Although it is understandable that fulfilling some of these recommendations in a research context can be challenging because of resource and time constraints, by following them we believe that researchers can significantly enhance the quality of their research.

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Authors' Contributions

This review was carried out by a multidisciplinary team of engineers, health scientists, nurses, anesthesiologists, human factors specialists, and medical consultants. EA, LQ, RH, and GÓL were responsible for defining the methodology, extracting the data, writing the manuscript, and designing the interfaces based on the information provided in the papers. DB, SC, FK, MS, JL, PP, and AB reviewed the manuscript and provided feedback related to the medical aspects. EF, MK, PO'C, and DO'H reviewed the manuscript to provide support with human factors expertise.

Conflicts of Interest

None declared.

Multimedia Appendix 1
Summary of studies reviewed.
[DOCX File , 22 KB - humanfactors_v7i3e15052_app1.docx]

Multimedia Appendix 2
Quality assessment summary.
[DOCX File , 22 KB - humanfactors_v7i3e15052_app2.docx]

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Abbreviations

APsys: systolic arterial pressure
Art: arterial blood pressure
BGD: bar graph display
BP: blood pressure
BV: blood volume
CO: cardiac output
CSO: current state object
CVP: central venous pressure
CWA: cognitive work analysis
DO_2: oxygen delivery
ED: ecological displays
EID: ecological interface design
EPD: etiological potential display
GD: graphical display
HR: heart rate
IBD: integrated balloon display
ICU: intensive care unit
IGD: integrated graphical display
LAP: left atrial pressure
MAP: mean arterial blood pressure
MV: minute volume
NIBP: noninvasive blood pressure
OR: operating room
O_2: percentage of inspired oxygen
PAC: pulmonary artery catheter
PAD: diastolic pulmonary artery pressure
PEEP: positive end–expiratory pressure
PM: patient monitor
PVR: pulmonary vascular resistance
SA: situation awareness
SaO_2: arterial blood oxygen saturation
SpO_2: blood oxygen saturation
SV: stroke volume
SVR: systemic vascular resistance
TSD: traditional strip-chart display
UCD: user-centered design

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Original Paper

Process Evaluation of an eHealth Intervention (Food4toddlers) to Improve Toddlers' Diet: Randomized Controlled Trial

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Abstract

Background: Parents seek trustworthy information online to promote healthy eating for their toddlers. Such information must be perceived as relevant and easy to implement and use.

Objective: The objectives of this study were to conduct a process evaluation of the electronic health (eHealth) intervention (Food4toddlers) targeting food environment, parental feeding practices, and toddlers' diet and to examine possible differences in these areas according to education and family composition.

Methods: A 2-armed randomized controlled trial, including 298 parent–toddler dyads from Norway, was conducted in 2017. In total, 148 parents in the intervention group received access to an intervention website for 6 months. Data on website usage were retrieved from the learning management platform used (NEO). Participants' satisfaction with the intervention was asked for in a postintervention questionnaire. Chi-square and *t* tests were used to examine differences in usage and satisfaction between education and family composition groups.

Results: Most participants were mothers (144/148, 97.2%), lived in two-adult households (148/148, 100%), and were born in Norway (132/148, 89.1%). Mean parental age was 31.5 years (SD 4.2). More than 87.8% (129/147) had a university education degree and 56.5% (83/147) had over 4 years of university education. Most (128/148, 86.5%) intervention participants entered the website at least once (mean days of access 7.4 [SD 7.1]). Most parents reported the website as appropriate to the child's age (71/83, 86%) and self-explanatory (79/83, 95%) and appreciated the interface (52/83, 63%) and layout (46/83, 55%). In total, 61% (51/83) stated that they learned something new from the intervention. Parents with over 4 years of university education and in 1-child households used the intervention website more than those with 4 years or less of university education (8.4 vs 5.9 days in total, *P*=.04) and households with more than 1 child (8.3 vs 5.8 days in total, *P*=.04), respectively.

Conclusions: The Food4toddlers intervention website was found to be relevant by most participants in the intervention group, although usage of the website differed according to educational level and family composition. For eHealth interventions to be effective, intervention materials such as websites must be used by the target group. Our results highlight the need to include users from different groups when developing interventions.

Trial Registration: ISRCTN Registry ISRCTN92980420; http://www.isrctn.com/ISRCTN92980420

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KEYWORDS

toddler; mHealth; usability; eHealth; diet intervention; digital intervention; education difference

Introduction

A healthy diet is fundamental to preschoolers' health and development, for which parents are responsible. A high proportion of parents feel insecure and seek advice regarding food parenting practices via different sources [1]. Internet is a powerful and popular source for health information among parents [2-4]. Still, very few theory- and evidence-based websites or digital apps with trustworthy information exist for this group. Among the few electronic health (eHealth) interventions addressing food parenting practices and child diet that have been developed [5-7], most have been conducted in children older than 1 year of age [5]. Furthermore, interventions targeting parents of preschoolers have shown divergent effectiveness [8].

Mobile health (mHealth) and eHealth interventions are gaining popularity, as such interventions have the potential to reach a large target group, can easily be adapted to new groups, are available 24/7, and can be cost-effective [8-10]. However, for eHealth interventions targeting parents of preschoolers to be effective, one needs to take the interplay between parents' needs and the eHealth intervention's content into account. This means that the information provided has to fit with the child's age, be relevant, be easily accessible by the parents, and be perceived as engaging and meaningful [9]. Although the usage and parental satisfaction of eHealth interventions are crucial, little attention has been given to process evaluation of eHealth interventions targeting parents of young children, addressing intervention use and parental intervention satisfaction.

A few other studies have reported on parental use and satisfaction of eHealth interventions targeting young children. One is the Early Food for Future health study, in which Helle et al [11] found that a high proportion of parents used the intervention website and were well satisfied. A recent paper from the Growing Healthy Program in Australia reported both quantitative and interview data on how parents used and whether they were satisfied with an infant health app, concerning mode of delivery and how the quality of the app was perceived [12]. They found that factors such as previous knowledge and parity affected how the participants appreciated the app. This highlights the need for identifying whether there are differences in the use and satisfaction with the app according to group characteristics. Within public health, there is a focus on socioeconomic differences in health and how to reduce this gap [13]. eHealth interventions aim to improve health and should, ideally, work equally well in different socioeconomic groups, meaning that use and perceived satisfaction should be similar in different socioeconomic groups, including in groups with different educational levels.

We have previously developed and evaluated the effect of a dietary eHealth intervention called Food4toddlers in a randomized controlled trial, targeting parents of 12-18-month-old children [14]. The objectives of this study were to conduct a process evaluation of this eHealth intervention by examining the usage and perceived satisfaction of the intervention website among parents of toddlers and to explore whether this differed according to educational level and number of children in the household.

Methods

Study Design

Food4toddlers is a randomized controlled trial, aiming to promote healthy dietary habits among toddlers [14]. A total of 404 parents of 12-month-old children were recruited through a Facebook advertisement, who then responded to a baseline questionnaire and were randomized into an intervention group and a control group. Participants in the intervention group were given access to the Food4toddlers website for 6 months. Further, they responded to questionnaires immediately after the end of the intervention (follow-up 1) that included process evaluation measurements, and again 6 months postintervention (follow-up 2).

Eligible individuals were parents of children born between June 2016 and May 2017. The parents had to be literate in Norwegian. Of the 404 recruited parents, 298 (73.8%) filled in more than half of the baseline questionnaire which was the minimum requirement to be randomized into either the control or intervention group (n=148). Postintervention, at child age 18 months (follow-up 1), 220 participants completed all or parts of the questionnaire, with 99 of these from the intervention group. Details of the recruitment strategy, the development of the intervention, and the randomized trial are described in the study protocol [14]. The study was approved by the Norwegian Centre for Research Data on June 08, 2016 (reference number 48643). Informed consent from parents was obtained when they signed in online for participation. Data from the intervention group at baseline and follow-up 1 are reported in this study.

The Food4toddlers eHealth Intervention

The intervention group had 6 months of access to the Food4toddlers website which comprised 4 main elements: (1) lessons (n=22) on how to provide healthy food and create a healthy eating environment for the toddler, (2) recipes, (3) a discussion forum, and (4) basic information about food and beverages (called *Good to know*). Initially, the web page was limited to information relevant for the child's age at baseline and gradually expanded in 20 steps as the child got older. The participants received a weekly email with a link to the newly available information. Each module had elements of activities, such as quizzes, videos to watch, facts, and myth busting [14].

Data and Measurements

In this paper, we present the following elements from the process evaluation: (1) the exposure or usage of the intervention, (2) parental satisfaction with the intervention, and (3) parental perception of learning something new from the intervention. To assess the exposure or usage of the website we used data automatically registered by the Learning Management System NEO. NEO is a platform for managing digital classroom activities and tracking student achievement. It has an intuitive design, making it easy to obtain access to information. The user data were manually retrieved from NEO. The data accessible were (1) number of days the participants accessed the website, (2) the use of the 22 *Food4toddlers* lessons, and (3) activity on

a discussion forum. No data on the use of the recipes and the *Good to know* section were available. Some participants visited the website but had no reports on the use of any lessons. They were coded as *1-day users* because they theoretically could have used the rest of the website except the lessons (eg, recipes).

In addition to the automatically registered information on participant's use of the website, we used data from the postintervention questionnaires. The intervention group responded to questions about the use and satisfaction of the intervention's website at follow-up 1 (end of intervention). Parents were asked how many of the recipes they had tried, with response alternatives *none*; *none, but was inspired*; *1-5*; *6-10*; and *11 or more.* We further asked them which part of the intervention they found most useful (lessons, recipes, *Good to know* site, or whether they did not know what they preferred). Further, the parents graded statements about their satisfaction (1-7) with the intervention and perception of learning something new (8): Do you agree or disagree with these statements: *(1) The content was well adapted to my child's age, (2) The text was understandable, (3) The website was user-friendly, (4)The website had an appealing layout, (5) The recipes were easy to follow, (6) The recipes were easily adapted for the whole family, (7) The films for the recipes were useful,* and *(8) I learned something new.* The response alternatives were given by a 5-point scale from 1=*strongly disagree* to 5=*strongly agree* with an additional *I don't know* response alternative. The answers were recoded into 3 groups for the analyses in this paper (*agree, indifferent,* or *disagree*).

Other Measures

Parents' height and weight were self-reported. For their child, measures recorded at the health care centers were reported if available. The participants reported their age and their child's age at baseline. Further, they reported the number of persons in the household in 2 different questions: (1) number of adults and (2) number of children. They also reported county of residence and marital status (married, partnered, single, divorced/separated, widow/er, or other). The number of children in the household was dichotomized into those with 1-child households and those with more than 1 child in the household. Participants also reported on their level of education (primary school or less, primary schools plus 1 year of further education, high school, vocational school, upper secondary school or less, college/university [≤4 years], college/university [>4 years], other, and do not know). Only 18 persons were categorized with no higher education, which is a low number when doing subanalyses; therefore, we dichotomized the education variable as presented above. Consequently, the comparisons in this study were between parents with more than 4 years and those with 4 years or less of education, and between parents with 1-child households and those with more children in the household.

Statistical Analysis

Means with standard deviations for continuous variables and frequencies and percentages for categorical variables were reported. The chi-square tests were used to test potential differences in the perceived value of the intervention between the 2 education groups and according to the number of children in the household. Independent sample *t* tests were used to test potential group differences for continuous variables. All analyses were conducted in SPSS version 25 (IBM). Statistical significance was set to the $P \leq .05$ level.

Availability of Data and Materials

The data set supporting the conclusions of this article will be available in the UiA Open Research repository.

Results

Participant Characteristics

The characteristics of the participants included in the intervention are summarized in Table 1. Mean parental age was 31.5 years (SD 4.2; Table 1). Most participants were mothers (144/148, 97.2%), lived in 2-adult households (148/148, 100%), and were born in Norway (132/148, 89.1%). There were participants from all over Norway, originally reported by county of residence, with representation from all 19 Norwegian counties; however, these data are presented in Table 1 as numbers from each of the main parts of Norway. Of the participants in the intervention group, 56.4% (83/147) had more than 4 years of university education.

Table 1. Baseline characteristics of parents and toddlers in the intervention group (N=148).

Characteristic	Intervention group
Parent	
Mother/father (n)	144/4
Age (year), mean (SD)	31.5 (4.4)[a]
Height (cm), mean (SD)	169 (6.0)
Weight (kg), mean (SD)	70.8 (14.3)
BMI (kg/m^2), mean (SD)	24.9 (4.6)
Two-adult household[b], n (%)	148 (100)
Total number of household members, mean (SD)	3.6 (1.0)
Born in Norway, n (%)	132 (89.1)
Educational level[a]	
Less than college/university (≤4 years), n (%)	64 (43.5)
College/university (>4 years), n (%)	83 (56.4)
Geographic residence	
Northern Norway, n (%)	8 (5.4)
Central Norway, n (%)	16 (10.8)
Western Norway, n (%)	34 (22.9)
Southern Norway, n (%)	24 (16.2)
Eastern Norway (including Oslo), n (%)	66 (44.5)
Toddlers	
Age (months), mean (SD)	10.9 (1.3)
Child's sex: Female, n (%)	69 (46.6)

[a]One missing case in this variable.

[b]Live together with the other parent.

Participants' Use of the Intervention (Usage)

All 148 persons in the intervention group were included in the analyses based on data retrieved from NEO, including 1 person that first got access to the intervention and then decided to quit and 2 participants that did not get access mistakenly (all 3 with no access data). From the NEO data we found that 13.5% (20/148) of parents in the intervention group did not enter the website at any point (Table 2). The mean number of days of access was 7.4 (SD 7.1). Each of the 22 lessons comprised more than 1 webpage and we registered whether the participants had completed the entire lesson or not. On average, the participants completed 8 of 22 lessons (range 0-22; Table 2).

In the intervention group, 99/148 (66.9%) participants answered at least parts of the questionnaire at follow-up 1. However, only 83/148 (56.1%) participants answered the last questions in the questionnaire that concerned the website use. When evaluating the use of the individual components on the website, most participants in the intervention group reported having used *1-5 recipes* (38/83, 46%) or *none but was inspired* (27/83, 33%; Table 2).

Table 2. Participants' use of the intervention website and recipes tried.

Intervention use[a]	Value
Website use (N=148)	
Did not enter, n (%)	20 (13.5)
Days of access, mean (SD); min-max	7.4 (7.1); 0-32
Finalized lessons, mean (SD); min-max	8.0 (7.6); 0-22
Recipes (number) tried (N=83)[b]	
None, n (%)	8 (10)
None, but was inspired, n (%)	27 (33)
1-5, n (%)	38 (46)
6-10, n (%)	9 (11)
11 or more, n (%)	1 (1)

[a]Data were retrieved from the Food4toddlers website. One participant got access to the intervention but decided to quit. Two did not get access to the intervention mistakenly. These 3 are included in the reported numbers.

[b]Questions answered at follow-up 1 (postintervention at child age 18 months).

Use of the Intervention Website According to Parental Education and Number of Children in the Household

Participants with more than 4 years of university education accessed the website for significantly more days than those with a lower educational level (P=.04). In addition, those with more than 4 years of university education completed more lessons than those with fewer years of education (P<.05). There was also a difference in use between parents living in 1-child households and those living in a household with more than 1 child. Parents in 1-child households accessed the website for significantly more days compared to those with more children (P=.04; Table 3).

Table 3. Comparison of website use between education groups (N=147) and between 1-child and >1 child households (N=148).

Analyzed component	≤4 years of university education[a] (N=64)	>4 years of university education[a] (N=83)	P value[b]	Household with 1 child[c] (N=86)	Household with >1 child[c] (N=62)	P value[b]
Days of access in total, mean (SD)	5.9 (6.8)	8.4 (7.2)	.04	8.3 (7.8)	5.8 (5.7)	.04
Number of lessons finished, mean (SD)	6.6 (7.3)	9.1 (7.7)	<.05	8.9 (7.8)	6.7 (7.2)	.09

[a]Parents were divided based on educational level into those with 4 years or less of university education and those with more than 4 years of university education.

[b]Independent sample t test.

[c]Asked about how many children were included in the household, divided into 1 child versus more children.

Satisfaction of the Intervention Website's Modules and Topics

When asked about what part of the intervention website the participants found to be most useful, 43% (36/83) were most satisfied with the recipes, whereas 31% (26/83) valued the modules as the most useful part of the intervention. Participants also reported to which degree they agreed with different statements regarding how they found the intervention website. The majority of the participants agreed that the website content applied to their child's age (71/83, 86%) and that the texts were easy to understand (79/83, 95%). Most parents in the intervention group reported that they appreciated the interface (52/83, 63%) and layout (46/83, 55%). We also asked to which degree the participants valued the recipes and films. In total, 83% (62/75) found the recipes easy to follow, and 80% (60/75) found them easy to adjust to the whole family. Only 32% (24/75) found the films posted on the intervention website useful. There were no significant differences in how the intervention website and the recipes were valued between those with more than 4 years of university education and those with a lower educational level (data not shown).

There was low activity in the discussion forum including in the learning platform. The most active participant posed questions and responded 5 times, whereas 7 other participants posed a single question during the period when they had access to the forum. The first author (MR) of this paper responded to all questions.

Perceived Acquisition of New Knowledge From the Intervention Website According to Educational Level and Number of Children in the Household

In total, 61% (51/83) reported that they learned something new from the intervention website (Table 4). There was a borderline significant difference between educational groups when asked whether the participants had learned something new (P=.052).

More of the highly educated participants agreed that they had learned something new, whereas more participants with moderate education were indifferent to this statement (Table 4).

Table 4. Perceived acquisition of new knowledge among parents in the intervention group according to educational level and number of children in the household, through response to the prompt "Think of the Food4toddlers website in total, and indicate how strongly do you agree/disagree with the statement *I learned something new*?"

Statement	All (N=83)	≤4 years of university education[a] (N=33)	>4 years of university education[a] (N=50)	*P* value	One-child household[b] (N=52)	>1 child in household[b] (N=31)	*P* value
Agree, n (%)	51 (61)	17 (52)	34 (68)	—[c]	35 (67)	16 (52)	—[c]
Indifferent, n (%)	21 (25)	13 (39)	8 (16)	—[c]	12 (23)	9 (29)	—[c]
Disagree, n (%)	11 (13)	3 (9)	8 (16)	.05	5 (10)	6 (19)	.30

[a]Parents were divided based on educational level into those with 4 years or less of higher-level education and those with more than 4 years of higher-level education.

[b]Parents reported how many children were included in the household, divided into 1 child versus more children.

[c]Not applicable.

Discussion

Principal Findings

Most parents today use the internet to obtain information relevant to their child's health [15]; however, they report that they need more training to distinguish between trustworthy and not trustworthy sources [16]. In the Food4toddlers study, we developed a website with evidence-based information relevant to toddlers' diet, food environment, and parenting practices. More than 86.5% (128/148) of parents in the intervention group visited the website and most of them found the website useful, especially the modules and the recipes. The website content, texts, and interface were highly valued by most parents, which may have influenced parental engagement on the website. Besides, most parents in the intervention group found the content applicable to their child's age. This is an important result, as it is established that finding the information presented appropriate and given at the right time are essential to change behavior [9].

Although the participants rated the recipes as the most important part of the intervention, they did not find the films made for the recipes as useful as the other components. This may indicate that written recipes might be sufficient for use, or that our produced films did not quite suit the target group. Few participants used the discussion forum which was a part of the website. It might be that parents discuss in other online forums and that our forum seemed new and different, or of no need. Using a closed Facebook group, which is a common discussion forum type, might have increased the activity in the discussions. This is supported by a study by Boswell and collaborators [17] in which parents reported Facebook as the preferred digital platform for participating in an intervention. However, in the parent-focused Time2bHealthy study closed Facebook groups were made available, but less than 40% agreed or strongly agreed that the Facebook component was useful [18]. Our goal with including such a discussion forum was that participants could motivate each other and share experiences; however, as also others have found [18], the inclusion of such a forum might not be worth the effort of setting up.

A total of 13.5% (20/148) of parents who had access to the intervention website did not enter it at any point, which is higher than what is observed in other studies. The Swedish MINISTOP study had a very high website visitor rate [19], possibly because the investigators met the participants in person and called them on the phone 2 days after log-in instructions were delivered. Although we sent email reminders to the participants who did not log in, the adherence might have been higher by adding, for example, a phone call as in the MINISTOP study. Other studies have also emphasized personal contact (eg, the Australian Time2bHealthy study) [18]. However, the costs rise with more intensive follow-up of participants and will limit distribution to a large population. In addition, the website visitor rate in our study is probably more in line with what can be expected when offering access to a web-based learning tool outside a test situation. Boswell and collaborators [17] interviewed parents about their preferred mode of intervention participation and found that they preferred a combination of online sources (websites, email, or Facebook). Parents with lower education levels also preferred this combination; however, in this group, more parents wanted to combine the online scores with face-to-face components [17]. It is worth noting that the use of more advanced push notifications is increasingly being used in digital health interventions [20,21], and could have boosted both the participation and the parental engagement on the website.

There were differences in website use between education groups and between those with 1 or more children in the household. It is somewhat surprising that those with the highest education spent more time using the website, and also that there is a borderline difference in whether they found that they had learned something new from the website, with results in favor of the more educated parents. Taki and collaborators [12] reported that parents defined as knowledgeable in parenting skills found eHealth interventions less useful because they did not learn anything new from it. Having a higher education does not translate directly into parenting skills, and one could speculate that higher education creates a higher drive to learn more. However, in the light of public health efforts to reduce social differences in health, this finding is not a positive one, as it indicates that interventions of this kind might increase the socioeconomic divide. It is worth noting that the cutoff between education groups in this study was set high, due to the

educational characteristics of the sample. The findings of this study may, therefore, indicate that there are differences in the gain of health-related information as well between parents with higher education. Although we included a diversity of user groups in the development phase of the intervention, including mothers of lower socioeconomic group, we could have put even more emphasis to tailor the content and interface to different groups. A pilot study including parents with different socioeconomic groups or parents with different educational levels would probably have given valuable input, especially followed by interviews targeting both high and low adherent participants.

It was not surprising that those with more children in the household, and thereby more experience in feeding toddlers and potentially less time available, spent less time on the intervention than those in 1-child households. This is in line with what Taki et al [12] describe, that is, previously acquired knowledge about infant feeding yields lower engagement in eHealth intervention of that topic.

Strengths and Limitations

We obtained objective information about parental access to the intervention from the learning management system (NEO). This means we did not need to solely rely on participants' self-reported responses to the postintervention questions, which is a clear strength of this study. When interpreting the effect results of this intervention, it is a clear strength that a detailed process evaluation has been conducted.

The participants in our study had a substantially higher educational level compared with national figures [22]. This may compromise the generalizability of our findings. A different spread in educational level would probably have yielded different results, as indicated in other studies [23,24]. Our results highlight the importance of working hard to include not just highly educated groups in studies, as is the case with this study. The overall high educational level in this study influenced our educational level cutoff. Further, although participants were from all Norwegian counties, proportionally more participants were from the southern parts compared with national figures [25], which may hamper generalizability.

Conclusion

Few previous eHealth interventions focusing on diet have reported data from process evaluations, including parental usage and satisfaction with the intervention, as is the case with this study. We found that most participants used the intervention website during the intervention period, and that they found it relevant and useful. Parents with more than 4 years of university education used and learned more from this intervention than those with a lower educational level. Our findings highlight the utmost importance of including users from different groups when developing eHealth interventions and may inform future interventions to take particular care in matching intervention content to different educational and socioeconomic groups' needs.

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Authors' Contributions

FNV, ERH, and NCØ initiated and designed the study. ERH, FNV, NCØ, and MR developed the intervention. MR, ACM, FNV, MR, WVL, ERH, and NCØ initiated and developed the paper. MR performed the data collection supervised by ERH, FNV, and NCØ. MR and NCØ analyzed and drafted the first version of the paper. All authors gave substantial input to the paper. All authors contributed to, read, and approved the final version of this paper.

Conflicts of Interest

None declared.

Multimedia Appendix 1
CONSORT-eHEALTH checklist (V 1.6.1).
[PDF File (Adobe PDF File), 3302 KB - humanfactors_v7i3e18171_app1.pdf]

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Abbreviations

eHealth: electronic health
mHealth: mobile health

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Original Paper

Opportunities and Recommendations for Improving Medication Safety: Understanding the Medication Management System in Primary Care Through an Abstraction Hierarchy

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Abstract

Background: Despite making great strides in improving the treatment of diseases, the minimization of unintended harm by medication therapy continues to be a major hurdle facing the health care system. Medication error and prescription of potentially inappropriate medications (PIMs) represent a prevalent source of harm to patients and are associated with increased rates of adverse events, hospitalizations, and increased health care costs. Attempts to improve medication management systems in primary care have had mixed results. Implementation of new interventions is difficult because of complex contextual factors within the health care system. Abstraction hierarchy (AH), the first step in cognitive work analysis (CWA), is used by human factors practitioners to describe complex sociotechnical systems. Although initially intended for the nuclear power domain and interface design, AH has been used successfully to aid the redesign of numerous health care systems such as the design of decision support tools, mobile patient monitoring apps, and a telephone triage system.

Objective: This paper aims to refine our understanding of the primary care office in relation to a patient's medication through the development of an AH. Emphasis was placed on the elements related to medication safety to provide guidance for the design of a safer medication management system in primary care.

Methods: The AH development was guided by the methodology used by seminal CWA literature. It was initially developed by 2 authors and later fine-tuned by an expert panel of clinicians, social scientists, and a human factors engineer. It was subsequently refined until an agreement was reached. A means-ends analysis was performed and described for the nodes of interest. The model represents the primary care office space through functional purposes, values and priorities, function-related purposes, object-related processes, and physical objects.

Results: This model depicts the medication management system at various levels of abstraction. The resulting components must be balanced and coordinated to provide medical treatment with limited health care resources. Understanding the physical and informational constraints on activities that occur in a primary care office depicted in the AH defines areas in which medication safety can be improved.

Conclusions: Numerous means-ends relationships were identified and analyzed. These can be further evaluated depending on the specific needs of the user. Recommendations for optimizing a medication management system in a primary care facility were made. Individual practices can use AH for clinical redesign to improve prescribing and deprescribing practices.

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KEYWORDS

patient safety; polypharmacy; potentially inappropriate medications; primary care

Introduction

Background

Despite making great strides in improving the treatment of diseases, the minimization of iatrogenic harm continues to be a major hurdle. The process of treating illness often requires the use of medications with known adverse effects. The delicate balance of risk versus benefit is often complex and individualized, making it difficult to be addressed properly.

Medication error is a common cause of patient morbidity and mortality [1]**.** Medication safety encompasses preventing medication errors (eg, giving the wrong drug) as well as preventing harm associated with the intentional prescription of otherwise appropriate medications. Medication safety and thus the prevention of medical error require both the appropriate prescription of medication as well as their subsequent deprescription, a concept developed to address overprescribing [2].

Two important concepts in medication safety, especially significant in promoting deprescribing, are polypharmacy and potentially inappropriate medications (PIMs). The term polypharmacy is defined as the use of multiple medications concurrently by a single patient. These concepts assist with risk stratification for drug-drug interactions and adverse drug events. The exact number of medications varies among researchers and clinicians, but it is often considered to be 5 or more medications [2]. Medication is classified as a PIM if the risk of an adverse event is likely to outweigh its clinical benefit [3]. Patient-specific contextual factors, such as age and comorbidities, often drive the classification of drugs as PIMs that may otherwise be the standard of care. Both polypharmacy and PIMs pose an increased risk to patients, including increased rates of adverse events, hospitalizations, and increased costs [4-7].

Factors that contribute to medication safety are both at the system level, such as communication and system workflow, as well as the individual level, such as clinician education and experience. Screening tools, such as the Beers criteria, have been developed to assist in the identification of PIMs [3,8,9] in hopes of aiding providers in the identification of patients and medication that may require deprescribing actions. Tools that assist the provider in determining the appropriateness of the medication increase their willingness to deprescribe [10]. They have been applied in clinician-provided medication reviews, patient education and activation, and clinical decision support tools [11-16]. However, despite the availability of these resources, PIMs and polypharmacy continue to be a prevalent problem [17].

However, applying appropriate deprescribing concepts into clinical practice has proven to be not so straightforward. Individual clinicians report difficulty in addressing these issues due to barriers such as lack of time, lack of published clinical guidance of when and how to stop medications, and fear of poor disease outcomes related to stopping medications [18-20]. Meanwhile, system-based interventions designed to optimize the medication regimen of a patient population often have difficulty being implemented into existing, complicated health systems [21]. Implementation factors, such as the lack of pharmacist integration into the medical team, resource constraints, and individualized patient needs, limit the effectiveness of interventions. Traditional methods, therefore, may be insufficient to tackle such a complex problem, perhaps providing an explanation for the continued adverse outcomes associated with medications.

In search of effective medication management strategies that support medication safety and deprescribing for everyday clinical practice, we propose to start by examining medication management in primary care as a system. To fully understand deprescribing, the management system as a whole can be evaluated with the long-term goal of promoting medication safety and removing PIMs. The primary care office represents a hub for clinicians and patients to exchange information and address medication issues on a regular basis. Exploring this hub in a systematic manner, informed by methods of human factors engineering, can help understand medication management and thus can be utilized to understand both barriers and facilitators of deprescribing.

Objectives

As a first step toward understanding current practices in deprescribing at the primary care level, this paper presents a model of primary care medication management in the form of an Abstraction Hierarchy (AH), which seeks to describe the possible actions and constraints of work performed within a system [22]. By emphasizing the functional structure of a work system, rather than describing specific concrete situations, information requirements can be extracted from an AH that is independent of events and time, and thus can be used to design systems and interfaces that can handle novel and unexpected situations.

AH has been successfully applied in health care to understand domain constraints to facilitate the design of decision support tools [23], mobile patient monitoring apps [24], a telephone triage system [24], and various other workflow decision tools [23,25,26]. For example, Effken et al [23] modeled nurse's decision support needs and constraints of the workplace on the design of computer interfaces to provide that support. Ge rges et al [24] identified decision support needs required for monitoring patient vitals and communicating with other providers in the unit. This was used to create a mobile app for all nurses in the unit to check patient status and respond accordingly. These displays depict data at various levels of abstraction to visually represent the relationships between the required data components and complete tasks.

Unlike other analysis methods, such as task analysis (which aims to model the best set of actions to achieve a goal) or cognitive task analysis (a variant of task analysis to account for behavioral variability associated with different cognitive strategies), the AH emphasizes the system constraints and capabilities that operators act on (in contrast to task analysis of what operators do). These constraints and capabilities may then be used to explicitly identify information requirements for system design or redesign that can better support problem identification, efficient diagnosis, and effective problem solving. Information requirements extracted from an AH have been shown to differ from those generated from a hierarchical task analysis [27]. One significant difference between the 2 approaches is that task analysis is context dependent, such that actions and behaviors are derived for a specific goal or function. In contrast, an AH may be bounded by a context of use to help focus on the scope of the model, but is more widely applicable to the system across a broad range of situations [27]. For example, St-Maurice and Burns [28] developed an AH to model patient treatment. This analysis is bounded by activities within the clinician's control, but does not exclude activities outside that specific workflow, such as processing the patient's arrival to the office.

The aim of this paper was to refine our understanding of the primary care office in relation to a patient's medication through the development of an AH. In doing so, AH can be utilized as a guide for future studies, interventions, quality improvement as well as system and interface design.

Methods

Initial Drafting

AH is a modeling tool that is a part of the work domain analysis, the first (out of 5) phase of cognitive work analysis (CWA), a human factors research approach for the analysis, design, and evaluation of work in complex sociotechnical systems. CWA was originally developed for use in the nuclear power industry to address the need for an optimized interface design of complex systems to prevent industrial accidents [29-31]. The methodology has since been adapted to a broad range of different sociotechnical systems, including health care.

Stanton et al [30] described a systematic way of approaching an AH. This methodology was utilized in our approach. Previous work, such as Read et al, Ashoori et al, Pigenot et al, and Xu et al [26,32-34], guided our analysis. This process included determining system boundaries, review, and consensus by a team of experts, followed by a detailed analysis.

Determining the boundaries of the system, the first step in developing an AH requires capturing the appropriate amount of detail to describe the work taking place without populating the model with information irrelevant to the model's objective [35]. Our model is intended to capture the medication management system of a typical primary care office. Primary care offices are central to all subdivisions of health care in the outpatient setting. Due to its central role in care coordination and disease prevention, the primary care office was an ideal system for addressing medication safety. We considered clinicians to be the *users* of the system in our analysis.

Once the system of interest was determined, the AH was iteratively drafted in 2 alternating phases. The first phase included initial drafting of the components of the medication management system as *nodes* by 2 authors (TK and AB), one being a PhD student in human factors engineering and the other a resident physician in family medicine. Each node was subsequently added to an appropriate level of abstraction. Previous literature on AH methodology guided node creation and placement.

Once each node was categorized at the appropriate level of abstraction, connections between nodes were made. Connections between nodes, also known as *means-ends* links, were then made. A means-ends link represents the connection of a node with nodes on a different level of abstraction. Each node was connected below its supporting nodes. In addition, each node was connected above its higher-level function or purpose. For example, the *Patient Assessment* node is connected above its end goals of *Patient-Centered Care* and *Appropriate Use of Medications*. The *Patient Assessment* node is simultaneously connected to the means by which it is accomplished below, which includes *Chart Review*, *History and Physical*, *Out-of-Office Communication Protocols*, and *Diagnostic Tests*. Thus, the resulting AH has each component of the system categorized into 5 levels of abstraction, with relationships between nodes being clearly demarcated.

Model Refinement

The second phase consisted of all authors coming together in an expert panel review of the draft AH. In addition to the student researchers, our team included 2 board-certified geriatric pharmacists, a clinical pharmacist, a family physician, a human factors engineering researcher, and social scientists. Collectively, the authors have extensive experience in education and research on PIMs, polypharmacy, deprescribing, and human factors analysis. Panel discussions provided key insights into a typical workflow of a primary care office, medication safety, ethical principles, and practical constraints in a clinical setting. Iterative discussions among the authors informed the subsequent revisions of the AH until a final model was agreed upon.

Once finalized, the AH was accepted to successfully represent the medication management system in a primary care office. The authors then carefully reviewed the AH with a focus on medication safety and deprescribing. On the basis of the AH and the existing CWA literature, recommendations for system design and improvement were drawn.

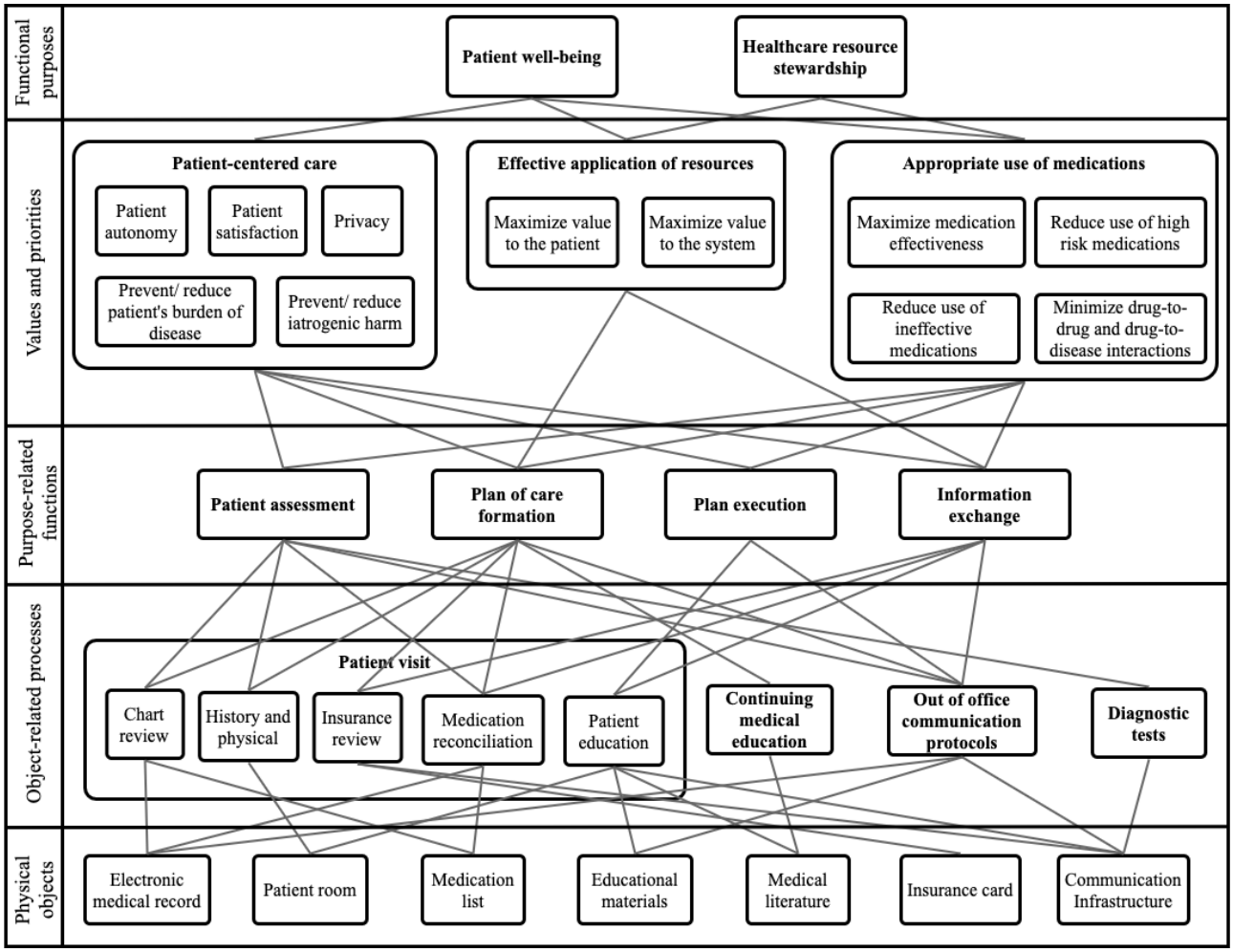
Results

Overview

The resulting AH graphically modeling the medication management system of a primary care office is depicted in Figure 1. The AH is a representation of the system at work. The model depicts each component of the medication management system in primary care at 5 different levels of abstraction. The top is the most abstract, and the bottom is the most concrete. In addition, it visually depicts the relationships between each

component via *means-ends* links. With a model of the system at hand via the AH, the system can subsequently be optimized and improved. Although this AH can be utilized for a broad range of medication-related systems issues, we focus on deprescribing and medication safety.

Figure 1. Abstraction Hierarchy of the medication management system in primary care.



Functional Purpose

The functional purpose of the system is depicted at the top level of the AH. This level represents the overall goals of the system [30,32]. This level is also the most abstract. All lower levels and nodes function to support these top goals. In other words, the means by which these goals are accomplished are the connecting nodes below. When optimizing a system, these top-level nodes are used as the guiding end goals of the system.

A total of 2 functional purposes were identified in the AH: maximize *Patient Well-Being* and maintain appropriate *Healthcare Resource Stewardship*. Maximizing *Patient Well-Being* refers to maintaining or improving the patient's current health status. *Healthcare Resource Stewardship*, as we define it, entails the effective and efficient mobilization of resources for the population. Resource allocation includes appropriate use of clinician's time and pharmaceuticals when beneficial to the patient, as well as professional restraint when clinical benefits are unclear or unproven or are outweighed by real or potential harm.

The modeled system depicts achieving both goals simultaneously. Typically, these goals work in sync with each other for the benefit of everyone involved. Both can be sufficiently achieved in most scenarios. However, extreme cases may make achieving both these goals difficult, thus highlighting the constraints of the system. For example, some circumstances may necessitate prioritizing *Patient Well-Being* over *Healthcare Resource Stewardship*.

By understanding the relationships between the overall goals and the individual components of the medication management system in primary care, the system can be optimized to achieve these goals more effectively and efficiently.

Values and Priorities

Values and priorities represent the way in which the system achieves its functional purpose [30,32]**.** They are the nodes most closely supporting the overall functional goals of the system. Each node at this level must be considered to support the above goals of the system. When optimizing a medication management system, these nodes must be utilized and balanced with each other to sufficiently support the functional purpose of the system.

A total of 3 categories of values and priorities were identified, which consist of *Patient-Centered Care*, *Effective Application*

of Resources, and *Appropriate Use of Medications* [36]. These categories can be further classified into distinct yet similar components.

Patient-Centered Care refers to the clinician finding common ground with the patient to understand them and to better respond to their needs [37]. The central role of the patient is a key ethical principle used by clinicians to guide their work. The key role of *Patient-Centered Care* is consistent with existing literature. There are many documented benefits of patient-centered care for Patient Well-Being and Healthcare Resource Stewardship. This includes improved patient health, increased care efficiency, and reduction of unnecessary diagnostic testing and referrals.

If more specificity is required, *Patient-Centered Care* can be further classified into *Patient Autonomy*, *Satisfaction*, and *Privacy* [38]. Patient autonomy refers to the idea that patients should be involved in their care planning and be allowed to make their own informed decisions without undue influence [39]. Patient satisfaction encompasses a broad set of beliefs that cannot always be easily measured but must be evaluated in terms of the setting in which the patient is receiving care [40]. The importance of these nodes is consistent with existing literature, as satisfaction with primary care services has been shown to influence a patient's health-related behaviors, such as compliance with medications [41].

In addition, *Patient-Centered Care* includes *Reducing the Patient's Burden of Disease* and *Reducing Iatrogenic Harm*. These concepts refer to the worsening of a patient's health status by the progression of their medical condition or through medical error [42]**.**

Another category at this level of abstraction is *Effective Application of Resources*. With limited health care resources and resources in high demand, any primary care office system must prioritize the effective application of resources to maximize value to their patient population. This includes minimizing out-of-pocket costs to the patient as well as minimizing costs for the health system at large. As expected, the impact of out-of-pocket expenses on health behavior is clearly observed by clinicians on a regular basis.

Appropriate Use of Medications is another value and priority of the medication management system in primary care. Although medications carry an inherent risk of iatrogenic harm, an astute clinician balances this risk with the medication's benefits to improve patient well-being and effectively apply health care resources. To increase the specificity required to optimize the system, *Appropriate Use of Medications* can be classified into several nodes. This includes *Maximizing Medication Effectiveness* by using a pharmacologic intervention in specific patients who will benefit most from its effects. It also includes reducing the use of both high-risk medications and medications with minimal benefit. In addition, patient-specific risk factors such as drug-drug interactions and drug-disease interactions must be minimized. These underlying values and priorities can be observed regularly when, for example, clinicians reserve high-risk and expensive medications for patients most likely to benefit from the medication.

These values and priorities must be taken into consideration by the clinician while attempting to achieve the functional goals of the system. Although sometimes in sync with each other, certain circumstances may require the clinician to prioritize one above others. Understanding the competing values and priorities faced by the clinician is critical in optimizing medication management in primary care.

Purpose-Related Functions

The next level of abstraction represents the purpose-related functions. This level is more concrete than those listed above and represents the work performed by the clinician. These are the general functions that need to be carried out to support the above goals of the system [30,32]. When designing or improving a system, understanding the relationship between these work functions and the rest of the system is critical.

The purpose-related functions of the medication management system in a primary care office include *Patient Assessment*, *Plan-of-Care Formation*, *Plan Execution*, and *Information Exchange*.

Patient Assessment includes the evaluation of all patient-related information by the associated clinicians and the subsequent consolidation of information into a diagnosis. The patient expects that this assessment will inform the clinician of what action needs to be taken to maintain or improve their health, provide a basis for communication between them and their clinician, and allow them to voice health concerns that are most important to them [43]. Specific to our focus, accurate medication administration and evaluation of both desired clinical outcomes and patient reported negative effects are included in this function. The clinicians' ability to assess the patient is one of their key work functions, and its importance to the overall system is intuitive. This is consistent with what is observed in the clinical setting, as electronic health record (EHR) systems frequently have a discrete section for the documentation of a clinician's assessment.

Plan-of-Care Formation involves the development of a plan to address the patient's concerns and medical conditions revealed during the patient assessment. This plan may include items such as initiation, titration, or discontinuation of a pharmacologic agent, ordering a diagnostic test, regular monitoring, patient education, or referring to a specialist for further evaluation [44]. Although informed by the patient assessment, formulating the plan-of-care represents a distinct work function. When comparing this model to the real world, the plan of care is typically given its own section of the EHR.

In the outpatient primary care setting, *Plan Execution* is a critical node that is often performed outside of the office and therefore left up to the patients or their caregiver. This includes medication adherence, going for laboratory evaluation, or making appointments with specialty services. This is commonly referred to as patient compliance and its importance in supporting Patient Well-Being and Healthcare Resource Stewardship is well known to clinicians.

Information Exchange among all relevant stakeholders is another key work function performed in the primary care setting by clinicians. When comparing our model to a real-world primary

care office, this refers to the patient education forms, sharing of medical records with other offices, electronic communication with other services such as laboratories, radiology departments, insurance companies, and pharmacies.

When observing the work of a clinician, it can be summarized into 1 of these 4 purpose-related functions. When optimizing the medication management system in a primary care office, understanding how these nodes relate to the rest of the system, including the overall functional purpose of the system, is critical.

Object-Related Processes

The fourth line in the AH represents object-related processes. These are the processes derived from physical objects, connecting physical objects to the higher functions of the system [30,32]. They are more specific and less abstract than the layer above. The processes at this level give purpose to physical objects in a way that serves the overall goals of the system; thus, understanding it is important for the optimization of the system.

There are numerous nodes at this level, as can be seen in Figure 1. For organizational purposes, many of these processes can be grouped together as a component of the *Patient Visit*. This includes *Chart Review*, *Medication Reconciliation*, *History and Physical*, *Insurance Review*, and *Patient Education*. These processes accurately reflect the components of a patient visit to a primary care office, reinforcing the model's consistency to a real-world setting. Additional object-related processes include *Continuing Medical Education (CME)*, *Out-of-Office Communication Protocols*, and *Diagnostic Tests*.

Similar to other levels of abstraction, these nodes must be integrated into the nodes above to serve the higher-level goals of the system. For example, a *Medication Reconciliation* is the process of creating an accurate, up-to-date representation of what medications the patient is currently taking. However, in order for it to be clinically useful, it must be integrated with the information discovered in the *Chart Review* and *History and Physical* to be clinically useful. This occurs during the higher-level process of *Patient Assessment*, where the clinician interprets and applies this information to maximize higher-level goals such as *Patient Well-Being*. This relationship highlights how the lower level, more concrete nodes across the system interact with higher-level ones to achieve the overall goal.

Streamlining these processes with the goal of maximizing *Patient Well-Being* and *Healthcare Resource Stewardship* may appear initially difficult. However, the layers of abstraction between the object-related processes and the functional purposes facilitate the design of small components of the system to effectively support the overall goal of improved medication safety.

Physical Objects

The fifth line and bottom of the AH represent the physical objects in the primary care office. At the bottom, these nodes are the most concrete of the AH. These are the resources and tools that clinicians use to make the system function [30,32]. However, without the processes previously listed, these objects have no relation to the overall goals of the system.

Although these may vary slightly depending on the specific office being evaluated, many of these objects are universal. This includes the *Patient Room*, *Medication List*, *Educational Materials*, *Medical Literature*, *Medical Insurance Card*, *Communication Infrastructure*, *Office Space* and the *Electronic Medical Record (EMR)*.

An experienced clinician can note the difficulty of achieving the overall goals of the system, such as *Patient Well-Being* without certain resources, like a patient's *Medication List*. However, for the medication list to be most useful, the clinician needs to perform a *Medication Reconciliation*, incorporate it into the *Patient Assessment* and *Plan of Care* while negotiating various priorities such as *Patient-Centered Care* and *Appropriate Use of Medications*. These connections emphasize the complex task imposed upon the clinician. By understanding the relationships and processes required by the system, the medication management system can be optimized with the clinician in mind.

Once developed, the AH can be used as a model for the medication management system in primary care. It visually depicts the numerous components in a primary care setting that needs to be sufficiently supported to achieve the overall goals of the system. This model can then be used to facilitate system optimization by guiding future quality improvement initiatives, research studies, and system and interface design.

Discussion

Principal Findings

By describing the system, it can then be analyzed for optimization. Our AH describes the medication management system in a primary care office. Further analysis reveals some general recommendations for building a primary care office designed with medication safety and deprescribing in mind.

Interpreting an AH may not be straightforward for those not accustomed to such representations. Examining a particular node of interest and its associated links may lead to a more complete understanding of the functions and constraints surrounding an element within the medication management system. The first characteristic to note about a node is the level of abstraction within which it is embedded. Certain general recommendations, described below, can be provided to optimize that node based on this information alone. For example, value and priority are typically used as metrics to evaluate the functioning of the system. *Patient Satisfaction*, identified here as a value and priority, is already commonly used as a metric in clinical care due to its ability to provide feedback on the overall functioning of the system.

To evaluate the node of interest even further, a *means-ends* [32] analysis can be performed. The connections below connect to the supporting nodes, also known as the *means*. For the node of interest to work effectively, the supporting nodes must be designed to sufficiently support the node of interest. For example, *Patient Assessment* is supported by a *Chart Review*. Thus, the chart review process needs to be designed in such a way that it facilitates effective patient assessment to achieve the overall system goals. Some EHR systems clearly display

medications that previously caused adverse events at the top of the patient's chart, making *Chart Review* simpler and more streamlined. This quickly and effectively shares medication safety information for the clinician to incorporate into their assessment.

In addition, by looking at the connections above the node of interest, its goals can be seen. These are also referred to as the *end*. The node of interest must be designed with this function in mind, or else it is not relevant to the overall goal of the system. For example, *Patient Assessment* is connected above *Patient-Centered Care*. Therefore, patient assessment must be designed in a way that promotes patient-centered care. This includes asking questions related to how a disease is impacting their life (*Reduce Burden of Disease*), their input for what the patient would like to be done (*Patient Autonomy*), and asking about any possible medication side effects (*Reducing Iatrogenic Harm*). Without these types of questions, the patient assessment is limited in its ability to maximize patient well-being, which is the overall goal of the system. Many clinicians already ask questions like these, intuitively understanding their significance.

Although these examples reflect existing primary care practices, AH can also be used to suggest new practices that can be incorporated into quality improvement, research, and system and interface design. Some of the selected suggestions are explored in this analysis, leaving many more to be uncovered by further evaluations of the AH. The suggestions derived from the AH are inherently abstract but can be used to guide concrete improvements to the system.

Functional Purpose

The 2 functional purposes, *Patient Well-Being* and *Healthcare Resource Stewardship*, represent the high-level design objectives [30,32]. When altering system design, for any reason, it should be asked how the changes will end up impacting these 2 goals.

For example, when a quality improvement project is being proposed, it should include an evaluation of its anticipated impact on both *Patient Well-Being* as well as *Healthcare Resource Stewardship*. A given project may benefit both simultaneously or benefit one while harming the other. Any negative impact can be addressed and mitigated ahead of time, preventing a needless headache later.

Values and Priorities

Values and priorities, representing the second highest goal of the system, reflect the overall functioning of the system. Monitoring these nodes provides insight into how the system is functioning [32]. By using these nodes as metrics, deficiencies in the system can be readily identified and addressed. Many of these are already in use as quality metrics in the primary care setting, such as patient satisfaction.

AH suggests that other metrics should be considered. The number of high-risk medications currently being used in a given patient population can reflect the effectiveness of the system. This metric is already used in research protocols to evaluate the effectiveness of interventions designed to deprescribe PIMs. Continuous monitoring of medication effectiveness may reveal the prevalence of ineffective and unnecessary medications in the primary care office. Keeping track of a patient's out-of-pocket costs can be an evaluation of the financial strain that the current prescribing practices are placing on the patient. All of these measurements, and others visually depicted as values and priorities in the AH, may provide deeper insight into the functioning of the medication management system in primary care.

It is important to note that these values and priorities may be in conflict with one another, highlighting constraints on the system. The reduction of high-risk medications, as with the example above, must be balanced by reducing the burden of illness. This conflict has been reported in the real world during interviews with providers [18-20]. By identifying these conflicts ahead of time, they can be more easily addressed. Educating clinicians on how to navigate these conflicts may reduce the resulting burden on the system. For example, teaching clinicians to prioritize *Patient Autonomy* when making this difficult judgment call and thus morphing the conflict into an opportunity for the patient to take control of their care.

Purpose-Related Functions

Purpose-related functions are the core work functions performed by clinicians. The design approach of task delegation, workflows, and user interfaces must be centered around these purpose-related functions to achieve the aforementioned values and priorities. Innovative and creative solutions are needed in the design of teams, user interfaces, task delegation, and workflow that effectively balance all the aforementioned values and priority nodes [32].

For example, *Patient Assessment* is completely delegated to the individual provider evaluating the patient. However, another model uses a more team-based approach. This may include delegating a component of this task to an in-house pharmacist dedicated to uncovering medication safety issues and making recommendations for deprescribing. This model has had some success in reducing the number of PIMs in a patient panel. In this situation, the pharmacist is utilizing the below *means* nodes such as *Chart Review*, *Medication Reconciliation*, and *History and Physical* to promote the higher-level *end* goals of the system, such as *Appropriate Use of Medications* and *Patient-Centered Care* [45]. The impact of this change can be monitored via the values/priorities as listed above, allowing for further iterations and fine-tuning for optimal results.

In addition, the importance of plan execution to support higher-level functions can be visually interpreted. Despite the primary care office being the coordinator of care, the actual execution of the care plan is often left up to the patient or their caregiver. This node may be the source of the deficiencies seen in the system. By supporting the *Plan Execution*, through the supporting nodes of *Patient Education* and *Out-of-Office Communication Protocols* the overall goals of the system may be better achieved. Examples of this could include a comprehensive patient education strategy as well as frequent follow-up after leaving the office.

Object-Related Processes

These nodes represent the tools and subprocesses that connect the physical objects to the higher functions and goals of the

system. This level of abstraction can be optimized by the creation of novel and flexible tools that can be used to support the above *end* nodes. [32].

The AH shows how *Medication Reconciliation* is required to support *Patient Assessment*, *Plan-of-Care Formation*, and *Information Exchange*. Proper medication reconciliation, one that accurately documents the patient's most up-to-date medication regimen, is therefore ripe for improvements that will have a large impact on the functioning of the system. As an example, one can envision an application that consolidates medication information from the patient, the pharmacy, and other prescribers and easily shares that information accurately with the primary care office. To be effective, this tool has to efficiently support the above *Patient Assessment*, *Plan-of-Care Formation*, and *Information Exchange* nodes.

Many of the tools described in the medical literature are incorporated at this level. The creation of tools that are easy to use and fit efficiently within a workflow can be applied here to promote deprescribing. The Beers criteria, an existing screening tool, assists clinicians in formulating an assessment of the patient and has been used to assist with deprescribing. Another example of a hypothetical tool to promote deprescribing may be one for identifying and tracking previous adverse drug events (ADEs). Although a clinician may be able to find a previous ADE within the electronic medical record, this information is often not readily apparent. A tool that can perform this function is easy to use and fits into the existing workflow would support the patient assessment as well as information exchange.

Physical Objects

Physical objects, the lowest and most concrete level of the AH, are required to support all of the higher-level goals of the system. They are the means by which the clinician directly interacts with the system. For these objects to be most effective, they should be designed with flexibility in mind and offer clinicians choices that can be adapted for new and unforeseen circumstances [32]. Communication infrastructure is a clear example of the benefits of tool variability and flexibility in clinical practice. Most offices have patient-messaging systems, available phones, fax machines, and Health Insurance Portability and Accountability Act–compliant texting services among clinicians. The clinician has a variety of communication options available depending on the specific needs and circumstances called for by their situation.

EHRs are another opportunity for increased flexibility of the system. With the AH, it can be seen that EHR systems are required to support *Chart Review*. Therefore, a user interface that facilitates this function is key. To adapt to new and unforeseen circumstances, EHR systems that are flexible and allow for customization by the clinician are ideal. For example, a clinician may want to review previously prescribed medications and reasons for their discontinuation to inform their patient assessment and plan of care. An EHR system that makes this cumbersome may prevent the clinician from engaging in a review that may be informative and fruitful for the overall goals of the system. In other circumstances, however, this additional information may be too clustering and cumbersome for the task at hand.

The same concepts of flexibility and variability can be applied to other nodes at this level. Patient educational materials should allow for variability based on patient health literacy, level of specificity, and preferred medium. For example, educational videos about medication side effects to monitor may be a more effective delivery tool for certain patients, whereas some patients wanting a deeper dive into the literature may prefer to be given direction to validated web-based resources.

Limitations and Future Work

Our AH specifically evaluated the primary care medication management system from the clinicians' perspective. Developing an AH from the patients' perspective may yield a similar yet modified AH. The patients' functional purposes are likely to be consistent with maximizing their well-being. Many values and priorities will likely overlap between a clinician's perspective and a patient's, including those related to patient-centered care and the reduction of harm. Greater differences between these models would be expected in the bottom 3 layers of the AH where these individuals would complete different tasks to achieve their goals.

Our AH is based on an expert panel of clinicians and human factors researchers, not direct observation. Although we attempted to include many different perspectives, the inclusion of more clinicians may have yielded a slightly different AH. In addition, all contributors to the model were based in Western New York. Higher-level purposes and priorities are expected to be consistent across all primary care practices throughout the United States; however, the processes and physical objects with which the clinician interacts may differ from site to site. Each site may modify how they complete these overarching goals based on the resources available and the population served by the primary care office.

Our future work includes an observational study, currently in planning, at a Western New York primary care clinic, and further observations at different types of primary care sites. Real-world data of clinical workflow and observed patient-clinician interactions would provide valuable data to help us better understand existing practices and barriers and to identify opportunities for appropriate prescribing and deprescribing opportunities. Such data will significantly add to the complex relationships modeled for medication management in general and deprescribing in particular.

Conclusions

On the basis of the prevalence of PIMs, the current design of primary care work is inadequate in addressing the complex sociotechnical problems related to identifying and addressing PIMs. Deprescribing concepts, intended to improve medication safety, have been difficult to apply in the real-world setting. Our AH, depicted at a fairly general level for the medication management system in primary care, provides insights and suggestions for the optimization of the existing system. Some suggestions were explicitly mentioned in this paper, but numerous other interpretations can be made by those wishing to utilize this AH in the improvement of a specific primary care office.

Through the interpretation of this AH, human factors practitioners, administrators, and clinicians may identify and develop strategies to optimize the medication management systems and promote deprescribing in various primary care settings. By using the available means-ends relationships, the AH can be visually interpreted to determine which subsystems and processes need to be supported to accomplish the overall goals of the system.

Future studies, including our own efforts, should expand upon the subsequent steps in CWA to provide a more complete model of medication management work in the primary care setting.

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AB, TK, CC, HC, LB, SM, RW, and RS participated in the initial development of the concept for the paper. AB and TK were responsible for the initial drafting of the AH. AB, TK, CC, HC, LB, SM, RW, and RS participated in the expert panel tasked with evaluating and revising the AH. Dr Scott Monte, PharmD, and Dr Laura Brady, PhD, also participated in the expert evaluation of the AH. AB and TK were responsible for the initial drafting of the paper. AB, TK, CC, HC, LB, SM, RW, and RS contributed to writing of the manuscript and participated in the final draft review.

Conflicts of Interest

None declared.

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Abbreviations

ADE: adverse drug event
AH: abstraction hierarchy
CWA: cognitive work analysis
EHR: electronic health record
PIM: potentially inappropriate medication

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Original Paper

A Novel Auditory-Cognitive Training App for Delaying or Preventing the Onset of Dementia: Participatory Design With Stakeholders

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Abstract

Background: Multiple gaming apps exist under the dementia umbrella for skills such as navigation; however, an app to specifically investigate the role of hearing loss in the process of cognitive decline is yet to be designed. There is a demonstrable gap in the utilization of games to further the knowledge of the potential relationship between hearing loss and dementia.

Objective: This study aims to identify the needs, facilitators, and barriers in designing a novel auditory-cognitive training gaming app.

Methods: A participatory design approach was used to engage key stakeholders across audiology and cognitive disorder specialties. Two rounds, including paired semistructured interviews and focus groups, were completed and thematically analyzed.

Results: A total of 18 stakeholders participated, and 6 themes were identified to inform the next stage of app development. These included congruence with hobbies, life getting in the way, motivational challenge, accessibility, addictive competition, and realism.

Conclusions: The findings can now be implemented in the development of the app. The app will be evaluated against outcome measures of speech listening in noise, cognitive and attentional tasks, quality of life, and usability.

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KEYWORDS

cognitive decline; mobile phone; hearing loss

Introduction

Background Research

Globally, approximately 50 million people live with diagnosed dementia, with this figure expected to increase to 82 million in the next 10 years [1]. At present, no treatment is available to either cure or prevent dementia, which has led the World Health Organization (WHO) to classify dementia as a public health priority. The call to action is to reduce the risk of developing dementia through early diagnosis of cognitive decline, intervention, and eventually prevention.

A commission by Livingston et al [2] concluded that 35% of dementia diagnoses were potentially preventable and have identified 9 modifiable risk factors with the capability of preventing dementia. Of these 9 risk factors, midlife hearing loss was found to be the highest potentially modifiable factor at 9%. In comparison, other modifiable factors in later life included smoking (5%), depression (4%), and social isolation (2%). This evidence concurs with previous research, suggesting that age-related hearing loss (presbyacusis) increases the risk of developing dementia in later life by up to 5 times [3]. Despite these findings, the causality in this relationship is still unknown. Furthermore, whether any form of rehabilitation, either through hearing aids, auditory training, or assistive listening devices,

could delay or prevent the onset of dementia symptoms is also unknown [2].

The most robust methodology to further investigate this relationship would be an adequately powered, longitudinal, randomized controlled trial. A complex study such as this would need to ensure that any treatments, such as hearing aids, were adhered to throughout the study. The adoption and use of hearing aids is relatively low. In the age bracket of people aged 55 to 74 years, 80% of people who require hearing aids do not have them [4]. This would be a key issue to address in the design of such a trial. Other methodologies should, also, be explored, and as hearing loss in midlife could be a preventable factor, the focus, as outlined by the WHO, should be on early detection and intervention. Cohort studies have suggested that presbyacusis tends to precede dementia onset by 5 to 10 years [5]. Interestingly, on average, people tend to wait for 10 years before they seek help for their hearing loss [6]. Hearing loss can be diagnosed with a simple and quick diagnostic test and is an easily measurable critical factor in potentially preventing cognitive impairment.

This study highlights an under-researched group of people who may be in the early stages of presbyacusis and present with a mild to moderate hearing loss, do not seek treatment but have an increased risk of developing dementia. There is potential to investigate these *preclinical symptoms* of dementia in this group by targeting the areas of the brain that contribute to auditory and cognitive functions, with the possibility of delaying the onset of these symptoms. This area of research has the potential to impact on what is likely to be one of the largest health care issues of the next century.

Gamification in Dementia Research

One potentially more achievable alternative to a formal randomized controlled trial is to engage people in preventing dementia symptoms through gamification. Gamification has been shown to be an effective research tool that can demonstrate and maintain health behavior change [7]. A gamified app would be highly accessible within the home environment and less challenging than seeking general practitioner (GP) treatment for initial changes in cognition.

A literature review of games aiding early diagnosis of dementia, particularly Alzheimer disease (AD) [8], concluded that games could be utilized to overcome important barriers in the AD diagnosis process. Delays in self-referral, physician factors, age, and available services for assessing cognitive disorders were all identified as potential obstacles. A gaming app could be more motivational than a written memory assessment, maintaining a low cost/high reward ratio if evidence demonstrated that the appl could delay or prevent the onset of dementia symptoms.

Anguera et al [9] tested the hypothesis that playing the three-dimensional multitasking driving video game *NeuroRacer* could improve cognition that was previously diminished through healthy aging. Older adults (n=46) demonstrated less multitasking costs when compared with controls over a 4-week playing period, with effects sustained at *6-month follow-up. Of particular importance was the finding of a Transfer of Benefit.* The authors claim that by playing the driving video game, participants demonstrated improvements in both working memory and sustained attention—2 abilities that were not specifically targeted by the video game. This transfer of benefit outside of the on-task performance was a novel finding. The authors suggest possible reasoning for this being (1) the use of a video game outside of a typical laboratory environment and (2) the custom nature of the video game. As far as we are aware, there has been no attempt to address hearing loss and impaired speech perception using such an approach.

Another example is *Kitchen and Cooking* [10], which was designed and evaluated as a game to assess the executive function of planning. Different cooking recipes could be played by participants with mild cognitive impairment (MCI) and AD. Compared with the AD group (n=12), the MCI group (n=9) showed significant improvement in the Stroop test performance over a 4-week period. It is unclear from the results if this improvement would be sustained over a longer period of time, as this pilot study collected data for only 4 weeks across a small sample. However, the results lend support to the notion that interventions aimed at training cognitive abilities may be more effective in the predementia stage [11].

It is unclear whether the MCI group's improvements compared with the AD group would have been any different from that of a healthy control group. There was a large variability in playing time within the small sample size. This not only emphasizes the importance of designing a game that is capable of engaging and maintaining interest but also focuses on the ability to measure levels of engagement and evaluate how different levels of engagement impact levels of effect. As suggested by Anguera et al [9], the success of *NeuroRacer* was attributed to the custom design of the game. *Kitchen and Cooking* was the premise for the design because food was rated as the most interesting area for older people in nursing homes. Thus, it would be prudent to employ a participatory design by involving key stakeholders in customizing the design of future games and evaluating the results with both validated quantitative measures and qualitative interviews.

One study used a qualitative methodology to investigate older adults' perceptions of playing the Xbox Kinect game *Dr. Kawashima's Brain Training* as a way of maintaining their cognition through intellectual exercise [12]. As previously suggested to ensure that a game is successfully adopted by the intended user group, the design should be appropriate to engage the specific population. Talaei-Khoei and Daniel [12] attribute this to a *perceived transfer effect.*

This occurs when adults who see a cognitive game as empowering, rather than supportive, which equate to a higher potential to yield long-term benefits. Rather, it is not only the content of the game but how participants view the content with respect to their own selves. A key finding was that the mini-games in *Dr. Kawashima's Brain Training* were perceived to be useful in maintaining cognition and transference to real-world daily tasks, such as reading. Participants (n=21) felt that by sustaining functions through the mini-games they would be able to live independently longer providing a long-term transfer of benefit.

Other key findings distinguish the perceptions of supportive and empowering technologies. For instance, the use of hearing aids is categorized as supportive. Hearing instruments can only aid a person in a functional ability that has already begun to decline. This could lead to hearing aids being perceived as less useful, particularly in the long term. In contrast, an empowering virtual game focusing on active auditory training could be perceived as having transferable long-term effects on cognitive ability. The authors also concluded that more qualitative research was required in the field, especially on why end users would think a training game would be useful and adopt it.

The literature shows that gamification can provide a platform for customized, home-based training in different areas of health behavior change, including cognitive performance. Previous studies have demonstrated that certain games have the potential to transform the benefits of virtual play into self-confidence for maintaining cognitive effort for daily activities. More specifically, using training games that are deemed useful and engaging for users at the predementia stage may be more effective than after a dementia diagnosis. Given the findings from Livingston et al [2], there is a demonstrable gap in the use of games to investigate age-related hearing loss and cognitive decline. An iteratively designed app using qualitative inputs from key stakeholders to investigate the role of hearing loss and speech perception in cognitive impairment is yet to be developed. The use of participatory design with specific stakeholder engagement would have the ability to further investigate this area.

Aims and Objectives

The overall aim of this study is to investigate whether an empowering gaming app can be designed to engage users in the midlife population at risk of presbyacusis and mild or subjective cognitive impairment to improve speech perception and cognitive performance.

This aim will be achieved with the following objectives:

- To adopt a participatory design approach with relevant stakeholders to produce an iteratively designed auditory-cognitive training app
- To understand the facilitators and barriers to producing an auditory-cognitive training app
- To identify the specific design requirements for an auditory-cognitive training app

Methods

Participants

A total of 18 relevant stakeholders (service users, clinicians, researchers) were recruited across audiology and cognitive disorder clinics at Imperial College Healthcare, across research groups at Imperial College London and their corresponding research networks. Participants were chosen using an opportunity sampling method as it was a convenient way of accessing clinical, service user, and researcher expertise. Participants were included in this study if they were considered to be a stakeholder and had the capacity to provide informed written consent. Professionals were considered key stakeholders by the research team if they had experience with patients and families at risk of either presbyacusis and/or mild or subjective cognitive impairment. Service users were considered key stakeholders by the research team if they or family members reported mild hearing loss or mild or subjective cognitive impairment.

As the app was to be designed for those who report mild or subjective cognitive impairment, it would not have been appropriate to recruit service users with a moderate-to-severe cognitive impairment. Therefore, potential participants who already had a medical diagnosis of dementia were not considered. Decisions for stakeholder inclusion were taken by the research team to ensure that the participants were representative of the desired end user of the final app. Table 1 describes in detail the types of stakeholders recruited and when they participated. This study was approved by the West Midlands–South Birmingham Research Ethics Committee. All interviews and focus groups were carried out at Imperial College Healthcare Trust, audio-recorded using a Zoom Q8, and transcribed verbatim.

Table 1. Description of participating stakeholders across both cycles.

Type of stakeholder	Cycle 1 (n=9)		Cycle 2 (n=14)			Total (n=23)[a]
	Interview (n=4)	Focus group 1 (n=5)	Focus group 1 (n=5)	Focus group 2 (n=5)	Focus group 3 (n=4)	
Service user	3	N/A[b]	5	3	N/A	11
Audiology	2	N/A	5	2	N/A	9
Cognitive disorder	1[c]	N/A	N/A	1[c]	N/A	2
Spouse	1[d]	N/A	N/A	1[d]	N/A	2
Volunteer	N/A	N/A	N/A	1[e]	N/A	1
Clinician	N/A	4	N/A	N/A	3	7
Audiologist	N/A	3	N/A	N/A	3	6
Older adult psychiatrist	N/A	1	N/A	N/A	N/A	1
Researcher	N/A	1	N/A	N/A	1	2
Dementia research nurse	N/A	1	N/A	N/A	N/A	1
PhD researcher	N/A	N/A	N/A	N/A	1	1

[a]A total of 23 participants participated across 2 cycles. Five stakeholders participated in both cycles.

[b]N/A: not applicable.

[c]This participant is primarily a service user of the cognitive disorders' clinic but has also used audiology services.

[d]This participant was recruited as a spouse of a service user but had also used audiology services for themselves.

[e]This participant is a volunteer in audiology but also has a hearing loss.

Data Collection

Cycle 1: Identifying Current Climate

The aim of the first cycle of data collection was to first gather knowledge about the potential facilitators and barriers to designing a novel auditory-cognitive training app. To maximize accessibility of the data, the first round of data collection consisted of 2 paired semistructured interviews for service users and a focus group of 5 professional stakeholders, which were 45 min each and 60 min, respectively. This division of the stakeholder groups was beneficial for various reasons. The use of the focus group allowed discussion of professional opinions and fostered further collective thinking. Interviewing service users in pairs allowed the interviewer to explore personal experiences and views in depth by comparing and contrasting. The topic guides used for both the interviews and the focus group are available in the Multimedia Appendix 1. The exploratory nature of cycle 1 allowed the data collected to be analyzed and used in conjunction with the literature base to design the first version of the app. Further evaluation of this first version was then performed in cycle 2.

Cycle 2: Exploring Specific Requirements and Needs for Collaborative Design

The purpose of including a second cycle was to demonstrate the initial version of the app and to stimulate participants to further think about the specific needs and requirements of the app. To achieve the objectives of cycle 2 and answer a more specific research question about the app design, an edited topic guide was used for both the professional and nonprofessional focus groups, which were approximately 60 min in duration. The topic guides can be found in Multimedia Appendix 2.

Two service users, 1 spouse, and 2 professional participants who wished to continue into cycle 2 participated alongside 9 new participants who did not have any prior involvement or knowledge of the app. A basic prototype of the app, using a coffee-shop scenario, was demonstrated with an iPad and the player was asked to listen to an order placed in the coffee shop, choose the correct customer order that was heard, and then choose the correct items from a list of 8 images/words to make up that specific order. The audio was originally played at a low signal-to-noise ratio, which the player could improve by 2 dB at a time by replaying the order before moving on to choosing what had been heard from a 4-option list. Screenshots from the prototype demonstrated in cycle 2 are shown in Figures 1 to 3. At the time of writing, the app is still in development and is not freely available.

A summary of the data collection, including the start and stop dates, the duration of each cycle, and stakeholder participation is shown in Figure 4.

Figure 1. Screen where the user chooses the instruction that was heard.

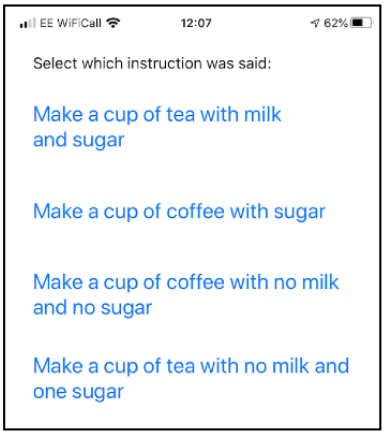


Figure 2. Screen where the user chooses the items that are needed to execute the audio instruction.

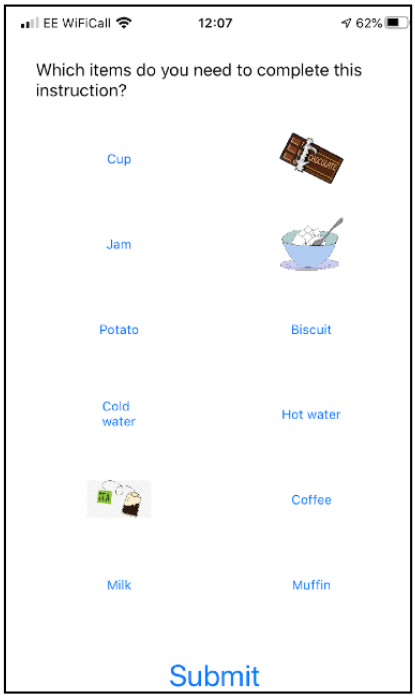


Figure 3. Example of incorrect answers submitted.

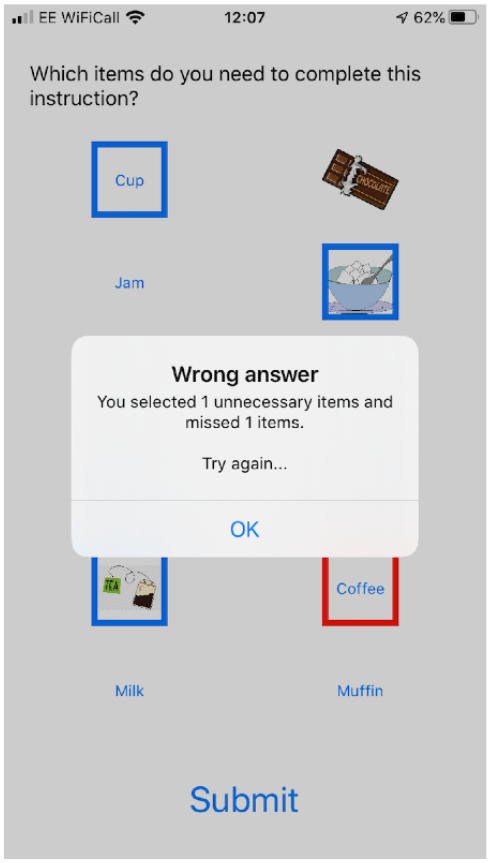
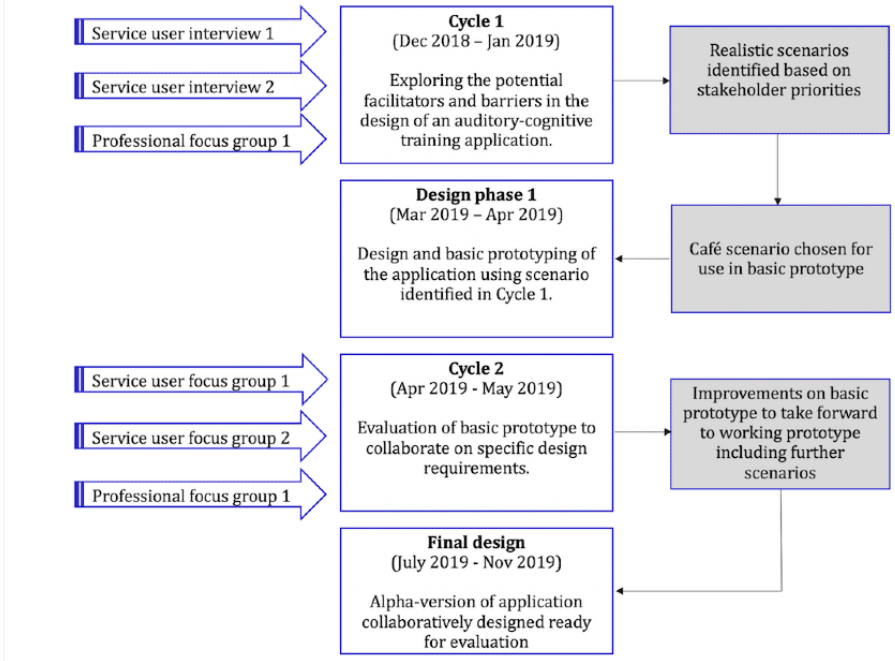


Figure 4. Summary of overall data collection period including design phases, start-stop for data collection, and stakeholder type participation.



Data Processing

Audio recordings from the interviews and focus groups were transferred immediately to an encrypted PC and deleted from the audio recorder. The recordings were transcribed by the lead author in cycle 1 and by medical students who had received prior training in cycle 2. The transcriptions were subsequently coded by the lead author in cycle 1 and medical students in cycle 2 and stored in Microsoft Excel. To verify the integrity of the data, each cycle was secondary coded by either the lead author or medical students. All excerpts from the transcriptions were anonymized using the participant number that identified each participant as either a service user or a professional.

Data Analysis

A thematic analysis approach [13] was used to identify themes from the data related to the facilitators, barriers, and needs of the stakeholders in developing a new auditory-training gaming app. This process involved the lead author and trained students identifying themes from the codes.

Results

Overview

Six themes were identified from the focus groups in relation to the needs, barriers, and facilitators for developing an auditory-cognitive app that would be useful, fun, and accessible. The themes were (1) congruence with hobbies, (2) life gets in the way, (3) motivational challenge, (4) accessibility, (5) additive competition, and (6) realism.

Congruence With Hobbies

Throughout the focus groups, service users commented particularly on what would continue to motivate them to play the game over an extended period of time, rather than a one-off use. At first, it appeared to be different styles or themes of games that motivated them, such as word games or web-based chess. However, further discussion by 2 service users who did not regularly play mobile games led to the consensus that if the theme of the game was an extension of an enjoyable hobby, then this would heavily facilitate not just initial interest, but extended and continued playing time:

> *I mean this game is educational but you want to make it fun as well, fun at the same time.* [SU9]
>
> *For example, if you had one about art?* [SU8]
>
> *Yes, I'd use it.* [SU9]
>
> *You'd be at it all day!* [SU8]

Life Gets in the Way

Although both service users and clinicians agreed that the premise of the app was good, they noted finding the time to use the app as a potential barrier. It was suggested that the user, for practical purposes, would need to be at home in a quiet space to be able to use headphones and concentrate. Others suggested that busy lives meant that other responsibilities, such as taking care of grandchildren or house chores, took priority over self-care. This feeling of being too busy to use the app has parallels with reactive or passive health care, such as using hearing aids after a hearing loss has been diagnosed, as opposed to a preventative or active approach, whereby spending a small amount of time each day may, in fact, benefit in the longer term:

> *I find that I don't pick up my iPad and read the paper anymore, I didn't realise I didn't do it. But then when I went to my iPad it had no battery and I didn't care, so it was kind of like oh I've stopped reading the paper, but I didn't really notice.* [SU10]
>
> *I'm also quite involved in the church and the grandchildren. So, I think when you are saying as to what might prevent you from doing these other pleasurable things, then it would be other equally pleasurable things that one has to do.* [SU8]

Participants suggested using notifications and reminders within the app to remind users that they were overdue for a training session or to use commuting time on the underground or train as an opportunity to play. Interestingly, in the professional group, there was a misalignment in views regarding whether people in an older age group would engage with smartphones and headphones while traveling:

> *I don't think I've seen anyone like in their sixties even [using a smartphone?].* [P1]
>
> *I have.* [P2]
>
> *Have you been on the tube?! I think they do!* [P3]
>
> *I could probably play it on the bus or something you know, when you are travelling, something to just fill time.* [SU7]
>
> *Yes, on the tube.* [SU10]

Motivational Challenge

Despite the need to set aside some time to play each day, one main facilitator identified by both the service user and clinician groups was that the app should provide the correct amount of motivation and an element of challenge to ensure it was fun, useful, and enticed the user back to play. The motivation did not necessarily need to come from improving one's own prowess. The idea of altruism as a motivator was discussed. It was suggested that if a person were aware that playing the app would contribute to research knowledge on dementia, they would be much more likely to play it though it may not necessarily gratify them personally in the short term. The professional group suggested that using multiple scenarios would increase the relevance to challenges faced by people with impaired hearing and, therefore, increase the motivation to improve in all situations:

> *For me I would be more encouraged if I knew it was paying back into research. If I knew that somebody thought it was good for me too. If I was playing it just for the sake of playing it then I would be playing it for nothing. But if I'm playing it and I'm contributing then I can pretend I'm contributing even if I'm just playing for myself.* [SU10]
>
> *It would be good if they can select what do you want to train. I had the problem the other day speaking with my friend at the cafe...Maybe I'll give it a go, yes today I'll play the cafe.* [P19]
>
> *It's motivation as well because if you do terribly at the one in the cafe but you're doing fantastic at all the others. I am going to the do that cafe one again, I am going to smash the cafe one today.* [P1]

Accessibility

One clear need highlighted from both cycles was that the app needed to be accessible to people of all ages, catering to those with visual or audio impairments and available for playing on appropriate platforms. Appropriate screen resolutions, font sizes, images, and colors were design parameters identified as important:

> *I have been testing patients as well, elderly patients for my study and I use an app on the iPad as well as computer tasks and they tolerate it very well. They never complain when I say let's switch it to the iPad, actually they like the one on the iPad more.* [P19]
>
> *I think most people are going to play for that age on a phone or an iPad. I think it would need to go across both platforms because what is it 25% Apple, 75% Android?* [SU3]
>
> *If I could do it via the computer... simply I'm used to using the computer.* [SU8]
>
> *I think the size is relevant actually, that tiny screen it [of a smartphone] it's not quite the same as if you were looking on the screen.* [SU9]

Addictive Competition

Comparing the premise of this app with those of other successful games that the participants played resulted in an agreement to the reason why people went back to playing certain games repeatedly and over a long period of time. The app or games that were the most successful were addictive, not only in terms of the aims of the games themselves but also in terms of the competitive nature of moving through levels to beat a family member, partner, or friend. Having a shared platform to engage in a healthy competition was seen as a driver for playing an app. Scores, rewards, and trophies were all seen as optional extras that would provide extra facilitation in prolonged and repetitive play:

> *Maybe I could compare this with my husband or my friends and then I would know they were able to do it like three tones before me, so maybe I am actually a bit worse.* [P19]
>
> *Another way that I've mentioned might be to pair up with a relative or have some kind of competitive nature you know in the household.* [P5]
>
> *My mother-in-law could see my scores if that was of interest to her.* [SU10]
>
> *Gives you more motivation I think, if you're in a competitive nature.* [SU13]

Realism

The app in cycle 2 was demonstrated using a coffee-shop scenario, which received positive feedback from all participants as it involved a real-world environment in which it was likely that a person may have difficulty hearing speech. All participants agreed that it would be most appropriate to use *real-life* scenarios in the game, instead of complete gamification. It was suggested that using realistic scenarios would make the app more useful and the skills built in the game more transferable. It was suggested that using realistic tasks would also make the game more appealing to an older person, as it made it feel less like a game. The clinician group felt that using these scenarios would also make it easier for them to recommend the game and also to use the game to obtain feedback about specific situations in which the person had specific difficulties. By being realistic, the game would also tie in with the theme of using hobbies as scenarios:

> *It has to cover areas that a person like myself would find it very difficult to hear, like for instance I said the gym, but also airports they can be a nightmare as well, you know I still have to travel even if I'm deaf.* [SU13]
>
> *Particularly if they are already isolated and they're already staying at home and they're sort of scared of going outside, it's a nice way to bring outside in, so they can build up their experience in other situations without actually having to get there.* [P3]
>
> *And it's an element of control that they're taking over their situation and so that it'll give me some confidence you know I'm doing something about it. Makes you feel good.* [P1]

Summary of Results

The summary of results has been provided in Table 2.

Table 2. Summary of findings in relation to the research question.

Theme	Facilitators	Barriers	Needs
Congruence with hobbies	• Initiate and maintain interest over time to allow repeated play • Concentrate on being educational and enjoyable	• Limitations in terms of the number of preprogrammed scenarios catering to all hobbies	• Relate to common enjoyable hobbies for the intended user groups
Life gets in the way	• Promote usage of the app during unavoidable daily tasks, for example, commuting	• Incorporating the app into busy daily lives • Reliance on passive health care models	• App to send notifications and reminders when the user is overdue for a training session. Allow offline play, for example, when commuting
Motivational challenge	• Promote altruism to contribute to research	• App not offering the right level or type of challenge leading to lack of repeated playing and training.	• Level of difficulty to be challenging enough to entice repeated play • Multiple scenarios relevant to difficult hearing situations
Accessibility	• Design considerations, for example, use of colors, font sizes, and images	• Smaller screens on smartphones • Inappropriate screen resolution for each device	• Accessible to all ages • Available on multiple platforms and devices, including PCs
Addictive competition	• Option to share progress with family and friends to encourage competition	• Not a driver for playing for people who are not of a competitive nature	• Include daily high scores that are comparable with friends or self across time
Realism	• Skills honed in the app would be more transferable • More likely to recommend to friends	• May prefer more realistic graphics rather than taking a gamified approach	• Relatable to real-life environments where hearing is difficult

Discussion

Principal Findings

This study aimed to engage relevant stakeholders from the worlds of audiology and cognitive disorders to collaborate in the design and development of an auditory-cognitive training game app. Stakeholders were recruited and engaged in 2 cycles of semistructured paired interviews and focus groups to understand the facilitators and barriers in producing such an app and to elicit specific design requirements for the app in addition to the existing literature.

Facilitators

A popular choice for facilitating a new gaming app was to provide a high level of addictive competition for the user. The results demonstrate that this can be achieved in a number of ways, including rewards, achievements, and competitive play with family and friends. This has parallels with the findings of Talaei-Khoei and Daniel [12], who found that their participants were motivated to improve their memory age as they experienced with a sense of achievement and reward. This study also found that participants wanted an extra level of socialization within the app through a virtual competition with friends to share scores and achievements.

This sharing of information was also addressed to ensure that the app was motivationally challenging enough to encourage them back to play. A particularly interesting finding was that the motivation to play the app was not necessarily to improve one's own skills, or for personal gain, but to provide data altruistically to a research database on a topic such as dementia. This has parallels with the popularity of *Sea Hero Quest* developed by Deutsche Telekom, which has been downloaded by over 4.3 million players [14]. *Sea Hero Quest* is an app developed to collect large data sets on how navigational cognition changes over the human life span. Collecting data through gameplay has provided data that would have taken a long time to obtain through standard dementia research practices.

Barriers

One of the themes that was perceived as a barrier to produce a successful app for high adoption was that other life activities would get in the way of using the app on a regular basis, as it would require a quiet space to concentrate. Participants gave examples of other activities that required their attention and efforts that were placed above auditory-cognitive training, such as household chores. The low level of importance placed on maintaining cognitive reserve in the light of other daily activities by participants is in contrast to the theory of Weinstein [15], who suggests that building cognitive resilience is of utmost importance in the window of opportunity that is midlife. It is critical to engage the cognitive reserve in midlife to allow the brain to cope better with damage in later life.

The findings from this study demonstrate that even with this knowledge, changing health behaviors is challenging and often unsuccessful [16]. It is therefore critical to adopt the proposals of Talaei-Khoei and Daniel [12] and employ qualitative methods, as in this study, to focus specifically on why end users would find a training game to be useful and adopt it.

One potential barrier to using hobbies as a motivator is the effect of apathy on motivation. Apathy is a major neuropsychiatric

symptom in dementia and is sometimes observed in patients with MCI [17]. Individuals with clinical apathy would be less likely to be motivated by the type of training described. However, it should be noted that the intended user group is specifically focused on individuals with subjective cognitive impairment and MCI, who have a much lower incidence of apathy than those with more severe cognitive impairment [18].

Needs

One of the specific requirements that was elicited from the discussion was to ensure that the app was accessible to older adults, who may be unfamiliar with using tablets or smartphones to access apps. This is also a potential barrier noted in the general gaming literature. However, according to Vallejo et al [11], no usability problems were reported for participants without previous computer experience when using a joystick or touchscreen.

Interestingly, participants felt that making the scenarios less gamified, more realistic, and more related to daily living would be more useful, transferable, and more appealing to older adults. The results showed that if the scenarios were congruent with or an extension of an enjoyable hobby for the end user, this would increase the level of interest, fun, and ultimately adoption. This finding could explain why laboratory-style auditory training programs, such as those evaluated by Ferguson and Henshaw [19], have failed to extrapolate on-task learning to off-task daily activities. As suggested by Anguera et al [9], their training game was successful as it was being delivered outside of the laboratory environment and because of its custom design. Similarly, the reason Manera et al [10] found large variations in playing time in their app based on cooking may be due to the lack of engagement and interest from some of their users. Therefore, the use of multiple common scenarios based on daily activities and a custom scenario based on a hobby might, in fact, increase the adoption and success rate outside of the app.

Limitations

The use of a small sample size is more common in participatory design, as it is about the rich quality of data rather than the quantity. Demographically, the age range and the use of hearing aids were skewed from the desired end user group. However, it allowed exploration of using this type of app as a supplement to hearing aid provision in more severe hearing losses in the future. As this app is in its infancy and is yet to be evaluated for its effectiveness, there is potential to use the app in other, more hearing-impaired populations. However, for the scope of this study, involving those with varying hearing loss severities would introduce a confounding variable during assessment if using the app does indeed improve unaided speech listening in noise.

Lessons Learned

Stakeholder Recruitment

The inclusion of nonclinical stakeholders that already have existing relationships can enhance data collection. In both cycles, the stakeholders included spouses and friends. This extended the depth of data collection around more sensitive questions, such as thoughts and feelings about developing cognitive impairment and current cognitive performance. Stakeholders were more comfortable discussing these issues with someone they already knew as opposed to the interviewer. This was observed in a design workshop with aphasia patients [20]. The author concluded that using a relative is essential in fostering a *communication culture*, which gives the stakeholder with the condition confidence to express and verbalize his or her thoughts and feelings.

It was also useful for stimulating further discussion, as the stakeholders had more background information about one another in comparison with the interviewer. Stakeholders were able to ask further appropriate probing questions when discussing content. This was evident when discussing possible scenarios for the gaming levels, as one stakeholder was able to talk more to his or her spouse about his or her enjoyment of art galleries and bring this idea to the discussion.

When holding clinical stakeholder focus groups, a multidisciplinary discussion should be used not only to uncover shared thinking that provides useful data for answering the research question but also to take the use further into wider clinical practice outside of the app design. In this instance, mixing clinicians from audiology, psychiatry, and cognitive disorders research brought together specialists who do not usually meet but share common patient groups and challenges. This allowed clinicians time away from their individual departments to discuss ways in which they could support each other to improve the care of patients who may unknowingly access each other's services; for example, implementing the use of a hearing screening pathway for patients referred for cognitive assessment to trigger a referral for audiology assessment and facilitate communication in cognitive assessments. Where possible, clinical stakeholders should include those with a range of experience from the newly qualified to the consultant level, to tap into both new learning and wealth of experience. Consideration should also be given to include geographical variance to allow for deviances in service delivery away from national guidelines. Woods et al [21] used co-design to develop a mobile health app in the area of cardiac health and concluded that using participatory design within a health care delivery setting with multiple clinicians improved patient-centered care. Using participatory design with multidisciplinary stakeholders can facilitate a wider and unforeseen positive impact across service delivery, both locally and nationally.

When focusing on designing an app to be used in a preclinical symptomatic population, it is prudent to recruit from multiple sources outside of the standard clinical settings, such as hospitals and GP clinics. Groups in the community, such as clubs, neighborhood associations, and religious groups, should be targeted as potential sources of recruitment as they are likely to include stakeholders that may have symptoms that are not severe enough to seek clinical intervention and therefore do not frequent clinical settings such as audiology or cognitive disorder clinics.

It may also be useful to include stakeholders from a wider pool that, although may be less relevant to prospective end users, can offer ideas for future implementation of the app. Stakeholders that have already experienced a condition can

provide data on past experiences. These stakeholders are also useful in patient and public involvement activities before data collection begin and can give advice on research question development, advertising materials, and focus group questionnaire design.

Developing Content and Gameplay

When asking stakeholders to contribute to designing content for a new game or task that requires an element of training or behavior change, it is important to begin the discussion by asking the stakeholders about hobbies or activities that they already enjoy participating in. Particular focus should be given to why they enjoy them and what stimulates them to participate regularly in that particular activity. For example, in cycle 2, web-based chess and web-based crosswords were introduced as enjoyable platforms for distraction, competition, and accessibility at all times of the day.

The reasons behind successful adoption and enjoyment of other apps should be understood and consequently integrated into tasks for the new game in conjunction with recommendations from the literature specifying special attention to customization and individualization. This was evident when discussing design for different scenarios. Stakeholders foresaw that they were more likely to regularly use the app if the scenario was individualized to an environment that they associated with enjoyment or relaxation, such as an exercise class or an art gallery. In addition, they were also likely to use it if it was customized to a situation in which they found it difficult to communicate in reality and would want extra practice virtually. Examples include cafés, airports, and train stations. Similarly, Jessen et al [22] used this approach while researching participatory design frameworks for a self-management app in a chronic disease population. They used common enjoyable games such as Super Mario, Crosswords, and Monopoly as a vehicle to elicit further thoughts for discussion on the concept of creating their design.

Further Development of the App

To overcome these barriers and incorporate the design needs from the findings, within the scope of the project, the app will include:

- The option to deliver daily notifications to remind the user to take some time to play the app
- The inclusion of scores and comparisons to daily or weekly high scores
- A redesign of the visual representation to use only images as opposed to a mixture of words and images
- Colored boxes (green=correct; red=incorrect) that will appear around the images when selected to notify the user of correct and incorrect selections during repeated attempts
- A range of 6 realistic scenarios reported by people with a hearing impairment as challenging
- Inclusion of a customized scenario for participants evaluating the app that they consider relevant to them
- Allowing offline play so that users will be able to play the app during other daily activities, for example, commuting

Conclusions

Using a participatory approach in conjunction with the literature base when designing a novel app ensures that the final product is useful, fun, and accessible to the intended user group. Both cycles of this project have demonstrated that an app that can provide training for both auditory and cognitive performance in a way that would motivate users to regularly play it would be welcomed as an alternative to hearing aids, and as a fun activity, and it will be used if it could keep the brain active and healthy. The idea of completing an active, preventative task still does not carry enough weight to drive people to use it and, therefore, would require other competitive and reward elements to overcome the barrier of having enough time to use it. The results of this study will now be used to finalize the app design and complete a randomized controlled study to evaluate the effectiveness of using the app on speech-in-noise, cognitive ability, and quality of life, in addition to usability evaluation.

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Authors' Contributions

EF and LP were involved in conceptualizing the study with input from TP on the methodology and data curation. EF was responsible for the investigation, conducting the interviews, analyzing the data, and writing of the original draft. All authors were involved in writing, reviewing, and editing the final manuscript.

Conflicts of Interest

None declared.

Multimedia Appendix 1
Topic guides used in cycle 1.
[DOCX File , 24 KB - humanfactors_v7i3e19880_app1.docx]

Multimedia Appendix 2
Topic guides used in cycle 2.
[DOCX File , 19 KB - humanfactors_v7i3e19880_app2.docx]

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Abbreviations

AD: Alzheimer disease
GP: general practitioner
MCI: mild cognitive impairment
WHO: World Health Organization

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Original Paper

Embodied Conversational Agent Appearance for Health Assessment of Older Adults: Explorative Study

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Abstract

Background: Embodied conversational agents (ECAs) have great potential for health apps but are rarely investigated as part of such apps. To promote the uptake of health apps, we need to understand how the design of ECAs can influence the preferences, motivation, and behavior of users.

Objective: This is one of the first studies that investigates how the appearance of an ECA implemented within a health app affects users' likeliness of following agent advice, their perception of agent characteristics, and their feeling of rapport. In addition, we assessed usability and intention to use.

Methods: The ECA was implemented within a frailty assessment app in which three health questionnaires were translated into agent dialogues. In a within-subject experiment, questionnaire dialogues were randomly offered by a young female agent or an older male agent. Participants were asked to think aloud during interaction. Afterward, they rated the likeliness of following the agent's advice, agent characteristics, rapport, usability, and intention to use and participated in a semistructured interview.

Results: A total of 20 older adults (72.2 [SD 3.5] years) participated. The older male agent was perceived as more authoritative than the young female agent (P=.03), but no other differences were found. The app scored high on usability (median 6.1) and intention to use (median 6.0). Participants indicated they did not see an added value of the agent to the health app.

Conclusions: Agent age and gender little influence users' impressions after short interaction but remain important at first glance to lower the threshold to interact with the agent. Thus, it is important to take the design of ECAs into account when implementing them into health apps.

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KEYWORDS

embodied conversational agent; appearance design; health status assessment; older adults; eHealth

Introduction

As people get older, they are likely to experience frailty, a decline in functional and cognitive abilities such as walking speed, balance control, and working memory [1,2]. Through electronic health (eHealth), frailty can be assessed using digital questionnaires. A large population can be targeted, including those who are less mobile and face difficulties in seeing a caregiver to perform frailty assessment. In addition, digital frailty assessments can be performed on a regular basis, be dynamically adapted based on information provided by the user, and provide immediate results. An eHealth app can coach the user in a personalized way toward a healthy lifestyle based on the outcomes of the frailty assessment. Research shows that collecting health data using a digital survey does not affect test reliability with respect to a paper version [3-5], and several

studies showed similar results for a population of older adults [6,7]. In addition, Fanning and McAuley [7] showed that older adults may accept a tablet for health surveys and van Velsen et al [6] showed that older adults preferred a tablet survey to a paper survey.

Research shows that the older and more frail adults get, the more they become nonrespondents to questionnaires [8,9], whereas refusal of face-to-face interviewing is less present in this population [8]. To overcome the problem of lack of face-to-face interaction in a digital frailty assessment, an embodied conversational agent (ECA) can provide an alternative. ECAs are more or less autonomous and intelligent software entities with an embodiment used to communicate with the user [10]. By interacting with the user face to face, ECAs can build trust and rapport—a close and harmonious relationship—leading to companionship and long-term continual use [11].

To establish trust and rapport with the agent, users should have a positive impression of the agent. These impressions can be shaped by static [12] and dynamic characteristics [12,13]. Static characteristics mostly relate to an agent's visual appearance, often tested using the so-called zero acquaintance approach, where a person observes the agent without interacting with the agent. Dynamic characteristics include an agent's verbal and nonverbal behaviors and are often tested using a thin-slicing approach, where a person draws inferences about an agent's personality based on short excerpts of social behavior [14].

Although ECAs have the potential to be used as eHealth apps such as digital frailty assessments, little is known about how these agents should be designed and how the design affects our impressions of the agents, and no design guidelines exist [15]. In one study, ter Stal et al [16] identified people's first impressions of agents varying in age, gender, and role using a zero acquaintance approach: there was no interaction involved, and participants rated static agent images at first glance. The study shows that characteristics of older and male agents were perceived differently than characteristics of young and female agents, respectively. In addition, older adults seem to prefer a young female over an older male agent. Other research focused on users' perceptions of static agent images at first glance [17-19], showing that the agent's gender and role affect the user's perception of the agent. However, little research exists on people's impressions after short interactions with agents and how the design of the agents affects these impressions. Therefore, research is needed to investigate how the design of an agent affects users' impressions of the agent during and after actual interaction (using a thin-slicing approach).

The aim of this study is to assess how an agent's appearance, particularly age and gender, affects the users' likeliness of following agent advice and users' perceptions of the agent's characteristics and feeling of rapport after short interaction with the agent. This study builds on previous work [16] by studying users' impressions of agents at first glance (using the zero acquaintance approach) and after a short interaction with the agents (using the thin-slicing approach). As a secondary aim, we investigate the potential of a frailty assessment app with an agent by evaluating its usability and intention to use.

Methods

Frailty Assessment App

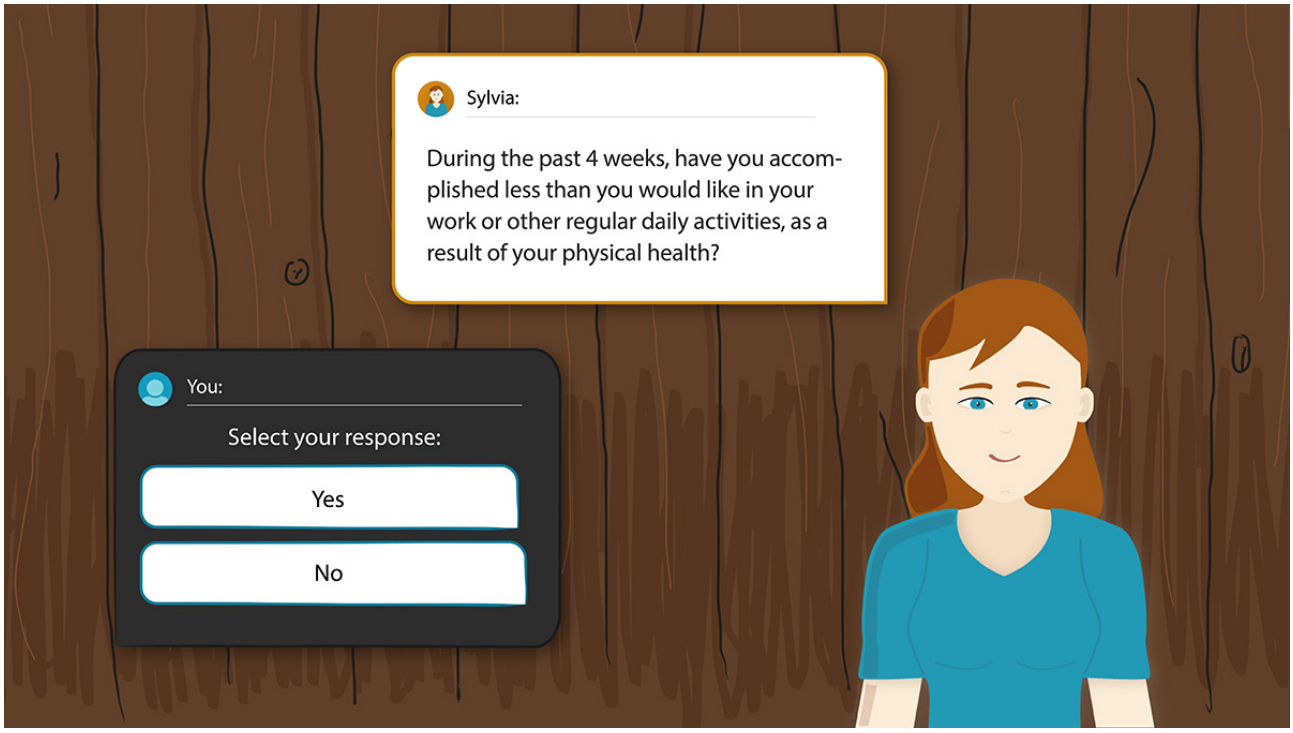
The ECA under study was embedded within a frailty assessment web app developed as part of a larger platform designed to counter frailty by offering older adults training modules in the domains of healthy nutrition and physical and cognitive training to maintain a healthy lifestyle [20]. Initial and continued use of the platform is stimulated by integrating gamification elements. In this study, we focused on the stand-alone frailty assessment app.

The frailty assessment app consisted of an index page (Figure 1) and a dialogue page (Figure 2). On the index page, an agent was displayed next to a blackboard. The blackboard provided a list of available dialogues: introductory small talk, questionnaire assessing aspects of the older adult's health, and small talk explaining the results of the questionnaires. When a dialogue was finished, the user returned to the index page. Before the questionnaire dialogues were performed, only the introductory small talk was available on the blackboard. In this dialogue, users were introduced to the agent and the goal of the frailty assessment. Afterward, the questionnaire dialogues were unlocked and shown on the blackboard. Three validated questionnaires were implemented to assess the older adult's frailty status covering multiple health domains. The 36-item Short-Form Health Survey [21] contains 36 multiple-choice questions related to health topics (eg, physical functioning, social functioning). The Alzheimer Disease Detection [22] tests for functional decline in memory using 8 yes or no items. The Mini Nutritional Assessment [23] tests for malnutrition with 6 multiple-choice questions related to nutrition and weight. We translated the three frailty assessment questionnaires into dialogues between the agent and older adults. After questionnaires were completed, the result dialogue was unlocked on the blackboard. In this dialogue, users received the outcomes of the assessment.

Only one dialogue was available at a time. Clicking on the start button of a dialogue opened the dialogue page (Figure 2). A dialogue consisted of multiple dialogue steps. Each dialogue step consisted of a statement by the agent and one or more reply options that could be selected by the user. The statement by the agent was shown in the white box with the orange border and the reply options for the user were listed in the black box. After finishing a dialogue with the agent, the user returned to the index page and available dialogues listed on the blackboard were updated.

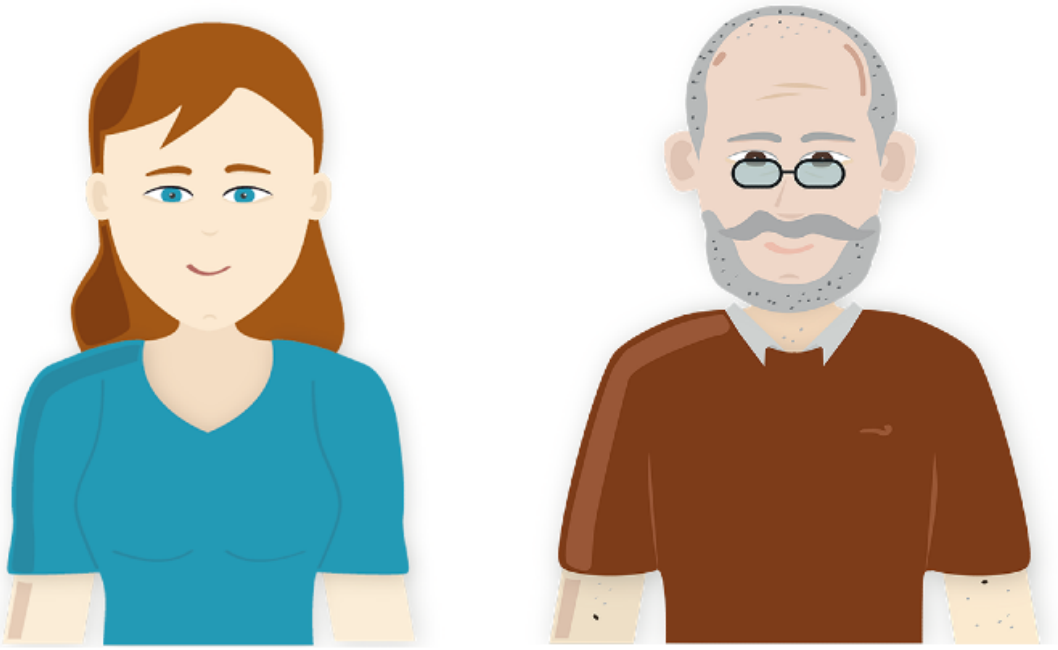
Figure 1. Frailty assessment app: opening page introducing agents Sylvia and Egbert.

Figure 2. Dialog page with peer agent Sylvia.



The agents used in the frailty assessment app (Figure 3) are Sylvia, a young female peer agent, and Egbert, an older male peer agent. By a peer agent, we mean an agent who is not a medical expert. Agent designs were selected based on findings from a previous study [16], in which the static images of eight agents were evaluated. The agent images differed on three features: age (young or old), gender (male or female), and role (experts had a high level of health expertise, and peers had a low level of health expertise). In an online questionnaire, images of all agents were shown to the participant at once, with participant selecting agent they preferred most (to be their health coach) at first glance. Afterward, participant rated characteristics for each agent. Results showed that a young female agent was preferred most and an older male agent was preferred least in both a general and elderly population (ie, these designs were extremes in terms of user preference). This study builds on the previous study by evaluating users' impressions of these two agents, both at first glance and after a short interaction with the agents. A blinking eyes animation was implemented for both agents. In addition, when the agent spoke (ie, when a new dialogue step was loaded), a mouth animation of a fixed duration was played.

Figure 3. Agents used during the experiment.



Study Design

We applied a within-subject design in which we counterbalanced the order in which agents were presented to participants. Half of the participants started the frailty assessment with the young, female peer agent and finished with the older, male peer agent (Figure 4, top). The other half of the participants were first presented with the older male peer agent, followed by the young, female peer agent (Figure 4, bottom). The study was performed in a lab setting, taking place either at a research institute or a local physiotherapy practice. The nature of this general study with healthy volunteers from the general population does not require formal medical ethical approval according to Dutch law. All participants provided their informed consent.

Figure 4. Study design including randomization process.

Participants

Participants should be aged 65 years or above and fluent in the Dutch language in order to be included. In addition, they should be cognitively able to work with an ECA as assessed via the Mini-Mental State Examination, scoring at least 23 out of 30 points [24]. We recruited the respondents via a Dutch panel of adults that indicated they were interested in participating in research on eHealth. Participants were also recruited via a local physiotherapy practice.

Measurements

Questionnaires

Before interacting with the frailty assessment app, the participant completed the preinteraction questionnaire gathering the participant's gender, date of birth, education, housing status, technology literacy, health literacy, and state of change for nutrition and physical activity [25].

After interacting with each agent (Figure 4), the participant completed the postinteraction questionnaire. To investigate the effect of the agent's appearance, we assessed the following:

- Likeliness of following the agent's advice (on a 7-point Likert scale)
- Agent characteristics ratings (all on 7-point Likert scales): friendliness, authority, involvement, reliability, intelligence
- Agent rapport scale rating (all on 7-point Likert scales) by Acosta and Ward [26]: emotional rapport, cognitive rapport, helpfulness, trustworthiness, likeability, naturalness, enjoyableness, human-likeness, persuasiveness, recommendability

Secondarily, we investigated the usability of the frailty assessment app and the intention to use the frailty assessment app on a single 7-point Likert scale.

Thinking Aloud

In order for us to triangulate the quantitative data, participants were asked to think aloud while interacting with the frailty assessment app. Audio was recorded and screen captures were taken. The researcher did not help or support the participant but only reminded the participant to think out loud when necessary.

Interviews

At the end of the session, the participant was interviewed. The interview was semistructured and guided by asking the user's opinion regarding positive and negative aspects around the effect of the agent's appearance, usability of the frailty assessment app, and intention to use the frailty assessment app.

Data Analyses

SPSS Statistics 25 (IBM Corporation) software was used to perform statistical analyses. Since the underlying data were nonparametric, for all relations testing differences between the two agents, a Wilcoxon signed-rank test was conducted. All tests used a 95% confidence interval. All variables were tested for statistically significant differences between the two agents by means of a model consisting of Wilcoxon signed-rank tests for cross-over designs. Effect size was calculated by $r=Z/\sqrt{N}$, using 0.1, 0.3, and 0.5 as cutoff values for a small, medium, and large effects, respectively.

The audio recordings of the thinking aloud sessions and interviews were transcribed and inductively thematically analyzed. In addition, screen captures of the interaction with the frailty assessment app were aligned with the audio recordings. This way, the screen captures were used to verify the thoughts of the participants on the audio recordings. All themes were coded using ATLAS.ti 8 (ATLAS.ti Scientific Software Development GmbH) based on an empirical method proposed by Pope and Mays [27]. One researcher (StS) created a first coding scheme based on the data and then labeled the transcripts. A second researcher (MB) used the coding scheme to code a subset of the data so that a discussion could be held between the first and second coder for improving the coding scheme. The procedure of creating a first coding scheme, labeling the data by two researchers, and discussing the coding scheme was repeated a second time leading to a final coding scheme. The final coding scheme was used by the first coder to code all data for final analyses. The final coding scheme contained the following codes: agent characteristics, appearance agents, interaction with agents, preference agent, content questionnaires, language usage in dialogues, presentation information, interaction with app, design, navigation, general computer interaction, and intention to use.

Results

Participants

A total of 21 participants began the study (Table 1). One participant was not able to complete the protocol due to a lack of computer experience and was excluded. The average age of participants was 72.2 (SD 3.5) years, and 13 males and 7 females participated. Ten participants started with the young, female agent, and ten participants started with the older, male agent.

Table 1. Participant demographics (n=20).

Demographic	Value, n (%)
Education	
Elementary school	1 (5)
High school	1 (5)
Vocational education	8 (40)
College	6 (30)
University	4 (20)
Living situation	
Living alone	1 (5)
Living with a partner	19 (95)
Stage-of-change nutrition	
Maintenance	18 (90)
Precontemplation	2 (10)
Stage-of-change physical activity	
Maintenance	13 (65)
Action	3 (15)
Contemplation	1 (5)
Precontemplation	2 (20)
Unknown	1 (5)
Technology literacy level	
Moderate or high	20 (100)
Health literacy level	
Moderate or high	19 (95)
Low	1 (5)
Physical limitations	
No risk of facing physical limitations	9 (45)
Risk of facing physical limitations	10 (50)
Already faced physical limitations	1 (5)
Cognitive limitations (Mini-Mental State Examination)	
No risk of facing cognitive limitations (score ≥23)	19 (95)
Risk of facing cognitive limitations (score <23)	1 (5)

Agent Appearance

Ratings Questionnaire

Table 2 shows the questionnaire results regarding (1) the likeliness of following the agent's advice, (2) users' perceptions of the agent characteristics (eg, friendliness, expertise), and (3) users' feeling of rapport (eg, emotional rapport, helpfulness) for both agents. Corresponding box plots can be seen in Figure 5 and Figure 6. For the ratings of the likeliness of following the agent's advice, no significant difference between Egbert and Sylvia was found. However, Egbert was rated significantly more authoritative than Sylvia (P=.03), resulting in a medium effect size (r=.344). No significant differences were found between the agents for all other agent characteristics and the rapport scale items.

Analysis of the thinking aloud sessions and interviews resulted in the following themes on the effects of agent appearance: agent characteristics, agent appearances, interaction with the agents, and agent preferences.

Table 2. Results of the Wilcoxon signed-rank tests (n=19 or 20) comparing the mean ranks of the ratings of likeliness of following the agent's advice, agent characteristics, and rapport scale items.

Characteristic	Median Egbert (Q1-Q3)	Median Sylvia (Q1-Q3)	*z* score	*P* value
Likeliness of following advice	5.0 (3.3-6.0)	6.0 (4.0-6.0)	–1.613	.11
Agent characteristics				
Friendliness	6.0 (5.0-6.0)	6.0 (5.0-6.0)	–0.264	.79
Expertise	5.0 (4.0-6.0)	5.0 (4.0-6.0)	–0.966	.33
Reliability	5.0 (4.0-6.0)	5.0 (4.0-6.0)	–0.276	.78
Authority	2.0 (2.0-4.0)	2.0 (1.0-4.0)	–2.121	*.03
Involvement	4.5 (4.0-6.0)	5.0 (4.0-6.0)	–0.158	.88
Rapport scale				
Emotional rapport	4.0 (2.0-5.0)	4.0 (3.0-5.0)	–1.310	.19
Cognitive rapport	4.0 (4.0-5.0)	5.0 (3.3-5.8)	–0.829	.41
Helpfulness	5.0 (4.0-6.0)	5.0 (4.0-6.0)	–0.877	.38
Trustworthiness	5.0 (4.0-6.0)	5.0 (4.0-6.0)	0	>.99
Likeability	6.0 (4.0-6.0)	6.0 (4.3-6.0)	–0.604	.55
Naturalness	5.0 (4.0-6.0)	5.0 (4.0-6.0)	–0.491	.62
Enjoyability	5.0 (3.0-6.0)	4.0 (4.0-6.0)	–0.182	.86
Human-likeness	4.0 (3.3-6.0)	4.5 (3.3-5.0)	–0.486	.63
Persuasiveness	5.0 (4.0-6.0)	5.0 (4.0-6.0)	–0.942	.35
Recommendability	5.0 (4.0-6.0)	5.0 (4.0-6.0)	–0.368	.71

Figure 5. Ratings of the likeliness of following advice and characteristics of the two agents (*P*<.05).

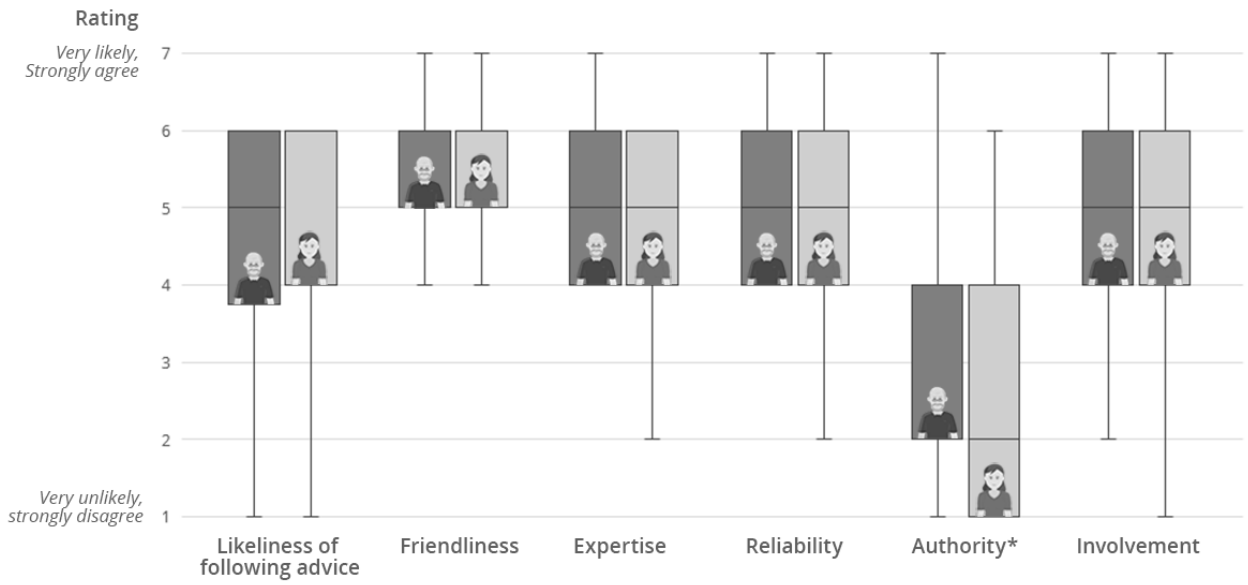


Figure 6. Ratings of the rapport scale items of the two agents.

Users' Perceptions of Agent Characteristics

A few participants indicated they had trouble getting an impression of the agents' personalities or found it difficult to connect personality to ECAs in general. A few others perceived the agents as natural and not artificial. On the other hand, the majority did not perceive the agents as human: they perceived the agents as cartoons, static dolls, computers, or machines.

> *It is a computer, it is still interaction from a distance, it does not become personal, it does not have any personality, I do not feel a connection.* [Male, 68 years]

> *The agents remain computers, you cannot call them friendly or unfriendly, they are computers and I do not connect any human characteristics to them.* [Male, 78 years]

In the interviews, some participants indicated they did not perceive the agents differently with respect to their personality. A few participants explained that both agents used friendly language, whereas others argued the agents were friendly, since they responded in a way that fit the situation and provided compliments. In addition, a participant explained that both agents were not too young or too old and seemed to be modern people due to responses such as "Gosh, how nice." Also, this participant said he liked that the agents were not too young, since a young agent would not have much experience. One participant particularly indicated that the female agent was friendlier than the male agent, whereas another participant believed that the male agent was more highly educated and more intellectual than the female agent.

Users' Perceptions of Agent Appearances

A participant indicated that the agents looked like cartoons or drawings, whereas she preferred the agents to look like real humans. This participant also indicated that the blinking eyes and mouth animation were distracting.

The rest of the comments related to the appearance of either one of the agents. One person particularly mentioned the female agent having a friendly face, whereas all other comments related to the male agent. The appearance of the older male agent evoked several associations, such as the agent looking old, and, therefore, unhealthy. Others associated the older male agent with a scientific staff member, a nerd or a male of the type of wearing sandals with socks, because of his glasses and popular beard. Participants preferred an energetic, spontaneous person and one that is more neutral and clean-shaven. One participant did not like the male agent, because he associated the agent with his or her uncle, having a similar name: a spoiled man with whom you would not be able to connect. Another participant found the male agent more distracting than the female agent, because of his glasses.

Users' Perceptions of Interaction With the Agents

Several participants explicitly indicated that they expected or would like the agent to speak. One participant expected the agent to speak due to its mouth animation, whereas another had this expectation, since humans interact via speech in real conversations. Another participant pointed out that, due to the absence of agent speech, the user has to multitask: the user simultaneously has to read and answer the questions and pay attention to the agent. Therefore, she would like the agent to speak.

> *Well, I have to read what you say to me, but instead open your mouth yourself!* [Female, 73 years]

Other opinions on the interaction with the agent focused on the naturalness of the interaction.

> *It felt as if there was a real human in front of me.* [Female, 71 years]

Another participant described the interaction as actually talking to someone, and yet another participant described the interaction as having a phone call, in which someone is checking how you are doing. Some participants were less positive. A few participants specifically said that the interaction with the agents was impersonal.

> *Actually, I do not have the feeling I am really communication with someone.* [Female, 65 years]

Another participant said that she did not take part in a conversation but was simply reading and answering questions. This participant did not establish a connection with the agents.

> *I barely know her.* [Female, 65 years]

> *Understanding each other? Then one would expect interaction.* [Female, 65 years]

Last, some comments related to the implemented small talk. On the one hand, some participants seemed to like the small talk, reflected by them laughing. On the other hand, a participant was irritated by the implemented small talk, she felt being treated like a child.

Agent Preference

The majority of the participants indicated they did not prefer one agent over the other. Most of them indicated they did not have a preference, since they perceived the agents to be similar. Some did not even remember they interacted with two different agents. However, some participants did show a preference. Most participants preferred the female agent, either because they believed she was friendlier or discussed a more interesting topic. Only one participant preferred the male agent but could not say why.

Usability and Intention to Use Frailty Assessment App

Questionnaire results show that the usability of and intention to use the frailty assessment app were high: the 20 usability ratings displayed a median of 6.1 (interquartile range [IQR] 6.1-7.0) and the 20 intention-to-use ratings displayed a median of 6.0 (IQR 4.0-6.0) on a 7-point Likert scale.

During the thinking aloud session and interviews, participants pointed out usability issues of the frailty assessment app or provided suggestions for improvements to the app. The following themes were identified: content questionnaires (mentioned 107 times), language usage in dialogues (mentioned 41 times), presentation information (mentioned 21 times), interaction with app (mentioned 14 times), design (mentioned 7 times), navigation (mentioned 7 times), and general computer interaction (mentioned 6 times).

Most comments or suggested improvements related to the content of the questionnaires and the language in the app. The majority of the participants reported that the questionnaires did not fit their personal situation and contained a lot of repetition or ambiguity. Participants suggested adapting the questionnaires according to previous answers given. In addition, participants commented on the language used: words being ambiguous, too popular or too old fashioned, unnecessary, patronizing, or not being known by people with a lower education or older adults. Furthermore, participants commented on the length and structure of the sentences and pointed out spelling mistakes. A participant suggested adapting the language in the app to the education of the user. Considerably fewer comments related to the presentation of information, interaction with the app, design or navigation of the app, and general computer interaction. As an example, with respect to navigation, some participants indicated they would like to be able to go back to a previous dialogue step.

With respect to the intention to use, the thinking aloud sessions and interviews showed that a minority of the participants would like to use the app. A participant indicated he would not use the app but would recommend the app to others who might benefit from it. In addition, some participants clearly indicated they would not use the app. The majority of the participants indicated that the agents did not add any benefit to the app, arguing that the app was not personal since answer options were limited and the opportunity to explain them was missing. A participant stated that for the app to be beneficial, it should also provide advice on what actions the user should perform to become more healthy. Another participant explicitly stated that he would use the app when the text was replaced by speech.

Discussion

Principal Findings

Our results show that the appearance of an agent, in particular age and gender, affects users' perceptions of agent authority but does not affect users' perceptions of other agent characteristics, users' feelings of rapport, or users' likeliness of following agent advice. Compared with a young female agent, an older male agent is only seen as more authoritative. These results are not in line with our expectation that agents are perceived differently after a short interaction with a user. To the best of our knowledge, there is no existing research comparing users' impressions of agents at first glance with those after short interactions. But research shows that in human-human interaction, first impressions, formed within milliseconds [28], are difficult to lose. Therefore, we assumed that the differences in perceptions of characteristics of a static image of a young female agent and an older male agent, as found in a previous study [16], would still be present after a short interaction with these agents. An explanation for this inconsistency could be that impressions in human-agent interaction differ from impressions in human-human interaction. Users' judgments of agents may modify with ongoing interaction, as research shows that agents do have a second chance to make a first impression [13,29]. Therefore, differences in perceptions of both agents may have been present at first glance but disappeared after interaction. Further research is needed to confirm this finding. Future research could study users' perceptions of agent characteristics with a larger study population. Eventually agents will be used in a long-term setting; therefore, it is interesting to research not only users' perceptions at first glance and after short-term interaction, but also after long-term interaction.

How do we explain the difference in perceptions of agent authority after a short interaction? Although research on short-term interaction with an agent indicates that an agent's appearance, including clothing [18], racial concordance with the user [30,31], and similarity with the user [30,32], could affect users' perceptions of the agent, to the best of our knowledge there is no research on agent authority after short interaction in particular. From a previous study [16], we see that at first glance, static images of male and older agents are indeed seen as more authoritative than female and young agents, respectively. In addition, the study shows that the differences found in authority are often higher compared with differences found for other characteristics tested, which could explain why the difference in authority level is still present after short interaction. However, since we did not control the age and gender of the agents in this study independently, it is difficult to say whether the difference in perception of agent authority is caused by agent age or gender in particular or solely by the combination. Future research could study which factors actually control the difference, researching users' perceptions of agent

authority by independently controlling the age and gender of the agents. In addition, future research could study how an agent's authority is perceived after long-term interaction.

We expect that the effect of the first impression established by agent age and gender on the impression after short interaction is small compared with the effect of other design features, such as the content and language of the messages, (absence of) agent speech, and the amount of embodiment. Our study shows that the majority of participants perceived the agents not as humans but as machines or cartoons and found interaction with the agents impersonal or artificial. They did not have the feeling of being in a conversation. These perceptions may indicate users had a negative adaptation gap [29], which occurs when a user overestimates the competency of an agent, creating a negative gap between expected and actual competency of the agent and resulting in the user being disappointed. This negative adaptation gap may have been caused by the content and language of agent messages, agents lacking speech, or agents having little embodiment, as supported by remarks made by participants during the thinking aloud sessions and interviews. Therefore, we believe it is important to manage users' expectations of agent characteristics and functionality up front, ensuring users' expectations match actual agent capabilities by explaining what the users can expect from the agent. Future research could study how an agent's content, language, speech, and embodiment affect users' perceptions of the conversation with the agent (eg, how these factors could make the conversation with an agent more human-like).

Although our study shows agent age and gender have little effect on users' impressions of the agent after short interaction, we believe that adapting these features to the user is important because they affect users' impressions of the agent at first glance [17,19,33], and research shows that people with favorable impressions of someone tend to interact more with that person than they do others who gave unfavorable impressions [34]. Selecting an agent with the right age and gender could thus lower the threshold to interact with the agent and use the app.

Second, our results show that usability of the developed frailty assessment app was judged positively overall; issues identified by participants related to the content or language of the questionnaires. We suggest tailoring the content and language toward the personal characteristics of the user, as confirmed by existing research [35], and adapting the content to previous answers given by the user.

Third, not all participants show an intention to use the app. Research indicates that older adults put effort into learning new digital technologies as long as they are believed to be worthy of time and dedication (eg, when technology can be used to keep in touch with others to foster relationships [36]). Similarly, research shows that the elderly value apps that address a social problem [37]. The app used in our study did not address a social problem, which could have resulted in some participants not seeing the added value of the app and not showing an intention to use the app. In addition, intention to use digital technologies in elderly persons is, next to the quality of the technology itself, affected by their personal context (eg, their ability to concentrate) and social context (eg, whether family is around to provide technical support) [37]. Both factors might have affected participant intentions to use the frailty assessment app in our study.

More specifically, the majority of participants do not believe the agent adds value to the frailty assessment app. Therefore, we suggest updating the design of the agent. We believe that the agent should convey additional information to its message in text via its embodiment. Existing research provides evidence for implementation of animations of the agent's embodiment, showing that animations positively affect users' impressions of the agent [38-40] and interaction time [13,39]. In addition, the use of speech is recommended because it could increase the sense of personality of an agent [41] and could be used to describe feelings [42]. Low-literate users could benefit from multiple output modalities [43]. Furthermore, participants indicated they would like the app to provide advice on what actions they should perform in order to become more healthy. We see an opportunity for using the agent to provide this advice. As an example, the agent could show videos of exercises to improve physical strength.

Strengths and Limitations

This is the first study that specifically evaluates effects of agent appearance after short interaction with the agent. In addition, this study uses actual health content, which is scarce in research on agent design.

Our study also has some limitations. First, the negative adaptation gap between user expectations of agent capabilities and actual agent capabilities suggests the app used might not have been mature enough. The agent conveyed the majority of the information via text. Participants might have been focused on reading the text and therefore paid little attention to the agent, resulting in participants having difficulties in creating impressions of agent characteristics and establishing rapport. Second, interaction time with the agents might have been too short to create impressions of agent characteristics and establish rapport. Third, although we found a difference in users' perceptions of authority of the young female and the older male ECA, it is difficult to identify whether this was caused by the ECA's gender or age, since these factors were not independently controlled in the study.

Toward Digital Frailty Assessment With Embodied Conversational Agents: Recommendations for Future Research

Agent Design Implications

First, convey empathy or emotion using the agent's embodiment. This way, agent design can positively affect users' impressions of the agent and interaction time. Second, reduce the user's cognitive load by providing the agent messages in speech. This way, agent design can positively affect users' impressions of the agent. Third, select an agent appearance that fits the age and gender of the user. This way, agent design can lower the threshold to start using the app.

Prerequisites Frailty Assessment

First, take into account the user's personal situation, such as disabilities and living situation, and adapt the content. Adapt

the questionnaire so users do not see questions that do not apply to their situation. Second, save the answers given by the user, and adapt the questionnaire accordingly. This way, users do not have to answer questions that are not applicable to them. Third, adapt the agent's language based on the educational level of user so the language is neither too simple nor too complex.

Conclusions

Our study shows that an agent's appearance, in particular age and gender, only affects users' perceptions of agent authority after short-term interaction. We conclude that adapting agent age and gender to users' preferences is important to lower the threshold to interact, whereas the content and language of the agent's messages and agent speech and embodiment are important factors for users' impressions of the agent after short interaction.

We believe that ECAs have potential to be used in digital frailty assessment, but future research is needed. Future research could study users' perceptions of agents after long-term interaction, whether users' perceptions of agent authority are related to agent age or gender in particular, and how an agent's content, language, speech, and embodiment affect users' perceptions of the conversation with the agent.

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Conflicts of Interest

None declared.

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Abbreviations

ECA: embodied conversational agent
eHealth: electronic health
IQR: interquartile range

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Original Paper

Understanding the Attitudes of Clinicians and Patients Toward a Self-Management eHealth Tool for Atrial Fibrillation: Qualitative Study

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Abstract

Background: Atrial fibrillation (AF) is the most common heart rhythm disorder and poses a growing disease burden worldwide because of an aging population. A multidisciplinary approach with an emphasis on patient education and self-management has been demonstrated to improve outcomes for AF through the engagement of patients in their own care. Although electronic tools (e-tools) such as *apps* have been proposed to provide patient education and facilitate self-management, there have been few studies to guide the development of these tools for patients with AF.

Objective: This study aims to explore the perceptions of patients and health care providers (HCPs) and their attitudes toward the use of e-tools for the self-management of AF. It also seeks to elicit the factors that contribute to these attitudes.

Methods: Semistructured qualitative interviews with HCPs and patients were conducted to understand the interpretations and expectations of an e-tool that would be used for the self-management of AF. Interview data were analyzed using an exploratory thematic analysis approach to uncover emergent themes and infer ideas of preferred features in a device. A modified technology acceptance model was developed as a framework to help interpret these findings. Data from the HCPs and patients were compared and contrasted.

Results: Both patients and HCPs thought that an e-tool would be useful in the self-management of AF. Although both groups favored educational content and monitoring of blood pressure, patients expressed more passivity toward self-care and an ambivalence toward the use of technology to monitor their medical condition. This appears to be related to factors such as a patient's age, social support, and their attitudes toward technology. Instead, they favored using the app to contact their HCPs.

Conclusions: This study provides insights into significant differences in the attitudes of patients and HCPs toward the use of e-tools for self-care against their priorities. Understanding patients' motivations and their needs are key to ensuring higher acceptance of such tools.

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KEYWORDS

mHealth; qualitative research; atrial fibrillation; self-management; chronic disease; mobile phone

Introduction

Background

Atrial fibrillation (AF) is the most common and clinically significant arrhythmia. It is an important risk factor for serious adverse events such as stroke, heart failure, and early mortality. Worldwide, there were an estimated 11 million cases of AF in 2013, which was underestimated because of the high prevalence of asymptomatic AF [1,2]. Its prevalence increases with age by 5% to 15% and is expected to rise 2.5-fold in the next 50 years. A recent study revealed that hospitalizations for AF increased by 420% from 767 to 3986 per 1 million Korean population from 2006 to 2015 [3]. The overall cost of AF in the same study showed an increase from EUR 68.4 million (US $86.2 million) to EUR 388.4 million (US $431.1 million) in the same period, highlighting the additional health care and economic burden from the condition [3].

In addition to providing AF care, the European Society of Cardiology guidelines underlined the importance of patient involvement in the self-management of AF [4]. The guidelines further state that patient "education is a prerequisite for informed, involved patients and patient-centred care." Nevertheless, overall patient knowledge about AF remains poor [5-8]. In recent years, electronic tools (e-tools) have been used as platforms for patient education and disease self-management. Some e-tools have shown to improve patient outcomes by either improving disease knowledge or medication adherence monitoring [9,10].

There remains a paucity of such app-based tools developed for patients with AF [11-13]. Therefore, the aim of this study was to determine perceptions of health care providers (HCPs) and patients and their attitudes toward an e-tool known as Self-management and Education Tool for AF patients (SETAF) that can be used to improve AF knowledge and self-manage the condition at home. The factors that affect how patients' HCPs respond to the e-tool and the functions and features they would consider desirable were also studied. Insights from this study may aid the further development and implementation of SETAF to a larger audience.

Theoretical Framework

The technology acceptance model (TAM) described by Davis [14] is one of the most commonly used models to predict the acceptance of technology. According to the TAM, technology acceptability is dependent on a user's perceived usefulness and the perceived ease of using the device. Perceived usefulness was defined as the tendency to use an app depending on a user's belief that it will enhance their task performance. Meanwhile, perceived ease of use is the user's belief that a particular system is easy to use. The combination of the 2 perceptions determined each user's attitude, behavioral intention (BI) to use, and ultimately, the actual use of the system. In the field of health care, the TAM was modified to include constructs from other health-related models [15]. Holden and Karsh [15] noted that as TAM was not designed "specifically in or for health care context," the use of TAM in its generic form "may not capture or indeed may contradict some of the unique contextual features of computerised health care delivery." The model also does not consider social factors that potentially influence a user's decision to use technology [16]. In a study that explored women's acceptance of seeking health information through models, the construct on self-efficacy from the social cognitive theory of Bandura was included and was found to be highly correlated to BI [17]. Another study examining the use of smartphones for chronic disease management also extended the TAM model to include constructs from the health belief model and other social and demographic factors [16]. Some of these additional constructs were found to have an influence on technology acceptance.

Methods

Study Design

This exploratory study used qualitative semistructured interviews to understand the perceptions of HCPs and patients with AF and their attitudes toward using the AF self-management e-tool.

Study Population

Purposive sampling was conducted to gather insights from HCPs who (1) were currently working in the outpatient cardiology clinic of a tertiary university hospital in Singapore and (2) have extensive experience working with patients with AF. We approached 23 cardiologists, nurses, and pharmacists who were working in the heart clinic through email to participate in the study. In total, 12 HCPs (4 physicians, 4 nurses, and 4 pharmacists) agreed to participate and were interviewed between February and April 2016.

A total of 16 patients with AF and their caregivers were recruited from the same cardiology clinic. The inclusion criteria were (1) age >21 years, (2) ability to speak English, and (3) hospitalizations in the past 6 months. Patients who had a history of cognitive impairment or were otherwise unable to provide informed consent for the study were excluded. Patients and their caregivers were interviewed together if they were both present at the clinic. The rationale for this was that most patients with AF are elderly and often rely on their caregivers as support to use e-tools. These caregivers either facilitate the patients' access to these tools or may in fact use them on the patient's behalf. Hence, patient and caregiver dyads were interviewed together, as the presence of the caregiver may affect how patients interacted with the e-tool. A total of 11 patients and patient and caregiver pairs agreed to participate in the study and were interviewed in July 2016. Patients who declined to be interviewed cited reasons such as needing to leave the hospital after their appointment or were uninterested in technology.

Interview Procedure

All HCPs and patients were interviewed either in the offices of the HCPs or in a quiet room within the clinic. Semistructured

interviews were conducted using an interview guide (Multimedia Appendix 1). The questions sought to understand the current care provided by the cardiology clinic, patients' experiences with self-care, the potential for the use of e-tools in AF self-management, preferred type of e-tool, and preferred features of the e-tool. Each interview lasted between 30 and 60 min.

Materials

Most patients with AF in Singapore are elderly and have limited formal education. According to data from the Singapore Department of Statistics, more than 63% of the population aged 65 years and older have only had formal education below the secondary school level [18]. Therefore, the demonstration tablet provided a visualization form. During the interview, patients were given tablets installed with a self-care program app (demonstration version) and a blood pressure (BP) machine loaned by Koninklijke Philips N.V. This is an Android tablet app built within the Philips Motiva Platform and has a touchscreen-based interface. Features of the e-tools were introduced to participants during the interview, and they were asked to provide their perspective about these features. The demonstration version consisted of 2 main functions. First, it provides information and educational content for patients to learn about AF and its management. This is in the form of videos related to general health, health-related reminders and messages, and survey questions. Second, the tablet also has monitoring functions and is linked wirelessly to the BP machine. This allows it to automatically log BP and heart rate of the patients, which is then uploaded to the Motiva cloud-based database.

Data Analysis

All 24 interviews were digitally recorded and transcribed verbatim by a professional transcriber. Most of the interviews were conducted in a colloquial form of English widely spoken in Singapore, known as Singlish, and the transcripts as well as the quotes in this manuscript retain the nonstandard grammar used. The transcripts were analyzed using thematic analysis using ATLAS.ti version 8 (ATLAS.ti Scientific Software Development GmbH) to organize the data. An initial codebook was developed by 2 researchers (BC and GK) using 3 transcripts. The remainder of the interviews were coded by one researcher (BC), with reliability checks performed on 7 interviews (GK). First-order codes were identified, then subsequently grouped into second-order nodes and, finally, key themes. The analysis was performed for each participant group separately (HCPs and patients) and then examined for thematic connections between the participant groups.

Ethics Approval

This study was approved by the domain-specific institutional review board (DSRB 2015/00940). Researchers conducting the interviews explained the purpose of the study and clarified any questions from the participants. Participants were informed that their data would be anonymized and that their participation in the study was voluntary, before signing informed consent documents. Patients were provided with SGD 10 (US $6.90) reimbursement for their participation.

Results

Participants Profile

The characteristics of the study participants are summarized in Table 1. HCP participants had worked in a cardiology clinic of a tertiary hospital for an average of 8 years (range 2-13 years). The patients' ages ranged from 50 to 76 years, and they had a diagnosis of AF between 0.5 and 17 years. There were mostly male and Chinese patients, and nearly all were on warfarin therapy.

Table 1. Health care providers' and patients' characteristics.

Characteristics	Values
Health care providers (n=12), n (%)	
Doctors	4 (33)
Nurses	4 (33)
Pharmacists	4 (33)
Years in practice of the health care providers, mean (range)	8 (2-13)
Patients (n=11)	
Patients interviewed alone, n (%)	7 (64)
Patients interviewed with caregiver, n (%)	4 (36)
Age (years), mean	61
Male, n (%)	7 (64)
Ethnicity, n (%)	
Chinese	8 (73)
Malay	2 (18)
Indian	1 (9)
Anticoagulation, n (%)	
Warfarin	9 (82)
Direct oral anticoagulant	2 (18)

Themes

A modified TAM framework (Figure 1) was developed using the findings from this study for 2 reasons: (1) the modified model sought to highlight the social factors that influence perceptions and acceptability and (2) the TAM construct of *actual use of the system* had to be removed, as this was an exploratory study with no actual utilization data. The modified TAM framework illustrates the major themes of this study. The analysis focused on how various factors influenced participants' perception of the usefulness of an e-tool and their attitudes toward using such a tool. The thematic analysis combines the findings from the HCPs and the patients. The results include comparisons between participant groups, where appropriate.

The themes derived from our interviews with patients and HCPs are summarized in Table 2 and presented in more detail below.

Figure 1. Proposed modified technology acceptance model. A: attitude toward use; E-tool: electronic tool; E: perceived ease of use; U: perceived usefulness.

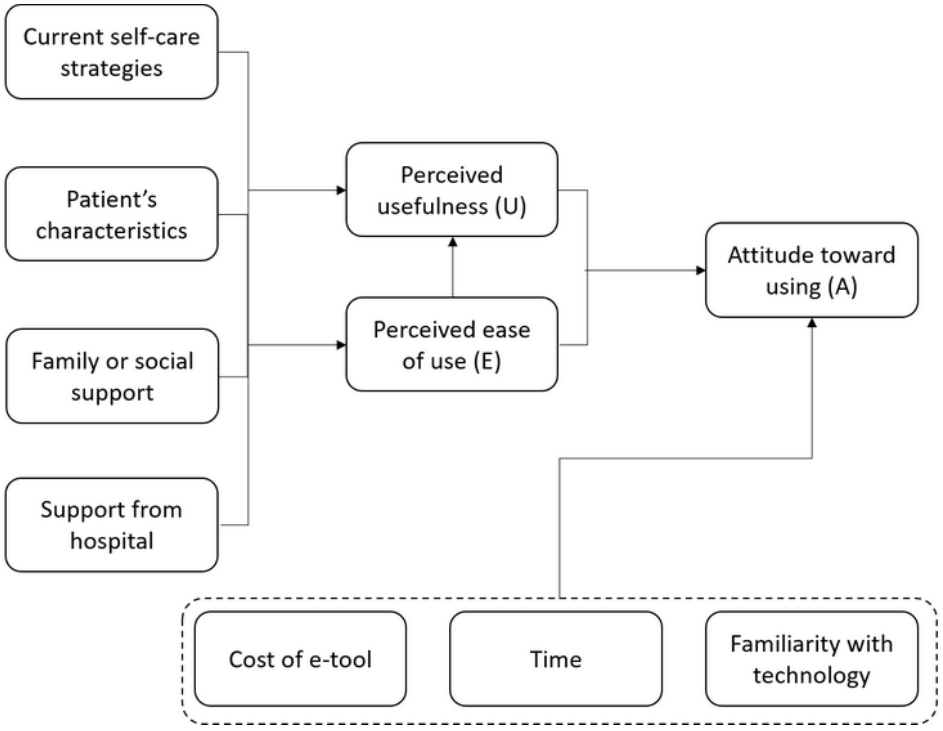

Table 2. Summary of themes from patient and health care provider interviews.

Themes	Patients	Health care providers	Other observations
Current self-care strategies	• Reading material about diet • Recording diet and medications	• Advised to monitor BP[a], diet, and exercise • Provided reading material	• Patients did not follow advice on exercise and diet
Patient characteristics and attitudes toward self-care	• Negative attitude generally, did not feel they can make a difference	• Younger patients more educated and more likely to self-care	• N/A[b]
Family and social support	• Family support important enabler	• Family support important enabler	• N/A
Support from hospital	• Access to health care advice important • Reliant on health care providers for health information	• Language barrier affects patients' ability to understand their condition	• N/A
Perceived usefulness	• e-tool[c] can be useful for self-management • Valued BP monitoring, educational videos, and support from health care providers	• Valued patient support groups, reminders about diet, medication, or clinic appointments	• Discrepancy between what patients and health care providers valued
Technical preferences for e-tool	• Preferred smartphone based • Some preferred larger screens	• Integration with eHealth record important	• Both groups emphasized the accuracy of monitoring tools and multilanguage support
Attitudes toward using e-tool	• Mostly reluctant to use as unfamiliar with technology • Concerned about lack of time and cost of devices	• More receptive than patients • Can empower patients and provide reassurance • Concerned that patients may be resistant to using the tools • Lack human touch	• N/A
Redefining the use of non–e-tools	• Generally preferred paper-based tools for education and recording BP measurements	• Engage primary and community care to customize care	• N/A

[a]BP: blood pressure.

[b]N/A: not applicable.

[c]e-tool: electronic tool.

Current Self-Care Strategies

In addition to general consultation for AF, HCPs mentioned that the clinic also provided patients with self-care strategies. Dietary consultation featured prominently for patients who were prescribed warfarin (a blood thinner to reduce stroke risk) because of the large number of food-drug interactions. Patients confirmed the provision of a booklet for foods they should avoid consuming. HCPs also advised patients to regularly attend clinical consultations; instructed them to measure and record their BP and heart rate at home; and advised them to exercise regularly and make other lifestyle changes, such as lowering stress levels.

Some self-care strategies were adopted by patients who mentioned that they went for frequent checkups, watched their diet, and consumed medications as directed, for example, through the use of pillboxes. However, in direct contrast to what was discussed by the HCPs, most patients mentioned that they did not exercise or measure their BP regularly because they were not advised to do so by clinicians:

> *Interviewer: So, did the doctor advise you that you should monitor your heart rate at home?*
>
> *Patient: No, he never ask me to do that.*
>
> *I: What about blood pressure?*
>
> *P: No, no.* [Patient 9]

From the HCPs' standpoint, medication and dietary restriction adherence can be challenging for some patients. This is particularly true for patients on warfarin, as dosage can be frequently altered, and it may be difficult for patients to keep up with the changes. The HCPs were also concerned about potential drug-drug interactions because of polypharmacy from other conditions and interactions with food that may contain traditional Chinese medicine ingredients. Finally, patients often cited a lack of time or comorbidities as a reason for not exercising regularly.

Patient Characteristics and Attitudes Toward Self-Care

Patient characteristics largely defined their attitudes toward self-care. The HCPs noted that younger patients tend to be more

educated and have a higher health literacy level and thus were better able to care for themselves. Better self-care was also observed in patients who had higher levels of motivation and technology-savviness. For example, one patient mentioned that he read medical books to better understand AF and experimented with different diets:

> *I start looking at the medical books like science guy you know so...ok, this is AF you know... ventricle [is this], not this, ok, so in us... there is some... misbehaviour somewhere in... those things and then that's how suddenly, you know, bad thing come up, you see? So what are what are precautions, I must do and so on, you see? So I, I...I [have] been very careful!* [Patient 8]

Conversely, negative attitudes in patients were seen as a major barrier to self-care. Some participants mentioned that apart from diet and medications, they did not make other lifestyle changes because they *could not be bothered* or were *too lazy* to do so. Others felt useless and hopeless, and these patients believed that they could not do much to improve or manage their condition:

> *I: Do you have experience using blood pressure machine?*
>
> *P: I have [it] at home but I don't bother with this. I kept there quite some time already.*
>
> *I: Why not? What is it that is preventing you from using it.*
>
> *P: I [am too] lazy to go and take (it) out [to use].* [Patient 4]

Family and Social Support

High levels of family involvement or good social support were facilitators of self-care. For some patients, caregivers helped them to either monitor their diet and/or medications and were also involved in educating them about their condition.

Conversely, lack of support from family members was a barrier to self-care. For example, dietary restrictions were noted by some patients and HCPs to be challenging. For these patients, family members who were not used to cooking with or eating healthier food options (eg, healthier oils and whole grains) were initially resistant to making dietary changes:

> *The oil must change. Now we never take the vegetable oil at home, we must buy the soya bean oil, the olive oil for him. At first a bit difficult, because my children can't take it when I cook with that oil. They say it's a bit different, the taste is a bit different. Then I said it's good for your father, must try to [change] the oil.* [Caregiver 7]

Support From Hospital

Patients with AF who are prescribed warfarin require regular monitoring of blood coagulation levels. The HCPs indicated that low-income patients who had difficulty attending frequent follow-up appointments at the clinic were loaned the international normalized ratio (INR) testing machines to self-test at home. Different levels of telecare were described by the HCPs. Telecare was provided to these patients by pharmacists from the anticoagulation clinic calling them to monitor their INR levels and to advise them on titrating their warfarin dosages:

> *[The] patient can do a phone consult. That means [the] patient comes, then [has the] blood [test], then they will go. Then pharmacy will trace the blood [results] later, because waiting for the blood test and all that right, so it takes some time, so they will let the patient go home so anything "I'll update you on the dosage." That means the dosage titration will be done over the phone, then the pharmacist will call the patient or the caregiver, "okay you can continue the drugs until 2 weeks' time then we see you again," something like that. There's another one where a patient can go to a polyclinic, the nearest polyclinic.* [Nurse 4]

Interestingly, although some patients mentioned that they occasionally discussed issues about their condition with their HCPs over the phone, this was not connected to the INR home monitoring service. They thought that the ability to call nurses when faced with problems was helpful to them and could facilitate self-care. Many patients were also unaware that they could do their blood tests at home. The availability of the INR machine is also an area of some confusion. Although the machine is available for purchase in the hospital pharmacy, one HCP mentioned that it was not currently available for purchase in Singapore.

In terms of health information seeking behavior, the majority of the participants relied extensively on their HCPs for information. This was particularly evident in patients who did not self-monitor their BP, as they felt that it was frequently checked in the hospital. Similarly, these participants only sought information about AF from their HCPs and did not actively search for information or speak to their friends or families about their condition:

> *I: Besides from the doctor, did you find out [information] from anyone else?*
>
> *P: No, I don't!*
>
> *I: What about from... the internet?*
>
> *P: No!*
>
> *I: Then, your friends?*
>
> *P: No!*
>
> *I: Or, anyone with the same conditions?*
>
> *P: I only... want to interact with the doctors, other than that, my friends and all, they don't know my case.* [Patient 11]

Despite the patients' reported reliance on HCPs, the HCPs stated that patients have problems understanding AF, in part because of language barriers between the HCPs and the patients. The language barrier was felt to result in misconceptions about AF in the patient population.

Perceived Usefulness

Overall, the majority of participants felt that an e-tool would be useful for self-management. In particular, features that were found to be useful by both HCPs and patients were BP monitoring and logging, educational videos, and support from HCP. In contrast, features such as patient support groups and reminders about diet, medications, and clinic appointments were consistently seen as useful by HCPs but not by patients. The following section outlines the participants' perceptions of the various suggested features.

Educational Videos

HCPs stressed the importance of education in AF self-management. In their view, patients require education about the management of AF (such as pharmacotherapy and other lifestyle advice) and knowing when and where to seek help. Moreover, as some patients may not necessarily know how to navigate the e-tool, education about how to use the tool was also seen to be important. When shown a demonstration of the e-tool, patients found the content about medication and dietary advice useful. Patients also wanted e-tools to include information about financial aid and other conditions.

BP Monitoring and Logging

Patients liked the ability to use the e-tool to monitor and automatically log BP results. In addition, both HCPs and patients would like to see this feature extended to other conditions. For example, one suggestion was that the same tool could be used to measure and log blood glucose levels of diabetic patients. Another suggestion was to have BP monitoring on top of existing heart rate monitoring in wearables.

Interaction With HCPs

Another feature of an e-tool desired by both HCPs and patients was interaction with a member of the clinical team. The level of interaction could range from having the HCP monitor a patient's vital signs through the e-tool or having a quick feedback or question section for patients to pose their questions to their HCP, to having a chat-bot and a messaging system with the clinical team. Patients generally preferred methods that provided more interaction with their HCP, as it would resolve issues faster.

Reminders for Medications, Diet, and Appointments

The HCPs felt that having a reminder system for medication use, diet, and clinical appointments may help to improve adherence in patients. However, this sentiment was not shared by most patients. Both HCPs and patients felt that it would be useful if the tool could provide a list of current medications prescribed to the patient. The HCPs also suggested that the cost of medications could be included in the tool.

Patient Support Group

A virtual patient support group was suggested as a useful element of the e-tool by HCPs. However, most of the patients felt that this was not useful. Reasons included not wanting to be overburdened with reading about other patients' issues, being misled by false information, feeling that their condition was not serious enough to warrant such a group, and an unwillingness to reveal health information to others:

> *I doubt people want to [reveal] their condition to us unless it is to [their] doctor. Usually patients I don't think they will want to let you know what's their outcome [is]. Unless it's your family member.* [Patient 4]

Technical Aspects of E-Tools: General Preferences

In general, participants had varied preferences in terms of the e-tool platform. Many participants felt that having an AF app on a smartphone would be more convenient as they always have access to their phones. Others felt that it would be easier to access the content if it were on bigger screens, for example, on a tablet or computer. Apart from apps, HCPs also mentioned the convenience of websites as they can be accessed from computers, tablets, and smartphones:

> *Computer will be better. Phone is also difficult. Bigger screen better. Tablet ok.* [Patient 1]

In terms of technical qualities of the e-tool, the HCPs and the patients emphasized the importance of having accurate information and accurate readings (eg, BP) in the e-tool. Both groups also emphasized the importance of making the e-tool a multilanguage tool. Both patients and HCPs also hoped to see an interactive e-tool. Furthermore, the HCPs added that there should be seamless data integration between the e-tool and the hospital system, although some expressed concerns over confidentiality and privacy with a linked system.

Attitudes Toward Using E-Tools

In general, HCPs were more receptive to the idea of using e-tools than patients. They believed that the use of e-tools could empower patients, provide them with reassurance, and, in the process, help reduce costs. The potential of using an e-tool to gain easy access to patients' self-monitoring data was seen to be advantageous.

Patients, in contrast, were less enthusiastic about e-tools. They thought that e-tools were generally useful and convenient, as they would be able to view information instantly. However, most of them expressed an unwillingness to use the tool. The primary reason for their reluctance was largely because of unfamiliarity with technology. Some mentioned that they do not own any of these devices (smartphone and tablet) and they do not know how to use the internet. This uncertainty about technology also extended to the perception that e-tools would be complicated and troublesome. Patients felt that e-tools were impractical and were unwilling to learn how to use one. This perceived difficulty was also coupled with the belief that medical terms are complicated, and thus, the content of the e-tool would be equally difficult to understand:

> *I: If I was to say that I want to introduce a tool like that to help you measure your heart rate, your blood pressure, all these things, would you find it useful?*
>
> *P: I, I find it not practical use for me lah. I don't think so.*
>
> *I: Why is it not practical? Is there any reason?*

P: No reason at all. [Patient 5]

Lack of time and costs also contributed to the patients' unwillingness to use an e-tool. Those who were working long hours prioritized rest over the use of an e-tool. Many felt that the cost of the e-tool would be high and indicated that they were only willing to pay up to SGD 200 (US $138) for the e-tool should it be developed for mass use. They also suggested that the e-tool could be paid for by Medisave (a mandatory savings scheme for health care) or Medifund (a government health care assistance scheme):

> *But before that I will ask, all these, right, will you charge [to] us? Because my husband is not working, I'm not working myself, [because] my daughter is from special school. Now I only have help from elder son, he [is] the one who support us now, but he himself got ... to pay [the] bill so one household. So I myself go hospital under Medifund, that is why I ask you first because we are... [having difficulty with] our finances also.* [Caregiver 7]

Despite their more positive attitude toward e-tools, HCPs had some reservations. HCPs worried that it would be difficult to convince patients to rely more on e-tools, as it lacks the *human touch* that patients seek during clinic visits. This is particularly so for patients who have frequent follow-ups. Moreover, HCPs were concerned that their patients' inability to use technology may hinder the adoption of e-tools. They also noted that an e-tool had the potential to increase anxiety if patients overmonitored themselves. The e-tool would be a constant reminder to patients about their condition and may affect their well-being. E-tools with a messaging function may also be an additional burden to HCPs as they may have to constantly respond to patients' messages.

Redefining the Use of Non–E-Tools

Patients mentioned that they were comfortable with printed material to provide information about their condition. For example, patients preferred the booklet of dietary restrictions that are currently provided to them by the AF clinic as opposed to having this information in an e-tool. Patients felt that they could also record BP measurements in notebooks rather than having the readings sync directly to the e-tools. In addition to pamphlets, HCPs suggested books, posters, roadshows, and the use of educational videos in the clinic to help educate patients:

> *I: Apart from all this I have shared with you, instead of putting them in electronic platform, I give you in, say, a book, is it better for you?*
>
> *Caregiver: Ya I think it's better because I can read it. If I don't understand, I can ask my son ... I can concentrate what is this [and] what is [that].* [Caregiver 7]

One interesting suggestion by HCPs was to use primary and community care services to help patients manage their condition closer to home. HCPs believed that general practitioners would have a better understanding of the patient's preexisting conditions, which would help in care management. However, they were concerned about the current cultural preference among patients of seeing specialists in hospitals for heart conditions and that this culture may be hard to change.

Discussion

Overall, the results from the interviews indicated that having an e-tool to help patients self-manage AF was acceptable to both clinicians and patients. In particular, both parties thought that having more educational content about AF was useful and that monitoring and logging of vital signs through the e-tool was convenient. Having the app on a smartphone appeared to be the preferred platform, given that the majority of patients had them, although some preferred the bigger screen sizes of tablets and computers.

A noteworthy finding was that there were important differences in the preferences of patients and HCPs. The latter wanted features that would enhance their clinical work, such as the ability to integrate data between the e-tool and the hospital network and quantify AF symptoms remotely. In contrast, patients' interest in the e-tool centered around access to advice from HCPs, BP monitoring, and education about their condition. Nonetheless, there appears to be significant barriers to patient acceptance of such e-tools, which underscores the need to design such tools with patients' needs in mind.

Reluctance Among Elderly Patients to Use E-Tools

Patients' current self-care behaviors are a strong determinant in defining their attitudes toward using e-tools. These self-care behaviors and strategies are, in turn, determined by individual-level characteristics and facilitated by the level of support from family and friends and support from the wider environment, such as from the hospital. For instance, although the HCPs reported asking patients to monitor their BP, the patients in this study did not consider this to be useful. Coupled with a general disregard for self-care, this meant that they did not consider BP monitoring a routine part of AF management.

Currently, patients' self-care mechanisms include the use of pillboxes, a booklet on dietary restrictions, and logging BP results in notebooks. However, the majority of the participants had a passive attitude toward self-care. Including these features in the e-tool, although potentially useful, may not translate into incremental benefits for patients who do not see the value of self-monitoring. Even among those who were currently self-monitoring, their unfamiliarity with technology created a perception that the device would be difficult to use, leading to a negative attitude toward using e-tools in general.

From a broader perspective, the prevailing environment does not appear to promote the use of e-tools for self-management. Patients with AF are generally older and have multiple comorbidities in addition to AF, such as hypertension and diabetes. Consequently, the patients in this study made frequent trips to the hospital for the management of other conditions due to fragmented specialty care. Frequent clinic contact perpetuates patients' reliance on the hospital and the HCPs. Although the HCPs mentioned that the e-tools can help reduce trips to the hospital, this may not be beneficial for the patients who are already used to making regular clinic visits. Furthermore, if the content of the e-tool does not include other chronic conditions,

it may not significantly reduce the overall need for hospital visits. To overcome this, a more integrated approach to managing these multiple conditions will be needed both in the form of clinical care as well as in the design of e-tools. A potential approach would be to integrate chronic care clinics for patients with AF [19].

Comparison With Prior Work

Our findings were largely similar to those of other eHealth studies in Singapore. In designing a lifestyle app for overweight pregnant women, Lau et al [20] found that these women also preferred to use smartphones as they are user-friendly and convenient. The need for multilanguage platforms was also reflected in their study. However, unlike our study population, these women expressed a preference for peer support to provide additional information during their pregnancy. The reason for this is uncertain, but the relatively younger patients in the study may be more comfortable relying on multiple information sources through social networks in a manner akin to social media.

Another study looked at apps to improve medication adherence in oncology patients, who valued educational and behavioral interventions [21]. Older patients and those who were less educated were also unlikely to use such smartphone health apps. In our study, although some patients preferred the use of smartphone apps, we also found that some other patients valued the larger screens of tablets or computers as they make it easier to read.

Advantages of the Modified TAM Framework

The TAM framework was originally devised to study the factors that contribute to the attitude toward the BI to use new technology [14]. However, this does not include some factors that impact the use of technology in a health care context. Hence, the modified TAM framework was developed to include the effects of external social or clinical factors on how patients interact with e-tools. In this study, we found that a patient's age, social support, and their attitudes toward technology as well as their self-care had important influences on how they perceived the usefulness and ease of use of e-tools. These psychosocial factors are not included in the original TAM, but, for our patients, could influence whether they use an e-tool. This framework extends the TAM beyond more technical considerations, such as the specification of the e-tool and the user interface, and allows a more complete assessment of how patients may respond to eHealth interventions.

Implications for AF Care

Specific to self-monitoring tools for patients with AF, there are other published studies that demonstrated that patients were generally satisfied with a mobile self-care and medication adherence app [12,13]. In the study by Hirschey et al [12], the majority of the participants reported using the medication reminder feature, despite stating that they would have remembered to take their medication without the app. Participants also liked that they were able to check their heart rates quickly. This is in stark contrast to our findings that such features in an e-tool were not seen to be useful and illustrate the importance of understanding the patient population for whom an e-tool is designed. In the study by Hirschey et al [12], the patients had an average age of 59 years, and the majority had at least some college education. Our participants were older and had much less formal education; more than 63% of Singaporeans aged 65 years or older in 2018 did not attain more than primary school education [18]. They generally had little or no experience using e-tools, given that care was mostly done within the health care setting. Such patient characteristics were likely to be influential in how patients perceive e-tools and need to be considered when designing them.

It is unsurprising that the HCPs in our study believed that the e-tool would only be useful for those patients who were already engaged in regular self-care for AF management. These patients were likely to be younger, have a higher level of education, have better health literacy, were motivated to care for themselves, and were more likely to use technological tools in their daily lives.

Another key finding of this study was that the content and functions of the e-tools suggested by the HCPs did not address what patients thought would be most useful to them. Poor medication and dietary adherence were some of the main concerns from the HCPs' perspective, and they felt that having educational content and reminders would help patients better manage their condition. However, these were not the main barriers faced by the patients, as the majority claimed to have no difficulty with adherence. What patients valued was the ability to contact or interact with HCP as they still perceived them to be the most reliable source of information and advice. This is likely a reflection of the heavily hospital-centric model of outpatient specialist care in Singapore where most patients with AF receive their routine health care. As such, patients strongly preferred direct access to their HCPs.

Given patients' current reliance on frequent hospital visits to access their HCPs, patients may benefit more from improved integration of care between hospitals and primary care settings for their chronic conditions, including AF. A systematic review by Gallagher et al [19] showed that multidisciplinary team and community support for patients with AF improved outcomes such as a reduction in all-cause mortality and cardiovascular-related hospitalizations. This supports the need to shift chronic care management away from the hospital. The combination of a well-designed, user-centric e-tool and right-siting health care delivery into the community may be the key to improving overall patient outcomes and may also deliver cost benefits to the health care system.

Limitations

This study has some limitations worth discussing. First, although the purpose of showing patients a prototype of the e-tool was to facilitate understanding and guide them in answering questions, the presence of the prototype may have limited their expression of ideas and restricted the conversation to their opinions on the features in the sample tablet as opposed to the generation of possible features for the e-tool. Second, because of the strict inclusion criteria, only English-speaking participants were recruited for the study, as the prototype was only available in English. This resulted in a cohort from a narrow demographic in Singapore and made a meaningful analysis of the influence

of demographic factors impossible, especially given the small number of patients involved. Nonetheless, it is likely that our study subjects closely reflected the patients most likely to use such e-tools in the real world. We recognize that non-English speakers may have different perceptions of e-tools. Thus, an exploratory study with non–English-speaking participants is crucial before implementing the e-tool countrywide.

The patient and their caregivers were interviewed together in this study, as elderly patients with AF often rely on their caregivers to access e-tools. However, as these were joint interviews, we were not able to analyze their responses separately, and we cannot comment on whether there were any differences between patients and caregivers. It is possible that they may separately respond differently to the e-tool, but we believe that as they are likely to interact with the e-tool in everyday situations as a dyad, interviewing them as a pair would allow a more realistic understanding of how they respond to the e-tool.

Conclusions

This study provides insights into the acceptability of e-tools as part of AF self-management from the perspective of both HCPs and patients. Educational content and monitoring ability of the e-tool were seen as useful features in patient self-care, but there was discordance between what HCPs and patients perceived to be most useful. Patients' passivity toward self-care in general will be a challenge when trying to engage them in the use of e-tools, and understanding the target patient population is crucial in designing a e-tool.

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Conflicts of Interest

None declared.

Multimedia Appendix 1
Interview guides for health care providers and patients.
[DOCX File , 36 KB - humanfactors_v7i3e15492_app1.docx]

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Abbreviations

AF: atrial fibrillation
BI: behavioral intention
BP: blood pressure
e-tools: electronic tools
HCP: health care provider
INR: international normalized ratio
SETAF: Self-management and Education Tool for AF patients
TAM: technology acceptance model

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