Commercial off-the-shelf consumer health informatics interventions: recommendations for their design, evaluation and redesign

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ABSTRACT

Objective The goal of this paper is to describe the successful application of a use case-based evaluation approach to guide the effective design, evaluation and redesign of inexpensive, commercial, off-the-shelf consumer health informatics (CHI) interventions.

Design Researchers developed four CHI intervention use cases representing two distinct patient populations (patients with diabetes with high blood pressure, post-bariatric surgery patients), two commercial off-the-shelf CHI applications (Microsoft HealthVault, Google Health), and related devices (blood pressure monitor, pedometer, weight scale). Three patient proxies tested each intervention for 10 days.

Measurements The patient proxies recorded their challenges while completing use case tasks, rating the severity of each challenge based on how much it hindered their use of the intervention. Two independent evaluators categorized the challenges by human factors domain (physical, cognitive, macroergonomic).

Results The use case-based approach resulted in the identification of 122 challenges, with 12% physical, 50% cognitive and 38% macroergonomic. Thirty-nine challenges (32%) were at least moderately severe. Nine of 22 use case tasks (41%) accounted for 72% of the challenges.

Limitations The study used two patient proxies and addressed two specific patient populations and low-cost, off-the-shelf CHI interventions, which may not perfectly generalize to a larger number of proxies, actual patient populations, or other CHI interventions.

Conclusion CHI designers can employ the use case-based evaluation approach to assess the fit of a CHI intervention with patients’ health work, in the context of their daily activities and environment, which would be difficult or impossible to evaluate by laboratory-based studies.

As authorized by the Health Information Technology for Economic and Clinical Health Act provisions within the American Recovery and Reinvestment Act of 2009, the Centers for Medicare and Medicaid Services has specified rules regarding the initial criteria that healthcare professionals and organizations must meet to qualify for specific monetary incentives (75 Fed. Reg. 44313). In particular, a portion of the Medicare and Medicaid Electronic Health Record Incentive Program addresses ‘patient engagement’ by requiring organizations to provide patients with a human readable and computable copy of their records. Stage 2 of meaningful use may require the use of personal health records—fostering heightened expectations about patients’ abilities to glean information from their providers’ records, maintain their own records, and share their records with various healthcare providers. As these national initiatives addressing patient engagement continue to expand, policy makers and healthcare providers must acknowledge that the home and other locations of daily living (LDL) such as workplaces, parks, exercise facilities and grocery stores are important sites for health and healthcare activities.

Consumer health informatics (CHI) interventions based on inexpensive, off-the-shelf technologies that can easily be implemented in a wide variety of LDL are needed to cost-effectively support high quality, technology-enabled healthcare. Fortunately, lay people now have access to a variety of inexpensive devices such as weight scales, heart rate monitors and blood pressure cuffs. Many of these devices have the capacity to store user information over time and connect to consumer-directed applications, from which they may be able to share information with family members, friends and their care providers.

CHI intervention developers face a challenging task in designing simple, effective CHI applications and devices that support a diverse range of lay people using the applications and devices in a wide range of LDL. In addition, CHI interventions composed of inexpensive, commercial off-the-shelf CHI applications and devices will likely have more use challenges than controlled, institutionally developed CHI interventions or electronic medical record vender-provided products, as off-the-shelf interventions link together several independent technologies. Resolving these use challenges will require the coordination of varied stakeholders. While some use challenges must be addressed by the commercial off-the-shelf CHI application and device designers, others can be addressed by supplemental intervention artifacts and processes or by patient training.

However, CHI intervention developers—who are often young, technology-savvy and without significant physical limitations—are largely taking a technology-centered design approach, paying minimal attention to lay people’s skills, knowledge and training, motivations, or psychosocial characteristics. CHI intervention developers often focus on automating existing tasks and rely on physicians’ perceptions of lay people’s problems and needs. Lay people are burdened by this approach, as it adds to their existing work, increases their frustration, and leads to errors, all of which may cause them to misuse and/or disuse CHI interventions.
design approach can reduce or negate the potential benefits of the CHI interventions, can increase developers’ investments, and can potentially compromise patient safety. Unfortunately, conceptual and methodological frameworks that effectively inform CHI intervention design and implementation are in flux because the field is growing quickly and is composed of researchers and practitioners from a variety of disciplines (eg, health communication, mass communication, information science and medical informatics). To improve the likelihood of the adoption and use of CHI interventions, developers need to understand lay people’s health work and the extent to which the CHI interventions support that health work. Although some studies have examined the usability of CHI applications by laboratory-based studies and heuristic evaluation, few have evaluated how CHI applications can best support lay people’s health work in context.7 14-19

The goal of this paper is to apply a use case-based human factors evaluation approach developed by Zayas-Cabán and Marquard to evaluate patient and provider proxies’ use of inexpensive, commercial off-the-shelf CHI interventions aimed at supporting two specific lay populations for which self-care and disease management are important, and in which poor outcomes can be costly—individuals with diabetes with high blood pressure20 and post-bariatric surgery patients.21 22 In this way, the goal of this paper is to serve as a feasibility study addressing the value of the proposed use case-based human factors approach. While many CHI interventions might aid these populations (eg, portals provided by electronic health record vendors or institutionally developed portals such as PatientSite and Patient Gateway), the CHI interventions examined in this study link inexpensive devices (eg, blood pressure cuff, weight scale, pedometer) with free applications (eg, Microsoft HealthVault, Google Health) that aggregate information from the devices and other data sources, such as commercial pharmacies and patient portals. Lay people can share information from the applications with family members, friends and providers, and the applications can be connected directly to their provider’s electronic health records. In this study, we focus on lay people who are actively engaged with a healthcare provider (hereafter referred to as patients).

BACKGROUND
Zayas-Cabán and Marquard posit that to be effectively adopted and used, CHI interventions must fit lay people’s physical, cognitive and organizational (or macroergonomic) ergonomic needs and constraints, and they provide use cases describing how these factors constrain patients’ abilities to use CHI interventions.3 In the context of this study, in which physical ergonomics encompasses the physical characteristics of patients and their work environments, cognitive ergonomics focuses on aiding patients as they process information while completing health work alone or in teams. Macroergonomics addresses the broader types of health work patients engage in (eg, disease management), their workflows (eg, the flow of health information across space and time, interactions with caregivers across space and time), and their work systems (eg, the social and organizational conditions under which their health work is performed). In the context of a patient self-monitoring blood pressure, physical ergonomics considers factors related to the patient operating the device (eg, securing the cuff) within the context of a physical environment (eg, at the kitchen table). Cognitive ergonomics considers factors related to processing information from the device’s user interface (eg, interpreting systolic and diastolic blood pressure values). Macroergonomics considers the context within which the device is used (eg, the patient should rest for a few minutes before taking a reading). Design attributes may affect multiple human factors domains. For instance, small print on the monitor interface limits patients’ ability to read the monitor values and consequently limits their ability to interpret and take action based on the readings. Their paper describes how the framework can inform the design, evaluation and redesign of inexpensive, off-the-shelf CHI interventions.

As CHI interventions are often targeted at patients with chronic diseases—frequently the elderly—patients may possess a variety of diminished physical characteristics (eg, reduced vision, hearing, dexterity and motor function).1 23 A patient’s use of CHI interventions may also be impacted by his/her decision-making style, diminished cognitive function, language, literacy level, perceptions of his/her current health status and predictions about his/her future health status.23-28 Designers must finally account for flexibility in CHI intervention context of use by macroergonomics approaches that address the types of work in which individuals might engage and their workflows (ie, the flow of information, people and artifacts across space and time) and work systems (ie, the social, workflow, organizational and environmental conditions under which work is performed).29 30 The three domains are tightly intertwined and the CHI intervention may not work as intended, or may fail, if designers do not account for all three domains during the design process.

Several well-developed methods exist to guide the design of tools and technologies to account for patients’ physical and cognitive abilities and the environments in which they will use the tools and technologies.15 31 32 The work described in this paper builds on and supports these approaches by using a synthesized method for discovering and mediating design challenges encountered by patients when they use CHI interventions in their LDL.

We propose that CHI intervention designers evaluate a CHI intervention with actual patients and providers only after refining the system by testing with patient and provider proxies, a successful approach in the medical device arena.9 33 34 If the initial intervention has a large number of use challenges, actual patients may reject the system altogether before discovering all challenges, whereas proxies—research team members in this case—can purposefully persevere in using the applications and devices.35 In addition, designers must rely on patients to document challenges as they occur, as designers cannot easily be present over the course of the extended trial. Finally, recruiting patients and providers is often time-consuming and costly, resulting in a longer development cycle and possibly early stage system rejection.35 Patients, providers and patient and provider proxies will likely identify differing sets of challenges with some overlap,6 33 34 the combination of patient types will likely yield most, if not all, system use challenges.

As the goal of this paper is to serve as a feasibility study addressing the value of the proposed use case-based human factors approach, this paper focuses on two patient populations (individuals with diabetes with high blood pressure and post-bariatric surgery patients), two sets of CHI applications (Microsoft HealthVault and Google Health) and related devices (blood pressure cuff, pedometer, weight scale).

METHODS
The research team developed patient use cases, with the aid of healthcare providers, for each patient population/CHI application and device dyad. We feel it is essential that we compare the results of our study using patient proxies with results from
The authors are involved. The use cases in Tables 1 and 2 detail processes. Along with each use case, the patient proxies were given a set of tasks required to successfully complete the use case. Box 1 provides a consolidated list of these tasks.

Three students—patient and provider proxies—tested each CHI intervention for 10 days. Two students performed ‘patient tasks’, while the other student, a registered nurse, performed ‘provider tasks’ to provide the patient proxies with realistic provider interactions. We provided the proxies with the detailed use cases and sets of related tasks to help them achieve their goals. In the diabetes use case, the patient proxies also tested the system while wearing medium-weight gardening gloves to simulate the 73-year-old patient’s arthritis, and researchers loaded pictures of the device and system screenshots into a tool to simulate the 73-year-old patient’s arthritis. You also have cataracts and have arthritis in your hands. Your primary care physician would like you to take your blood sugar and blood pressure readings daily so that a nurse can change your medication level if your blood sugar or blood pressure levels get too high or too low. You have been given a blood pressure cuff to take these readings at your home. You are told to take the readings 1× per day at the same time of day, and to enter your blood pressure and blood sugar readings as test results, and your medications into Google Health, and share your Google Health record with him/her. Your nurse will contact you if (s)he wants you to change your medication type or dose.

Table 1 Use cases provided to patient proxies with diabetes and high blood pressure

<table>
<thead>
<tr>
<th>Use case</th>
<th>HealthVault</th>
<th>Google Health</th>
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<td>You are a 73-year-old type 2 diabetic with high blood pressure. You are currently taking glipizide 5 mg once a day before breakfast for your diabetes and lisinopril 10 mg once a day for your high blood pressure. You also have cataracts and have arthritis in your hands. Your primary care physician would like you to take your blood sugar and blood pressure readings daily so that a nurse can change your medication level if your blood sugar or blood pressure levels get too high or too low. You have been given a blood pressure cuff to take these readings at your home. You are told to take the readings 1× per day at the same time of day, and to enter your blood pressure and blood sugar readings as test results, and your medications into Google Health, and share your Google Health record with him/her. Your nurse will contact you if (s)he wants you to change your medication type or dose.</td>
<td>You are a 42-year-old who has just undergone bariatric weight-loss surgery. Your choices and behaviors regarding your diet and physical activity levels over the next 12–18 months will affect how much weight you lose. Your surgeon would like you to weigh yourself each day, and enter non-walking physical activities you complete. Your surgeon also tells you to connect the scale and pedometer to your computer and upload the readings into an online system called Microsoft HealthVault. The surgeon would like you to share the weight, pedometer and ‘My Wellness Center’ data with him/her through HealthVault. Your surgeon will contact you by email or telephone if (s)he wants you to make any changes.</td>
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Table 2 Use cases provided to bariatric surgery patient proxies

<table>
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<tr>
<th>Use case</th>
<th>HealthVault</th>
<th>Google Health</th>
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<tr>
<td>You are a 42-year-old who has just undergone bariatric weight-loss surgery. Your choices and behaviors regarding your diet and physical activity levels over the next 12–18 months will affect how much weight you lose. Your surgeon would like you to weigh yourself each day, and enter non-walking physical activities you complete. Your surgeon would also like you to use an online tool called ‘My Wellness Center’ from MSN to track the food you eat each day, and enter non-walking physical activities you complete. Your surgeon also tells you to connect the scale and pedometer to your computer and upload the readings into an online system called Microsoft HealthVault. The surgeon would like you to share the weight, pedometer and ‘My Wellness Center’ data with him/her through HealthVault. Your surgeon will contact you by email or telephone if (s)he wants you to make any changes.</td>
<td>You are a 42-year-old who has just undergone bariatric weight-loss surgery. Your choices and behaviors regarding your diet and physical activity levels over the next 12–18 months will affect how much weight you lose. Your surgeon would like you to weigh yourself each day, and enter non-walking physical activities you complete. Your surgeon would also like you to use an online tool called ‘LiveStrong,’ through Google Health, to track the food you eat each day, and to enter physical activities you complete. The surgeon would like you to share your weight data with him/her through Google Health. You should also export your ‘LiveStrong’ diet and physical activity log, and email it to your surgeon after 10 days. Your surgeon will contact you by email or telephone if (s)he wants you to make any changes.</td>
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Box 1 Tasks performed by the patient proxies during the use cases

1. Learn to use the blood pressure monitor.
2. Take a blood pressure reading.
3. Learn to use the pedometer.
4. Learn to use the weight scale.
5. Create a (HealthVault/Google Health) account.
6. Log into your (HealthVault/Google Health) account.
7. Install HealthVault software to upload device readings.
8. Upload (BP/weight/pedometer) data into HealthVault.
9. Enter blood pressure readings into Google Health.
10. Enter blood sugar readings into (HealthVault/Google Health).
11. Enter medication data into (HealthVault/Google Health).
12. Enter weight into Google Health.
13. Link MSN 'My Wellness Center' to HealthVault.
15. Link ‘LiveStrong’ to Google Health.
16. Enter food intake into ('My Wellness Center'/'LiveStrong').
17. Enter activity data into ('My Wellness Center'/'LiveStrong').
18. Export food and activity information to spreadsheet.
19. Email the spreadsheet to your provider.
20. Grant provider access to record.
21. Log out.
22. General.

HealthVault bariatric use case and 95% for the Google bariatric use case. All four use cases had challenges for each of the domains. Across the four use cases, physical challenges were the least common and cognitive challenges were the most common. Several of the challenges overlapped use cases. If we count those that overlapped use cases as one challenge, 12% of the identified challenges were physical, 50% were cognitive and 38% were macroergonomic.

As shown in figure 1, the HealthVault diabetes use case yielded 16 severe challenges (57% of 43 total challenges), whereas the Google Health diabetes use case yielded 12 severe challenges (27% of 45 total challenges). The HealthVault bariatric surgery use case yielded 18 severe challenges (34% of 53 total challenges), whereas the Google Health bariatric surgery use case yielded 11 severe challenges (21% of 52 total challenges). While both applications had a similar number of total challenges, the Google Health use cases had fewer severe patient challenges than those of HealthVault. Many of the severe HealthVault challenges were macroergonomic.

Three data supplements (available online only) detail all 122 physical, cognitive and macroergonomic patient use challenges, the tasks with which the challenges are associated, the severities of the challenges, and the appropriate approach(es) for resolving challenges—either via application or device redesign, supplemental intervention artifacts and processes, or patient training.

A fourth data supplement (available online only) provides a spreadsheet detailing the number of physical, cognitive and macroergonomic patient use challenges associated with each of the 22 use case tasks in box 1. If we count those challenges that overlap use cases as one challenge, nine of the 22 tasks accounted for 72% of identified challenges.

Discussion

Our evaluation approach identified a significant number of challenges likely to interfere with patients' abilities to use a particular CHI intervention. While this list is likely not exhaustive, the large number of identified challenges provides intervention designers with a starting place from which to begin redesigning the intervention. Intervention designers can thus resolve challenges before conducting further, higher-cost testing with patients. Actual patients will likely encounter other challenges in addition to those identified through the described methodology, but the additional challenges will become more salient and easier to identify once the initial set of challenges is mediated.

The use case tasks enabled the patient proxies to know their goals, but still allowed them flexibility in completing each task. For instance, we directed each patient to 'Create a (HealthVault/Google Health) account.' The research team could have specified subtasks that would enable the patient proxies to complete this task, such as which icons the patient should click on to create an account. However, this fine level of detail takes almost all cognitive load and reasoning away from the patient, thus likely limiting insightful information the researchers would otherwise obtain about what challenges the patient encounters in completing the tasks. The researchers could have, similarly, specified only higher level activities, such as 'Use (HealthVault/Google Health) to send your blood pressure readings to your nurse.' This activity-level guidance would likely not provide the patient proxies with enough direction to elicit detailed information on what challenges the patient proxies encountered using various aspects of the system, and the elicited challenges may be so diverse that comparing and synthesizing challenges across the patient proxies would be difficult. Therefore, the approach used (ie, use cases with a set of tasks) is more structured than heuristic usability evaluation (ie, providing little guidance and minimal information regarding the patient proxies’ tasks), but more flexible than cognitive walkthrough approaches (ie, using step-by-step task descriptions).

The categorization of the challenges as physical, cognitive, or macroergonomic is useful, in that design changes to mediate these challenges should align with the type of problem patients are experiencing. For instance, one could extract all cognitive challenges from the data set to understand how the system is or is not supporting patients’ cognition and how the design could be changed or supplemented to enhance this support.

Physical challenges were most often linked to patients’ use of CHI intervention-related devices: both diabetes use cases involved a blood pressure cuff, both bariatric surgery use cases involved a weight scale, and the HealthVault bariatric surgery use case also involved a pedometer. The number of cognitive challenges was quite consistent across use cases, with most cognitive challenges associated with one-time activities such as learning to use the devices and applications. The number...
of macroergonomic challenges varied more across use cases, with most macroergonomic challenges associated with repeated activities such as uploading device data, and regularly manually entering blood pressure, blood sugar and food intake data.

While some patient challenges are specific to particular use cases, others span devices and applications independent of use cases (eg, HealthVault for both diabetes and bariatric surgery). Device and application designers are best suited to address these challenges. For instance, if a device vendor resolves all challenges associated with its blood pressure cuff, it is resolving a subset of challenges that will arise for all use cases involving that blood pressure cuff. In addition, intervention designers can use supplementary intervention artifacts and processes and training material to guide patients as the patients interact with the devices and applications.

Other challenges are inherent to the task, so the challenges span use cases regardless of which devices and applications patients use (eg, both HealthVault and Google Health for bariatric surgery). These challenges provide rich opportunities for innovators to bring new technologies to the CHI marketplace, which may drive down the costs of existing technologies. For instance, the development of innovative and standardized proxies identiﬁed 122 unique patient challenges, suggesting that this method can be used to successfully identify challenges that patients will encounter when using CHI interventions. Second, while our goal was to identify a set of use challenges using patient proxies before evaluating the system with actual patients, we did not compare proxy ﬁndings with challenges faced by actual patients. We realize that the set of challenges identiﬁed by actual patients will likely differ from those identiﬁed in this study and plan to conduct this analysis in future work. Our study focused on two speciﬁc patient populations, which have unique characteristics and limitations. However, these two patient populations are quite diverse: one is focused on a prevalent set of chronic diseases (diabetes, high blood pressure), and the other is focused on recovery from an acute intervention (bariatric surgery). It is also unlikely that any challenge is actually particular to only one use case. For instance, we identiﬁed challenges associated with uploading blood pressure data through HealthVault’s connection center during the HealthVault diabetes use case, but this challenge would be present for any use case involving the blood pressure cuff and HealthVault. Finally, because the study focused speciﬁcally on CHI interventions based on low-cost devices and applications that are not jointly designed, the challenges associated with these commercial applications may not well represent the type of challenges associated with customized systems. However, the approaches we used could be generalized to evaluate and redesign any type of CHI intervention.

CONCLUSION

We identiﬁed a large number of unique challenges by the use case-based evaluation approach, allowing CHI intervention designers to systematically assess the physical, cognitive and macroergonomic ‘ﬁt’ of a particular commercial off-the-shelf CHI intervention with patients’ health work. In particular, we identiﬁed challenges that would be difﬁcult, if not impossible, to detect in a laboratory-based usability study (eg, errors that happen every ﬁfth time a device is used and errors that occur when uploading device data without an internet connection).

The extended testing period allowed patients to log challenges as they occurred in the context of their daily activities and environment. Some tasks may be challenging on a given day and not on another (eg, being busy during the time of day one usually checks his/her blood pressure). Other tasks may unexpectedly present challenges (eg, computer equipment failure). Finally, the extended trial allows the designers to capture patients’ learning curves.

While testing with patients is ideal, our use case-based evaluation allowed proxies to take on the roles of patients and providers, which allowed the research team to identify a wealth of potential use challenges. The research team can now mediate these challenges before conducting extensive patient testing.

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