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# Patient-centered Design Grounded in User and Clinical Realities: Towards Valid Digital Health

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Valid design of patient-centered digital health or health information technology (IT) systems is based on a thorough and accurate understanding of both “user reality” and “clinical reality.” Type 1 Design Error (User-Reality Error) occurs when designers do not accommodate user characteristics, tasks, context of use, needs, or preferences. Type 2 Design Error (Clinical-Reality Error) occurs when designers do not accommodate the clinical reality, including biomedical knowledge, clinical workflows, and organizational requirements. Both types of errors can invalidate the design, leading to products being rejected by patient end-users or their healthcare delivery systems, product non-use or inappropriate use, and risk of harm. This paper describes our attempts to achieve valid health IT design and avoid the two design errors. We performed iterative, patient-centered design to prototype a mobile application, Power to the Patient (P2P), supporting heart failure self-care management. Our multidisciplinary team of human factors, cardiology, and design experts developed and iteratively refined requirements based on data collection, review, and testing with patient research participants, a patient advisory board, a clinical advisory board, and experts on the team. We describe our process and reflect on working with multiple stakeholders toward the goal of valid health IT design.

## INTRODUCTION

Valid design of patient-centered digital health or health information technology (IT) systems is based on a thorough and accurate understanding of both “user reality” and “clinical reality.” Type 1 Design Error (User-Reality Error) occurs when designers do not accommodate user characteristics, tasks, context of use, needs, or preferences. Type 2 Design Error (Clinical-Reality Error) occurs when designers do not accommodate the clinical reality, including biomedical knowledge, clinical workflows, and organizational requirements. Both types of errors can invalidate the design, leading to products being rejected by patient end-users or their healthcare delivery systems, product non-use or inappropriate use, and risk of harm.

This paper describes our team’s design of IT for patients with chronic heart failure (CHF), focusing on how our iterative, user-centered and clinically-informed design process attempted to avoid the two design errors, towards valid digital health design.

## Chronic Heart Failure (CHF)

CHF is a debilitating chronic condition affecting primarily older adults (Roger, 2013). Cardiologists recommend patients with CHF to follow self-care regimens composed of restrictions (e.g., sodium, fluids, tobacco), medication adherence, monitoring (e.g., weight, vitals), and recommendations (e.g., physical activity, diet) (Lainscak et al., 2011).

A subset of patients with CHF have cardiac implantable electronic devices, or CIEDs. Some of these devices (e.g., pacemakers, defibrillators), besides providing cardiac therapy to the patient, also transmit sensed data to the healthcare system. As demonstrated in recent studies (e.g., Hawkins et al., 2016), these data can be used to predict future cardiac events, as well as acute CHF decompensation. CIED data are typically sent to clinicians and not incorporated in patient-facing technologies (Zeitler & Piccini, 2016). However, there is an interest in displaying CIED data to patients, illustrated by recent research (e.g., Daley et al., 2017; Rohani Ghahari et al., 2018) and device vendor Medtronic’s release of MyCareLink Heart™, a “portfolio of

pacemakers that can communicate directly with patients' smartphones and tablets" (Medtronic plc, 2019). Thus, it is reasonable to consider CIED data as another source of information for empowering patients with CHF by raising awareness about self-care and self-monitoring, delivering just-in-time alerts or recommendations, and supporting decision making (Cornet, Volda, & Holden, 2017; Mirro et al., 2018; Zeitler & Piccini, 2016).

### **Power to the Patient (P2P): Health IT to Support Patients with CHF by Incorporating CIED Data**

We undertook a two-year project with the goals of: a) designing Power to the Patient (P2P), a patient-facing IT integrating CIED data to inform and support CHF self-care management; and b) assessing the usability and acceptability of P2P prototypes for older adults with CHF.

Power to the Patient was conceptualized as a mobile application to provide better and timelier self-care among older adults with CHF who had CIEDs and help them react to risk of CHF events as detected by their devices, thus preventing unnecessary hospitalizations. A unique, central feature of P2P is its display of a Heart Index, a hypothetical score representing a predicted personal risk for a future CHF event based on an analysis of CIED data. P2P also collects self-assessment on the four CHF self-care domains of medication self-administration, dietary sodium intake, fluid intake, and physical activity. Based on user self-assessments in each domain, P2P displays recommended self-care activities and practical strategies such as buying and wearing comfortable shoes to make walking (physical activity) more enjoyable. Self-care recommendation content was developed in cooperation with the team's research nurse, who had clinical experience in cardiology. P2P design assumed the ability to collect and process a patient's CIED device data then send related information to the patient's personal mobile device. However, P2P prototypes did not specify the full flow of data from CIED to mobile device.

### **A Multidisciplinary Team**

A multidisciplinary team of Indiana University faculty and students and clinical, research, and informatics experts at Parkview Health undertook this project. The project team was led by a healthcare human factors expert and included a cardiologist, research nurse with cardiology experience, two human-computer interaction (HCI) experts (one led the design team; the other led the usability testing), a team of Master's and PhD students, and research staff.

## **ITERATIVE DESIGN PROCESS**

Figure 1 presents an overview of the iterative, patient-centered design process undertaken to research, design, and evaluate the P2P prototype.

## **Problem Analysis**

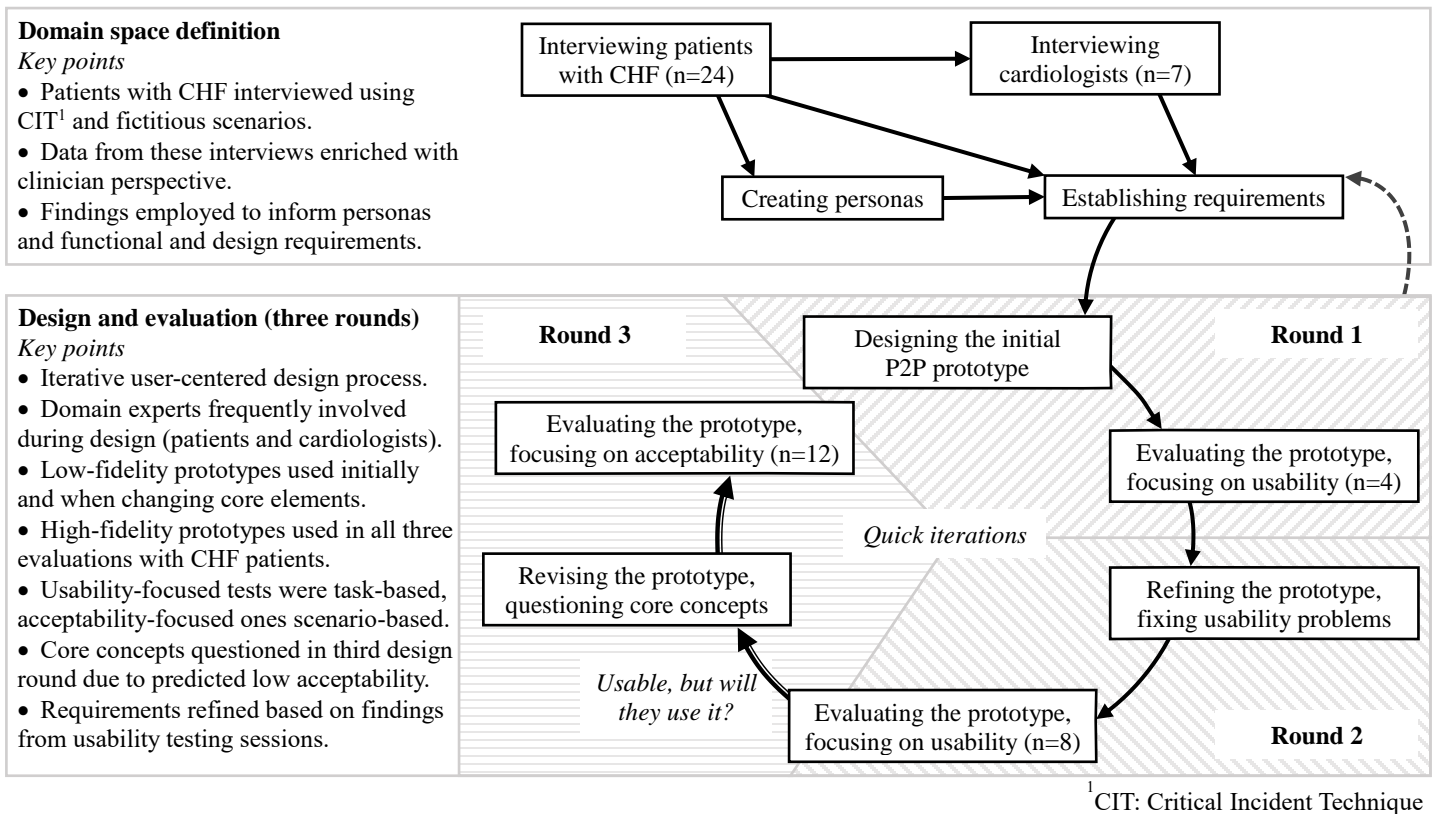
We conducted cognitive task analysis of data collected from 24 older adult patients with CHF and 14 friend or family support persons. Primary data were gathered through two-part interviews using critical incident technique and fictitious scenarios. Data collection and analysis was designed to study patients' decision-making processes and their use of device- and non-device data during decision making. Findings were analyzed through a naturalistic decision-making lens (Daley et al., 2018) and also produced user personas based on decision-making approach (Holden et al., 2018). These design products and interview data were used to develop P2P's functional and design requirements and use-case scenarios.

## **Design and Evaluation of P2P**

*Overview of design.* A design team of one HCI faculty and three HCI graduate students iteratively designed the initial version of the P2P prototype. The design team met weekly and reported their progress to the broader project team every other week. The design team also presented its work to a three-person patient advisory board and a clinical expert advisory board. This included individual meetings with two cardiologists, where we presented scenarios of fictitious patients with CHF and asked how they would respond if seeing the patients in the clinic or over the phone, including what they would need to know from the patients in order to assess their situation and what CIED data might help them answer their clinical questions. We then presented these scenarios to a group of seven clinicians, including cardiologists, technicians from the ADC (arrhythmia diagnostic center), and other experts from the cardiology clinic over a group dinner to obtain their feedback on the scenarios.

*Overview of usability and acceptability testing.* A total of 24 patients with CHF were recruited from a hospital system in the Midwest. For Rounds 1 and 2, we recruited 12 total participants without CIEDs. For Round 3, we recruited 12 participants with CIEDs. Participants were aged 65 years or older, and some were accompanied to testing sessions by an informal caregiver. Patients completed a pre-test survey including demographics information, and a post-test survey including the System Usability Scale (SUS; Brooke, 1996) modified for older adults (Cornet, Daley, Srinivas, & Holden, 2017; Holden et al., 2016; Holden et al., 2019; Srinivas, Cornet, & Holden, 2017), the NASA Task Load Index (NASA-TLX; Hart & Staveland, 1988), and a survey with scales from the consumer technology acceptance literature (Venkatesh, Thong, & Xu, 2012). In all rounds, testing sessions ended with open-ended questions about how P2P would fit into participants' CHF self-care.

*Round 1 Design and Testing.* Our patient advisory board commented on the core concepts of P2P by evaluating two low-fidelity prototypes. We then created a high-fidelity



**Figure 1.** Main steps of our user-centered design process used in the development of P2P.

interactive prototype running on an Android phone and evaluated its usability with four patients with CHF without CIEDs. These testing sessions focused on evaluating participants' performance of small tasks within P2P, such as self-assessing sodium intake on a rating scale.

*Round 2 Design and Testing.* We fixed pressing usability issues during a two-week redesign sprint and re-evaluated the prototype in a larger usability study with eight older adult patients with CHF without CIEDs. The testing method was nearly identical to that of Round 1. Results of testing demonstrated improved observed and self-reported usability, workload, and acceptance, compared to Round 1.

*Round 3 Design and Testing.* A longer period of redesign was scheduled to prepare the P2P prototype for the final round of testing with a larger sample of patients with CHF with CIEDs. During the redesign period, the team evaluated both usability testing findings from Rounds 1 and 2 and interview findings from the earlier exploration of the problem space. Upon reflection, the team questioned whether individuals would use P2P long-term in daily practice, despite notable improvements in usability scores. We consequently undertook a more radical redesign between rounds 2 and 3 than between rounds 1 and 2; we questioned P2P's main concepts and we were able to reimplement them with clinical oversight from our team clinicians. We are currently testing this redesigned prototype in a 12-participant scenario-based evaluation, with an emphasis on predicted acceptance of P2P in participants' daily lives.

## DISCUSSION

Based on the above experiences and the literature, we present a set of recommendations for the valid design of digital health applications. We then reflect on the ways in which we were able to versus failed to achieve these recommendations in our own work.

### Recommendations for Valid Digital Health

*Designers of patient-facing IT must constantly juggle patient and clinician perspectives.* As “experts about their own life” (Bodenheimer, Lorig, Holman, & Grumbach, 2002), patients tend to share their experiences of CHF in their own context, describing for example their comorbidities, treatment non-adherence, and how caregivers help with self-care (Aidemark, Askenäs, Nygårdh, & Strömberg, 2015; Blandford et al., 2018; Cornet, Vaida, et al., 2017; Holden, Schubert, & Mickelson, 2015). Clinicians, in contrast, tend to share population-specific information (e.g., general trends and recommendations, such as that most patients with CHF must limit daily sodium intake to 2000mg). Designers have to reconcile these different perspectives and it is unclear whether reconciliation means compromise, synthesis, making choices, or other strategies. One way to merge perspectives might be to bring patient and clinician stakeholders into co-design sessions, during which each can have an influence on the final product (Aidemark et al., 2015; Blandford et al., 2018).

*Patients and clinicians should be involved early and often in the design of digital health, even between evaluation phases.* Consistent involvement of patients and clinicians throughout the development of digital health projects helps reconcile disparate perspectives and allows for more frequent informal evaluations of designs (Buck, 2017). Involvement can be achieved through patient and clinician advisory boards, focus groups, or inviting patients and clinicians to serve on the design team either as standing design team members or through co-design workshops (Aidemark et al., 2015; Blandford et al., 2018; Marvel, Wang, & Martin, 2018; Sanders & Stappers, 2008).

*Evaluation of digital health applications should be frequent and involve multiple methods.* Rapid usability testing (e.g., of a prototype) as part of iterative design should be complemented by longer, larger, and possibly controlled trials evaluating acceptance and clinical outcomes that are difficult to measure in brief user tests (Ben-Zeev et al., 2014; Gould & Lewis, 1985). Additional evaluation methods could include A/B testing (Ben-Zeev et al., 2014) and longer-term in-the-wild user experience evaluations (Nunes et al., 2015).

*True Agile methodology is difficult to implement for digital health projects.* Although short, iterative design-and-evaluation cycles are valued when focusing on usability (Gould & Lewis, 1985), they are not ideal for evaluating clinical outcomes (Ben-Zeev et al., 2014). This fact—apart from the difficulty of combining agility with the development of user experiences (Resnick et al., 2012)—makes implementing pure Agile processes in digital health projects especially challenging in healthcare (Van Velsen, Wentzel, & Van Gemert-Pijnen, 2013) and mixed academic-clinical environments (Holden et al., 2016).

## **Reflections from P2P**

The design of our prototype subtly swung between patient and clinician perspectives. For example, patient feedback during prototype evaluation led us to create an organizing structure called “plans” that would contain other elements, namely self-care activities and practical strategies. In another instance, discussions with clinicians led the team to shift the emphasis away from the Heart Index and towards the four CHF self-care domains (medication, sodium, fluids, and physical activity). While most patient participants accepted this change, some did not understand the relevance of some of these domains. For example, a few participants were not restricting fluid and did not find the fluid restriction plans in P2P to be personally relevant. Clinicians’ population-level vision of CHF resulted in a few design generalizations that inhibited some patients’ acceptance of the technology.

We were able to counteract problems in our concept and prototype designs due to feedback from patient and clinical advisory boards and our multiple rounds of design and testing. Clinicians on the team, the clinical advisory board, and patient advisory board all helped to verify, validate, or

correct design. However, the input occurred in phases, resulting in pendulum swings in design. For example, the design initially leaned toward designing to support patients’ perspectives of CHF, based on data collected during patient interviews and feedback from the patient advisory board on early prototypes. Clinician feedback was provided on initial prototypes, resulting in corrections to achieve a more clinically valid design.

Our first two evaluation rounds with small sample sizes were useful for finding most usability issues (Nielsen, 1993). Round 1 discovered many glaring usability issues that we were able to address, allowing us to focus round 2 on collecting better data about how participants viewed P2P in relation to their self-care and daily lives. However, the small laboratory-based evaluations and the diversity of participants’ ages, experiences with technology, and CHF status made it difficult to validate the design concept and how P2P could actually support self-care. This could have been mitigated by re-engaging our patient advisory board or conducting new testing. We addressed this issue in our study in round 3 usability testing, using a larger sample to evaluate users’ simulated use of P2P for daily self-care with questions about integrating P2P in daily life.

Although our process was agile in many respects, it was not a faithful Agile methodology implementation (Schwaber, 2004). Indeed, the project went through three design and evaluation iterations in one year; design rounds stretched over several months; and prototypes in rounds 2 and 3 were only reviewed internally before testing their usability with patients, and not evaluated by our patient and clinician advisory boards.

## **CONCLUSION**

Iterative design and testing, with input from patient and family research participants, patient advisors, clinician advisors, and team experts, helped designers accommodate both user and clinical realities. However, our approach was not perfect and resulted in important lessons learned. Nevertheless, we argue it is both possible and necessary to address user and clinical realities in order to achieve valid digital health design.

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