FINAL PROGRESS REPORT

Power to the patient: Design and Test of Closed-Loop Interactive IT for Geriatric Heart Failure Self-Care

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ABSTRACT

Purpose: To design and test an information technology called Power to the People (P2P) to support self-care management among older patients with chronic heart failure (CHF).

Scope: CHF is a costly chronic disease affecting nearly 6 million Americans and 12% of older adults. Treatment of CHF often includes use of a cardiovascular implantable electronic device (CIED) for monitoring the heart and delivering therapy.

Methods: Cognitive task analysis interviews, supplemented by standardized surveys, were performed with 24 patients with CHF aged 65 and older. Three rounds of design and laboratory-based prototype testing for acceptance and usability were performed with 24 new patients. Three external experts performed heuristic evaluation on a refined final design. Patient and clinician advisors were consulted throughout.

Results: Data analysis produced personas, use-case scenarios, a naturalistic decision-making model for CHF self-care management, and early P2P design concepts. Three prototypes were created based on our findings, which received a mean system usability scale (SUS) score of 79 (an "A-" grade), but varied between rounds from 74 ("B-") to 88 ("A+"). Perceived usefulness, ease of use, satisfaction, and behavioral intention were above average in all three rounds of testing.

Key Words: Consumer health IT; self-care management; patient ergonomics; cognitive task analysis; user-centered design; usability testing; chronic heart failure.

PURPOSE

This study's objective was to design and test an information technology called Power to the People (P2P) to support self-care management among older patients with chronic heart failure (CHF). We aimed to apply user-centered design with older adults to produce interactive prototypes that could be tested for usability and acceptability, in order to support future studies of P2P's safety and efficacy for improving health behavior and clinical outcomes among older adults with CHF.

The study had the following specific aims.

Specific Aim 1: Design novel interactive, prototypes of P2P to inform and support CHF self-care management.

Specific Aim 2: Assess the usability and acceptability of P2P prototypes for older adults with CHF.

SCOPE

Chronic cardiovascular disease is arguably the deadliest and costliest problem facing older adults today.[1] Among all cardiovascular diseases, CHF is the leading and fastest growing cause of death in the US.[2] In adults over 65, CHF prevalence is estimated at 12%.[3,4] Its high costs – $34.4B annually and expected to triple by 2030 – include many preventable emergency room visits and hospital admissions.[3,5,6] Since 2012, health systems incur Medicare/Medicaid payment penalties for excess 30-day CHF readmission rates (42 CFR part 412).

The evidence-based plan of care for a typical CHF patient is complicated.[7-9] In addition to medications, diet, and exercise, patients are responsible for close self-monitoring of symptoms and other changes in functioning or health.[10] Indeed, fluid overload—accompanied by several noticeable symptoms—appears to be the primary reason for CHF emergency room visits and hospitalizations. The leading theory of CHF self-care states, "symptom recognition is the key to successful self-care management;"[11] this includes assessments of symptom severity *and* variability.[12] Once recognized, symptoms must be interpreted and patients must make appropriate decisions on continuing to monitor conditions, contacting clinicians, seeking acute or emergency care, and (for some) adjusting their self-care regimen, for example, taking an extra dose of diuretic medication.[13] The above process is called *self-care management*.[14]

Self-care management is notoriously flawed, indicated by a lack of knowledge about symptom causes and their importance, symptom monitoring non-adherence rates of 80% to 90%,[15,16] non-reporting of symptoms to clinicians, misinterpreting symptoms and taking the wrong course of action (erroneous self-medication), and seeking treatment too late.[17-21] Self-care is more challenging for older patients because their self-care regimens are complex and older adults experience multiple symptoms and side-effects from multimorbidity and polypharmacy.[8,22] As a result, older adults may have trouble recognizing or interpreting symptoms.[23,24] Importantly, self-care failures and late detection of symptoms correlate with disease deterioration, preventable emergency room visits, (re)hospitalization, and early mortality.[14,25]

Many patients with CHF are surgically implanted with a cardiovascular implantable electronic device (CIED). CIEDs in patients with systolic CHF are known to prevent sudden death and increase life expectancy by delivering pacing, shocks, or resynchronization therapy and serving as an early warning of device malfunction or clinical events.[26] The recent addition of remote digital transmission of CIED data has led to remote patient monitoring via a wireless system at home that transmits CIED data to the implanting clinic via an industry sponsored server.[27] Remote monitoring allows for effective and timely surveillance of the device (e.g., battery status, lead integrity), the heart (e.g., intrathoracic impedance), and delivery of therapies (e.g., ventricular pacing, defibrillation).[28]

Remote monitoring of CIED data has been shown to produce timelier responses, a 43% reduction in visits per patient-year, and improved safety and patient satisfaction.[26,29] However, patients are blinded to the transmission data and completely dependent on the operational performance of their clinic for notification and follow-up. A study of 385 CIED patients found 84% desired more detail about CIED data and 21% desired faster follow-up.[30] As evidence that CIEDs are a 'black box' for patients, studies show that many patients with CIEDs are uncertain or confused about the data collected from their CIED[31] and 55% avoid certain activities because they misunderstand how the CIED works.[32] Indeed, the most recent study of CIED patient experience showed elevated anxiety due to a lack of direct or timely feedback on CIED remote transmissions.[31] We note that because standard practice is to not deliver raw or interpreted data directly to patients, little is known about patient decision-making with CIED data.

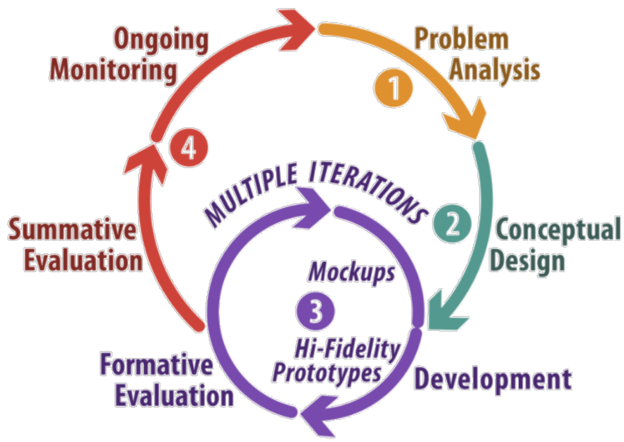
For similar reasons, no prior work exists on using health information technology (IT) to deliver and visualize CIED data to support self-care management. However, properly designed health IT could improve CHF patient self-care decision-making. Health IT applications for patients (e.g., patient portals) lag behind clinician-facing systems but have enjoyed increased attention due to recent public advocacy, regulation, and initiatives by the Office of the National Coordinator for Health IT and other national bodies.[33] AHRQ-sponsored literature reviews report the value of patient-centered or consumer-facing health IT for healthcare process, intermediary outcomes such as adherence, and health outcomes.[34-36] A recent systematic review found geriatric health IT such as web sites and smart pillboxes improved patient health, patient satisfaction, and other outcomes.[37] Importantly, these and others reports specifically indicate that health IT can effectively support self-care management for patients with chronic disease, including geriatric CHF.[38,39] With rise in computer literacy, IT ownership, geriatric technology use, and data democratization, consumer-facing health IT is a significant avenue of research.[33] Health IT research is especially important for chronically ill individuals and older adult users:[36,38,40] both groups are designated as AHRQ priority populations (www.ahrq.gov/health-care-information/priority-populations).

METHODS

Study Design

The study followed the industry-standard user-centered design process, illustrated in Figure 1.

Figure 1. User-centered design process



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It began with a problem analysis (Aim 1A), followed by design and prototype development (Aim 1B), interleaved with three iterations of formative testing (Aim 2), namely laboratory-based evaluations of acceptability and usability with older adults with CHF. The study was performed 2017-2019 and was approved by Parkview Health Institutional Review Board (IRB).

Data Collection and Measurement

Table 1 summarizes data collection across the study.

Aim 1A, Problem Analysis (Table 1a). We developed and pilot tested with 6 participants a patient-centered cognitive task analysis (P-CTA) method, described in an accepted publication.[41] (The pilot tests were approved by the Indiana University IRB and were performed in Indianapolis in an effort to refine and practice the new method.) We then applied the P-CTA in 24 data-collection sessions from July – September, 2017 at Parkview Research Center. These sessions also collected demographic data and a measure of CHF knowledge; participants received a take-home survey to complete with additional measures (87.5% response rate).

The interview-based P-CTA took on average 70 minutes, always in the order of Critical Incident, then Fictitious Scenario. Two researchers, one lead/interviewer and one observer/note-taker, conducted the P-CTA interviews with each patient or patient-support person collective.

The Critical Incident interview began with a verbal prompt to elicit a memory of a recent (within 2 years), relatively minor, health-related event that resulted in taking an action. The health-related instance did not need to be related to CHF, as the objective was to learn about the thought process without focus on the content. Once an incident was identified, the interviewer selected from a set of prepared probes (Table 1a) to elicit more detail about thoughts, environmental conditions, and interactions with others that took place during the event and subsequent action. The interviewer used a large whiteboard to document the incident as the participant spoke, to counteract forgetting, confusion, and deviations from the central line of questioning (Figure 2).

The Fictitious Scenario interview involved a hypothetical implanted device called “Tron-17,” described as an electronic device connected to the heart that continually captures physiological data related to CHF. Participants were told the device transmits collected data over the airwaves and presents to the patient a number from 1-10, where 10 is optimal. The interview began with a prompt to imagine the participant received a “9,” then begin thinking aloud about how they would react and what questions occurred. The scenarios and device information were intentionally vague, affording an understanding of information sought and used during decision making under uncertainty.[42] The interviewer selected from a set of probes for the initial scenario and then with each variation in the scenario, as the device readout changed (e.g., sudden drop to a “5” vs. gradual decline).

For cognitive ease, we performed the scenarios interview using conversational roleplaying elements. In addition to instructing participants to act as if they were in the given scenario, a paper mock-up of the Tron-17 device was displayed throughout the interview. As shown in Figure 3, the mock-up described the device and the range of values it displays: 1-4 (Low), 5-7 (Middle) and 8-10 (High). An actual implantable device was also available for participants to touch and hold, to enhance the feeling of reality and reduce confusion for those unfamiliar with implanted devices.

Figure 2. Illustration of the Critical Incident interview using a whiteboard to document and subsequently map an incident.

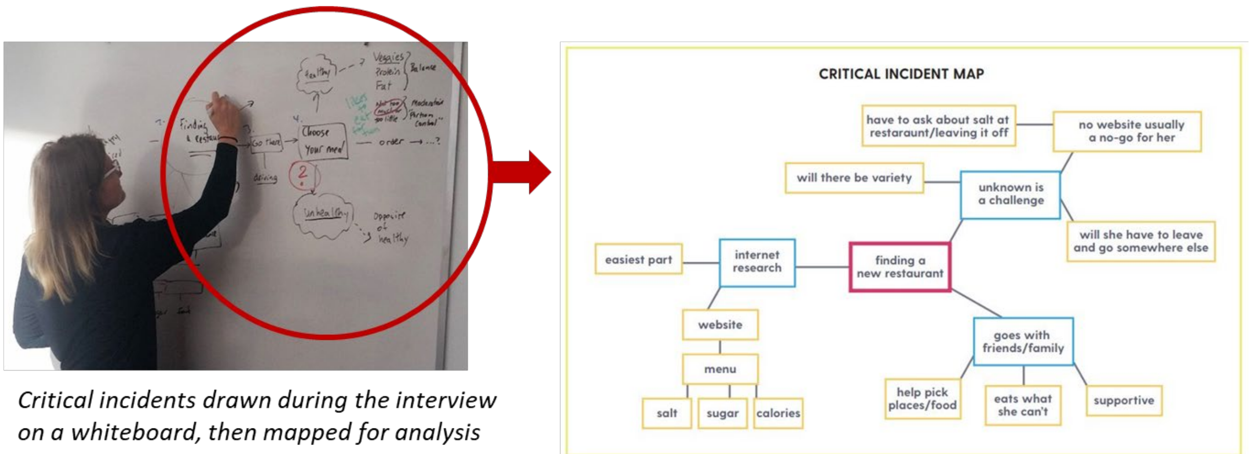
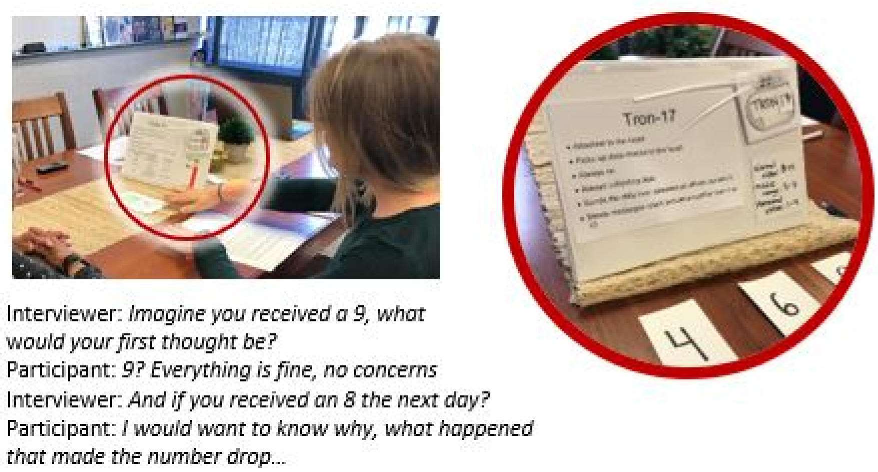


Figure 3. Illustration of the Fictitious Scenario interview, using a mockup device to structure a participant's roleplayed responses to variations in a scenario, while thinking aloud. (Note: interview text is fictitious.)



Aim 1B, Design (Table 1b). Design did not involve formal data collection. However, additional input was obtained continually from patient and clinician stakeholders, as described in a 2019 conference proceedings paper.[43] Patient input was provided by two patient advisors, older adults with CHF living in Indianapolis and engaged for several brief input sessions. Clinician advisors were individuals employed at Parkview Health and representing the device clinic, cardiology, and telehealth programs.

Aim 2, Formative Evaluation (Table 1c). Data for Aim 2 were collected in three consecutive rounds, R1 (October 2018), R2 (November 2018), and R3 (February - April, 2019). Data were collected in 24 sessions with older adults at Parkview Research Center. Participants were instructed to use the prototype and perform specific, preset tasks. In R3, we used fictional scenarios[44] to simulate longitudinal use of P2P over 14 days, with participants randomized to one of three scenarios: heart index stable, heart index declined and heart index improved. Participants performed the tasks on a mobile device while thinking aloud and their hands and screen were video-recorded. The research team recorded written observation notes of the session. At the end of the session, participants completed standardized measurements of technology perceptions and acceptance, usability, and workload. Participants also completed a demographics form and the Newest Vital Sign measure of health literacy.

Table 1. Data collection summary.

Type of data collection	**Measures used**
(a) AIM 1A, Problem Analysis	
Demographic and medical data	Electronic medical record review, self-report demographic survey
Survey (standardized)	Atlanta Heart Failure Knowledge test; Multidimensional Health Locus of Control (MHLC); Self Care of Heart Failure Index (SCHFI); Kansas City Cardiomyopathy Questionnaire-12 (KCCQ-12); Acute care utilization self-report
Patient-centered cognitive task analysis (P-CTA)	Critical Incident and Fictional Scenario
(b) AIM 1B, Design*	
Patient advisory input	Meetings with patient advisors for feedback on data analysis, early concepts, and designs
Clinician input	Meetings with cardiologists, device clinic staff, and other clinical experts for feedback on data analysis and early concepts
(c) AIM 2, Formative Evaluation	
Demographic and medical data	Electronic medical record review, self-report demographic survey
Survey (standardized)	Newest Vital Sign, User Acceptance Surveys (33 items), System Usability Scale (10 items), NASA Task Load Index (6 items),
Objective usability evaluation	Video-recording and note-taking during user performance of preset tasks, with think aloud
Heuristic evaluation	Three external experts provided formal usability inspection of the refined final prototype

*These activities were part of the design work and not considered human subjects data collection. They are described here for completeness.

Participants

For Aims 1A and 2, we recruited a total of 48 non-overlapping patient participants from an outpatient cardiology clinic, part of Parkview Health, a large Midwestern hospital system in Ft. Wayne, Indiana. A research nurse screened electronic medical records for English-speaking adults aged 65 years or older diagnosed with CHF (New York Heart Association Class II-IV). Another researcher then made recruitment calls, attempting a balanced enrollment on gender. In most cases, we sought balanced presence of CIED across the sample and for R3 of formative evaluation, all 12 participants had CIEDs. Support persons were invited to participate with consent alongside the patient, if the patient so desired. Study visits took place at Parkview's Research Center.

Strengths and limitations

We note a substantial limitation of our work was the demographic restriction of the sample, which were mostly White and favored males. We met our proposed sample sizes and milestones of 48 total participants – 24 for problem analysis and 24 for formative testing – and three rounds of design-evaluation cycles. Testing was designed to be formative and to asses acceptability and usability, and not summative or capable of assessing clinical feasibility, efficacy, or safety. While we used multiple methods, including interviews, surveys, various analytic and product design methods, and both subjective (self-report) and objective (performance-based) usability testing, we did not conduct in-depth observations or techniques such as eye-tracking, that could have produced additional, complementary data. The prototypes produced through this study were functional, interactive, and high-fidelity; however, additional software development will be required to translate the prototypes into software that can be deployed in a real clinical and HIPAA-compliant environment.

RESULTS

Participant characteristics

Tables 2 and 3 describe the characteristics of participants in the problem analysis data collection. For more details, please see a forthcoming publication in *Applied Ergonomics*.[41] Table 4 describes usability test participant characteristics.

Table 2. Aim 1A participant and support person characteristics.

Characteristic	Patient (n=24)	Support person (n=14)
Age in years, mean (SD)	72.7 (6.7)	69.6 (8.7)
Gender, male	16 (66.7%)	2 (14.3%)
Implanted cardiac device	13 (54.2%)	-
Heart failure diagnosis < 5yr	13 (54.2%)	-
Marital status, married	14 (58.3%)	13 (92.9%)
Race, white	24 (100%)	13 (92.9%)
Highest education		
High school	11 (45.8%)	9 (64.3%)
Post-graduate	5 (21.0%)	2 (14.3%)
Employment, retired	18 (75.0%)	8 (57.1%)
Use smart phone daily	13 (54.2%)	10 (71.4%)
Use text messaging daily	10 (41.7%)	8 (57.1%)
Use web browser daily	10 (41.7%)	10 (71.4%)

Table 3. Aim 1A participant survey results.

Survey	Scores
Atlanta Heart Failure Knowledge Test (n=24)	Mean (SD) = 24 (3.2), range 18-29
Multidimensional Health Locus of Control (n=21)	Internal score, mean (SD): 22.9 (6.5) Chance score, mean (SD): 15.5 (7.1) Doctors score, mean (SD): 15.7 (2.6) Others score, mean (SD): 10.6 (3.2)
Self Care of Heart Failure Index (n=21)	Maintenance score, mean (SD): 80.8 (12.6) Confidence score, mean (SD): 62.5 (17.5) Management score, mean (SD): 62.1 (28.0)
Kansas City Cardiomyopathy Questionnaire-12 (n=21)	Summary score, mean (SD): 63.8 (18.5)

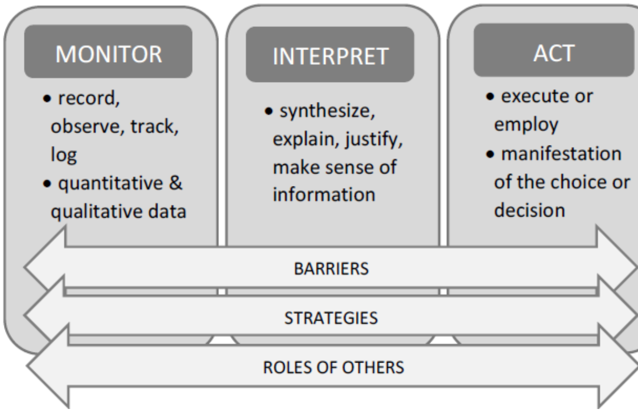
Table 4. Aim 2 participant characteristics.

		Round 1 (R1)	Round 2 (R2)	Round 3 (R3)
N		4	8	12
Age (years)	Mean	73	67	74
	Min	67	65	66
	Max	77	74	86
Gender	Male	25%	50%	58%
	Female	75%	50%	42%
Marital Status	Married	50%	75%	58%
	Widowed	50%	13%	8%
	Divorced	-	13%	25%
Race	White / Caucasian	100%	100%	100%
Highest Education	Master's Degree	0%	0%	25%
	Bachelor's degree	25%	38%	8%
	Some college	50%	13%	-
	Associate degree	-	25%	8%
	High School	25%	13%	50%
	Less than High School	-	13%	8%
Employment	Employed full time	25%	13%	8%
	Employed part time	25%	13%	-
	Retired	25%	75%	83%
	Other	25%	-	8%

Aim 1A Findings and Outcomes

Analysis of data produced three principal findings that served as input into design. First, we created from the findings a naturalistic decision-making model illustrated in Figure 4. In sum, patients' decision making occurred in phases of monitoring, interpreting, and acting. We identified how these phases were performed, independently and in sequence, for various decisions. Analyses also uncovered that in naturalistic decision making, there are barriers and strategies affecting the performance of these phases, other actors can play important roles, and health decisions are made in context. Preliminary findings were reported in published proceedings papers[42,45] and full findings are being prepared for publication.

Figure 4. Naturalistic decision-making model of CHF self-care (reproduced from Daley et al[45]).



Second, we developed three decision-making personas, depicted in Figure 5 and Table 5. The three distinct self-care decision-making personas—Rule-Following, Researching, and Disengaging—represent situation-specific modes in which patients operate. As described elsewhere,[41] we used these personas throughout the design process for internal and external communication, in combination with other design tools, to question design decisions, to develop new features, and to prioritize and set boundaries. Additional detail on personas findings are available elsewhere.[41,46]

Figure 4. Summary of the three decision-making personas.

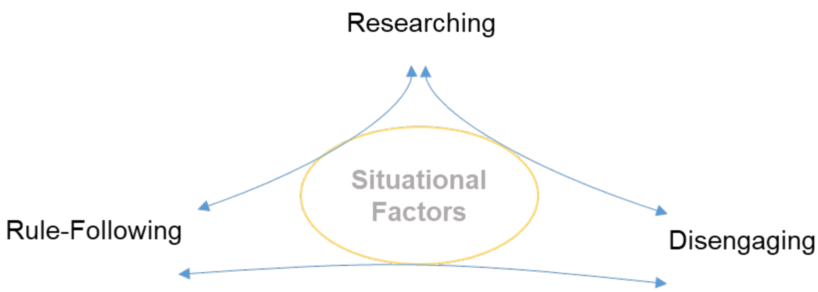


Table 5. Example design implications for personas and associated characteristics.

Persona	Characteristic	Example design implications
Rule-Following	Seeking clear rules	• If-Then rules • Unambiguous status displays • Recommendations for each status
	Caution under uncertainty	• Step-by-step directions
	Actions grounded in confidence in experts	• Recommendations provided or validated by trusted clinician or other authority figure
Researching	Seeking better understanding	• Tools to collect, track, display, and reflect on data
	Inventing and conducting experiments	• Forum for sharing inventive strategies • Tools for evaluation or comparisons
	Actions grounded in self-confidence	• Documentation tools for tracking own actions or communicating them to clinicians
Disengaging	Not seeking, not experimenting, not acting	• Reduce demand/burden • Align intervention with current preferences/values

Third, we developed three use-case scenarios (Table 6), designed to be clinically valid and consistent with the three decision-making personas. These were used to structure design work and obtain feedback from advisors. They were iteratively refined during the design phases.

Table 6. Three use-case scenarios developed for design work and obtaining feedback.

Scenario 1: Alerted to action. Meet Sarah, a retired woman in her 70s who had a CIED device implanted , which now remotely transmits monitored data to her health system's device clinic. Sarah underwent a CRT-D Implant 2 years ago with the presence of HFrEF (20% -nonischemic) and LBBB. Currently she receives Optimal medical Therapy but continues to demonstrate NYHA Class III symptoms. She attends clinical appointments about every four weeks with a cardiologist and other outpatient care providers. She is managing her blood pressure with medications and self-monitors blood pressure 2-3 times per day. She weighs herself daily on a bathroom scale, before taking her morning medications. One morning, **she notices a sudden overnight change in her weight and blood pressure that causes her concern**. She contacts her cardiologist's office and has **a 5-10 minute conversation during which a nurse asks her questions**. Based on this conversation, the nurse consults with the cardiologist and **tells the patient to come directly to the hospital**. Sarah does not question her doctor's advice and immediately goes to the hospital, where she is admitted with acute decompensated heart failure and receives IV diuretic.
Scenario 2: Staying in-bounds. Meet Aaron, an active man in his 70s who works part-time. A few years ago he had a CIED device implanted , which now remotely transmits monitored data to his health system's device clinic. The patient has CAD with a previous AMI and an ICD was implanted for primary prevention (VVI) with initially HFrEF (EF32%) and NYHA Class II CHF. The patient has been maintained on Optimal Medical Therapy for both CHF and CAD. Aaron is a long-time trucker and firmly believes in "staying in your lane." He applies this concept to **closely managing his daily sodium intake**, which he knows from past experience is what "aggravates my heart condition," though he doesn't understand the science behind it. As a result, he is **cautious to not over consume sodium, while having enough to enjoy his meals**. When he eats at home, he writes down his sodium intake. When he eats out with friends, he insists on "sodium-friendly" places that he knows well. At a new restaurant, he will ask the server about low-sodium items. He is **vigilant for days when he's had too much sodium**, so he can cut back in the next few days and avoid "two bad days in a row." He knows if he has one really bad day or several bad days in a row, his legs will swell and he'll feel out of breath. His doctor told him to watch for those two symptoms, but **he doesn't want it to ever get that far** – "by that time, I've already crossed into the wrong lane."
Scenario 3 – Failure post-mortem and reflection. Meet Roger, a retired man in his 80s who had a CIED device implanted , which now remotely transmits monitored data to his health system's device clinic. The initial implant for secondary prevention (DDD-ICD implanted for VT/VF arrest with SSS). The patient has a remote AMI with HFrEF (EF=45% -NYHA Class I) and receives Optimal Medical Therapy for CAD and CHF. Roger has his device checked every three months and every six months with his doctor. He does not understand what the device does and usually looks to his doctor for an explanation. Roger values knowing what is happening because it gives him peace of mind to feel in control, even if he believes deep down that he's really not. **Last time the device shocked him, he spent 15 minutes with his doctor just trying to figure out what happened and why. Not only was he curious but he was looking for a way to predict the next one so he can brace himself for it.** At his regular visit with the device clinic, he asks for the EP specialist to print off some data tables with timestamps from his CIED device. **He takes these data tables home and hand-plots them on several graphs so he can study the patterns before, during, and after he was shocked.** Roger finds that he can use these data points to also look at other events, such as the day he woke up with fluttering in his chest or the time he was too tired to get out of bed one morning.

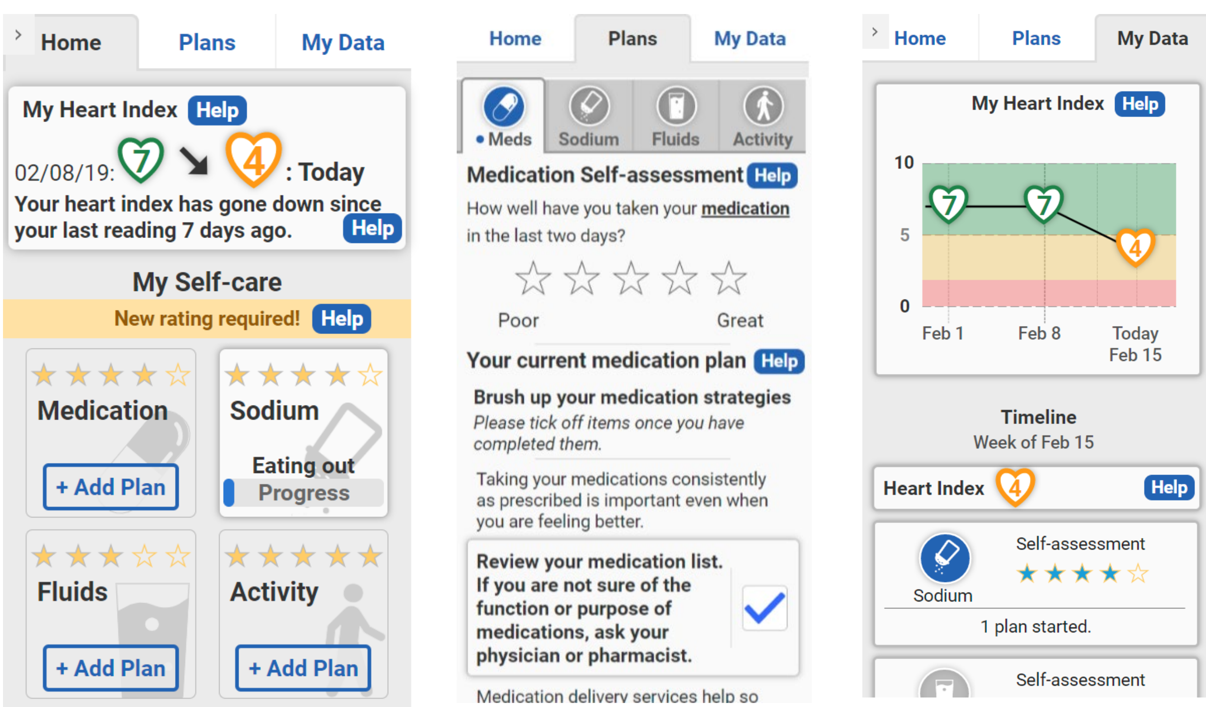
Aim 1B Findings and Outcomes

Design products are summarized in Table 7. Each product is available from the research team, upon request. (Note: direct links to each product were provided during interim reports.) The design process we used, including challenges encountered and lessons learned, are described in a conference proceedings paper[43] and are being prepared for journal publication. Select screenshots are provided in Figure 5.

Table 7. Design products formally created in Aim 1B.

Design product	Description
Early design concepts	Sketches, storyboards, and design mock-ups
Personas, decision-making model, and use-case scenarios	Analyses to support design, namely: (a) descriptions of three user archetypes (personas), differing in how they make self-care decisions, (b) a model of naturalistic decision making for self-care; and (c) use-case scenarios in which a decision-making situation might benefit from the use of CIED data
Requirements document	A formal requirements document, comprised of: Business Requirements; Vision; Scope and Limitations; Business Context; System Features; Nonfunctional Requirements; Target Users; Patient Scenarios; and Work Cited
Advanced design prototypes	Ten rounds of prototypes were created. An example can be accessed here: https://www.figma.com/file/jicujWve6tlahEpnwcB5F3/P2P-6-27-2018?node-id=259%3A463
Final prototypes	Prior to each round of testing, a prototype was finalized, and the final round of testing was followed by a revision to the final prototype (R1 prototype, R2 prototype, R3 prototype, revised final prototype). An example of a final prototype can be accessed here: https://gu93np.axshare.com/

Figure 5. Exemplar screenshots of P2P mobile app interactive prototype.



Aim 2 Findings and Outcomes

Tables 8, 9, and 10 present test results for acceptance, usability, and workload, respectively. These tables show the results for each of three rounds of testing, R1, R2, and R3. However, caution should be taken in interpreting differences between rounds for two primary reasons: 1) sample sizes were small and appropriate for usability testing but not adequate for statistical comparison; and 2) the manner of testing and goal of R3 were different compared to R1 and R2, with earlier rounds focusing on identifying usability violations in the design and later rounds on assessing acceptance of the longitudinal use of P2P.

Table 8. Acceptance results over 3 rounds.

Acceptance measure, mean	Round 1 (n=4)	Round 2 (n=8)	Round 3 (n=12)	Total
Perceived usefulness (5 items)	4.23	5.05	4.23	4.50
Perceived ease of use (5 items)	3.93	4.88	4.45	4.50
Satisfaction, mean (2 items)	4.00	4.75	4.14	4.33
Behavioral intention (2 items)	3.88	5.00	4.45	4.54

*mean score computed from scale items on a 7-point intensity scale: 0=not at all; 1 = a little; 2 = some; 3 = moderate; 4 = pretty much; 5 = quite a lot; 6 = a great deal.

Table 9. System usability scale (SUS) self-reported "subjective" usability results over 3 rounds.

SUS score parameter	Round 1 (n=4)	Round 2 (n=8)	Round 3 (n=12)	Total
Mean (SD)	73.7 (21.8)	88.1 (11.4)	74.0 (17.3)	79.1 (17.0)
Median	81.2	91.2	71.2	83.75
Range	42.5 – 90	65 – 100	55 – 100	42.5 – 100
Interpretation*				
Letter grade	B-	A+	B-	A-
Adjective	Good	Best imaginable	Good	Good-to-Excellent
Acceptability	Acceptable	Acceptable	Acceptable	Acceptable

*based on mean score; https://measuringu.com/interpret-sus-score/

Table 10. NASA Task Load Index (NASA TLX) workload results over 3 rounds.

NASA TLX score	Round 1 (n=4)	Round 2 (n=8)	Round 3 (n=12)	Total
Mean (SD)	25 (14)	13 (8)	19 (13)	18 (12)
Median	31	13	22	22
Range	4 – 33	1 – 23	2 – 44	1 – 44

In addition to self-report findings, comprehensive analyses were performed on written observation notes and video recordings of testing sessions. These produced internal reports, which were used by the design team to revise the prototype. Results from testing sessions are being prepared for publication.

Lastly, three user-centered design experts external to the project performed usability inspections of P2P on the basis of consistency, interface simplicity, navigation and visibility, workload, informative feedback, error management, user-appropriateness, and user-engagement.[47] They gave P2P an average "B-" grade and identified opportunities for redesign.

Discussion and Conclusions

Applying user-centered design can produce acceptable and usable mobile health (mHealth) technologies for older adults, with promising benefits for self-care management and other health-related behaviors. In this case, a standard human factors method called “cognitive task analysis” was adapted to older adults with CHF to better understand how they make self-care decisions.

We found that decision making can be simply modeled as interdependent phases of Monitoring, Interpreting, and Acting, but that self-care decision making is also shaped by various barriers, strategies, the involvement of others, and contextual factors. There also appear to be three modes or decision-making styles, i.e., ways in which the decision-making process is performed: Rule-Following, Researching, and Disengaging.

The P-CTA method is one that can now be used in other design work and research studies, to produce, for example, models of decision making, use-case scenarios, and personas, to underpin subsequent design. We found these design objects invaluable for design team activities; we used them during weekly design meetings to make design decisions, prioritize efforts, and evaluate the validity of design concepts. The products of our problem analysis were also highly useful for communicating about the design with patient and clinician advisors. Involving these stakeholders as advisors was challenging but rewarding.

Design work is often slow and linear in academic settings;[48,49] working with industry partners and adopting rapid prototyping and project management techniques, we were able to conduct three iterations of design and testing in relatively quick succession. Our interdisciplinary team was able to overcome other logistic challenges, such as being geographically dispersed or having limited time, and kept records of challenges encountered and strategies used (manuscript in preparation). The procedures and techniques used, products developed, and lessons learned from our design work should be useful to us and others in future projects.

The evaluation of P2P showed above-average acceptability and acceptable usability, with general improvement over time and design iterations. This supports the use of user-centered design and laboratory-based user testing with actual patients as a method for creating acceptable and usable technologies. Although acceptability and usability are not the only criteria that determine whether an mHealth product is effective, they are necessary, given the ubiquitous finding of discontinued use of poorly designed technologies.

From a human factors and systems engineering perspective, future work must embed user-centered design in academic and non-academic projects seeking to improve health and healthcare.[50-52] Progress toward this end will include the development and sharing of user-centered design tools such as P-CTA and patient personas[51,53] that are applicable to studying and improving “patient work.”[54-57]

From a health services perspective, future work is needed to prepare P2P for implementation and testing for safety and efficacy in a randomized trial powered to detect the effect of P2P on outcomes such as self-care adherence and acute care utilization among older adults with CHF.

Significance and Implications

We designed and evaluated a patient-facing technology to address the known problem of inadequate self-care management among a vulnerable population of older adults living with CHF, a costly and prevalent condition. The user-centered design methods we adapted and resultant design objects can be used for future projects for CHF and other conditions. The Power to the Patient (P2P) prototype passed conventional thresholds for acceptability and usability, implying readiness for feasibility, safety, and efficacy testing in a larger trial.

List of Publications and Products

- Cornet VP, Daley C, Bolchini D, Toscos T, Mirro MJ, Holden RJ, editors. Patient-centered design grounded in user and clinical realities: Towards valid digital health. Proceedings of the International Symposium on Human Factors and Ergonomics in Health Care; 2019: SAGE Publications Sage CA: Los Angeles, CA.
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- Daley CN, Cornet V, Patekar G, Kosarabe S, Bolchini D, Toscos T, et al. Uncertainty management among older adults with heart failure: Responses to receiving implanted device data using a fictitious scenario interview method. Proceedings of the International Symposium on Human Factors and Ergonomics in Health Care. 2019;8:127-30.
- Holden RJ, Daley CN, Mickelson RS, Bolchini D, Toscos T, Cornet VP, et al. Patient Decision-Making Personas: An Application of a Patient-Centered Cognitive Task Analysis (P-CTA). Applied Ergonomics. accepted.
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