



Using cardiac implantable electronic device data to facilitate health decision making: A design study

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ABSTRACT

For some individuals who live with chronic heart failure (CHF), cardiac implantable electronic devices (CIEDs) offer lifesaving therapy. Remote monitoring data from CIEDs are transmitted on a routine schedule for highly trained clinical staff to review. However, the remote monitoring data and clinical interpretations are not directly accessible to patients. Hence, people living with CIEDs are not able to reflect on their health data, let alone take any health action based on relevant data buried in their electronic health record (EHR). Prior research has shown that properly timed and tailored health data through a personal health record (PHR) can enable individual decisions about health in novel ways. However, in order to be effective, patients' needs must be well described before designing a tailored intervention. This study is an early investigation into ways in which complex CIED data can be harnessed to guide the health decisions of individuals living with CHF. To understand these information needs, we conducted four focus groups (N = 24) comprised of adults living with CHF (who were undergoing remote monitoring of their CIED data) and their informal caregivers (spouse or adult child). Focus group participants shared preferences for on-demand and personalized push message education. Through our analysis, we identified specific elements of device data and delivery design that can help promote reflection on changes in disease progression and CIED function over time. In this paper, we describe design ideas for the delivery of tailored CIED data and education that supports patient-level decision making.

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1. Introduction

Patients with chronic heart failure (CHF), who have impaired cardiac function, often benefit from cardiac resynchronization therapy (CRT). This lifesaving therapy is delivered through a device

directly implanted in the patients' heart, improving CHF symptoms and reducing mortality (Shea and Sweeney, 2003). These cardiac implantable electronic devices (CIEDs) collect data about cardiac function, life-threatening rhythm disorders, and device performance while automatically delivering treatment. Data from CIEDs are routinely transmitted to specialized cardiac rhythm clinicians who are responsible for following up with patients when changes in therapy are required (Burri and Varma, 2013; Kalahasty et al., 2013). However, currently, transmitted CIED data are not directly accessible to most patients (Campos, 2017; Daley et al., 2015; Marcus and Weaver, 2012; Skov et al., 2015). This contributes to patient frustration and anxiety due to the inability to access their own health information (Campos, 2017; Daley et al., 2015; Marcus and Weaver, 2012; Skov et al., 2015). Although research shows that sociotechnical solutions (e.g., glucose monitoring devices,

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physical activity trackers, wearable sensors, and monitoring patches) have been successful in supporting people living with chronic health conditions such as diabetes and heart disease (Mamykina et al., 2006; Randriambelono et al., 2015; Smith et al., 2007; Swan, 2012a,b; Kelsey, 2013), there is a paucity of research focused on the needs of patients with CIEDs (Daley et al., 2015; Denning et al., 2010; Skov et al., 2015).

Providing meaningful information from CIED transmissions may allow patients with CHF to reflect and take important health-related action (e.g., checking for other symptoms and/or calling the clinic for an adjustment in therapy). Previous research found that providing properly tailored health data should be considered as a mean to activate individuals (Ball et al., 2007; Klasnja and Pratt, 2012; Pagliari et al., 2007). However, simply providing data to patients (e.g., via a personal health record (PHR)) will not automatically result in improved patient engagement or health outcomes (Toscos et al., 2016; Ancker et al., 2015). For instance, CIED reports contain hundreds of data elements (from complex electrical heart rhythms to device battery life and lead status – both data types and amounts of data); thus, provision of data to patients must be carefully designed to be accessible and engaging without being overwhelming. Prior research suggests patients prefer to be presented with a sub-set of essential and easy to understand data that will not overwhelm them (Longo et al., 2010), but this requirement is yet to be translated for the delivery of CIED remote monitoring data.

Both the human-computer interaction (HCI) and human factors engineering (HFE) approach to patient-centered design require an understanding of users' needs (Holden et al., 2016; Krist and Woolf, 2011; Srinivas et al., 2016) before sharing CIED data with patients. Hence, in this study, we aimed to understand patients' experiences and needs around CIED data delivery and education to support patient decision-making.

2. Background

2.1. Implanted device for patients with CHF

Many patients who have CHF with reduced ejection fraction are at risk for sudden cardiac death from fatal arrhythmias (Epstein et al., 2008). Implantable cardioverter defibrillators (ICDs), one type of CIED, are implanted in the chest wall with wires attached to the heart. These wires detect lethal arrhythmias and deliver high-energy and life-saving shocks when patients are at risk of sudden cardiac death (DiMarco, 2003). Some patients with heart failure require CRT, a more advanced technology, that restores normal electrical activation of the right and left ventricles, thereby improving CHF symptoms and reducing mortality (Shea and Sweeney, 2003). These treatments have been combined into the CRT – cardiovascular implantable electronic device (CRT-CIED), which provides carefully timed electrical stimulus to the cardiac muscle (pacing) to simultaneously activate the right and left ventricles. This simultaneous activation of both sides of the heart improves the heart's pumping ability and effectiveness. As a result of this therapy, patients have experienced fewer hospitalizations, less procedural cost, an increased lifespan, and an overall improved quality of life (Iyengar and Abraham, 2005). Between 2002 and 2010, a total of 374,202 patients received CRT-CIED treatment (Sridhar et al., 2016).

To ensure that patients with CHF receive the most benefit from undergoing CRT-CIED, it is imperative to monitor the percent of ventricular pacing (Jentzer and Jentzer, 2011). Patients treated with CRT-CIED experience deterioration in left-ventricular (LV) performance when the percent synchronized ventricular pacing drops below 93% (Koplan et al., 2009). Therefore, clinicians monitor LV

pacing to identify subthreshold values. Typically, clinicians use wireless remote monitoring, which transmits data from the CRT-CIED to the clinic via a variety of technologies. Remote monitoring reports are sent to the clinic for routine monitoring and appropriate intervention (Burri and Varma, 2013; Kalahasty et al., 2013). Remote monitoring has increased efficiency for healthcare providers, improved patients' quality of care and decreased mortality (Crossley et al., 2011; Guédon-Moreau et al., 2012; Landolina et al., 2012; Watanabe et al., 2013). However, clinicians can be overwhelmed by the volume and complexity of CIED data coming into their patients' electronic health record (Ajami and Bagheri-Tadi, 2013; Levine et al., 2014), which might interfere with the communication of important information to the patient (Petersen et al., 2012; Slotwiner et al., 2015). If patients were able to access this data in a meaningful way, they could augment the current process that requires clinician review before patient notification. Therefore, one possible benefit of sharing transmitted data with patients is a shorter time interval between deterioration of LV pacing and related adjustments in CRT-CIED.

2.2. Patient access to health data

In prior research investigating patients' opinions on remote monitoring, patients reported not receiving their cardiac function data or any indication of deterioration or improvement (Campos, 2017; Daley et al., 2015; Marcus and Weaver, 2012; Skov et al., 2015). For these patients, not having access to one's own health data can cause anxiety and frustration (Campos, 2017; Daley et al., 2015; Marcus and Weaver, 2012). Additionally, devices have limited utility without tailored data delivery to promote meaningful use of data, reflection and action (Abedtash and Holden, 2017).

Prior research has shown that patients with CHF have difficulty interpreting physical symptoms and making determinations about appropriate actions pertaining to specific symptoms (Mickelson et al., 2016; Srinivas et al., 2016). Artifacts (e.g., pillboxes and medication lists) and strategies (e.g., rules of thumb, relying on others) exist that may support patients with CHF in decision making and taking an action (Cornet et al., 2017; Mickelson and Holden, 2017). However, there are still barriers to access and use of these artifacts and strategies, such as patients' biomedical conditions, knowledge deficit, and usability of the artifacts (Holden et al., 2015; Mickelson et al., 2015). One way to encourage patients to take action is to transform data into understandable information (Meyer et al., 2014) and include directions for necessary actions (Swan, 2012a,b).

Features of technological decision support tools have proved beneficial for the following health-related concerns: *diabetes* (Mamykina et al., 2016a,b; Mamykina et al., 2006; Mamykina et al., 2008; Toscos et al., 2012a,b), *cancer* (Patel et al., 2012), *physical activity promotion* (Consolvo et al., 2008; Lin et al., 2006; Toscos et al., 2011), and *sleep behaviors* (Choe et al., 2011; Choe et al., 2015). In this previous work, scaffolding patients' thought processes with relevant information for health conditions promoted reflection. For example, parents of children with diabetes were presented with a trend report of blood sugar values along with a list of potential explanations for the low blood sugars that the child was experiencing overnight (Toscos et al., 2012a,b).

Building on these studies, our research is novel in its focus on patients with a CRT-CIED and its related complexities. For one, the nature of a CRT-CIED is quite different from other health monitoring technologies in that CRT-CIEDs are embedded, "in-the-body" versus other wearable sensing technologies (e.g., continuous glucose monitoring devices, GCM, for individuals with diabetes) that are "on-the-body". Second, these CRT-CIEDs can deliver a lifesaving (Shea and Sweeney, 2003) shock at any moment that

creates fear for the patients. Third, these devices deliver therapy that, in addition to being lifesaving, protects the patient's heart from further deterioration. Fourth, patients with CRT-CIEDs have specific activity restrictions, such as not using items with a strong magnetic field. Fifth, CRT-CIEDs capture multiple data elements versus one type of measurement (e.g., blood glucose). Hence, the patient must distinguish which elements correspond to current symptoms. Some data may not be highly correlated with observable events or they are hard to interpret without proper educational support.

Despite these differences, the common theme across prior research studies and monitoring devices is that patients need accurate and tailored information about their health condition. Hence, the **purpose of this research** is to accomplish the following objectives: 1) Explore patient experience with CIEDs and CIED remote monitoring; 2) Identify patient preferences for receiving alerts about heart function and other CIED related data; 3) Understand educational support available to patients with CIEDs and other opportunities for providing educational support.

3. Study method

After obtaining approval for the study from the Parkview Health Institution Review Board, we conducted four focus groups comprised of adults living with CHF and their informal caregivers (spouse or adult child). The questions and activities included in the focus groups were aimed at better understanding the patients' experiences with CIED and remote monitoring, preferences for receiving alerts and CIED related data, and educational support.

3.1. Participants

The study population included all adult patients with a CRT-CIED who participate in remote monitoring of their CIED and who were not pacemaker dependent. Patients had CRT-CIEDs from a variety of manufacturers. Patients were identified through staff (research nurse) at a large outpatient cardiology practice in the Midwest and also through electronic health record (EHR) reporting tools. Patients living with chronic disease have caregivers who support them and play an essential role in their care that cannot be easily untangled from the patient's efforts at self-management (Gillick, 2013). Therefore, patients' informal caregivers were also invited to participate in focus groups because health habits in the home are impacted by the interplay in these complex relationships.

For example, it is equally important for a patient's caregiver to be able to interpret CIED data and collaborate in decision making if this is a patient's normal workflow of self-care.

Of the four focus groups, two included patients with a CRT-CIED implanted within the previous 12 months (N = 12, 8 patients and 4 informal caregivers) and two included patients who had CRT-CIED implanted for more than one year (N = 12, 8 patients and 4 informal caregivers).

3.2. Procedure

Upon arrival to the focus group meeting, patients and caregivers met individually with a research team member to complete the informed consent process. After consent, participants completed a survey packet containing demographic items (age, gender, employment status, educational background, and race) and two validated survey instruments. First, the Newest Vital Sign (NVS) (Weiss et al., 2005) is a six-item health literacy survey; second, the Altarum Consumer Engagement (ACE) Measure (Duke et al., 2015) is a 12-item scale to assess patient engagement. For the NVS (Weiss et al., 2005) survey, patients are given a nutrition label for an ice cream container, followed by six corresponding questions. The ACE Measure (Duke et al., 2015) includes three subscales: *Commitment*, *Informed Choice*, and *Navigation*. *Commitment* refers to a person's capability to manage his or her own health. *Informed choice* is the extent to which a person looks for and uses information related to his or her health. *Navigation* refers to how expert a person is at using the health system.

The focus groups included one moderator (HCI researcher), one co-moderator (research nurse), five note takers/observers (three HCI researchers, one project manager, and one health informatics researcher). Fig. 1 depicts the typical room configuration during the focus groups. The focus groups began with staff introductions, expectations and ground rules for participation. Then, participants were presented with the first of two fictitious scenarios. The first scenario was designed to initiate discussion about general preferences related to receiving alerts. Actual CRT-CIEDs (Fig. 2) were handed out to participants to hold while discussing a fictitious CRT-CIED called the "Biotron-85." We told the participants to imagine that the "Biotron-85" had the ability to transmit data directly to them and send alerts based on how their heart functions. To be more conservative in this fictitious scenario, pacing above 95% was considered as green status instead of above 93% (Koplan et al., 2009). The participants were then prompted with questions to

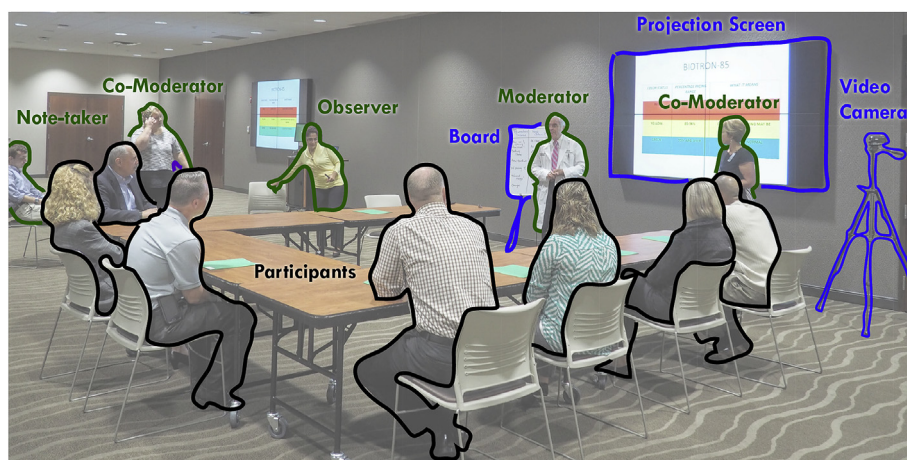


Fig. 1. Representation of the focus group setup.



COLOR STATUS	PERCENTAGE PACING RANGE	WHAT IT MEANS
RED	UNDER 85%	SOMETHING IS WRONG
YELLOW	85-94%	CAUTION/SOMETHING MAY BE WRONG
GREEN	95% AND OVER	ESSENTIALLY NORMAL

Fig. 2. Fictitious alert system from the “Biotron-85” device.

further explore their preferences and design ideas related to receiving these alerts. The stoplight metaphor was utilized in this scenario because it was simple and straightforward; indeed, participants were able to quickly understand and appropriately apply the concept in context. After the “Biotron-85” discussion was completed, a cardiac nurse delivered basic education regarding CHF and CRT-CIEDs. The education covered CHF symptoms, CHF causes, definition of ejection fraction, definition of CRT, and a video clip from the American Heart Association illustrating the difference in heart function before and after CRT-CIED therapy (American Heart Association, 2017).

After the educational session, the moderator presented a second scenario that was “real-world.” Patients were invited to reflect on the potential benefits and barriers of using CRT-CIED data in the context of everyday activities. For example, participants were asked to reflect on how they would prefer to get an alert about an abnormal trend in their LV pacing if they were out shopping. Participants were also queried about what type of questions they most often ask during clinic visits and questions that arise between appointments. While the first scenario was specific and fictitious, the second scenario was a broad, real-world example. Presenting the scenarios in this order ensured patients understood the concept behind different types of alerts. Then, patients suggested adaptations to this fictitious device appropriate to their personal experience with their CRT-CIED. Each focus group session lasted approximately three hours. The focus group sessions were video and audio recorded and transcribed. Researchers also took field notes (Fig. 1). Each participant received a \$40 debit card for participation.

3.3. Analysis

Over the course of three meetings, the research team (three HCI researchers, one research nurse, one health informatics researcher, one project manager, one health services researcher) performed thematic analysis (Boyatzis, 1998) on the focus group observation notes to create a preliminary codebook. Then, the research team members independently coded a focus group transcript using the preliminary codebook. The research team discussed discrepancies to clarify coding categories and revisions to the codebook. This process was repeated one more time to refine and finalize the codebook. One of the team members utilized qualitative data analysis software (NVivo 11.0) to import the final codebook and transcripts.

To code the remaining transcripts, the team was divided into three pairs and assigned specific transcripts to code. Members coded independently and then compared codes with their coding partner to discuss discrepancies and achieve 100% consensus (Corbin and Strauss, 2014). The whole team met four times to

complete coding for all transcripts. New pairs were assigned for each session so that by the end, every member of the team had achieved consensus with another member of the team. Any concerns or major discrepancies were brought to the team’s attention and updated in the codebook. This process ensured the validity of the codebook among an interdisciplinary team. After coding was complete, the team began abstraction of each coded category, which involved representing data at a higher level of abstraction such that observations were integrated across cases to show patterns and consistencies (e.g., preferences for CIED alerts and experiences with CIED and remote monitoring). In addition, the research team did not examine differences of opinion between individual patients and their caregivers. Quantitative data analysis included descriptive statistics (frequency, range, mean, median) for items and subscales contained in the survey packet. These analyses were conducted using Excel 2010.

4. Results

Twenty-four people participated: 16 patients (P) and eight informal caregivers (C). In each of the focus groups, five to seven people participated. On average, patients were 67.4 years old (range = 41–85, median = 68) and caregivers were 64.5 years old (range = 53–72, median = 66). Table 1 shows that most of the patients were male, while most of the caregivers were female. Most of the participants were white, retired and had completed high school. Twenty-five percent of participants rated their ability to use a computer and to navigate the internet as “very poor” or “poor.”

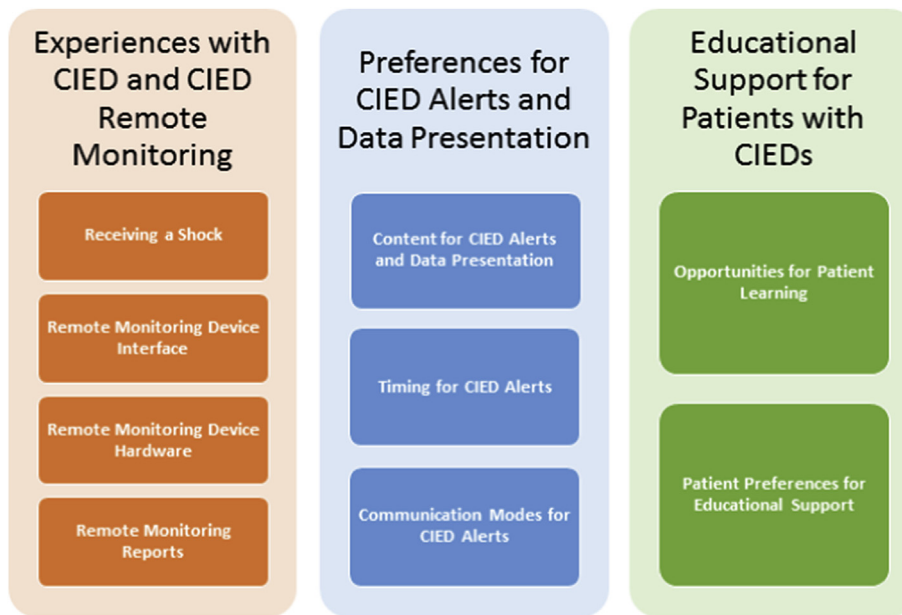
As displayed in Table 1, the NVS survey results showed that the majority of our focus group participants had “adequate literacy,” (62.5% patients; 75% caregivers). Responses to the ACE questionnaire reveal that most participants had a low score for the commitment domain (63%), a medium score in the informed choice domain (54%) and a medium score in the navigation domain (38%). The thematic analysis revealed the following three primary categories: 1) experiences with CIED and CIED remote monitoring, 2) preferences for CIED alerts and data presentation, and 3) educational support (see Fig. 3).

4.1. Patient experiences with CIED and CIED remote monitoring

Participants reported positive experiences with the CIED and the remote monitoring process. In particular, patients attributed improvements in their heart condition to the CRT-CIED and valued having clinicians reviewing their data. For example, one participant (P6, Male, 78) stated “I was able to get up and actually do things that I couldn’t before. I got better.” One caregiver (C6, Female, 73) expressed “Before his device he [patient] would think he couldn’t even

Table 1
Characteristics of focus group participants.

24 Participants		16 Patients (P)	8 Caregivers (C)
Gender	Male	10	2
	Female	6	6
Average age (years old)		67.4	64.5
Ethnicity	Caucasian	15	8
	no answer	1	0
Employment	Retired	10	4
	Employed	2	4
	Unemployed	1	0
	Unable to work	3	0
Education level	Postgraduate degree	1	1
	High school or some college	14	7
	No answer	1	0
Ability to use computer/internet	Very good/good	4	2
	Average	7	5
	Very poor/poor	5	1
NVS score	Adequate literacy	10	6
	Possibility of limited literacy	4	0
	High likelihood of limited literacy	2	2
ACE measure	Average Commitment	Low	Low
	Average Informed Choice	Medium	Medium
	Average Navigation	Medium	Medium

**Fig. 3.** Themes emerging from the analysis of focus group transcripts.

make it through the day sometimes.” Participants also valued the reassurance received through the remote monitoring report. One participant (P12, Female, 86) expressed this feeling in the following way: “Well I do get a letter regularly telling me and it says essentially no change ... I like that.” Despite overall positive experiences, participants expressed some concerns with both CIED and remote monitoring, such as fear of receiving a shock, dissatisfaction with the remote monitoring device interface, desire for a portable remote monitoring device, and accessibility to remote monitoring reports.

4.1.1. Receiving a shock

Several participants discussed their past experience receiving a shock from their CIED and nearly all participants expressed fear and anxiety about the possibility of receiving a future shock. For

example, one participant (P14, Female, 42) shared his experience of receiving a shock while driving, “I wish [my CRT-CIED] would have given me more warning when it was coming ... I didn’t really know what to do ... couldn’t stop the vehicle or nothing.” (P13, Male, 61) Another participant (P4, Female, 67) described her anxiety about receiving a shock immediately after CIED implant stating, “it took four months to get to the point where I wasn’t waiting for something to happen.”

4.1.2. Remote monitoring device interface

Participants experienced dissatisfaction with the remote monitoring interface design including specific attributes that caused uncertainty or were a nuisance (e.g., bright lights on the device). For example, one patient (P5, Male, 64) noted that without visual feedback on the device, he was not assured that the remote

monitoring device was functioning properly. Specifically, he stated that “Certain lights come on. Ok does it indicate when it's sending stuff out or how do you know if it's sending stuff out or getting anything back or how do you know to follow up on is it working or not?” Moreover, some patients were bothered by the bright lights on the display and would attempt to cover the lights. The following exchange describes this concern: “I was going to say that light is bright when it's on (P15, Female, 69) ... yeah it's bright (P13, Male, 61) ... and not only that, sometimes I feel like I'm being watched (P15, Female, 69) ... throw a towel over it (P13, Male, 61) ... unplug it and it will beep at you (P14, Female, 42).”

4.1.3. Remote monitoring device hardware

Participants discussed concerns about traveling with a CRT-CIED along with remote monitoring and the ability to continue to transmit data. Participants desired a device that was portable and could transmit data wirelessly. One participant expressed this preference in the following way: “They could have a monitor, portable monitor that you could actually carry with yourself you know ... Yeah, just something small you know.” (P13, Male, 61) Participants discussed the inconvenience of the required landline phone for transmitting data from the CRT-CIED. Participants believed that other methods for transmitting data should be available, given the availability of other wireless technologies (i.e., mobile phones).

4.1.4. Remote monitoring reports

Participants described the need for all of their healthcare providers, at any location, to have immediate access to their device data. One participant (P8, Male, 70) stated: “I want the clinic to get information on it too (P8, Male, 70).” However, participants noted that even when healthcare professionals have access to their device data, the long lag time for receiving notification of an event hinders their understanding of the event. Participants noted that delayed reports about previous problematic heart functioning caused difficulty in recalling and linking that event to their experience (i.e., coinciding symptoms and activities). The following exchange describes this concern: “Yeah well you don't get any feedback till you go back to the doctor or something, and if it went red at ten in the morning finding out the next day isn't that great (P5, Male, 64) ... well, that's what they did to us at one of our visits recently is say you had an incident on such and such a day (C3, Female, 69) ... three weeks ago you had a rapid heartbeat don't know why but (P5, Male, 64) ... and it and it really (C3, Female, 69) ... it wasn't enough to shock you but (P5, Male, 64) ... re-corrected itself so like we're looking at each other like did you feel ok (C3, Female, 69).”

4.2. Patient preferences for CIED alerts and data presentation

4.2.1. Content for CIED alerts and data presentation

Pertaining to ‘normal’ or ‘abnormal’ alerts, participants preferred content signifying the level of importance (e.g., a visual representation and meaningful use of color) along with simple warning words and instructions for action. For example, participants suggested the following language: “something is wrong, consult the doctor,” (C7, Male, 54) or “... a yellow [alert] that would say ‘Make an appointment’” (C6, Female, 73). Participants explicitly did

Table 2
Timings of alert delivery preferences.

Timing	Green	Yellow	Red
Immediately		X	X
Weekly	X		
Monthly	X		
On-demand	X	X	X

not want to decipher the alert severity using CIED data, such as interpreting the actual pacing percentage. Participants preferred simplified information instead of having to interpret numerical data on their own. “It has to be in language that we can understand. We aren't physicians. I mean, yes I can read my labs results on [my PHR] but what do they mean? Unless they're in a normal range, then I don't have a clue.” (C7, Male, 54).

Also, participants pointed to specific information as being critical to view, including CRT-CIED battery status and whether the CRT-CIED was working effectively. One participant (P13) remarked, “I knew it was working but was it doing what it was supposed to do?” Additionally, participants desired to receive CRT-CIED data for a specific time period to view trends in heart function. For example, one participant (P16, Male, 69) expressed the need for historical reports from his device such as LV pacing trends and device activity, “I would like to see a history of ... am I all green or is there some red spots in here.” The same participant desired to add the chronological history of CIED data on his PHR: “I really would like to see history in MyChart [my PHR], you know, graphs [to explain] what's going on.”

4.2.2. Timing for CIED alerts

Participants preferred to receive ‘abnormal’ alerts immediately and differed on their interest in receiving ‘normal’ alerts for LV pacing data (see Table 2). P13 (Male, 61) discussed the importance of receiving ‘abnormal’ alerts in real time so he could take needed action while driving: “If Siri could come on and say ‘Hey you better pull that thing over man, you'll be having some problems.’ That would be great.”

There was dissension among participants about timing for ‘normal’ alerts. Some participants wanted to receive it on a weekly or monthly basis. One participant stated that he did not need a daily calls or notifications about normal heart functioning. He (P5, Male, 64) explained: “I don't need somebody calling me every day saying yeah you're ok today.”

Another participant (C8, Female, 65) described the potential convenience of simply pushing a button for an on-demand update of heart functioning, “... if you have a concern, let's say you think that there might be a problem. Maybe you could press a button and it would either flash green, yellow or red”.

4.2.3. Communication modes for CIED alerts

Participants also discussed a variety of modes to communicate important information about CRT-CIED status: ‘normal’ and ‘abnormal’ alert delivery (elicited using the stoplight metaphor; see Table 3). Table 3 is derived from participants' discussion and agreement on how they would prefer to receive an alert. In the case of ‘normal’ reports, participants preferred to receive letters. For example, one participant (P12, Female, 86) stated, “Well I do get a letter regularly telling me and it says essentially no change ... I like that. There is nothing like old school, I like old school.” In the case of deterioration or an ‘abnormal’ alert, participants preferred

Table 3
Modes of alert delivery preferences.

Mode	Green	Yellow	Red
Remote Monitoring Station at Bedside	X	X	X
Phone Call		X	X
Smartwatch	X	X	X
Smartphone App	X	X	X
Personal Health Record (MyChart)	X	X	
Mobile Phone Text Message		X	X
Haptic from CIED			X
Sound/Light from CIED			X
Letter	X		

notification or alerts by phone. For example, one participant (P11, Male, 75) stated, “Oh [the letter] just gives the basics, how you're doing, the progress. [the clinic] sometimes call on the phone right away, saying that you just got [shocked].” In general, participants preferred a smartwatch display, an application on a smartphone, a computer screen display, or a display panel on the remote monitor transmission equipment as a means to view this notification at a glance. Also, one caregiver (C7, Male, 54) brought up how a quick look at a color display and without other information would be helpful for a ‘normal’ alert “just a color, green or something ... I'm on the road anyway so just a quick look.” While many participants felt secure receiving a red or yellow alert through their mobile phone, others were concerned about missing an alert on a phone or not always having their phone. Several focus group members suggested a haptic alert delivery mechanism to avoid audibility problems. One participant suggested the following: “Like a Fitbit type thing or something ... [some] kind of vibration or buzz in the display so that you would look at it ... that might be easier than a phone. I sometimes forget my phone. (P5, Male, 64)” Specifically, for a ‘red alert’, P13 (Male, 61) preferred a vibration in the body “I guess for myself if there was something seriously wrong, I would want ... to know rather than someone calling me saying ... I want to know right now. I would like a tone or a vibration [in my body] that would let me know right away.” Most participants favored notification alerts directed to the caregiver, as well as the patient.

4.3. Educational support for patients with CIEDs

4.3.1. Opportunities for patient learning

Participants expressed consistent questions about their CIED and related physical conditions. For example, after implantation of CRT-CIEDs, all participants reported being concerned about if and when they could resume their normal physical activities. In addition, participants were unsure about the safety of using or being near specific machinery and appliances (e.g., lawnmower, generator, microwave, hairdryer, chainsaw, NuWave oven, welding equipment) due to magnetic field implications for the CRT-CIED. Participants also expressed a need to better understand their device data and other related cardiac test results. For example, one participant (P16, Male, 69) mentioned a misunderstanding regarding LV pacing “That's what I want to know because I was worried if it was ninety. You know, if they want [it] to work at 100% why doesn't it?” Participants needed more information about prescribed medications for CHF and related symptoms. One participant, P15 (Female, 69), mentioned: “I'm not sure exactly what they (medicines) do.” Many were concerned that they would not be able to differentiate a symptom that was serious (due to their disease, medication or device) or a common illness (e.g. cold or flu). Finally,

participants expressed needing instructions and training material for emergency situations or in the case of an ‘abnormal’ alert. For example, if a person with a CRT-CIED receives a shock while swimming, the caregiver would like to know what actions to take in that situation. One caregiver (C8, Female, 65) explained the need for access to such self-training modules, “So that you would kind of be training yourself what to do and there's nothing like that out there and I think that would be really good for us.” Another participant shared that she asked her mom to accompany her to a regular in-clinic CRT-CIED check so that the staff could share with the participant and her mom what an alert tone from the device sounds like and what actions to take if the participant ever hears this alert tone.

Participants had experiences receiving information about their medical condition and CRT-CIED through detailed instruction from clinic staff and physicians during in-person meetings. However, one drawback to this method was that participants noted sometimes forgetting information after leaving the visit. In addition, participants expressed concern that their physicians have limited time during clinic visits and often worry about asking too many questions during an office visit. One caregiver (C1, Male, 69) explained the perceived difference in time for nurse practitioners compared with physicians saying, “[Nurse Practitioners] are actually giving me more information than what the doctor would because he seems to have a different time crunch.”

4.3.2. Patient preferences for educational support

Participants expressed preferences, in terms of timing and mode of delivery, for receiving CIED-related educational information dependent on the particular information being delivered (see Tables 4 and 5). Participants felt that having general information and educational content sent every day would be too much. However, participants preferred any updated educational information to be sent immediately. Similarly, participants had varied delivery method preferences for receiving educational information dependent on the particular information being delivered. For example, participants were open to e-mail, text, and using secure messaging via PHR as methods for receiving information. One participant (P1, Male, 62) suggested that asynchronous messaging may have benefits by reflecting, “I suppose email wouldn't be too bad because you wouldn't take away from a doctor's valuable time.” However, texting and phone calls were viewed as appropriate for receiving more urgent educational information. Several participants mentioned that it was easier to retain educational information when they were able to read it. For example, one participant (P2, Female, 67) stated “the doctors come in and draw pictures about what they're doing ... I could see what they were doing and I took pictures [of their drawings] with my smartphone.”

Table 4
Timings of educational information preferences.

Timing	General Educational Information	Updated/Urgent Educational Information
Immediately		X
On-demand	X	X

Table 5
Modes of educational information delivery preferences.

Mode	General Educational Information	Updated/Urgent Educational Information
Email	X	
Mobile Phone Text Message	X	X
Personal Health Record (MyChart)	X	
Phone Call		X

On-demand information was another option that participants discussed for receiving educational support. In particular, a caregiver (C8, Female, 65) reflected about the benefit of having the option to access the data as needed vs. getting a push message saying, “*That way it wouldn't bother anybody if they didn't need that information but you can get it when you need it.*” Another caregiver (C4, Female, 73) stated, “*It's there if you need it, but you can delete it if not.*” Pre-recorded video was also mentioned as a potential mechanism to deliver educational information that a patient or caregiver could revisit as needed. One caregiver (C8, Female, 65) from our focus groups voiced concern of not knowing what health-related events to expect and described the benefit of having access to video content, “*I think we need to have some place [where there is] a video available and that shows exactly what to expect so that you can go maybe to MyChart [PHR] and there would be a video ... and you could watch it whenever you felt insecure.*”

5. Discussion

5.1. Experiences with CIED and CIED remote monitoring

A person with a CRT-CIED constantly lives with a health monitoring technology implanted in their chest and has no immediate access to data from the device (Andersen et al., 2017; Campos, 2017; Daley et al., 2015; Marcus and Weaver, 2012; Skov et al., 2015). Furthermore, these individuals do not receive any feedback from their remote monitoring device when their CIED data is transmitted to the clinic (Skov et al., 2015). In consequence, these people can experience increased anxiety (Andersen et al., 2017; Skov et al., 2015) and have a fear of receiving a shock without any notification (Cook et al., 2013; Koopman et al., 2012; Schulz et al., 2013; Dougherty, 1995; Heller et al., 1998). Our participants, who had never received a shock, were also anxious and confused about what to expect, some even felt they may have had one without knowing it. Hence, our participants wanted to receive a warning prior to the delivery of a shock specifically while driving (Ahmad et al., 2000).

Although currently, it is not possible to notify a person with CRT-CIED prior to this event, we could alleviate their fear and anxiety by the following recommendations:

- 1) Grant *individuals with immediate access to their CIED remote monitoring data* (further discussed in section 5.2) – For example, prior research (Andersen et al., 2017) suggested designing e-health technologies for co-experience to enable these individuals to have greater connectedness with their healthcare team and their CIED data.
- 2) *Provide them with adequate educational support* (further discussed in section 5.3).
- 3) *Add specific indicators for successful data transmission to the clinic on the CIED remote monitoring device* – As an indicator for successful data transmission, prior research (Skov et al., 2015) proposed integrating a time stamp of the last data transmission on the remote monitoring interface to provide feedback to individuals and improve their experiences. Since prior studies have focused on the interface design of remote monitoring, this topic is not discussed in this study.
- 4) *Enable individuals to transmit the CIED data via a portable monitor (including a wearable device).* – Currently, some people with CIED have portable remote monitoring device.

Among these four recommendations, two of them (recommendation 3 and 4) are confirming prior research findings and solutions. However, the other two of them (recommendation 1 and 2) are unique to this research study by recommending design ideas to deliver tailored CIED data and education that supports patient-

level decision making.

5.2. Preferences for CIED alerts and data presentation

5.2.1. Present critical CIED data with simple and meaningful interpretation

Unlike other health monitoring devices (e.g., CGM devices, activity trackers, blood pressure monitoring, etc.) that transmit only one or few data points (e.g., blood glucose) (Dolan, 2010; Eng and Lee, 2013), CRT-CIED sends hundreds of data points - some of which only a clinician with specialized training can interpret. Therefore, patients could quickly become overwhelmed with the volume of data and how to make sense of it. In order to help patients with CRT-CIEDs prioritize and process this large data set from their device, our participants suggested receiving the following data elements: device battery status (Petersen et al., 2012), indication of whether the CRT-CIED is working effectively (Petersen et al., 2012; Skov et al., 2015), and the number of shocks or therapies delivered (Andersen et al., 2017; Petersen et al., 2012).

These design considerations are important for developing a patient-centered delivery system that conveys critical information and allows patients to make appropriate health-related actions. For example, if the CRT-CIED battery reserve declines, the patient must schedule a surgical replacement; moreover, access to this information is important for sustaining optimal performance of this life-saving device. Similarly, displaying device information that confirms the delivery of a shock or resynchronization therapy can provide reassurance that the device is working. Hence, this information allows patients to identify coinciding symptoms and environmental context/exposures.

Our focus group members also suggested that having a way to link patterns of LV pacing with activity would be useful. In reality, LV pacing does not deteriorate with physical activities but our participants sought answers to questions: “*Why am I not feeling well? Is this feeling relevant to the function of my CRT-CIED or activity?*” Therefore, offering a visualization of LV pacing trends for a specific time period may help patients identify coinciding symptoms. This design recommendation is called comprehension by a prior study (Andersen et al., 2017) and it is generalizable to other conditions. For example, presenting a trend report of blood sugar values from CGM to a person with diabetes (Toscos et al., 2012a,b). Fitting with previous research, providing specific vital-type data to patients improves their ability to understand their own symptoms. In the case of patients with CRT-CIED, patients are able to connect their CHF symptoms with their activities in order to understand their condition and make appropriate decisions (Andersen et al., 2017).

Additionally, it is critical to provide simple language and clear interpretation of data instead of numerical data (Buckley et al., 2013; Hong et al., 2013; Safeer and Keenan, 2005). One final design recommendation is to use a visual representation signifying the level of importance along with few words when sending an alert to the patient (Shneiderman et al., 2013).

5.2.2. Provide alert immediately and grant reassurance on-demand

Similar to our findings, prior research (Andersen et al., 2017; Daley et al., 2015; Skov et al., 2015) has shown that patients with CHF and an ICD want to receive reassuring information about their condition and device function. Based on our findings, for alerting, green status information (remote monitoring data within a normal range) must be available to the patients all the time and *on-demand*. In contrast, participants prefer an alert immediately for deteriorating cardiac function using a phone or haptic delivery (such as vibration on the phone or in the body). Therefore, it is essential to notify patients with an alert and clear instructions for necessary

follow-up action, such as calling the clinic or evaluating their symptoms in emergency situations. This design recommendation is critical to optimize the device's utility as life-saving; assure patients that the device is functioning properly; and to facilitate informed and timely health action.

5.3. Educational support for patients with CIEDs

5.3.1. Provide on-demand educational content

In regards to education, currently patients receive a lot of information and education at the time of diagnosis or discharge when they are not optimally receptive to education (McCarthy et al., 2012; Krumholz, 2013; Romagnoli et al., 2013). Similar to prior study (Skov et al., 2015), our focus group participants consistently demonstrated many misconceptions about CHF and CRT-CIEDs, including the poor understanding of remote monitoring and LV pacing interpretation. However, participants were aware of their limited understanding and expressed a preference for *on-demand* education. This type of delivery allows patients to access

information on their own at a convenient time and when their condition is stable (Knox et al., 2001). Although providing patients with *on-demand* education is generalizable to other conditions, the educational content can be vastly different for patients with CHF in regards to the actions that need to be taken in emergency situations or when warning signs are present (see Table 6 for education trainings). Furthermore, we found that our focus group participants had a strong desire to get education on medication side effects (Osborn et al., 2013) that would allow them to differentiate their symptoms related to their medication versus therapeutic events from their device. This information could further enhance sense-making about symptoms these individuals are experiencing.

5.3.2. Authorize flexible and personalized access

Participants' preferences for receiving education and CRT-CIED data elements were highly variable and included both non-technological methods (letters) and new technology. They were interested in various types of technology (e.g., phone, smartphone apps, e-mail, letters, PHR) and format (e.g., phone call, text, video,

Table 6

Design implications for enhancing experiences with CIED and remote monitoring, sending alerts, presenting CIED data, and providing educational support.

Design Implications	Themes/Sub-themes	Generalizability Across Other Chronic Health Conditions
Visual feedback on the remote monitoring for data transmission (Skov et al., 2015)	<i>Experiences with CIED and CIED remote monitoring/remote monitoring device interface</i>	Y
Portable or wearable remote monitoring device	<i>Experiences with CIED and CIED remote monitoring/remote monitoring device hardware</i>	Y
Access to critical CRT-CIED data, such as battery and device status, and LV pacing to compare with activities.	<i>Preferences for CIED alerts and data presentation/ N content for CIED alerts and data presentation</i>	N
Historical trends: patients' LV pacing data for a specific time period (Andersen et al., 2017)	<i>Preferences for CIED alerts and data presentation/ Y content for CIED alerts and data presentation</i>	Y
Provide number of shocks and therapies administered	<i>Preferences for CIED alerts and data presentation/ N content for CIED alerts and data presentation</i>	N
Prioritized content and clear instruction for the patients on what actions they need to take in emergency situations and when warning signs are present.	<i>Preferences for CIED alerts and data presentation/ N content for CIED alerts and data presentation</i>	N
Red status = send clinic contact information with instructions to call or send a message to the clinic immediately.		
Yellow status = encourage patients to watch for the presence of other health-related symptoms and then contact the clinic if needed.		
Clear instruction to evaluate any other health-related symptoms, such as sudden weight gain, leg or feet swelling, frequent cough, or difficulty breathing.	<i>Preferences for CIED alerts and data presentation/ N content for CIED alerts and data presentation</i>	N
Simple language and clear interpretation of data instead of numerical data only (Buckley et al., 2013; Hong et al., 2013; Safer and Keenan, 2005)	<i>Preferences for CIED alerts and data presentation/ Y content for CIED alerts and data presentation</i>	Y
On-demand access to LV pacing information when in the normal range (reassurance). This reassuring information will help the patient to connect their new feelings of having more energy with the fact that their device is working and within the range.	<i>Experiences with CIED and CIED remote monitoring/positive experiences</i>	Y
Immediate notification if the LV pacing is deteriorating.	<i>Preferences for CIED alerts and data presentation/ timing for CIED alerts</i>	
Glanceable device status that includes both color and numbers (Khan et al., 2012)	<i>Preferences for CIED alerts and data presentation/ Y communication modes for CIED alerts</i>	Y
Haptic delivery (e.g., vibration on the phone or in the body) for the red or yellow alert.		
Visualization of patients' current status (green, yellow, or red) based on the LV pacing data with few words. (Shneiderman et al., 2013)	<i>Preferences for CIED alerts and data presentation/ Y communication modes for CIED alerts</i>	Y
Enable patients to communicate through the same platform where information is delivered.	<i>Preferences for CIED alerts and data presentation/ Y communication modes for CIED alerts</i>	Y
Access to educational training and materials on the following: <ul style="list-style-type: none"> • Functions of CRT-CIED and remote monitoring. • Patients' disease and safe activities. • Type of machinery and equipment that is safe to use. • Meaningful information on medication side effects. (Osborn et al., 2013) • Actions patients need to take in emergency situations or when warning signs are present. 	<i>Educational support for patients with CIEDs/ opportunities for patient learning</i>	N
On-demand access to education and information.	<i>Educational support for patients with CIEDs/ patient preferences for educational support</i>	Y
Immediate notification when educational information is updated.		
Enable patients to personalize their settings based on how frequently they prefer to receive important information (once a week vs. once a month) (Årsand et al., 2012; Khan et al., 2012)	<i>Educational support for patients with CIEDs/ patient preferences for educational support</i>	Y
Paper-based or pre-recorded video that can be available on-demand.	<i>Educational support for patients with CIEDs/ patient preferences for educational support</i>	Y
New technologies, such as mobile applications or wearable devices to provide patients with important information while on the go (Jimenez Garcia, 2014)		
Enable patients to personalize their settings, e.g., patients can choose to receive training information on e-mail, but important alerts on mobile application (Khan et al., 2012)	<i>Educational support for patients with CIEDs/ patient preferences for educational support</i>	Y

paper handout, secure messaging through PHR) for accessing health educational information on the go (Jimenez Garcia, 2014). Although participants were older adults, they expressed strong preferences for newer technologies – smartwatch displays, applications for smartphones, or a computer display – that would allow them to view information at a glance. However, we also had participants who were interested in very minimal information delivery. Prior research (Andersen et al., 2017) proposed a compassion dimension for individuals with the implanted device in their heart. This dimension is about attending to individuals' needs (McKenzie et al., 2014) and care (Andersen et al., 2017) when designing patient-centered e-health. Thus, we suggest that designers offer a wide range of delivery modes to accommodate individual preferences in such a way that patients could receive tailored health education information by selecting the platform and format they prefer. Tailored health delivery is also generalizable to various health concerns (Årsand et al., 2012; Frøisland et al., 2012; Khan et al., 2012) including diabetes and cancer.

In summary, prior research (Andersen et al., 2017; Skov et al., 2015) discussed the importance of sharing data with patients with CRT-CIEDs, connecting patients' symptoms with their events, sending reassuring information about patients' condition and their device function, and educating these patients. However, these research did not identify critical data points to share with patients, how to represent and prioritize these critical data points for a better patient experience, connecting patients' symptoms with LV pacing trends, how frequently to represent reassuring information, and the content and the representation of educational information.

Table 6 summarizes the above-mentioned design implications based on the findings and indicates whether each item is generalizable across conditions or specific to individuals with CHF and CRT-CIEDs. Those design implications which are generalizable across other chronic health conditions are decided based on the expert consensus of our interdisciplinary research team. This team includes physicians, nurses, engineers and HCI experts. In addition, some of our design implications can also be supported in the literature as noted in Table 6 and with the citations. For example, data must be represented in a simple language with clear interpretation is applicable to patients in different chronic health conditions (Buckley et al., 2013; Hong et al., 2013; Safeer and Keenan, 2005) rather than patients with certain types of health conditions. As another example, enabling patients to personalize their settings is relevant to patients with diabetes (Årsand et al., 2012) and other chronic health conditions (Khan et al., 2012).

Individuals with a CRT-CIED may experience deterioration in cardiac function if LV pacing drops below 93%, and pacing may decline to dangerous levels without symptoms. Hence, the ability to easily translate deteriorating cardiac function into an easily understandable and timely alert is critical. Alerts that include tailored information and instructions could enable patients to take health-related action. Based on the insights from patients with CRT-CIEDs, our work offered design implications for alerts, data presentation, and educational support specific for this population. While many of these design recommendations have been identified as important for sense-making and management of other disease states, our contribution follows from the unique content considerations for CRT-CIEDs.

5.4. Limitations

Focus groups may have a general bias due to the characteristics of the type of person who volunteers to participate. Also, the presence of the researchers and caregivers could have affected the attitudes and behaviors of the participants. Some of the focus group scenarios were based on hypothetical technology. Hence,

participants can only speculate as to what they would like and dislike. However, participants did have firsthand experience with remote monitoring of their CRT-CIED and ideas about how this technology could be improved. The study population was also quite limited, lacking in ethnic and educational diversity, and therefore might not be generalizable to other groups of people. We did not distinguish differences between individual patients and their caregivers' opinions. Therefore, this study might not have detected important disagreements in the opinions of patients and caregivers.

6. Conclusion

Prior research suggests that use of remote monitoring of CIED data has reduced mortality and healthcare expenditures of patients with CHF (Crossley et al., 2011; Guédon-Moreau et al., 2012; Landolina et al., 2012; Watanabe et al., 2013). However, the current standard clinical process, (Cronin et al., 2012) where patients are dependent on their provider for remote monitoring reports, could delay the communication of important information to patients. Further, this disconnect between patient and device data may contribute to issues with adherence to remote monitoring protocol. Our research gives promise to properly timed and tailored health data as a mean to engage and activate patients to take timely and appropriate health action. For example, giving patients access to their CRT-CIED data could reduce the time between heart function deterioration and adjustment in therapy. Our contribution is translating elicited experiences, needs and preferences into requirements and design implications for a patient-facing CIED data delivery system. Incorporating these design implications may also enhance an individual's experience with their CIED and remote monitoring. The next step is to prototype PHR messaging options and use it in participatory design sessions to further understand the preferences and impacts for delivering critical health information to patients with CRT-CIEDs.

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