6-2020

Involving Patients as Key Stakeholders in the Design of Cardiovascular Implantable Electronic Device Data Dashboards: Implications for Patient Care

Carly Daley

Romisa Rohani Ghahari

Michelle Drouin

Ryan Ahmed

Shauna Wagner

See next page for additional authors

Authors

Carly Daley, Romisa Rohani Ghahari, Michelle Drouin, Ryan Ahmed, Shauna Wagner, Lauren Reining, Amanda Coupe, Tammy Toscos PhD, and Michael Mirro MD

Involving patients as key stakeholders in the design of cardiovascular implantable electronic device data dashboards: Implications for patient care

Carly Daley, MS,*† Romisa Rohani Ghahari, PhD,* Michelle Drouin, PhD,*
Ryan Ahmed, MS,* Shauna Wagner, BSN, RN,* Lauren Reining, MS,*
Amanda Coupe, BA,* Tammy Toscos, PhD,*†
Michael Mirro, MD, FACC, FHRS, FAHA, FACP*†‡

*From the *Parkview Mirro Center for Research and Innovation, Parkview Health, Fort Wayne, Indiana, †Department of BioHealth Informatics, IUPUI School of Informatics and Computing, Indianapolis Indiana, and ‡Department of Medicine, Indiana University School of Medicine, Indianapolis, Indiana.*

BACKGROUND Data from remote monitoring (RM) of cardiovascular implantable electronic devices (CIEDs) currently are not accessible to patients despite demand. The typical RM report contains multiple pages of data for trained technicians to read and interpret and requires a patient-centered approach to be curated to meet individual user needs.

OBJECTIVE The purpose of this study was to understand which RM data elements are important to patients and to gain design insights for displaying meaningful data in a digital dashboard.

METHODS Adults with implantable cardioverter–defibrillators (ICDs) and pacemakers (PMs) participated in this 2-phase, user-centered design study. Phase 1 included a card-sorting activity to prioritize device data elements. Phase 2 included one-on-one design sessions to gather insights and feedback about a visual display (labels and icons).

RESULTS Twenty-nine adults (mean age 71.8 ± 11.6 years; 51.7% female; 89.7% white) participated. Priority data elements for both ICD and PM groups in phase 1 (n = 19) were related to cardiac episodes, device activity, and impedance values. Recommended replacement time for battery was high priority for the PM group but not the ICD group. Phase 2 (n = 10) revealed that patients would like descriptive, nontechnical terms to depict the data and icons that are intuitive and informative.

CONCLUSION This user-centered design study demonstrated that patients with ICDs and PMs were able to prioritize specific data from a comprehensive list of data elements that they had never seen before. This work contributes to the goal of sharing RM data with patients in a way that optimizes the RM feature of CIEDs for improving patient outcomes and clinical care.

KEYWORDS Digital health; Health informatics; Implantable cardioverter–defibrillator; Pacemaker; Remote monitoring

Introduction

Cardiovascular implantable electronic devices (CIEDs) are increasing in number and complexity and require timely monitoring and patient follow-up for optimal care.[1] Technical advances have enabled the use of remote monitoring (RM) in lieu of in-office interrogations to record and transmit CIED data.[2] RM increases clinical efficiency, lowers health care costs, and improves patient safety, satisfaction, and clinical outcomes.[3] Foundational in caring for patients with complex cardiac disorders requiring CIED implant is engaging the patient in shared decision-making, as recently mandated by the Centers for Medicare and Medicaid Services (CMS) for cardiovascular procedures.[4] This work is part of a larger effort to leverage RM data elements in a meaningful way to move patients along a path of increasing engagement and ultimately enhance decision-making for self-care.

This research is funded by Medtronic PLC. The content is solely the responsibility of the authors and does not necessarily represent the official views of Medtronic PLC and Parkview Health. Dr Toscos has received research grants from Medtronic PLC, Biotronik, Agency for Healthcare Research and Quality (AHRQ), Janssen Pharmaceuticals, and iRhythm Technologies, Inc.; and honoraria from Medtronic PLC. Dr Mirro has received grants from Biotronik, Inc, Agency for Healthcare Research and Quality (AHRQ), Medtronic PLC, and Janssen Scientific Affairs; consulting fees/honoraria from iRhythm Technologies, Inc., and Zoll Medical Corporation; and reports non-public equity/stock interest in Murj, Inc./Viscardia outside the submitted work. Dr Mirro's relationships with academia include serving as trustee of Indiana University. All other authors have reported that they have no conflicts relevant to the contents of this paper to disclose. **Address reprint requests and correspondence:** Ms. Carly N. Daley, Parkview Mirro Center for Research and Innovation, 10622 Parkview Plaza Dr, Fort Wayne, IN 46845. E-mail address: carly.daley@parkview.com.

https://doi.org/10.1016/j.hroo.2020.04.005

KEY FINDINGS

- Adult patients with pacemakers and implantable cardioverter–defibrillators were able to prioritize which data elements were important to them from a comprehensive list of remote monitoring data elements, facilitated by a user-centered design process.
- Preferences for the amount of data varied. High priority data selected by patients with either pacemakers or implantable cardioverter–defibrillators were cardiac episodes, device activity, and impedance values.
- Simplified yet informative language (descriptive, nontechnical terms) and intuitive icons are needed to enhance presentation and communication about the data.

Currently, there is little to no transparency of data collected through RM for patients.[5] Some applications allow patients to see a limited amount of information, such as battery status and when a transmission has occurred.[6,7] Patients desire increased access to their RM data,[8–13] including patient advocates, who have asserted their right to access the data generated by a device implanted permanently inside their body.[14] Patients also report a general lack of knowledge about their device,[15] so engagement in RM data may improve their understanding. Furthermore, understanding patients' information needs and what they perceive as important may enhance patient–clinician communication about RM, particularly for patients who are concerned about replacing in-person visits with RM.[16,17] Importantly, access to health data may lead to improvements in value-based care and reduction of health care costs by helping connect patients with their health care providers.[18] In previous work, we examined the feasibility of delivering a summary and full disclosure (all data in the RM report) of implantable cardioverter–defibrillator (ICD) data to patients through a personal health record or portal.[8,9] These studies revealed the need for greater understanding of the design elements required to assist patients in using the data. We then conducted focus groups and design-related queries to understand how patients with heart failure would want to receive alerts about left ventricular pacing from their device.[19,20] The findings from this entire body of work confirmed that many patients are interested in receiving RM data (eg, battery status); however, the data in the RM report should be simplified and tailored.[8,9,19,21] The current study expands on the previous user-centered design work by asking patients to consider the utility of a comprehensive list of ICD and pacemaker (PM) data elements in the very nascent stages of the design of RM dashboards toward the goal of more fully tailoring information to individual needs.

Understanding patient preferences for specific data is increasingly important, as patients are faced with a growing number of sources of health data.[22] Understanding patient preferences also provides insight into tailoring clinically relevant data to patients' needs and expectations.[23–25] Thus, we used a user-centered approach with people who have ICDs and PMs to generate rich insights regarding patients' preferences for receiving RM data that can be translated into design.

User-centered design actively engages end-users and stakeholders throughout the entire design process.[26] A variety of scientific methods (eg, questionnaires, interviews, and focus groups), along with generative design activities, are typically conducted in multiple sessions with a small group of 6–20 participants[27] to identify user needs, explore meaningful communication (content and presentation), and validate ideas in realistic use case scenarios. Through user-centered design research, patterns may emerge on how to create solutions that work for a larger population.

The present study engaged patients in 2 design phases. In the first phase, patients participated in an educational session and discussion about RM data with experts and other patients. They received a comprehensive list of RM data elements from Medtronic (Medtronic PLC, Minneapolis, MN) RM reports (37 discrete data elements for dual-chamber PMs and 55 discrete data elements for dual-chamber ICDs) from which to select the data they would want included in an online dashboard. In the second phase, patients' preferences for the presentation (icon and label) of data elements were explored. Building on our previous report of findings,[28] the primary aims of this design study were to (1) identify which RM data elements are of high priority to patients with PMs and ICDs; (2) identify which supplemental information can help with interpreting the data and how frequently patients would like to receive the data; and (3) gather patients' feedback on a visual display of the highest prioritized data elements, including icons, data labels, and descriptions.

The findings from this study contributed to initial recommendations for designing digital dashboards of CIED data for patients with ICDs and PMs. The findings can help clinicians understand areas of support that patients need to comprehend RM data and their device functionality. This work is foundational in order to engage patients in a meaningful way, improve their understanding of the functionality of their CIED through the use of digital health technology, and further enhance their personal understanding and self-management of underlying cardiac disease.

Methods

Design

This exploratory, user-centered design study used a mixed-methods approach involving surveys, card-sorting sessions (phase 1), and one-on-one design sessions with a second set of participants (phase 2). All participants provided informed consent and were given a $40 debit card incentive payment. Both phases were recorded on video (with audio), and researchers took observation notes. The study was approved by the institutional review board (Parkview Health).

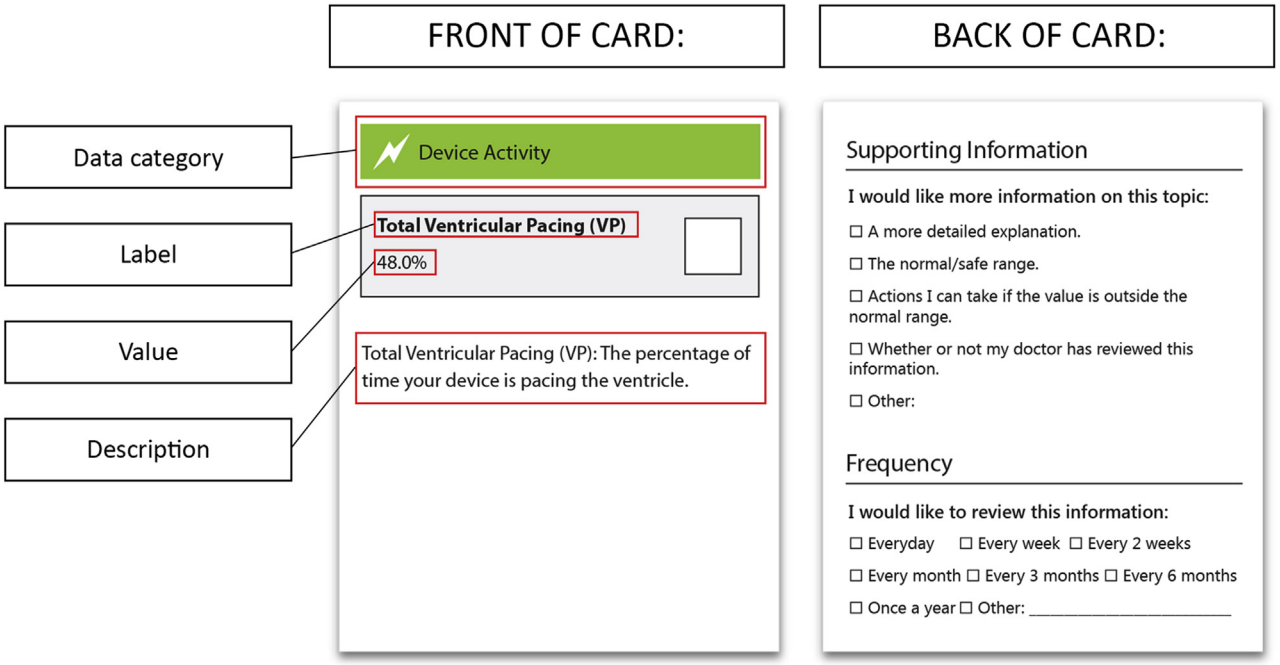


Figure 1 Example of card used during card-sorting activity.

Setting and sample

The study was conducted at a large, not-for-profit health system in the Midwestern United States that serves >5000 patients with CIEDs. Adult (age >18 years) outpatient cardiology patients were recruited via telephone if they had a Medtronic dual-chamber ICD or dual-chamber PM, had been enrolled in CareLink (Medtronic PLC) RM for ≥6 months, and were approved by the principal investigator for contact. Patients who met these criteria (approximately 155) were contacted in alphabetical order to recruit for the sessions until 10 ICD and 10 PM participants were scheduled for phase 1, and 5 ICD and 5 PM patients were scheduled for phase 2, with no overlap between phases. Dual-chamber ICDs and PMs, specifically, were included to harmonize the dataset provided. Informal caregivers were invited to join patient participants for phase 1; however, the card-sorting task was completed solely by the patient participants.

Surveys

After the consent process and at the start of the sessions, all participants were surveyed using 3 validated instruments: (1) the Newest Vital Sign (NVS),[29] a 6-question health literacy survey; (2) the Multidimensional Health Locus of Control (MHLC) scale, Form C,[30] a 24-item scale to assess a person's beliefs regarding who or what has control over their health and wellbeing; and (3) the Altarum Consumer Engagement (ACE) Measure,[31] a 12-item scale to measure patient engagement across 3 subscales: Commitment, Informed Choice, and Navigation. Commitment refers to capability to manage one's own health, Informed Choice is the extent to which a person looks for and uses health-related information, and Navigation refers to expertise at using the health system.

Phase 1 procedure

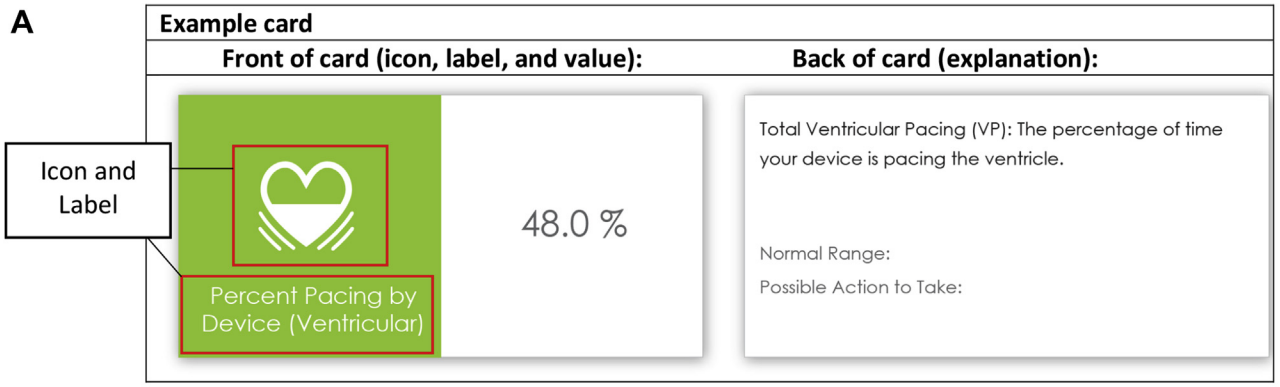
Phase 1 involved 4 group sessions with a total of 10 participants with PMs and 9 with ICDs. The first and second sessions included 4 and 6 participants with PMs, respectively. The third and fourth sessions included 3 and 6 participants with ICDs, respectively. Each session lasted up to 3 hours, starting with the consent process and including team introductions and breaks during the sessions.

Educational introduction (10 minutes)

Each session began with an educational video explaining how the device (PM or ICD) works to treat a diagnosed condition, the purpose of RM, and how health care providers interpret RM data. The video was created by 2 study team members, a research registered nurse (RN) with 10 years of electrophysiology experience (S.W.), and a cardiologist specializing in electrophysiology with 30 years of clinical experience (M.M.).

Card-sorting activity (45 minutes)

Participants were given a stack of paper cards containing discrete data elements (37 PM; 55 ICD) from Medtronic RM reports, grouped under categories assigned by the research RN (Supplemental Appendix A). Each card included the data category (eg, Device Activity), label, value, and description of what the value meant in the context of CIED operation (Figure 1). Each participant individually sorted the cards as "High Priority," "Low Priority," or



B

Example of alternative icons and labels

Front of card			Back of card
Icon options:	**Label options:**	**Value**	**Explanation**
AT/AF	**RM Report:** Treated AT/AF Episodes	1 Episode	The total number of AT/AF episodes that received treatment
	Simplified: AT/AF Episodes Receiving Therapy		
AT/AF	**Descriptive:** Number of Atrial Tachy/Atrial Fibrillation episodes that received therapy		

Figure 2 Example cards used in individual design sessions. **A:** Front and back of the "Total Ventricular Pacing (VP)" card with the "simple" label option. The other 2 alternatives were "original": Total Ventricular Pacing (VP) and "descriptive": Percentage of Time Device Pacing Ventricle. **B:** Possible icons and labels for the "Treated AT/AF Episodes" card. AF = atrial fibrillation; AT = atrial tachycardia; RM = remote monitoring.

"Discard." Only 5 cards could be selected as high priority. For high- and low-priority selections, participants were prompted to select from a list on the back of the cards (generated by the research team) of desired supporting information and frequency of data delivery.

Discussion (45 minutes)

Researchers facilitated the discussion among participants regarding rationale for data prioritization. Discussions in this phase also provided an opportunity for participants to learn more about the data from each other and make changes to their original selections if desired.

Dashboard card development

After completion of phase 1, researchers calculated the 9 highest-priority data elements by applying the following formula to each element: [(number of participants who selected high priority × 2) + (number of participants who selected low priority × 1)]/(total number of participants × 2), producing scores of 0–1. High-priority selections were weighted twice as much as low-priority selections. Using this formula, if all participants chose a data element as high priority, that data element would have the highest possible score (1.0). Once the 9 highest-priority data elements were determined, researchers developed cards that included 3 label options (original from RM report, simplified, and descriptive) and 2 icon options, for a total of 6 alternative representations (Figure 2).

Phase 2 procedure

Phase 2 involved 10 one-on-one design sessions, lasting approximately 90 minutes each. Five participants had PMs, and 5 had ICDs. Participants in phase 2 did not participate in phase 1.

Dashboard building activity

Participants were given 9 stacks of 7 cards (the 6 alternative representations of each high-priority phase 1 data element, plus a blank card for additional suggestions). They interpreted each data element based on the front side before reading the explanation on the back, then placed the card they felt was the best representation out of the 6 alternatives on top of each stack. Participants were also asked to rate (on a 5-point scale) the overall ease of understanding and usefulness of the 9 cards they selected.

Data analysis

Descriptive statistics (frequency) were calculated for survey items using Excel 2016. Qualitative data were gathered from field notes and video recordings from both phases.

Table 1 Participant characteristics

Participant characteristics	Phase 1 (N = 19)	Phase 2 (N = 10)	Total (N = 29)
Device type			
Dual-chamber PM	10 (52.6)	5 (50.0)	15 (51.7)
Dual-chamber ICD	9 (47.3)	5 (50.0)	14 (48.2)
Age (y)			
>76	7 (36.8)	3 (30.0)	10 (34.5)
66–75	5 (26.3)	6 (60.0)	11 (37.9)
56–65	6 (31.6)	0 (0.0)	6 (20.7)
46–55	0 (0.0)	0 (0.0)	0 (0.0)
36–45	1 (5.3)	1 (10.0)	2 (6.9)
26–35	0 (0.0)	0 (0.0)	0 (0.0)
Gender			
Female	10 (52.6)	5 (50.0)	15 (51.7)
Male	9 (47.4)	5 (50.0)	14 (48.3)
Ethnicity			
Hispanic or Latino	0 (0.0)	0 (0.0)	0 (0.0)
Not Hispanic or Latino	17 (89.4)	10 (100)	27 (93.1)
Decline to answer	2 (10.5)	0 (0.0)	2 (6.8)
Race			
White	17 (89.5)	9 (90.0)	26 (89.7)
Black or African American	1 (5.3)	1 (10.0)	2 (6.9)
Other	1 (5.3)	0 (0.0)	1 (3.4)
American Indian, Alaska Native	0 (0.0)	0 (0.0)	0 (0.0)
Native Hawaiian, Pacific Islander	0 (0.0)	0 (0.0)	0 (0.0)
Asian	0 (0.0)	0 (0.0)	0 (0.0)
Education			
Trade/some college	7 (36.8)	4 (40.0)	11 (37.9)
College graduate	6 (31.6)	3 (30.0)	9 (31.0)
High school/GED	5 (26.3)	0 (0.0)	5 (17.2)
Postgraduate	1 (5.3)	3 (30.0)	4 (13.8)
Did not complete high school	0 (0.0)	0 (0.0)	0 (0.0)
Current employment status			
Retired	14 (73.7)	7 (70.0)	21 (72.4)
Disabled/unable to work	4 (21.1)	1 (10.0)	5 (17.2)
Employed part-time	0 (0.0)	2 (20.0)	2 (6.9)
Employed full-time	1 (5.3)	0 (0.0)	1 (3.4)
Unemployed	0 (0.0)	0 (0.0)	0 (0.0)

Values are given as n (%).
GED = General Educational Development test; ICD = implantable cardioverter–defibrillator; PM = pacemaker.

Results

Participant characteristics

Participants in this study were mostly older than 65 years (mean 71.8 ± 11.6 years), white (89.7%), and retired (72.4%); gender distribution was fairly equal (51.7% female, 48.3% male) (Table 1).

Survey results

Participants demonstrated adequate health literacy on the NVS survey (79.3%) and high health engagement on the ACE measure (96.6% of participants scored high for Commitment and Navigation, and 62.1% scored high for Informed Choice). Participant scores on the MHLC measure were high for doctor locus of control, internal, and others; scores were low for chance (Table 2).

Prioritization of device data elements

During phase 1, 865 total cards were sorted. Three of the highest-priority data elements for both ICD and PM groups were related to the Cardiac episodes category. Whereas recommended replacement time was high priority for the PM group, none of the battery-related data elements were highest priority for the ICD group (Table 3).

Observation notes captured during the discussion revealed reasons for discarding data, including perceived irrelevance to their health condition, too much information, numbers being less useful than the interpretation, and lack of understanding. One participant stated, "I would rather go into the office and speak to the cardiologist one-on-one."

Desired supporting information and frequency of receiving data

Among the 428 total cards selected as high or low priority, there were 563 selections for supporting information (participants could select more than one or none of the options). "The normal/safe range" was selected most (31.6%) along with "Whether or not my doctor has reviewed this information" (31.0%), followed by "Actions I can take if the value is outside the normal range" (26.3%) and "A more detailed explanation" (11.1%). "Other" was not selected. A total of

Table 2 Aggregated survey results for each phase

	Phase 1 (N = 19)	Phase 2 (N = 10)	Total (N = 29)
NVS			
Adequate literacy	14 (73.7)	9 (90.0)	23 (79.3)
High likelihood of limited literacy	2 (10.5)	1 (10.0)	3 (10.3)
Possibility of limited literacy	3 (15.8)	0 (0.0)	3 (10.3)
ACE			
Informed choice			
Low	0 (0.0)	0 (0.0)	0 (0.0)
Medium	6 (31.6)	5 (50.0)	11 (37.9)
High	13 (68.4)	5 (50.0)	18 (62.1)
Commitment			
Low	0 (0.0)	1 (10.0)	1 (3.4)
Medium	0 (0.0)	0 (0.0)	0 (0.0)
High	19 (100.0)	9 (90.0)	28 (96.6)
Navigation			
Low	0 (0.0)	0 (0.0)	0 (0.0)
Medium	1 (5.3)	0 (0.0)	1 (3.4)
High	18 (94.7)	10 (10.0)	28 (96.6)
MHLC			
Internal			
High	16 (84.2)	8 (80.0)	24 (82.8)
Low	3 (15.8)	2 (20.0)	5 (17.2)
Chance			
High	6 (31.6)	1 (10.0)	7 (24.1)
Low	13 (68.4)	9 (90.0)	22 (75.9)
Doctors			
High	19 (100.0)	10 (100.0)	29 (100.0)
Low	0 (0.0)	0 (0.0)	0 (0.0)
Others			
High	12 (63.2)	9 (90.0)	21 (72.4)
Low	7 (36.8)	1 (10.0)	8 (27.6)

Values are given as n (%).
ACE = Altarum Consumer Engagement; MHLC = Multidimensional Health Locus of Control; NVS = Newest Vital Sign.

391 selections were made for frequency. "Every 3 months" was selected most (56.3%), followed by "Every month" (18.2%) and "Once a year" (12.5%). Notably, "Every day" was never selected.

Feedback about the display and receiving data

In phase 2, participants rated the ease of understanding at 3.15 of 5 and usefulness at 4.4 of 5 for the overall visual representations and offered specific feedback and insights for improvement.

Labels: Of the 3 label options provided (simplified, descriptive, or as it appears on the standard RM report), most participants (51.7%) chose the descriptive labels. Generally, participants felt the language on the standard RM report was "too technical." One person stated, "I am an educated man and still had a lot of difficulty with understanding the cards. Simplify it." Participants (ICD) suggested using "canceled" instead of "aborted," and "wire" instead of "lead." Two participants suggested using "wire condition" to replace "lead impedance."

Icons: Although participants understood the icons overall, several misinterpreted or had trouble integrating pictures with explanations. One person noted, "It's not like we're looking at street signs that we all know." Suggestions included an icon with a device connecting to the heart indicating which part of the heart was being paced by the wire, a heart with a lightning bolt symbol for treated atrial tachycardia/atrial fibrillation episodes, and a "happy heart" symbol when there were no episodes.

Amount of data: Participants ranged from not wanting information at all or only directly from their doctor, to wanting details such as dates and times of episodes. This was consistent with phase 1, in which some participants expressed the idea that "what I don't know doesn't hurt me," whereas others were enthusiastic about the possibility of receiving all possible "hidden" data.

PM and ICD dashboards created after phase 2 findings show the aggregated top choices for labels and icons representing the 9 highest-priority data elements (Figure 3).

Discussion

Because device data are ubiquitous, clinicians may soon be called upon to provide support for ICD and PM patients who engage in self-monitoring and interpretation of their device data. To that end, we used user-centered design principles to engage patients in feedback for a digital dashboard

Table 3 Card prioritization by category and preference score for high-priority data elements within each category, for participants with ICDs and PMs

Data category	Device (n)	Cards	Total selections	HP (%)	LP (%)	D (%)	Highest-priority data elements (9 from each group; 18 total)	Preference score
Battery life	ICD (9)	5	45	6 (13.3)	12 (26.7)	27 (60.0)	None	N/A
	PM (10)	5	50	20 (40.0)	7 (14.0)	23 (46.0)	RRT	0.60
	Total	10	95	26 (27.4)	19 (20.0)	50 (52.6)	—	—
Device activity	ICD (9)	7	63	10 (15.9)	26 (41.3)	27 (42.9)	Aborted charges AT/AF	0.50
							Total ventricular pacing (VP)	0.50
	PM (10)	2	20	12 (60.0)	5 (25.0)	3 (15.0)	Atrial sensing (AS)	0.85
							Atrial pacing (AP)	0.60
	Total	9	83	22 (26.5)	31 (37.3)	30 (36.1)	—	—
Device information	ICD (9)	8	72	16 (22.2)	16 (22.2)	40 (55.6)	RV defibrillation impedance	0.61
							SVC defibrillation impedance	0.61
							Atrial pacing impedance	0.56
							RV pacing impedance	0.56
	PM (10)	6	60	13 (21.7)	20 (33.3)	27 (45.0)	Atrial pacing impedance	0.75
	Total	14	132	29 (22.0)	36 (27.3)	67 (50.8)	—	—
Device settings	ICD (9)	15	135	4 (3.0)	26 (19.3)	105 (77.8)	None	N/A
	PM (10)	13	130	21 (16.2)	43 (33.1)	66 (50.8)	None	N/A
	Total	28	265	25 (9.4)	69 (26.0)	171 (64.5)	—	—
Health information	ICD (9)	5	45	5 (11.1)	12 (26.7)	28 (62.2)	None	N/A
	PM (10)	6	60	18 (30.0)	25 (41.7)	17 (28.3)	Observations	0.65
							Average ventricular rate during AT/AF	0.65
	Total	11	105	23 (21.9)	37 (35.2)	45 (42.9)	—	—
Cardiac episodes	ICD (9)	15	135	18 (13.3)	54 (40.0)	63 (46.7)	Monitored AT/AF episodes	0.67
							Treated AT/AF episodes	0.50
							Pace-terminated VT/VF episodes	0.50
	PM (10)	5	50	21 (42.0)	18 (36.0)	11 (22.0)	Monitored AT/AF episodes	0.75
							Pace-terminated AT/AF episodes	0.70
							Treated AT/AF episodes	0.60
	Total	5	185	39 (21.1)	72 (38.9)	74 (40.0)	—	—

AF = atrial fibrillation; AT = atrial tachycardia; D = discard; HP = high priority; ICD = implantable cardioverter–defibrillator; LP = low priority; N/A = not applicable; PM = pacemaker; RRT = recommended replacement time; RV = right ventricle; SVC = superior vena cava.

(which would be accessible to both clinicians and patients) for ICD and PM data.

Importantly, participants with PMs and ICDs were able to prioritize preferred data elements from a comprehensive list of RM data. Battery status (recommended replacement time) was highly prioritized among PM participants but not ICD participants, which may be due to the indication of significant bradyarrhythmia (sinus node dysfunction or atrioventricular block) and effect of intermittent pacing on the battery. In previous research, patients with CIEDs expressed a desire for battery status information.[15,19,21] However, participants with ICDs who received their device for primary prevention of sudden cardiac death may find ventricular events and therapies, and the integrity of the leads involved, to be of the highest priority rather than the battery. The education session prior to the card-sorting prioritization task may have influenced participant choices. Table 4 summarizes the findings from this study that contribute to design recommendations and related implications for patient care.

Future studies

As data from RM become available to patients with all types of CIEDs, efforts to design personalized dashboards for various devices and conditions should build on the current findings to provide meaningful impact. These designs can be tested in a larger pilot study to validate patient needs across populations. Furthermore, personalized dashboards of RM data should be evaluated for their ability to optimize remote data monitoring and enhance communication about the device between patients and clinicians. There is also a need to explore clinicians' preferences and needs for data presentation to facilitate communication through a shared interface.

Study limitations

The study sample was small and predominantly white, which is representative of the population of patients with Medtronic ICDs or PMs in the health system where recruitment took place. No stratification during recruitment was used to increase the diversity of the study sample. Participants were mostly retired, with adequate health literacy and high engagement in their care. Thus, the findings of this study are not generalizable to all patients with ICDs and PMs due to the size and uniformity of the sample. Future research should include a more diverse sample to more thoroughly examine user needs and reduce disparities.[38] Reasons for implant and experience with the device (eg, shocks, generator changes, etc) could impact patients' preferences for RM data and should be examined in future work. Although this

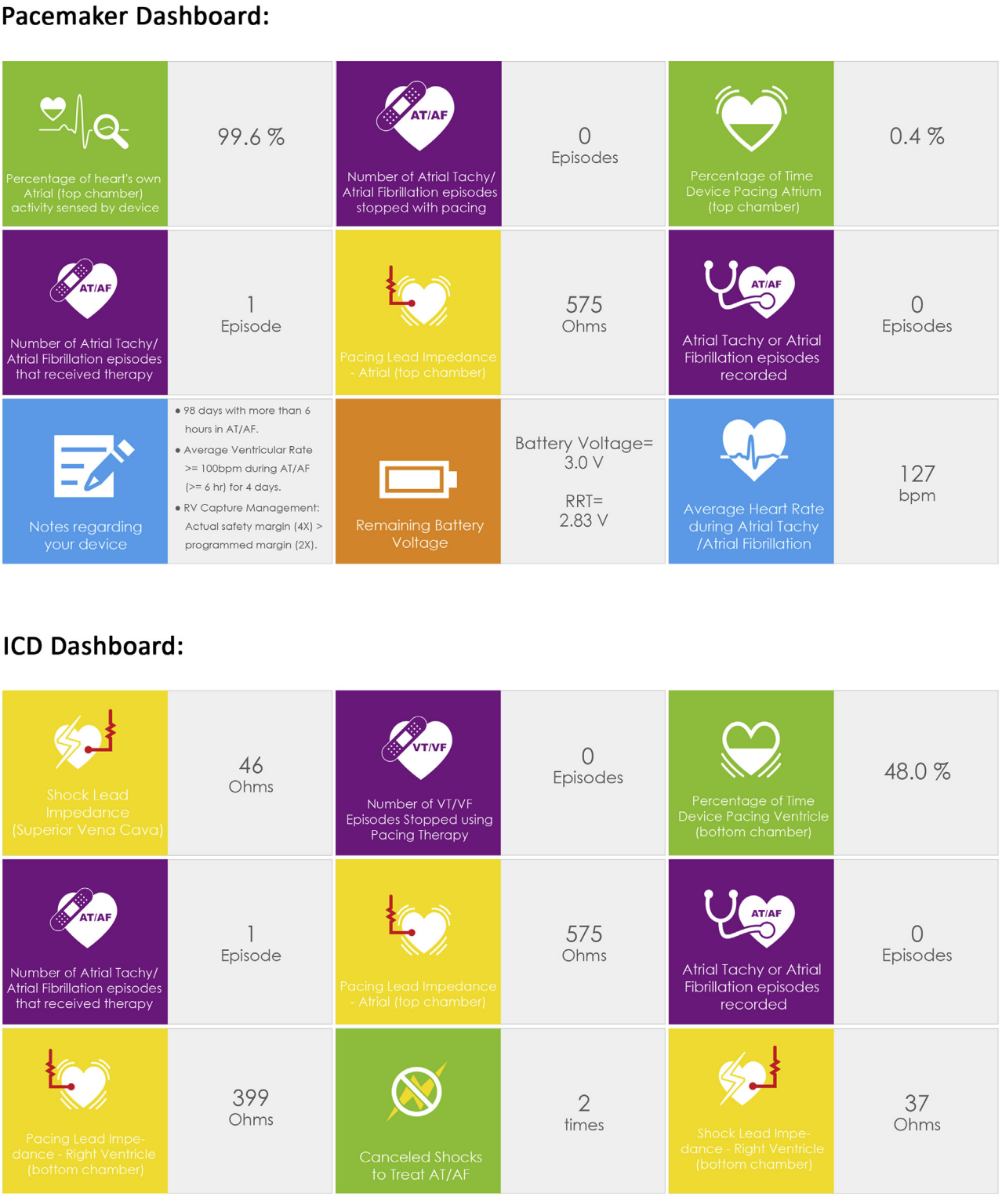


Figure 3 Pacemaker and implantable cardioverter–defibrillator (ICD) dashboards created from phase 2 findings. AF = atrial fibrillation; AT = atrial tachycardia; RRT = recommended replacement time; RV= right ventricle; VF = ventricular fibrillation; VT = ventricular tachycardia.

study provided a descriptive assessment of patient preferences, standard measurements to evaluate interpretation and emotive responses to data and displays would provide additional insight to support design decisions.

Clinical implications

This work provides a foundational step in investigating how to engage CIED patients with their device data. For example, patients with cardiac resynchronization therapy PM and

Table 4 Design recommendations and implications of the findings for sharing RM data with patients

Study finding			
Design category	Preference	Design recommendation	Implication
• Amount of data	• None to as much as possible.	• Integrate a flexible display to allow minimal to high detail of information.	• Understanding how much RM data to share with individuals may be optimized using a shared decision-making process[32] to explore preferences and needs.
• Supporting information	• Include reference ranges, instructions on what to do, and notification that the clinician is seeing the data. • Talking to a clinician may be preferred over digital data alone.	• Provide supplemental information that supports self-care without losing clinician guidance and expertise.	• Supporting information in the dashboard should aim toward establishing connection between patient and clinician, an aspect of in-person visits that is important to some patients.[17,33]
• Language	• Simplify overall and change certain words (eg, "aborted" to "canceled").	• Use language that is familiar and preferable while still clinically accurate.	• Efforts to standardize terminology across device vendors[34] should also consider establishing plain, clear, and familiar language for labeling data in patient-facing interfaces,[35,36] as this may enhance understandability and interpretability for clinicians outside of electrophysiology.
• Frequency	• Most chose "every 3 months," which may reflect their current RM frequency of scheduled transmissions.	• Designs should be adaptable, as patients' needs may change with new experiences.	• Over time, as patients gain experience with monitoring their data and/or changes in health, preferences may change[37] and may need to be re-evaluated.

RM = remote monitoring.

defibrillator devices undergoing treatment for heart failure with reduced ejection fraction have a complex self-care regimen. This cohort could benefit from engaging in their CIED data as part of a holistic care plan that includes optimization of guideline-directed medical therapy and lifestyle modifications (eg, diet and activity). Our future work will focus on subpopulations of CIED patients with specific care needs and measure the impact of patient engagement on medication adherence as well as economic and clinical outcomes. The clinical implications of leveraging CIED RM data would be transformational in caring for patients with advanced cardiac disease.

Conclusion

This study demonstrates that patients with PMs and ICDs were able to prioritize which data were important to them when provided with a list of RM data elements. This user-centered design method demonstrates a valuable approach for developing informative yet simple displays to facilitate understanding and promote self-care. Engaging patients with their data through a meaningful display could help facilitate decision-making between patients and their clinician and optimize the RM aspect of patient care.

Acknowledgments

We would like to thank the participants in this study and staff at Parkview Health. We acknowledge Victor Cornet, MS, and Sarah Ellsworth-Hoffman, MLS, for editorial support.

Appendix

Supplementary data

Supplementary data associated with this article can be found in the online version at https://doi.org/10.1016/j.hroo.2020.04.005.

References

1. Wilkoff BL, Auricchio A, Brugada J, et al. HRS/EHRA expert consensus on the monitoring of cardiovascular implantable electronic devices (CIEDs): description of techniques, indications, personnel, frequency and ethical considerations. Europace 2008;10:707–725.
2. Slotwiner D, Varma N, Akar JG, et al. HRS expert consensus statement on remote interrogation and monitoring for cardiovascular implantable electronic devices. Heart Rhythm 2015;12:e69–e100.
3. Landolina M, Perego GB, Lunati M, et al. Remote monitoring reduces healthcare use and improves quality of care in heart failure patients with implantable defibrillators: the evolution of management strategies of heart failure patients with implantable defibrillators (EVOLVO) study. Circulation 2012;125:2985–2992.
4. Merchant FM, Dickert NW, Howard DH. Mandatory shared decision making by the Centers for Medicare & Medicaid Services for cardiovascular procedures and other tests. JAMA 2018;320:641–642.
5. Slotwiner D, Khaldoun TG, Al-Khatib SM, et al. Transparent sharing of digital health data: a call to action. Heart Rhythm 2019;16:e95–e106.
6. Tarakji KG, Vives CA, Patel AS, Fagan DH, Sims JJ, Varma N. Success of pacemaker remote monitoring using app-based technology: does patient age matter? Pacing Clin Electrophysiol 2018;41:1329–1335.
7. MyLATITUDE™ Patient App. Available at https://www.bostonscientific.com/en-US/products/remote-patient-monitoring/mylatitude-patient-app.html. Accessed November 23, 2019.
8. Sami A, Chen E, Daley C, et al. Innovation in cardiac care: direct transmission of remote implantable cardioverter defibrillator data to patients through their electronic personal health records. Circulation 2014;130(Suppl 2). A16894–A16894.
9. Mirro M, Daley C, Wagner S, Rohani Ghahari R, Drouin M, Toscos T. Delivering remote monitoring data to patients with implantable cardioverter-defibrillators: does medium matter? Pacing Clin Electropysiol 2018;41:1526–1535.
10. Andersen TO, Andersen PR, Kornum AC, Larsen TM. Understanding patient experience: a deployment study in cardiac remote monitoring. In: PervasiveHealth '17: Proceedings of the 11th EAI International Conference on Pervasive Computing Technologies for Healthcare. New York, NY: Association for Computing Machinery; 2017. p. 221–230.
11. Skov MB, Johansen PG, Skov CS, Lauberg A. No news is good news: remote monitoring of implantable cardioverter-defibrillator patients. In: CHI '15: Proceedings of the 33rd Annual ACM Conference on Human Factors in Computing Systems. New York, NY: Association for Computing Machinery; 2015. p. 827–836.
12. Haugaa KH, Potpara TS, Boveda S, et al. Patients' knowledge and attitudes regarding living with implantable electronic devices: results of a multicentre, multinational patient survey conducted by the European Heart Rhythm Association. Europace 2017;20:386–391.
13. Petersen HH, Larsen MC, Nielsen OW, Kensing F, Svendsen JH. Patient satisfaction and suggestions for improvement of remote ICD monitoring. J Interv Card Electrophysiol 2012;34:317–324.
14. Hugo Campos has waged a decade-long battle for access to his heart implant. Available at https://www.economist.com/technology-quarterly/2019/09/12/hugo-campos-has-waged-a-decade-long-battle-for-access-to-his-heart-implant. Accessed November 23, 2019.
15. Patel D, Hu P, Hilow H, et al. The gap between what patients know and desire to learn about their cardiac implantable electronic devices. Pacing Clin Electrophysiol 2020;43:118–122.
16. Ottenberg AL, Swetz KM, Mueller LA, Gerhardson S, Mueller PS. "We as Human Beings Get Farther and Farther Apart": the experiences of patients with remote monitoring systems. Heart Lung 2013;42:313–319.
17. Timmermans I, Meine M, Szendey I, et al. Remote monitoring of implantable cardioverter defibrillators: patient experiences and preferences for follow-up. Pacing Clin Electropysiol 2019;42:120–129.
18. Adler-Milstein J, Embi PJ, Middleton B, Sarkar IN, Smith J. Crossing the health IT chasm: considerations and policy recommendations to overcome current challenges and enable value-based care. J Am Med Inform Assoc 2017;24:1036–1043.
19. Ghahari RR, Holden RJ, Flanagan ME, et al. Using cardiac implantable electronic device data to facilitate health decision making: a design study. Int J Ind Ergonom 2018;64:143–154.
20. Ahmed R, Toscos T, Ghahari RR, et al. Visualization of cardiac implantable electronic device data for older adults using participatory design. Appl Clin Inform 2019;10:707–718.
21. Daley CN, Chen EM, Roebuck AE, et al. Providing patients with implantable cardiac device data through a personal health record. Appl Clin Inform 2017;8:1106–1116.
22. O'Connor S, Hanlon P, O'Donnell CA, Garcia S, Glanville J, Mair FS. Understanding factors affecting patient and public engagement and recruitment to digital health interventions: a systematic review of qualitative studies. BMC Med Inform Decis Mak 2016;16:120.
23. Irizarry T, Dabbs AD, Curran CR. Patient portals and patient engagement: a state of the science review. J Med Internet Res 2015;17:e148.
24. Toscos T, Daley C, Heral L, et al. Impact of electronic personal health record use on engagement and intermediate health outcomes among cardiac patients: a quasi-experimental study. J Am Med Inform Assoc 2016;23:119–128.
25. Klugman CM, Dunn LB, Schwartz J, Cohen IG. The ethics of smart pills and self-acting devices: autonomy, truth-telling, and trust at the dawn of digital medicine. Am J Bioeth 2018;18:38–47.
26. Gould JD, Lewis C. Designing for usability: key principles and what designers think. Commun ACM 1985;28:300–311.
27. Kujala S, Kauppinen M. Identifying and selecting users for user-centered design. In: NordCHI '04: Proceedings of the Third Nordic Conference on Human-Computer Interaction. New York, NY: Association for Computing Machinery; 2004. p. 297–303.
28. Mirro MJ, Ghahari R, Ahmed R, et al. A patient-centered approach towards designing a novel CIED remote monitoring report. J Card Fail 2018;24:S77.
29. Weiss BD, Mays MZ, Martz W, et al. Quick assessment of literacy in primary care: the Newest Vital Sign. Ann Fam Med 2005;3:514–522.
30. Wallston KA, Stein MJ, Smith CA. Form C of the MHLC Scales: a condition-specific measure of locus of control. J Pers Assess 1994;63:534–553.
31. Duke CC, Lynch WD, Smith B, Winstanley J. Validity of a new patient engagement measure: the Altarum Consumer Engagement (ACE) Measure™. Patient 2015;8:559–568.

32. Ali-Ahmed F, Matlock D, Zeitler EP, Thomas KL, Haines DE, Al-Khatib SM. Physicians' perceptions of shared decision-making for implantable cardioverter-defibrillators: results of a physician survey. J Cardiovasc Electrophysiol 2019;30:2420–2426.
33. Kielmann T, Huby G, Powell A, et al. From support to boundary: a qualitative study of the border between self-care and professional care. Patient Educ Couns 2010;79:55–61.
34. Slotwiner DJ, Abraham RL, Al-Khatib SM, et al. HRS White Paper on interoperability of data from cardiac implantable electronic devices (CIEDs). Heart Rhythm 2019;16:e107–e127.
35. Gaglio B, Glasgow RE, Bull SS. Do patient preferences for health information vary by health literacy or numeracy? A qualitative assessment. J Health Comun 2012;17(Suppl 3):109–121.
36. Ivynian SE, Ferguson C, Davidson PM. Time to re-think the terminology of heart failure? Eur J Cardiovasc Nurs 2019;18:648–650.
37. Rapp A, Cena F. Personal informatics for everyday life: how users without prior self-tracking experience engage with personal data. Int J Hum Comput Stud 2016;94:1–17.
38. Toscos T, Drouin M, Pater J, Flanagan M, Pfafman R, Mirro MJ. Selection biases in technology-based intervention research: patients' technology use relates to both demographic and health-related inequities. J Am Med Inform Assoc 2019;26:835–839.