Patient and Provider Perspectives on Remote Monitoring of Pacemakers and Implantable Cardioverter-Defibrillators

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The use of remote monitoring technology for cardiovascular electronic implantable devices has grown significantly in recent decades, yet several key questions remain about its integration into clinical care.

We performed semi-structured interviews of patients, clinicians, and device clinic technicians involved in clinical remote monitoring of cardiovascular implantable devices at our institution. Twenty-eight interviews comprised of 15 patients and 13 clinicians were conducted from October 2019 through February 2020. Interview transcripts were analyzed using a mixed inductive and deductive approach.

Perspectives among clinicians and patients varied regarding familiarity, educational experiences, and preferences regarding how remote monitoring data are handled. Three key domains emerged including knowledge and understanding, managing alerts, and cost transparency. Within these domains, key findings includedvery limited understanding of how remote monitoring functions and how alerts in particular are handled. These knowledge deficits (both patients and providers) appeared to arise in part from different equipment and platforms among manufacturers, the complexity of the technology, and lack of formalized education in remote monitoring. However, interviewees expressed generally high levels of trust in the technology and care systems supporting remote monitoring. Few respondents described concerns around cybersecurity, but patients in particular did raise concerns about cost transparency and frequent billing. In conclusion, conflicting perceptions around remote monitoring persist and indicate important knowledge gaps despite high trust in the care pathway. This qualitative analysis offers insight into patient and clinician understanding of and attitudes toward remote monitoring, and may guide future efforts to improve education and patient-centeredness of remote monitoring. **(Am J Cardiol 2021;149:42−46)**

Remote monitoring for heart rhythm devices has advanced rapidly to include nimble diagnostics for clinical management.[1] Current pacemakers and implantable cardioverter-defibrillators (ICDs) are paired with manufacturer-specific "base stations" in patients' homes, or connected to a smartphone app. Either method generally communicates with the ICD or pacemaker once daily, and selected findings are relayed to servers maintained by manufacturers. Studies support the usefulness of pacemaker and implantable cardioverter-defibrillator (ICD) remote monitoring to rapidly identify abnormal device function and reduce office visits.[2-7] Remote monitoring in real-world settings appears under-utilized, however, and several key questions about its integration into clinical care remain largely unexplored.[8] In particular, it is unclear whether patients and providers understand many details about the use of remote monitoring, communication of important findings, and other areas of knowledge, preferences, and expectations. Understanding all parties' views, and potential areas of disagreement or conflict, is a critical prerequisite to incorporating informed consent or user contracts into remote monitoring clinical care. Thus, this qualitative study explored knowledge, expectations, preferences, economics/costs, and privacy involved in the remote monitoring of CIEDs.

Methods

We performed semi-structured interviews of patients and providers involved in clinical remote monitoring of CIEDs. We selected a qualitative approach given a lack of data evaluating the perspectives of these groups on remote monitoring either in isolation or compared directly. Structured interviews were chosen rather than surveys in order to allow for more open-ended responses within broad categories of interest. This study was approved by the Beth Israel Deaconess Medical Center institutional review board. Verbal consent was obtained at the time of the interview. Because of the nature of the data collected, data sharing including the transcripts is not feasible for this study.

Study participants came from the Beth Israel Deaconess Medical Center, an academic referral center in Boston,

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Massachusetts. Two populations of interviewees were identified for this study. For providers, we recruited physicians, nurses, nurse practitioners, and device clinic technicians by email. We purposely sought to include providers across the spectrum of professional licensure and day-to-day integration with remote monitoring to capture a broad array of perspectives. Those responding with interest provided the sample of providers.

Patient participants were identified in two ways. First, during pre-selected weeks of recruitment, all patients with ambulatory device clinic appointments were noted and eligible subjects identified based on the following criteria: 1. English-speaking; 2. Presence of CIED capable of remote monitoring; 3. Sufficient cognitive function to provide consent and participate in meaningful discussion. All eligible subjects were asked about interest in the study and provided a study information sheet if preliminary interest was indicated. The study team then contacted these patients to confirm interest in participation, and to schedule the study interview. In addition, a small number of patients became aware of the study through discussion with providers and volunteered to participate.

Interviews were conducted either in person or by phone at the interviewees' convenience. The interview guide was developed iteratively by the study investigators. First, selected demographics and interviewee characteristics were selected for the purpose of characterizing the cohort. Next, general areas of interest were identified and used to develop several questions within each area with prompts to promote further comment (see interview guides for patients and providers in the supplement). Overall, the interview was designed to solicit views regarding remote monitoring knowledge, expectations, preferences, economics/costs, and privacy. Interviews were performed by the first author (AMF) a cardiology fellow who was not involved in the clinical care of any of the patient participants and by two research coordinators (WG and FAB). Interviews were purposefully not conducted by one author (DBK) whose clinical or institutional relationship with participants might have interfered with interviewee candor. All interview audio was digitally recorded and professionally transcribed and reviewed for accuracy.

Interview transcripts were entered into the Dedoose Version 8.3.35 web application which is designed for the purposes of managing, analyzing, and presenting qualitative and mixed method research data (2020).[9] We utilized a mixed inductive/deductive approach to analysis where some codes were based on the domains of interest while others were allowed to emerge inductively. We then began the process of analyzing the transcripts for codes and subcodes through studying the interviews. The initial codebook was analyzed by the multidisciplinary group including the senior author who purposefully did not interview participants. Two members of the team (AMF and FAP) blindly reviewed the transcripts to apply codes and subcodes to the interviews utilizing the final code book that came about through multidisciplinary meetings among the authors to edit and/or add codes to reflect key issues brought about by the interview transcripts. Once the initially open coding was complete, we met again as a multidisciplinary group to discuss emerging themes and to ensure comprehensiveness and compare impressions to attempt to avoid potential bias. We repeated this process of discussion and returning to the transcripts using the constant comparative method.

Results

Interviews were conducted from October 2019 through February 2020. Twenty-eight interviews were conducted in-person or by telephone based on patient or clinician preference. The interviewees were comprised of 15 patients and 13 clinicians. Of the clinicians, 6 were non-electrophysiologist cardiologists; 2 were electrophysiologists; 2 were device nurses; 2 were device technicians; and 1 was a cardiology nurse practitioner. There was an equal distribution between ICDs and pacemakers among the patients interviewed. Of the participants, 32% were female, 82% identified as white/Caucasian, 10% Asian, 4% Black, and 4% Hispanic. The average age of the interviewees was 61 (range 27−84 years). The majority of participants had college (46%) or some degree of post-graduate (43%) education training.

Perspectives varied regarding familiarity, experiences, and preferences regarding remote monitoring technology and how the data is handled. Three domains with several themes emerged surrounding the use of remote monitoring. The domains included knowledge and understanding, managing alerts, and cost transparency. Within the knowledge domain, limited understanding of how remote monitoring works, reactions to knowledge gaps ranged from little concern to alarm, and a desire for formalized training in remote monitoring surfaced as themes. The alert domain included opinions regarding alert customization and conflicts between patient trust and autonomy. Finally, cost transparency prior to device placement was a distinct area of interest. Representative participants' responses within these domains are presented below.

Most patient and physician interviewees articulated some lack of knowledge surrounding how remote monitoring functions. These knowledge gaps were highlighted in patients when participants were asked to compare remote monitoring technology to inpatient telemetry.

> *"It's probably the same. I don't see where it would be any different, whether I'm in the hospital, and they're monitoring it, or I'm doing it via remote. The technology is the same."* −-patient

Many participants, particularly patients, admitted a lack of understanding about how remote monitoring works, yet also felt that this was *not* concerning as long as the device did what it was designed to do.

> *"What you're asking is 'Do I understand how my refrigerator works?' Or 'Do I understand why my car is able to go when I turn on the ignition and how all the parts are working?' I don't understand how my car works at all. I go in and turn the key and it runs. The refrigerator runs. The TV runs. So, I have no understanding of how this all works. It's fascinating, but I don't think it's necessary that I understand as long as it does work."* − patient

> *"It sits there. It minds its business and I mind mine."* − patient

Additionally, clinicians and device clinic staff recognized substantial knowledge gaps surrounding how remote monitoring works, yet articulated that if educational resources exist, complete understanding is not required.

"I think [my understanding of how remote monitoring works] could be better with the caveat that this is not something, to my opinion at least, it's not something that's my direct purview or that's directly for me to oversee. I view it as something that's under the domain of EP. So, they need to know everything about it. I need to know something about it." – cardiology NP

By contrast, several providers and a few patients did express concerns about knowledge deficiencies regarding remote monitoring. Some physicians appeared embarrassed by how little they understood the technology:

"I mean I guess I probably should understand a little bit more about how it works as far as just the mechanics of it. I just assumed it was a phone transmission and that. But the exact nuts and bolts, I don't really have a good understanding of that." - clinician

Both patients and clinicians described insufficient formalized education in remote monitoring. Several clinicians described training as mostly experience-based during clinical activities. Many interviewees supported formalized education in remote monitoring. Patients also articulated limited memory of formal education regarding the device and how it functions.

"Between having been in a coma much of that time and I guess having several sessions of sedation, I must admit I remember nothing of what I was told in the hospital about the device." - patient

Some clinicians and patients felt that patient preferences should be integrated into remote monitoring alerts. However, opinions how the alerts should be tailored to preferences were more variable. Some interviews felt that patients should be notified for all alerts, but it was the viewpoint of others that that only life-threatening alerts should be communicated:

"*I think that each patient should be viewed as a unique individual. I think what I would probably do is ask the patient before the fact. Give him or her some scenarios and say "In this circumstance how would you like us to handle it?" because I think you'll get very different answers from different patients. That in an ideal world would be the way I would handle it... But you want to kind of ascertain patients' attitudes on a bell curve and then try and meet those needs to the best degree you can. It's not easy*. " - clinician

A struggle emerged between patients and clinicians surrounding expectations about remote monitoring as a 24-hour safety mechanism. Several patients described remote monitoring as akin to an alarm system whereas device clinic providers explicitly stated they purposefully attempt to educate patients to the contrary in order to empower them not to rely on remote monitoring.

"If it's not like a burglar alarm system or a fire alarm system where it's designed to give them a remote trigger, so if it's just being collected for the sake of longitudinal studies or something like that, I wouldn't expect them to be calling me at all. But if in fact it's supposed to be of some benefit to me? I would certainly expect that." - patient

"But we do make sure they know that 'This is not 24-hour manned. Someone's not always looking at these things' and that kind of thing… After-hours or weekends, again, we are very clear with the patients when they first come in that 'There is no one looking at these on the weekends or that kind of thing, holidays or weekends. If you're having symptoms, you need to reach out to...' - clinician

"It's not a substitute for actual medical care. I think the best you can do is provide timely response and then educate them on what to do should they develop worrisome symptoms off-hours." - clinician

This dichotomy between patient desire for immediate notification and clinical filtering is highlighted when the timing of device alerts was addressed.

"Anything more severe is probably something that I would detect myself in my health and probably would take action on my own if it was something that demanded immediate action." - patient

"Obviously, I should be informed immediately. I'll probably be on my way to the emergency room anyway." - patient

Finally, cost transparency prior to device implantation was important to both patients and clinicians.

"Then some patients, depending on their plan, have a high copay. Really, I think it's something that should've been considered before that mode of monitoring was considered for the patient and discussed with them and it's not." - device clinic nurse

"The biggest concern I have is lack of price transparency before the fact. For example, I had no clue about whether there would be any cost involved in monitoring the device and I was never informed of that." - patient

"I just think some sort of notification prior to the device implant that there could be a cost incurred would be so dramatically helpful so that they're not as surprised. We feel so bad as techs and nurses when they already have this device implanted and we see them at the…wound-check. We don't want to tell them at that point that they're going to be billed…because then they're going to be like "I want this taken out." And there's nothing we can do about it now, so we're always kinda stuck between a rock and a hard place." - clinician

Discussion

The aim of this qualitative study was to understand patient and clinician perceptions regarding remote monitoring of CIEDs. Several noteworthy findings materialized through our analysis of the interviews: First, all types of stakeholders described a limited understanding of how remote monitoring functions and how alerts are handled. These knowledge deficits appeared to arise in part from different equipment and platforms among manufacturers, the complexity of the technology, and lack of formalized education in remote monitoring. Two, even interviewees admitting to knowledge gaps did not find this troublesome, expressing high levels of trust in the technology and care systems supporting remote monitoring. Three, while trust appeared high overall and diminished concerns around issues such as cybersecurity, patients did articulate concerns about cost transparency and frequent billing. This particular concern emphasizes a tension between the optimal use of remote monitoring for patient care and the lived experience of the technology.

Heart Rhythm Society guidelines from 2015 emphasize the critical role of communication during patient enrollment in remote monitoring including thorough education regarding the role and limitations of the technology as well as documentation of this education process.[1] Yet consent forms or contracts vary widely in content, and their utilization is not well-characterized in actual practice.[10] One reason for this may be an incomplete understanding of patients' experiences with this care. For example, in the Effect of Remote Monitoring on Patient-reported Outcomes in European Heart Failure Patients with an Implantable Cardioverter-Defibrillator (REMOTE-CIED) trial, nearly 600 patients were assessed with patient-reported outcomes comparing in-office evaluation alone versus the addition of remote monitoring using established questionnaires.[11] There were no differences seen across the two groups, suggesting limited appreciation of the benefits of remote monitoring or actual satisfaction with its use. This is in contrast with single-arm surveys identifying high satisfaction among remote monitoring users, including a subgroup analysis of the remote monitoring arm in REMOTE-CIED.[12] Importantly, studies have shown a "dose-response" relationship between adherence and outcomes for remote monitoring, suggesting that engaging patients successfully is critical to maximizing its benefits.[8]

Our interviews also shed light on the range of opinions concerning the management and customization of remote monitoring alert findings. Notably, clinicians wanted to involve patients in the decision-making process regarding the nature of alert communication. However, this was described as the ideal scenario, and the actual real-world implementation of this was felt to be more challenging given personnel needs, diverse technology capabilities, the variability of patient and physician preferences, and the incredible amount of data available. Most participants felt that life threatening alerts should be communicated in a timely if not immediate fashion. However, there were knowledge gaps about how this is actually accomplished in both patients and clinicians (the latter excluding device clinic representatives). While patient-level customization of alert conditions and communication has some appeal clinically and appears supported by our interview data, applying this in practice to hundreds or thousands of patients (in a modestly sized clinic) or millions of patients nationwide would not be practical. Design of consent forms will therefore need to confront this tension.[6,13]

Similarly, consent forms need to explicitly incorporate costs and burdens on individual patients since this was emphasized as a significant issue in the interviews. Yet, the actual costs may be difficult to ascertain at the patient level. Most insurance schemes make patient responsibilities for specific services opaque, and these may vary according to deductibles, secondary insurance, and other factors. This will challenge efforts to promote cost transparency in practice.

Improvement around knowledge, alerts understanding, and cost transparency might converge going forward by shifting remote management towards an alerts-only system that reduces the stream of patient data towards actionable findings, while harmonizing the way in which remote monitoring functions across manufacturers. Use of artificial intelligence and other techniques may improve the signal/noise ratio, while data management solutions increasingly support clinic sites' ability to monitor patients in a dashboard-like platform that confirms connectivity without generating huge amounts of notes and formal clinical encounters that subsequently generate bills. This paradigm of an alerts-driven, dashboard-like scheme has both empirical and theoretical support based on current technology, and may be simpler to explain to stakeholders then the current hodgepodge of strategies.[14,15] Further expansion of remote monitoring to include wearables and consumer-driven devices will put further strain on clinical systems, making patient-centered integration even more critical.[16]

Our study should be viewed with certain limitations in mind. First, interviews were completed at a single academic institution with patients identified both through random screening at the time of an in-person visit in the electrophysiology clinic and through volunteering in conversation with a provider about the study. The latter presents a potential for selection bias whereby patients who may have had more provocative views were included. Our sample also included high proportions of higher education, which may influence generalizability. However, this was a small sample of the patients interviewed and in general seemed to lead to robust dialogue and similar themes emerged to patients screened and included otherwise. Both non-electrophysiology-trained cardiologists, electrophysiologists, device clinic technicians and nurses, and one heart failure nurse practitioner were interviewed in the study which may have influenced responses regarding remote monitoring knowledge base. Additionally, we attempted to avoid bias by eliminating the senior author from coding and initial data analysis and reviewed codes and themes with a multidisciplinary team including non-clinicians. Finally, our questionnaires attempted to generate in-depth inquiry into a variety of subjects pertaining to remote monitoring perceptions of patients and clinicians. Still, there are issues not addressed during our thirty-minute interviews that may warrant on-going exploration and inclusion into the advancement of remote monitoring practices.

In summary, remote monitoring provides opportunities for improved patient care, but is underutilized and confusing to many stakeholders. Our qualitative assessment points towards potential ways to improve the uptake and patient-centeredness of remote monitoring and to ensure that all participants are thoughtfully engaged in a positive way in this useful clinical practice.

Authors Contribution

Fraiche: Methodology, Investigation, Data Curation, Writing – Original, Writing – Revisions. Matlock: Methodology, Data Curation, Writing – Revisions. Gabriel: Methodology, Investigation, Data Curation. Rapley: Investigation, Data Curation. Kramer: Conceptualization, Methodology, Writing – Original, Writing – Revisions, Funding, Supervsion, Project Administration.

Disclosures

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Supplementary materials

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