Remote monitoring of cardiac implantable electronic devices in Australia, barriers and enablers of routine clinical practice implementation

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Abstract

Background: The use of remote monitoring technology for patients with cardiac implantable electronic devices (CIED) is the standard of care as highlighted by international guidelines. However, remote monitoring has not yet been integrated to universal, routine clinical practice.

Objective: We aimed to identify barriers and enablers of routine implementation of CIED remote monitoring.

Methods: We conducted semi-structured interview to explore the barriers and enablers encountered when incorporating remote monitoring to CIED management. Participants included a broad range of stakeholders including cardiologists, cardiac clinicians/physiologists, nurses and patients. Interviews were transcribed verbatim and analysed through inductive thematic analysis and deductive approaches. We used the theoretical domains framework to understand barriers and enablers through an implementation science lens. Our study aligns with the COnsolidated criteria for REporting Qualitative (COREQ) research checklist.

Results: 35 interviews were conducted, including 16 patients, 10 cardiologists, and 9 cardiac physiologists and nurses. Five main themes and 13 subthemes were identified. The five main themes and the associated subthemes were 1) Patient benefits from remote monitoring, such as improved CIED and Cardiovascular management, and improved patient-centred care; 2) Insufficient allocation of CIED remote monitoring resources, which included insufficient funding and staffing, insufficient reimbursement, infrastructure and access inequity; 3) Suboptimal management of data which includes inconsistent workflow, lack of guidance for clinic staff and has resulted in an increased alert burden; 4) Insufficient patient education post-CIED implant, this was attributed to limited healthcare worker availability and resulted in inadequate patient knowledge and anxiety associated with remote monitoring; and 5) Patient engagement with CIED management, which included the need for increased patient interaction and ability to share data with patients. These subthemes were mapped to 6 specific domains of the theoretical domains framework: ‘Beliefs about capabilities’, ‘Environmental Context and Resources’, ‘Beliefs about consequences’, ‘Knowledge’, ‘Emotions’, and ‘Goals’.

Conclusions: Patient engagement was identified in 3 of the 5 themes describing barriers and enablers to RM. These highlight the importance of addressing patient engagement with RM to better implement and integrate the use of RM into routine clinical practice. Barriers and enablers extend across multiple domains and suggest a multi-pronged approach is required to translate the gold standard care of remote monitoring to routine clinical practice.

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Background

The use of remote monitoring (RM) is the standard of care for patients with cardiac electronic implantable devices (CIED), and is poised for wider adoption in the coming years, backed by growing endorsements from large cardiac societies such as the Heart Rhythm Society and Cardiac Society of Australia and New Zealand [1, 2]. Whilst this uptake in RM is a positive move for improving patient care, in-turn it raises concerns about the capacity for device clinics to manage the associated workload [3, 4]. Recent studies have estimated that managing 1000 CIED patients with RM necessitates a workforce commitment of approximately 30-46 hours per week by the clinical team [5].

The relative novelty of the technology creates challenges when incorporating CIED remote monitoring into clinical practice. Insufficient funding, lack of appropriate infrastructure and lack of standardised workflow are commonly cited barriers [3, 4, 6, 7]. Furthermore, despite some cardiac organisations placing a greater emphasis on patient engagement in the CIED, engagement initiatives are lacking, particularly surrounding patient education and information delivery [8, 9]. The research to date suggests that implementation of RM requires cohesive management among many stakeholders such as cardiologists, nurses, cardiac physiologists, and patients.

It is recognised across multiple sectors of healthcare that effective and sustainable implementation of research and innovations into clinical care relies on relevant stakeholders input into integration of the intervention [10]. A comprehensive implementation analysis of RM across all relevant stakeholders has not been conducted internationally. Currently, there is a scarcity of information on stakeholder perspectives of the barriers and enablers of CIED remote monitoring. Thus, our study aimed to 1) establish broad stakeholder perspectives on issues surrounding the routine implementation of CIED RM and 2) apply the theoretical domain framework to highlight through an implantation science lens, the most effective approaches to facilitate routine adoption of CIED RM.

Methods

Study overview

This was a qualitative study, using semi-structured interviews to explore individual perspectives on barriers and facilitators to RM of CIED devices and patient engagement. This study adhered to the COnsolidated criteria for REporting Qualitative (COREQ) [11] research checklist for study execution and subsequent reporting. Ethics approval was granted by the Western Sydney Local Health District (2022/ETH00271).

Theoretical Domains Framework

We used the theoretical domains framework (TDF) to understand barriers and enablers through an implementation science lens. The TDF is comprised of 14 domains and 84 constructs to bring together many behaviour-change theories. It was designed to bridge the gap between behaviour-change theory and various medical disciplines, making it both accessible and applicable for a wide range of healthcare professionals [12].

Research team and reflexivity

The research team was composed of cardiologists (CC, AL, SL, AS, KC), a doctor-in-training and PhD student (BS), clinical researchers (EO, CC, AL, SL, AS, KC) and digital health expert (TS). Researchers (BS, EO, CC and TS) have experience conducting qualitative research while clinician-researchers (CC, AL, SL, AS, KC) have clinical cardiology experience. Interviews were conducted by lead researcher (BS). Participants were aware that the interviewer was a PhD student and doctor-in-training; however, had not met him prior to their interview.

Study setting and recruitment

Between July 2022 and April 2023, we identified stakeholders (cardiologists, cardiac physiologists, nurses and patients) who either utilised RM or were involved in analysing and deciding on appropriate action for the data/alerts received via CIED remote monitoring, from 5 hospitals providing CIED and at least some RM services to urban and regional areas of New South Wales (NSW) Australia: Westmead, Wollongong, Royal Prince Alfred, Concord and, John Hunter. Stakeholder eligibility criteria included being 18 years or older, and English speaking. Patient-specific criteria included currently having a CIED in-situ which is undergoing RM. Cardiologist

specific criteria included being a consultant, public hospital or private practice based and managing at least one patient currently receiving RM. Cardiac physiologist and nurse specific criteria included managing at least one patient currently receiving RM and public hospital or private practice based.

Procedure / Data collection

Specific interview guides (Supplementary appendix box 1) were developed based on the stakeholder being interviewed (cardiologists, cardiac physiologists, nurses/allied health clinicians and patients). The interview guides explored 1) stakeholder perspectives on the barriers and facilitators of CIED remote monitoring and 2) patient engagement with CIED and overall CVD management. To develop the interview guides, we conducted a comprehensive literature review, identifying relevant articles on patient perspectives and existing interview guides used in similar studies. Interview guides were further refined after consulting with a cardiologist and conducting pilot interviews to ensure the questions were clear, comprehensive, and appropriate for the target audience. Potential clinical participants (cardiologists, cardiac physiologists, and nurses) were identified through snowball sampling conducted by the principal investigators and clinical staff from each site, then invited to participate either via email or in-person. Patients were identified through convenience sampling by site clinicians and were invited to participate via phone call or in-person. There were no dropouts and all participants who were approached agreed to partake in the study. Participants were consented either electronically or verbally prior study commencement. All interviews were conducted either over telephone calls or in-person at a CIED clinic with only the researcher present. Interview duration ranged between 15-45 minutes and were conducted until data saturation occurred, where new concepts were not emerging. Interviews were audio recorded and transcribed verbatim, without field notes being taken. Participants did not receive a copy of the transcript to review nor provide feedback on study findings.

Data analysis

Interview transcripts were uploaded to NVivo 14 (QRS International Pty Ltd., Melbourne, Australia) software. Two investigators (BS and EO) analysed using a hybrid approach, combining the benefits of an inductive thematic analysis with a deductive approach [13] to represent the data in a generalisable way using the TDF (Figure 1).

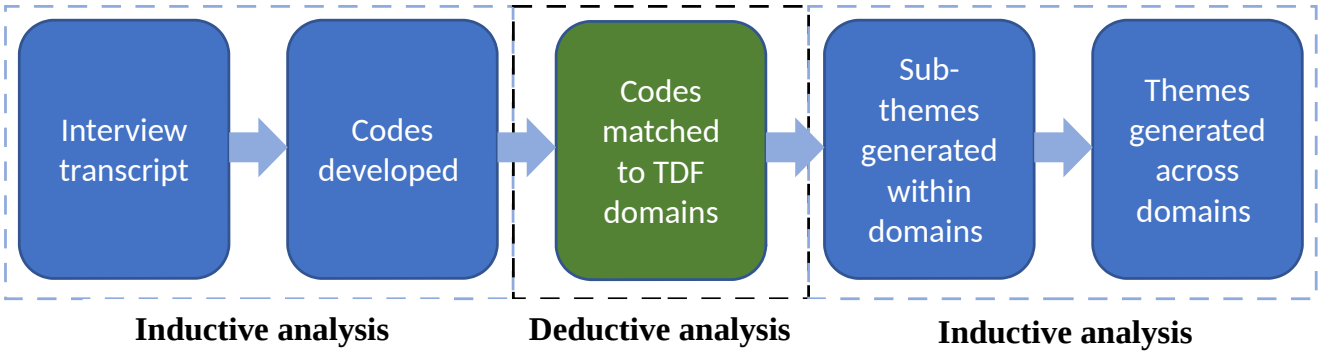

Figure 1: Thematic analysis of the interview data using an inductive and deductive approach

Data were analysed in an iterative process. Initially two researchers (BS, EO) read and re-read the first 5 transcripts and coding fragments relevant to the research question. The codes were reviewed, discussed, and deliberated between investigators (BS and EO) to compare the data interpretation. The deliberation aimed to ensure we had comprehensively covered all aspects of the research question, to explore any potential nuances in the interpretation and resulted in the initial codebook development. One investigator (BS) continued analysis of the remaining transcripts. This process was continually reviewed with refined versions of the codebook reviewed by investigator (EO).

Using a deductive analysis approach, codes were then matched to the appropriate TDF domains. This process was reviewed, discussed, and deliberated between investigators (BS and EO) until consensus was reached and consistent.

One investigator (BS) used an inductive analysis approach to develop sub-themes from the codes before developing over-arching themes [14]. Themes and sub-themes were generated from codes across all participants, rather than stratifying by stakeholder title (cardiologists, cardiac physiologists, nurses, and patients). This process was reviewed and discussed between investigators (BS and EO) until consensus was reached resulting in the final data output.

Results

A total of 35 interviews were conducted between July 2022 and April 2023. 16 of the interviews were conducted with patients, 10 with cardiologists and 9 with cardiac physiologists and cardiac nurses. Mean patient age was 73.1 (standard deviation (SD) 10.7) years, majority were male (75%), and born in Australia (75%). Pacemakers (50%) were the most common CIED type, and mean duration of RM was 4.3 (SD 2.6) years. Mean cardiologist age was 46.2y (SD 6.3), majority were

male (90%), sub-specialised in electrophysiology (70%), had a mean duration of 12.3 (SD 6.6) years as a cardiologist and a mean duration of 7.7 (3.6) years managing patients with RM. Mean physiologist/nurse age was 36.6 (sd9.4), majority were female (56%), and had a mean duration of 4.3(SD 2.6) years managing patients with RM. Participant demographic and clinical experience results are presented in table 1.

Table 1. Demographic, CIED and RM characteristics of n=35 interviewed stakeholders

Characteristic	n (%)
Patients	**16**
Age, years [mean (SD)]	73.1y (10.7y)
Male [n (%)]	12 (75%)
Country of birth [n (%)]	
Australia	12 (75%)
England	3 (19%)
Lebanon	1 (6%)
CIED indication [n (%)]	
VT Primary prevention	7 (44%)
Atrial fibrillation	3 (19%)
Bradycardia	3 (19%)
Syncope	1 (6%)
Arrhythmia (Unknown to patient)	2 (12%)
CIED type [n (%)]	
Pacemaker	8 (50%)
Defibrillator	5 (31%)
CRT-P	3 (19%)
Duration receiving RM, years [mean (SD)]	4.3y (2.6y)
Physiologists / Nurses	**9**
Age, years [mean (SD)]	36.6y (9.4y)
Male	4 (44%)
Location	
Western Sydney	5 (55.6%)
Illawarra	1 (11%)
Newcastle	2 (22.2%)
Sydney	1 (11%)
Duration managing RM, years [mean (SD)]	6.1y (2.6y)
Cardiologists	**10**
Age, years [mean (SD)]	46.2y (6.3y)
Male	9 (90%)
Location	
Western Sydney	3 (30%)
Illawarra	1 (10%)
Newcastle	3 (30%)
Sydney	3 (30%)

Cardiologist sub-specialty	
Electrophysiologist	7 (70%)
Heart failure specialist	2 (20%)
Proceduralist	1 (10%)
Duration as cardiologist, years [mean (SD)]	12.3y (6.6y)
Duration managing RM, years [mean (SD)]	7.7y (3.6y)

Themes and sub-themes are summarised in Figure 2, with sub-themes and codes described below. Illustrative quotes for each sub-theme and code are presented in supplementary tables S1-13 in the supplementary appendix.

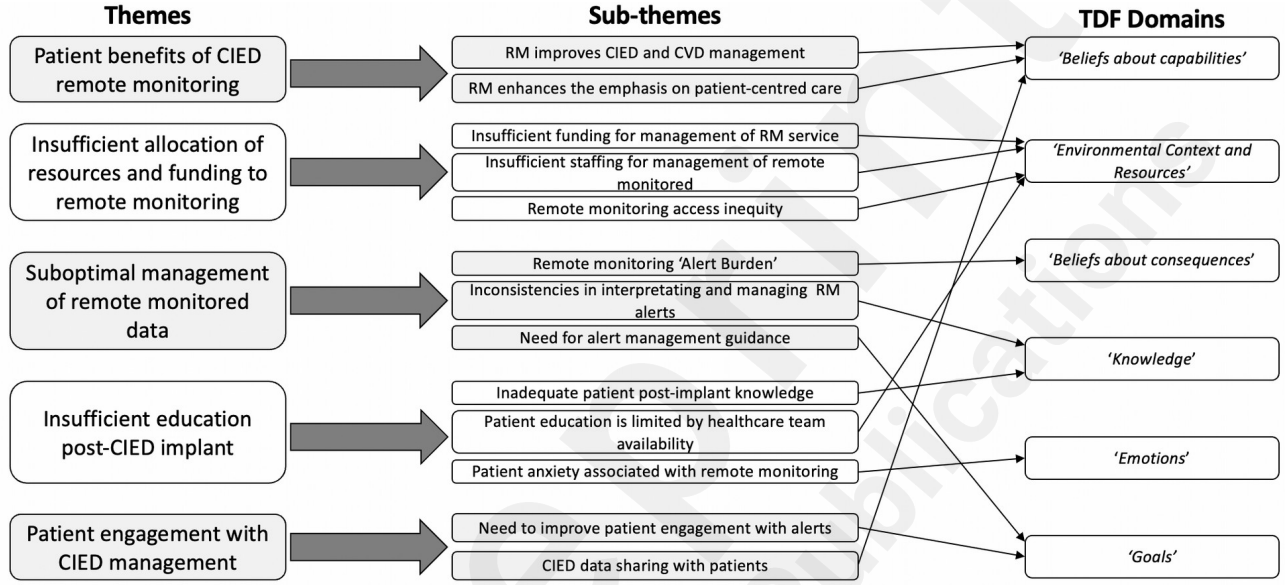

Figure 2: Themes and sub-themes emerged from qualitative thematic analysis with allocation to the relevant TDF domains

Theme 1: Patient benefits on remote monitoring

RM improves CIED and CVD management - The main benefits noted by stakeholders included the improved patient treatment outcomes facilitated by RM (supplementary appendix table S1, quotes 1-3). These benefits were perceived to be largely driven by earlier detection of clinical issues (supplementary appendix table S1, quotes 4-9), reduced post-implant issues (supplementary appendix table S1, quotes 10-11), prevented hospital admissions (supplementary appendix table S1, quote 12) and deployment of a service to rural and remote patients who otherwise have restricted access to CIED care (supplementary appendix table S1, quote 13). Furthermore, clinicians reported RM-based care enabled CIED management to be provided to patients without face-to-face review during the COVID-19 pandemic (supplementary appendix table S1, quote 14).

RM enhances the emphasis on patient-centred care - Cardiologists noted RM processes

are designed to be user-friendly for patients (supplementary appendix table S2, quote 1). Physiologists highlighted that RM facilitates improved care for patients in nursing homes, who previously had difficulties attending face-to-face clinics (supplementary appendix table S2, quote 2). Patients expressed gratitude for the reduced hospital visits required for CIED reviews (supplementary appendix table S2, quote 3). Additionally, patients reported a sense of safety derived from having the healthcare team monitor their data through RM (supplementary appendix table S2, quotes 4-5).

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Theme 2- Insufficient remote monitoring resources, funding and recognition of workload and skills

Funding for management of RM service – Barriers to the implementation and management of RM were centred around inadequate funding for clinics within the public sector. Cardiologists and physiologists reported that current reimbursement schemes fail to recognise the extensive tasks involved in providing the RM service and in-turn do not provide adequate funding to deliver the service for improved patient care (supplementary appendix table S3, quotes 1-7). Currently, clinicians reported that the delivery of RM comes with additional costs to the CIED clinics (supplementary appendix table S3, quote 8) with some public hospitals reluctant to cover these costs despite the patient benefits (supplementary appendix table S3, quote 9). Due to the inadequate funding, some clinicians reported they are unable to employ adequate staff to manage RM alerts (supplementary appendix table S3, quote 10). Improved funding, infrastructure and recognition by health services was recommended for RM development (supplementary appendix table S3, quotes 11-12).

Staffing for management of remote monitored alerts – Interpreting and responding to alerts can be time-consuming due to the range of ‘invisible’ tasks required, which includes but not limited to confirming the alert accuracy, reviewing previous alerts, re-programming, patient history and medications, patient contact, re-programming, education, report development and cardiologist escalation. Time to complete these tasks varyied among physiologists based on their experience and confidence levels (supplementary appendix table S4, quote 1). Physiologists mentioned there are an inadequate number of staff employed to manage the RM workload (supplementary appendix table S10, quotes 2-4), which can result in alerts not being managed in a timely fashion (supplementary

appendix table S4, quote 5). Cardiologists mentioned that physiologists need more allocated time to manage alerts and scheduled reviews (supplementary appendix table S4, quote 6). Additionally, some cardiologists reported not having the capacity to review RM alerts (supplementary appendix table S4, quote 7).

Remote monitoring access inequity – Not all patients receive RM, and factors associated with receiving RM drive inequity in access (supplementary appendix table S5, quotes 1-2). Cardiologists identified some of these factors: public payment models are poorly suited to provision of RM, existing health services may not provision RM support and smaller services may not have the skill mix to support RM (supplementary appendix table S5, quotes 3-4). Additionally, smaller cardiology clinics often lack the necessary resources and capacity to offer the service (supplementary appendix table S5, quote 5). Other factors hindering the equitable distribution of RM include the incompatibility of CIEDs, with many older models unable to support this technology (supplementary appendix table S5, quote 6), and inadequate patient internet access, particularly affecting rural patients (supplementary appendix table S5, quote 7).

Theme 3: RM data management burden and risks

Remote monitoring 'Alert Burden' – Reviewing and managing alerts transmitted through RM was reported to be a time-consuming process for CIED clinic staff due to the range of 'invisible' clinical and non-clinical tasks associated with alert receipt (supplementary appendix table S6, quotes 1-3). Physiologists partly attributed this alert burden to their inability to modify alert parameters due to manufacturer system restrictions (supplementary appendix table S6, quotes 4-5). Additionally, the transmission of alerts which are false positives further amplifies the workload for physiologists, which will only worsen with increasing CIED implants and RM utilisation (supplementary appendix table S6, quote 6). Consequently, the heightened alert burden resulting from a generalized alert setup and increased workload may compromise patient care and raise the likelihood of overlooking critical alerts (supplementary appendix table S6, quotes 7-8).

Inconsistencies in interpretating and managing RM alerts – Physiologists raised that there is lack of uniformity in knowledge, skills, experience and training to manage RM alerts (supplementary appendix table S7, quotes 1-3). It was noted that in some countries cardiac physiologist workforce regulation requires registration with a Clinical Physiologists Registration

Board, but in other countries like Australia, this is not mandatory. It was also raised that the lack of more specific clinical guidelines, or pragmatic training on responding and managing RM alerts presents risks and challenges to service delivery (supplementary appendix table S7, quotes 4-5). Further participants highlighted that there were significant differences among cardiologists and cardiology services in the appropriate management of RM alerts (supplementary appendix table S7, quote 6), including what information is relevant to convey by physiologists to clinicians upon alert detection (supplementary appendix table S7, quote 7). Furthermore, cardiologists highlighted a lack of standardisation in the 'baseline' settings of alert thresholds (supplementary appendix table S7, quote 8).

Need for alert management guidance – To enhance RM data management efficiency, physiologists have emphasised the need for RM alert management guidelines to provide support to CIED clinic staff (supplementary appendix table S8, quote 1-2). Additionally, cardiologists emphasise the importance of eliminating non-essential activities and implementing a process to receive alerts only for relevant, actionable issues (supplementary appendix table S8, quote 3). Furthermore, cardiologists have expressed the need for a national consensus statement from experts in the RM field to provide standardised care for alert management (supplementary appendix table S8, quote 4). Some clinics have taken the initiative to develop their internal alert management protocols, resulting in a reduction of "*unnecessary*" alerts and an overall decrease in workload (supplementary appendix table S8, quotes 5-6).

Theme 4- Insufficient patient education and understanding of CIED and RM

Inadequate patient post-implant knowledge – Patients mentioned that the information provided post-CIED implant was inadequate for their needs. Key areas of knowledge deficit upon discharge included a poor understanding of the RM service (supplementary appendix table S9, quote 1) and poor understanding of restrictions to daily activities (supplementary appendix table S9, quotes 2-7). A barrier to effective patient education can be the timing of information delivery, with patients reporting being overwhelmed peri-implant and struggling to retain information (supplementary appendix table S9, quote 8). Also, discrepancies in information delivery exist between CIED types, with physiologists reporting that ICD patients routinely receive greater education than PPM patients (supplementary appendix table S9, quote 9). Furthermore, discrepancies exist based on insurance status, with private patients often receiving greater information than public patients (supplementary appendix table S9, quotes 10-11). Following hospital discharge, patients reported that there is a lack

of resources to acquire information (supplementary appendix table S9, quote 12) and lack of communication channels to ask specific questions (supplementary appendix table S9, quote 13). Ultimately, both patients and physiologists acknowledge that there is no formal post-discharge program available to provide on-going patient education and support, which in future is something that is required for RM progression (supplementary appendix table S9, quote 14-17).

Patient education is limited by healthcare team availability – Cardiologists acknowledged that discussions with patients and the delivery of '*proper*' education does not often occur, largely due to workload and time constraints (supplementary appendix table 10, quotes 1-2). Both patients and physiologists believe insufficient explanations and education are provided to patients upon scheduled reviews (supplementary appendix table S10, quotes 3-4). Patients frequently mentioned that they often have questions regarding their care and restrictions, however they do not have access to the healthcare team to ask these questions (supplementary appendix table S10, quotes 5-6).

Patient anxiety associated with remote monitoring – The use of RM could be associated with heightened patient anxiety, influenced by various factors. Cardiologists noted that patients may be hesitant to embrace the RM service, primarily due to concerns about the privacy of their data (supplementary appendix table S11, quote 1). Patients reported that they experienced increased anxiety when receiving inconsistent information regarding their data, such as the battery life of their CIED (supplementary appendix table S11, quote 2). Also, patients reported travel-related scenarios would exacerbate their anxiety, with patients and their families expressing mistrust in both the CIED and the RM system when travelling and not having close access to a hospital (supplementary appendix table S11, quotes 3-4). This mistrust has stemmed from inconsistencies in patient explanation of CIED clinic and RM capabilities.

Theme 5: Patient engagement

Need to improve patient engagement with alerts – Patients and cardiologists mentioned the need for improved communication with patients following alert detection (supplementary appendix table S12, quotes 1-3). However, patient contact should only occur if the alerts are actionable and relevant to the patient (supplementary appendix table S12, quotes 4-5). Patients and physiologists mentioned the benefit of using a digital tool such as an SMS platform or app, to contact patient regarding alerts and for patients to ask questions (supplementary appendix table S12, quotes

6-8).

CIED data sharing with patients – There were varying perspectives on the provision of CIED data to patients. Cardiologists felt that patients should be able to access their CIED data (supplementary appendix table S13, quote 1) and that personalised in-time data provided to the patient would improve engagement (supplementary appendix table S13, quotes 2-3). However, nurses and physiologists anticipate that data sharing could increase patient anxiety and concern (supplementary appendix table S13, quotes 4-6). Patients noted that if they were to have access to their data, there would have to be careful consideration on what was presented (supplementary appendix table S13, quote 7), and suggested that the data would need to be delivered in a user-friendly format (supplementary appendix table S13, quotes 8-9).

Theoretical Domains Framework

Sub-themes were categorised to six TDF domains. The sub-themes ‘RM improves CIED and CVD management’, ‘RM enhances the emphasis on patient-centred care’ and, ‘CIED data sharing with patients’ were developed within the *Beliefs about capabilities* domain. Sub-themes ‘Insufficient funding for management of RM service’, ‘Insufficient staffing for management of remote monitored’ and, ‘Remote monitoring access inequity’ were developed within the *Environmental Context and Resource* domain. The sub-theme ‘Remote monitoring alert burden’ was developed within the *Beliefs about Consequences domain.* Sub-themes ‘Inconsistencies in interpretating and managing RM alerts’ and ‘Inadequate patient post-implant knowledge’ were developed within the *Knowledge* domain. The sub-theme ‘Patient anxiety associated with remote monitoring’ was developed within the *Emotions* domain. Lastly, the sub-themes ‘Need for alert management guidance’ and ‘Need to improve patient engagement with alerts’ were developed within the *Goals* domain.

Discussion

Principal results

Remote monitoring of CIEDs offers significant advantages for individuals with cardiovascular disease; however, there is still a large scope for improved implementation. This study provides a current multidisciplinary perspective on RM implementation and a framework of barriers and enablers to address for improving future implementation and scale up. We identified 5 main themes

representing the barriers and facilitators to CIED with RM use. These themes mapped to 6 domains of the TDF to which can inform targeted interventions to enhance implementation and maximise the potential benefits of CIED RM.

Comparison with other work

Across the themes there was a re-enforcement of the benefits of CIED RM directly to the patient in both improved efficiencies in healthcare delivery and improved health outcomes through early detection of issues, prevention of hospital admissions and better provision of care to rural/remote patients. These perspectives are corroborated by several recent studies which have demonstrated that RM enables earlier detection of actionable alerts [15], improves outcomes including reduced inappropriate shocks [16], decreased rates of strokes [15], and reduced mortality rates demonstrated in the pooled analysis of three RCTs using continuous RM [17]. Furthermore, improvements in healthcare service utilisation have been demonstrated with reduced emergency department presentations [18], hospital admissions [19, 20] and hospitalisation length-of-stay times [20]. However, in heart failure patients, RM has not consistently demonstrated benefits in mortality and heart failure hospital readmissions [21].

Three of the 5 themes identified centred on patient engagement, understanding and perceived utility. Across sub-themes it was identified that RM enhances the focus on patient-centred care (offering a user-friendly service, minimising in-person reviews, correlating concerns with CIED data, and extending the service to patients who would otherwise lack such care) and enhances the patient's sense of care. This is underscored by expressions of patient satisfaction, appreciation, reassurance, and an improved sense of safety in managing their CIED and CVD. These observations align with prior studies that have consistently shown positive outcomes in terms of patient satisfaction [22, 23], acceptance [24], and an enhanced feeling of safety [22, 23, 25].

However resourcing and an inadequate recognition of the tasks arising from RM as well as the skills and training needed to manage alerts were a consistently identified as barriers to CIED RM. Lack of funding and appropriate reimbursement schemes have also been seen as a prominent barrier in European and North American countries [6, 26]. While a recent meta-analysis has demonstrated that CIED RM is a cost-effective intervention for healthcare systems [27], current models of care are not yet accounting for the additional tasks that arise from RM implementation particularly those associated with alert management. Staff described alert management comprising multiple additional

phone calls, trouble-shooting connectivity issues, alert triage and scheduling in-person reviews [28]. Many staff and health services are not recognised for the increased workload associated with RM [26] which maybe expected to rise with increasing complexity of CVD, complexity of technology and numbers of CIED implants.

RM data management was also consistently identified as a challenge to RM implementation. The ‘alert burden’ associated with non-clinically significant alerts was particularly called out as a process management challenge. Contributing to this were the generalised nature of alert parameters, the discrepancies between alert interpretation, and the lack of clinical appropriateness guidance. Potential risks could also arise if the ‘alert burden’ arising from ‘non-actionable’ alerts jeopardise patient care through the missing of time-critical alerts, a phenomenon described as ‘alert fatigue’[29]. Consequently, clinicians have expressed the need for the standardisation of RM data management from the guidance of a national expert consensus panel. This call for RM standardisation processes is not novel to our study, with multiple recent studies identifying the growing alert burden and need for guidance on standardised improved management approaches [6, 30, 31]. Recently, an international expert consensus statement was created by the Heart Rhythm Society and other large cardiac organisations to provide guidance for device clinics and clinicians on managing CIED follow-up, with some recommendations on operationalising RM follow-up; however, this guidance lacks specificity on how to react to clinical issues detected via CIED RM [32]. In our study, some clinicians reported that their respective hospitals had instituted internal protocols for managing RM data, yielding positive outcomes in workload management without compromising patient care. Given the clinician desire and potential benefits of a standardised approach to RM data management, improved clinical guidance on RM data management is required.

Insufficient post-CIED implant education was a key barrier identified across stakeholders. Our study identified that many patients believe they do not receive adequate information both peri-implant and upon discharge. This is in line with previous studies that have identified that patients have a substantial deficit in their CIED knowledge, despite having a strong desire to receive more information, specifically around restrictions on daily living and how to deal with device related issues [8, 9, 33]. Clinicians noted that limited understanding of the technology by the patients can prevent the uptake of the RM service and increase patient anxiety living with a CIED. Despite this concern, clinicians noted that patient education is not enforced nor standardized, with variation seen in the provision of information due to factors such as CIED type, insurance status, CIED

manufacturer and clinic staff availabilities. Future co-design studies with key stakeholders are required to develop an effective and efficient program to allow adequate and standardised patient education, without significantly increasing clinician workload.

Lastly, patient engagement with CIED management emerged as a prominent theme across stakeholders. CIED remote monitoring has the unique opportunity to better engage patients with their CVD management through the frequent transmission of cardiac data. Clinicians outlined that a future goal for RM is to better engage patients with the alerts received, through early contact on ‘actionable alerts’. A potential modality proposed from stakeholder for this engagement is through a digital tool such as an SMS platform or app, where patients could access their data/alerts and communicate with their healthcare team. Clinicians had mixed beliefs on the utility of data-sharing with patients, with some believing that it would positively increase engagement, where others are concerned it would increase patient anxiety and clinic workload. Patients believe that if data/alerts were to be provided to them, it would need to be presented in a user-friendly format. Previous studies focusing on CIED RM data interoperability with patients found that the data shared should be simplified, yet informative [34], be personalised and accompanied with informational support [35], and can ultimately enhance shared-decision making without increasing clinical workload [36]. Whilst CIED data sharing with patients may improve patient management, the feasibility of this technology is yet to be thoroughly explored.

Strengths and limitations

The strength of this study is the involvement of both patients and multi-disciplinary clinicians, thus providing a comprehensive perspective of CIED RM barriers and enablers. The study also mapped the elicited themes and subthemes to behaviour change techniques, which can be used to target actionable strategies for future adaptions to improve the RM service. However, this study has some limitations which need to be considered. Firstly, participants were only recruited from New South Wales, Australia, with most included patients located in metropolitan and regional areas. However, the included multi-disciplinary clinicians also service patients from rural and remote regions and thus have a strong understanding of the barriers and enablers of the RM service in these areas. Secondly, the approach to participant recruitment used convenience sampling, which may limit the generalizability of our results. Despite this, the participant population sampled are varied in their backgrounds, with patients having a wide spread of CIED types and indications for CIED implant and clinicians having an appropriate mix of gender, occupations, and sub-specialisations for

cardiologists. Thereby, the collected information is insightful and likely applicable to the wider population when informing future research and clinical directions of RM.

Conclusion

This study highlights the benefits and challenges of CIED remote monitoring from the perspectives of patients and multidisciplinary clinicians. It emphasises both the role of the patient with themes centring on patient engagement, education and benefits, as well as that of multidisciplinary clinicians challenged by the wealth of data, alert burden and complexity of tasks arising from RM. The findings can serve as a roadmap to action to guide the continued development and implementation of RM services into the future. It seems clear that there are great potential patient and health system benefits from the implementation of good systems for RM, but that we are not there yet.

Funding

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Supplementary Files

Multimedia Appendixes

Participant interview guides.
URL: http://asset.jmir.pub/assets/90bc5bfb07d4d3376869b87a51a5da6b.pdf

Supplementary appendix S1-S13: Subthemes, codes and participant quotes.
URL: http://asset.jmir.pub/assets/306c969991f8d9082683417921f3cbd3.docx