2023 HRS/EHRA/APHRS/LAHRS Expert Consensus Statement on Practical Management of the Remote Device Clinic

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KEYWORDS [keywords to be added]

ABBREVIATIONS AF = atrial fibrillation; AHP = allied health professional; BiV = biventricular; CIED = cardiovascular implantable electronic device; COR = Class of Recommendation; CRT = cardiac resynchronization therapy; CRT-D = cardiac resynchronization therapy with defibrillator; ED = emergency department; EHR = electronic health record; HF = heart failure; HIS = health information system; ICD = implantable cardioverter-defibrillator; ILR = implantable loop recorder; IEGM = Intracardiac electrogram; LOE = Level of Evidence; LV = left ventricle; OR = operating room; MRI = magnetic resonance imaging; NSVT = nonsustained ventricular tachycardia; PM = pacemaker; RM = remote monitoring; RV = right ventricle; SVT = supraventricular tachycardia; VF = ventricular fibrillation; VT = ventricular tachycardia
Developed in collaboration with the American College of Cardiology (ACC), the American Heart Association (AHA), the Asia Pacific Heart Rhythm Society (APHRS), the European Heart Rhythm Association (EHRA), the International Society for Holter and Noninvasive Electrocardiology (ISHNE), the Latin American Heart Rhythm Society (LAHRS), and the Pediatric and Congenital Electrophysiology Society (PACES). Endorsed by XX, YY, ZZ, AA, BB affirmed the value [to be added after endorsement review]. For copies of this document, please contact the Elsevier Inc. Reprint Department (reprints@elsevier.com). Permissions: Multiple copies, modification, alteration, enhancement, and/or distribution of this document are not permitted without the express permission of the Heart Rhythm Society. Instructions for obtaining permission are located at https://www.elsevier.com/about/our-business/policies/copyright/permissions. This article has been co-published with the permission of the EP Europace, Journal of Arrhythmia, and the Journal of Interventional Cardiac Electrophysiology, and Heart Rhythm. All rights reserved. The articles are identical except for minor stylistic and spelling differences in keeping with each journal’s style. Any citation can be used when citing this article. Correspondence: Heart Rhythm Society, 1325 G St NW, Suite 400, Washington, DC 20005. E-mail address: clinicaldocs@hrsonline.org.

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Abstract
Remote monitoring for patients with cardiovascular implantable electronic devices is beneficial for the management of these patients by impacting morbidity and mortality. With increasing numbers of patients using remote monitoring, efficient implementation of remote monitoring services creates challenges to device clinic staff. This international multidisciplinary document is intended to guide cardiac electrophysiologists, allied professionals, and hospital administrators in managing remote monitoring clinics. This includes guidance for remote monitoring clinic staffing, appropriate clinic workflows, patient education and alert management. Other topics such as communication of transmission results, use of third-party resources, manufacturer responsibilities and programming concerns are addressed in this expert consensus statement. The recommendations represent the consensus opinion of the expert writing group, graded by Class of Recommendation and Level of Evidence utilizing defined criteria. The recommendations were made available for public comment. The document underwent review by Heart Rhythm Society Scientific and Clinical Document Committee, external peer review, and endorsement by the partner and collaborating societies. Changes were incorporated based on these reviews. The goal is to provide evidence impacting all aspects of remote monitoring services. Gaps in current knowledge and guidance for future research directions have been identified.

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[to be added by the publisher]
Take-Home Messages

1. For patients with Cardiovascular Implantable Electronic Devices (CIED), Remote Monitoring (RM) is standard of care.

2. Prompt patient enrollment into RM and maintaining connectivity and adherence by patients with CIEDs are essential to effective RM. Patient and caregiver education geared toward individual learning needs is extremely important for maintaining that connectivity and adherence.

3. Recognizing the need for adequate staffing and acknowledging appropriate patient to staff ratios for both clinical and non-clinical personnel is essential to providing manageable and efficient RM clinic workflows. Establishing roles and responsibilities for each member of the RM clinic staff team must be defined. Adequate time dedicated to performing those responsibilities must be included in the daily clinic workflow.

4. Clinical staff playing key roles in the RM clinic should be appropriately credentialed and have a program for ongoing quality assurance and improvement.

5. The workload for RM programs has increased exponentially. Actions to efficiently accommodate this volume include programming alerts specific to device type and indication for the CIED implantation. Mechanisms for dealing with high priority, yellow and red alerts, in a prompt and timely way, must be established.

6. Communicating results of CIED RM transmissions to the patient builds a trusting clinical relationship. A process for communicating RM device reports with the patient, their health care providers and entering the device report into the patient electronic medical record is important. This should be accomplished in a secure and confidential manner according to the workflow of individual device clinics.

7. A RM clinic relationship with the device manufacturers for bidirectional exchange of ideas is imperative to having a collaborative approach to provide staff training, patient education, patient care services and for managing safety advisories and recalls.

8. Utilization of third-party resources can assist in device clinic workflows, especially during non-working hours. They may offer financial, as well as practical benefits for dealing with increased volume for certain device clinics with limited staffing.

9. Pediatric patients with CIEDs on RM require similar scheduling of RM, when compared to adult patients, but have specific needs requiring additional consideration.

10. Implantable loop recorders require immediate connectivity to RM with special programming needs for their clinical indication. Programming to maximize sensitivity for atrial fibrillation episodes must be performed. For those with syncope, patients must be instructed to transmit immediately following an episode for accurate and prompt diagnostic capability.
11. Alert-based remote management relying on RM transmissions with continuous connectivity allows for extended time intervals between in-office device interrogations.

Section 1 Introduction

1.1 Preamble

The Heart Rhythm Society (HRS) has developed expert consensus documents that have guided clinical care in the management of cardiac arrhythmias since 1996. This HRS-led Expert Consensus Statement was developed in partnership with the Asian Pacific Heart Rhythm Society (APHRS), the European Heart Rhythm Association (EHRA), and the Latin American Heart Rhythm Society (LAHRS), and in collaboration with the American College of Cardiology (ACC), the American Heart Association (AHA), the Pediatric and Congenital Electrophysiology Society (PACES), and the International Society of Holter and Noninvasive Electrocardiology (ISHNE).

1.2 Document Scope and Rationale

This international expert consensus statement led by the Heart Rhythm Society (HRS) provides comprehensive guidance to cardiac electrophysiologists, allied professionals, and other supportive health care technicians and administrative professionals who participate in the management of Cardiac Electronic Implantable Device (CIED) remote monitoring (RM) programs.

The years since the publication of 2015 HRS Expert Consensus Statement on Remote Interrogation and Monitoring of Cardiovascular Implantable Electronic Devices (2015 HRS Expert Consensus Statement) have seen several key factors that had direct and lasting impact on RM and RM management. The number of CIEDs implanted has grown to, approximately 1.7 million CIEDs implanted on an annual basis worldwide. The number of patients followed remotely has significantly increased. A major recent driver of this has been the Class I recommendation from HRS to use RM for CIED patient and staff safety during the coronavirus pandemic. The utilization of implantable loop recorder (ILR) has had a major impact on RM clinics. As they are focused on alert-based management, they have significantly added to the daily volume of data generated for RM clinic workflow.

The overarching goal of this document is to provide the best evidence and expert consensus opinion on how to effectively run a RM clinic. This takes a joint effort from RM clinic staff, hospital and health system administrators, payers, manufacturers, and regulators. Many topics considered for these recommendations were proposed through a survey of RM device clinic staff. Several patient partners were included in the writing committee to ensure that the focus on delivering optimal patient care was not lost. RM is an international issue, but different jurisdictions face very different circumstances related to RM availability and reimbursement. The writing committee included of a diverse group of individuals, with diversity among the members including geography, subspeciality, professional role, stage of career, and sex.

Although RM is beneficial, its increased utilization has placed a significantly increased strain on already limited device clinic resources. This additional workload magnifies pre-existing challenges associated
with CIED RM. Some of the issues identified by RM clinic stakeholders include managing differences
unique to each CIED manufacturer (e.g., monitoring hardware, connectivity, programmability,
nomenclature, accessibility, and web-based platforms), as well as the dynamic evolution and complexity
of new devices and technology. There are other issues specific to the needs of individual RM clinics.
These include the coordination of patient enrollments, scheduling, reporting, billing, and interfacing
with electronic medical records. Appropriate staffing roles, ratios and credentialing have been
discussed. Adequate staffing with both clinical and non-clinical personnel is required for an effective and
efficient RM program. Third-party services have emerged that allow for outsourcing some or all RM
services. Some of the advantages, challenges, and costs that can come with these services are discussed.

Patients and their caregivers are central to the RM process. Education is key to maintaining patient
adherence and connectivity. Concepts related to patient and caregiver engagement are suggested for
guiding RM clinics in maintaining their interest and understanding the value of the benefits of RM. There
is a pediatric section reviewing the specific needs of the pediatric patient with a CIED as it relates to RM.
Although the pediatric RM recommendations are similar to the adult recommendations, it is recognized
that their needs may be different in specific circumstances. Industry partnership is essential for updating
key stakeholders to maintain quality initiatives related to ever-emerging new technology and the
potential need to coordinate safety notifications and advisories. Some ideas presented in this document
may be a “wish list” of ideas with the hope that manufacturers can provide the means to accomplish
certain goals as a collaborative team inclusive of patients and their caregivers.

The document finishes with a discussion of future research and goals for improving RM. Knowledge gaps
are evident, and it is only through the ongoing process of acquiring evidence through research that
these gaps in knowledge can be addressed.

1.3 Editorial independence

These expert consensus statements are sponsored by the HRS and were developed without commercial
support. All writing group members volunteered their time to the writing and review efforts.

1.4 Organization of the writing committee

The writing committee consisted of internationally recognized experts from 11 countries in the fields of
clinical electrophysiology, cardiology, pediatric cardiology, and heart failure, representing the ACC, AHA,
APHRS, EHRA, ISHNE, LAHRS, and PACES. Three patient partners were included in the writing committee.
HRS strives to ensure that the 2023 HRS Expert Consensus Statement writing committee both contains
requisite expertise and is diversely representative of the broader medical community by selecting
experts from a broad array of backgrounds representing different geographic regions, sexes, races,
ethnicities, intellectual perspectives, and scopes of clinical practice, and by inviting organizations and
professional societies with related interests and expertise to participate as partners or collaborators.
The HRS strives to ensure diversity in formation of the writing group. HRS has rigorous policies and
methods to ensure that documents are developed without bias or improper influence. The complete
policy on relationships with industry (RWI) and other entities can be found online.

In accordance with the HRS policies, disclosure of any RWI and other entities was required from the
writing committee members (Appendix 1) and from the peer reviewers (Appendix 2). Of the 25
committee members, 16 (64%) had no relevant RWIs. Sections with recommendations were drafted by the writing committee members who did not have relevant RWIs.

1.5 Evidence Review and Formulation of Recommendations

The writing committee reviewed evidence gathered by electronic literature searches (MEDLINE, PubMed, Embase, Cochrane Library). No specific year was chosen for the oldest literature. Search terms included but were not limited to [search terms to be added]. Systematic reviews used to inform recommendations are listed in Table 1.2. Literature searches focused whenever possible on randomized controlled trials, but systematic reviews, nonrandomized and registry studies, cohort studies, and case series were included. Case reports were not used to support recommendations. Evidence tables are included in Appendix 3 and summarize the evidence used by the writing committee to formulate recommendations. References are representative of the totality of data and are not meant to be all-inclusive. Limitations of the evidence base are discussed in individual sections. Clinical practice documents relevant to this Expert Consensus Statement are listed in Table 1.2.

To assess consensus after discussions, the writing committee members participated in surveys. A predefined threshold of 70% approval for each recommendation was required, with a minimum quorum of two-thirds of the writing committee. An initial failure to reach consensus was resolved by subsequent discussions, revisions as needed, and re-voting. Writing committee members with RWI did not vote on recommendations concerning relevant topics. The final mean consensus over all recommendations was 98.0%, with 31 of 72 recommendations reaching 100% consensus.

1.6 Class of Recommendation and Level of Evidence

The recommendations were formulated according to the ACC/AHA Class of Recommendation (COR) and Level of Evidence (LOE) system (Table 1.1). The COR denotes the strength of the recommendation based on the assessment of the magnitude and certainty of the benefits in proportion to the risks. The LOE reflects the quality of the evidence that supports the recommendation based on type, quantity, and consistency of data from clinical trials and other sources.

For clarity and usefulness, each recommendation is linked to the supportive science through the specific references from the literature used to justify the LOE rating, which are also summarized in the evidence tables (Appendix 3). Each recommendation is accompanied by explanatory text. Flow diagrams and appropriate tables provide a summary of the recommendations, intended to assist clinicians at the point of care.
Table 1.1 ACC/AHA recommendation system: Applying Class of Recommendation and Level of Evidence to clinical strategies, interventions, treatments, and diagnostic testing in patient care (updated May 2019)*

<table>
<thead>
<tr>
<th>CLASS (STRENGTH) OF RECOMMENDATION</th>
<th>LEVEL (QUALITY) OF EVIDENCE$</th>
</tr>
</thead>
<tbody>
<tr>
<td>CLASS 1 (STRONG)</td>
<td>Benefits &gt; Risk</td>
</tr>
<tr>
<td>Suggested phrases for writing recommendations:</td>
<td>Benefits &gt; Risk</td>
</tr>
<tr>
<td>• Is recommended</td>
<td>Benefits &gt; Risk</td>
</tr>
<tr>
<td>• Is indicated/useful/effective/beneficial</td>
<td>Benefits &gt; Risk</td>
</tr>
<tr>
<td>• Should be performed/administered/other</td>
<td>Benefits &gt; Risk</td>
</tr>
<tr>
<td>• Comparative-Effectiveness Phrases†:</td>
<td>Benefits &gt; Risk</td>
</tr>
<tr>
<td>− Treatment/strategy A is recommended/indicated in preference to treatment B</td>
<td>Benefits &gt; Risk</td>
</tr>
<tr>
<td>− Treatment A should be chosen over treatment B</td>
<td>Benefits &gt; Risk</td>
</tr>
<tr>
<td>LEVEL A</td>
<td>Benefits &gt; Risk</td>
</tr>
<tr>
<td>• High-quality evidence‡ from more than 1 RCT</td>
<td>Benefits &gt; Risk</td>
</tr>
<tr>
<td>• Meta-analyses of high-quality RCTs</td>
<td>Benefits &gt; Risk</td>
</tr>
<tr>
<td>• One or more RCTs corroborated by high-quality registry studies</td>
<td>Benefits &gt; Risk</td>
</tr>
<tr>
<td>LEVEL B-R</td>
<td>Benefits &gt; Risk</td>
</tr>
<tr>
<td>• Moderate-quality evidence‡ from 1 or more RCTs</td>
<td>Benefits &gt; Risk</td>
</tr>
<tr>
<td>• Meta-analyses of moderate-quality RCTs</td>
<td>Benefits &gt; Risk</td>
</tr>
<tr>
<td>LEVEL B-NR</td>
<td>Benefits &gt; Risk</td>
</tr>
<tr>
<td>• Moderate-quality evidence‡ from 1 or more well-designed, well-executed nonrandomized studies, observational studies, or registry studies</td>
<td>Benefits &gt; Risk</td>
</tr>
<tr>
<td>• Meta-analyses of such studies</td>
<td>Benefits &gt; Risk</td>
</tr>
<tr>
<td>LEVEL C-LD</td>
<td>Benefits &gt; Risk</td>
</tr>
<tr>
<td>• Randomized or nonrandomized observational or registry studies with limitations of design or execution</td>
<td>Benefits &gt; Risk</td>
</tr>
<tr>
<td>• Meta-analyses of such studies</td>
<td>Benefits &gt; Risk</td>
</tr>
<tr>
<td>• Physiological or mechanistic studies in human subjects</td>
<td>Benefits &gt; Risk</td>
</tr>
<tr>
<td>LEVEL C-EO</td>
<td>Benefits &gt; Risk</td>
</tr>
<tr>
<td>• Consensus of expert opinion based on clinical experience</td>
<td>Benefits &gt; Risk</td>
</tr>
</tbody>
</table>

Class (strength) of recommendation and level of evidence: The CLASS OF RECOMMENDATION is determined based on the overall quality of evidence and the balance of benefits and risks associated with the recommendation. The LEVEL OF EVIDENCE$ is determined based on the methodology and quality of the evidence supporting the recommendation. The grades correspond to the strength of the recommendation (class) and the quality of evidence (level).

† For comparative-effectiveness recommendations (CLASS 1 and 2A: LOE A and B only), studies that support the use of comparator verbs should involve direct comparisons of the treatments or strategies being evaluated.
‡ The method of assessing quality is evolving, including the application of standardized, widely-used, and preferably validated evidence grading tools, and for systematic reviews, the incorporation of an Evidence Review Committee.

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1.5 Document review and approval

The HRS invites public and stakeholder involvement in document development. In addition to patient representation in the writing committee, draft recommendations were posted for public comment, and contribution was solicited from regulatory agencies and patient organizations.

This expert consensus statement was approved by the writing committee and underwent internal review by the HRS Scientific and Clinical Documents Committee (SCDC). The document underwent external peer review by reviewers appointed by HRS and each of the collaborating societies, and revisions were made by the chairs. A record of writing committee response to reviewer comments and rationale is maintained by the HRS.
1.7 Updating

The HRS SCDC reviews each clinical practice document for currency at least every 5 years, or earlier in the event of newly published data. Literature is routinely monitored to evaluate the continued validity of recommendations.

1.6 Relevant clinical practice documents

Table 1.2 lists pertinent guidelines and expert consensus statements that the writing committee considered for this document. The included documents contain relevant information for the practical management of the remote device clinic.

Table 1.2 Relevant clinical practice documents.

<table>
<thead>
<tr>
<th>Title</th>
<th>Publication Year</th>
</tr>
</thead>
<tbody>
<tr>
<td>ISHNE/HRS/EHRA/APHRS Collaborative Statement on mHealth in Arrhythmia Management: Digital Medical Tools for Heart Rhythm Professionals</td>
<td>2021</td>
</tr>
<tr>
<td>ESC Guidelines on Cardiac Pacing and Cardiac Resynchronization Therapy</td>
<td>2021</td>
</tr>
<tr>
<td>2021 PACES expert consensus statement on the indications and management of cardiovascular implantable electronic devices in pediatric patients</td>
<td>2021</td>
</tr>
<tr>
<td>Guidance for Rebooting Electrophysiology Through the COVID-19 Pandemic from the Heart Rhythm Society and the American Heart Association Electrocardiography and Arrhythmias Committee of the Council on Clinical Cardiology</td>
<td>2020</td>
</tr>
<tr>
<td>HRS/EHRA/APHRS/LAHRS/ACC/AHA Worldwide Practice Update for Telehealth and Arrhythmia Monitoring During and After a Pandemic</td>
<td>2020</td>
</tr>
<tr>
<td>HRS White Paper on Interoperability of Data from Cardiac Implantable Electronic Devices</td>
<td>2019</td>
</tr>
<tr>
<td>Transparent Sharing of Digital Health Data: A Call to Action</td>
<td>2019</td>
</tr>
<tr>
<td>HRS Expert Consensus Statement on remote interrogation and monitoring for cardiovascular implantable electronic devices</td>
<td>2015</td>
</tr>
<tr>
<td>ISHNE/EHRA expert consensus on remote monitoring of cardiovascular implantable electronic devices (CIEDs)</td>
<td>2012</td>
</tr>
<tr>
<td>HRS/EHRA Expert Consensus on the Monitoring of Cardiovascular Implantable Electronic Devices (CIEDs): Description of Techniques, Indications, Personnel, Frequency and Ethical Considerations</td>
<td>2008</td>
</tr>
<tr>
<td>Recommendations from the Heart Rhythm Society Task Force on device performance policies and guidelines endorsed by the American College of Cardiology Foundation and the American Heart Association and the international Coalition of Pacing and Electrophysiology Organizations.</td>
<td>2006</td>
</tr>
</tbody>
</table>
Section 2 General Concepts

Studies since 2015 have continued to show the value of RM and its potential positive effects on morbidity and mortality, cementing RM as an essential part of CIED patient care. All of these factors have led to a deluge of patients on RM, RM data and RM-related work. While the 2015 HRS Expert Consensus Statement made sound recommendations regarding the benefits of RM and the importance of integrating RM into CIED patient care, it did not foresee or account for the challenges related to RM that have been realized in the intervening years. These include the need for organizational RM infrastructure, staffing, and workflow to handle RM data and RM-related work. It also includes ensuring that the RM CIED patient remains connected and at the center of RM programs. There is also a need for developing an improved RM reimbursement structure. The remote device clinic includes a multidisciplinary team involved with RM of CIEDs. The increasing number of CIEDs implanted as well as unexpected challenges such as the COVID-19 pandemic, have resulted in high demands on in-person services and a shift towards virtual outpatient clinics.

2.1 Definitions

To standardize the terms used in the description of RM, terms used in this expert consensus statement are defined in Table 2.1.

Table 2.1 Definitions.

<table>
<thead>
<tr>
<th>Term</th>
<th>Definition</th>
</tr>
</thead>
<tbody>
<tr>
<td>Programmer</td>
<td>A manufacturer-specific device designed to receive and transmit information from CIEDs and allow temporary and permanent programming of CIEDs.</td>
</tr>
<tr>
<td>Device interrogation</td>
<td>Data transmission from the CIED to the programmer, including device settings and data stored in the CIED memory. The data can be viewed and stored directly on the programmer or transformed to a report that can be exported to a personal computer, dedicated CIED follow-up software, and internet servers.</td>
</tr>
<tr>
<td>Device programming</td>
<td>Bidirectional telemetry allowing the programmer operator to assess CIED function, select CIED settings and optimize system performance tailored to the individual patient’s condition in a non-invasive and reversible manner.</td>
</tr>
<tr>
<td>Home monitor</td>
<td>Remote telemetry device, is either a strategically positioned device in the proximity of the patient or a smartphone-based application, able to communicate with CIED which serves as a substation to transmit the encrypted data to dedicated servers.</td>
</tr>
<tr>
<td>RM platform</td>
<td>Manufacturer-specific remote web-based communication system allowing access to the encrypted data transmission from the home monitor to individual clinic and/or third-party resources.</td>
</tr>
<tr>
<td>Third party resources</td>
<td>External systems available using manufacturer-specific RM systems to collect and communicate patient data.</td>
</tr>
</tbody>
</table>
Remote follow-up / interrogation | Programmable scheduled transmissions during which routine CIED parameters are collected remotely from the RM platform by members of the remote device clinic team in a format like that obtained during a routine in-person clinic visit.

RM | Automated remote transmissions of pre-specified alerts related to clinical events, i.e., ICD therapies, or related to device functioning, i.e., lead integrity alerts.

- Individual-Based RM | RM where the manufacturer-specific monitor is enrolled to an individual patient.

- Site-Based RM | RM where the manufacturer-specific monitor is enrolled to a specific site and could be used to collect device data for many individual patients (even if they are not individually enrolled).

Patient-initiated interrogation | Non-scheduled data transmission initiated by the patient due to experiencing real or perceived clinical events, for which the patient is seeking expert evaluation.

Actionable event | Device-related or clinical event which requires intervention prior to the next scheduled in-person clinic visit.

Continuous Monitoring | Continuous data collection with automatic transmission using manufacturer-specific transmission frequency which often occurs once daily.

Non-Continuous Monitoring | Non-continuous data collection requiring manual transmission using manufacturer-specific transmission either scheduled by the clinic or initiated by the patient.

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CIED – cardiovascular implantable electrical device; RM – remote monitoring

2.2 Remote Monitoring Considerations

Since the 2015 HRS Expert Consensus Statement, more recent studies have strengthened the evidence of the organizational benefits of RM and have offered new insights of the impact of RM on patient outcome, particularly in those with heart failure. RM as first-line strategy for CIED follow-up has been established by the “2020 HRS/EHRA/APHRS/LAHRS/ACC/AHA document on worldwide practice update for telehealth and arrhythmia monitoring during and after a pandemic” and in 2021 “ESC Guidelines on Cardiac Pacing and Resynchronization Therapy”.

| Recommendations for Remote Monitoring Considerations |
|---|---|---|
| COR | LOE | Recommendations |
| 1 | A | 1. In patients with CIEDs, RM is recommended as part of the standard of care. |
| 1 | B-R | 2. In patients with CIEDs on RM, routine surveillance of lead function and battery status is recommended to ensure device integrity. |
| 1 | C-EO | 3. In patients with CIEDs on RM with a device capable of continuous monitoring, connectivity should be maintained. |

References:

14, 17-26

18, 27, 28
Synopsis
In patients with CIEDs, RM has already been endorsed as standard of care in the 2015 HRS Expert Consensus.17 Several large randomized studies as well as large registries and observational studies consistently demonstrated major organizational benefits, such as follow-up optimization, and clinical benefits, with improved patient management and clinical outcome associated with RM.

Recommendation-Specific Supportive Text
1. RM reduces the number of health care visits, increases follow-up adherence and patient retention. It provides earlier detection of actionable events such as atrial and ventricular arrhythmias. without compromising safety.18-22, 24, 26, 29, 30 It has been demonstrated to be useful in reducing inappropriate ICD shocks31, 32 by early detection of atrial fibrillation with rapid ventricular response rates,33 T wave oversensing, electromagnetic interference and device malfunction. No study to date has shown a reduction in appropriate ICD shocks with RM. RM is generally regarded as cost effective, depending on the health care model and items assessed.34 and include reduction of in-hospital scheduled and emergency visits, reduction of diagnostic test burden, reduction of follow-up duration and physician and nurse time.35-37 RM also reduces patient costs for travel to in-person visits, time off from work, and interruption of daily activities of patients and accompanying persons.38 Conflicting results do exist regarding the impact of RM on patient acceptance and quality of life. Several studies have reported a high rate of patient satisfaction for diverse aspects such as patient’s perceived relationship with their health care providers, ease of use, psychological impact, and the ability to maintain follow-up compliance.23, 39-42 Other studies observed neutral effects.43-45 RM can facilitate early detection and quantification of atrial fibrillation (AF) episodes and arrhythmia burden3, 13, 46-48 which may prompt clinical reaction, preventing adverse events such as stroke, shock therapy, and heart failure (HF). Continuous monitoring allows individualized patient treatment and continuous updating of therapeutic strategy. Observational studies,46, 49 subanalysis of randomized trials25 and metanalysis5 suggest potential benefits of RM in preventing stroke; these findings have yet to be confirmed by randomized studies.50 Ability of RM to prevent disease progression and improve outcomes with HF is still controversial. Modern implantable devices continuously provide diagnostic information to monitor for HF decompensation, creating opportunities for early intervention prior to deterioration and hospitalization. Some trials demonstrated significant benefits of RM51 in reducing hospitalizations and mortality,52, 53 corroborated by real-world large registries54. Continuous daily monitoring55, 56 and prompt and structured reaction to alerts8, 57, 58 may be key to improving patient outcomes. Automatic multiparameter monitoring59-61 seems promising in prevention of HF exacerbation. Analysis of mega-cohorts7, 62 showed improved survival in patients followed by RM, with high connectivity being the greatest benefit. This is consistent with the pooled analysis of three trials55 in which RM reduced all-cause mortality and the composite endpoint of all-cause mortality or worsening HF hospitalization. The similar magnitudes of absolute risk reductions for worsening HF and cardiovascular endpoints suggest that the benefit of RM is driven by the prevention of HF exacerbation.

2. RM allows effective and safe surveillance of device functioning with alerts for battery depletion, circuit disruption and lead failure ensuring device function and integrity. Early detection of malfunctions when the patient is still asymptomatic, may prevent catastrophic consequences.6,
That's particularly important in case of leads or devices in advisory. RM also allows for continuous monitoring of pacing thresholds, allowing optimization of battery longevity.  

3. For patients with continuous monitoring capable connectivity depends on appropriate functioning of the RM home device as well as on telecommunication system availability and patient adherence to the follow-up plan. Many manufacturers currently provide mobile smartphone applications that can facilitate CIED RM transmission and alert patients to the status of RM connectivity, encouraging patient engagement and partnership vital to maintaining RM. Consistent connectivity is critical to maximize RM benefits, by early detection of actionable events, allowing for early intervention for arrhythmias and HF decompensation, with potential to improve overall patient outcomes.  

2.3 Remote Monitoring Payment/Reimbursement Models

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<th>Recommendations</th>
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<tr>
<td>1</td>
<td>B-NR</td>
<td>4. For the care of patients with CIEDs on RM, it is recommended that healthcare payers adopt adequate reimbursement for RM that is tailored to regional health system care patterns and facilitates sustainable and cost-effective CIED follow-up care.</td>
<td>23, 34-37, 39, 43, 73-85</td>
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Synopsis

There are an increasing number of economic studies that report the cost-effectiveness (ie, increased clinical benefits for additional costs that fall within country-specific, societally accepted thresholds for healthcare value) or cost-savings of RM compared to conventional in-clinic visits. Possible mechanisms of economic benefit include fewer clinic visits without clinically actionable events, reduction in hospitalizations or emergency department visits due to earlier detection of clinical deterioration, or a reduction in patient- and caregiver-borne costs related to travel and missed work. It is important to note that these prior studies describe the economic outcomes associated with the RM of ICDs, CRTs and PM, but not ILRs, where the evidence of clinical benefit is less certain. Lack of reimbursement is frequently cited as a barrier to wide-spread adoption of RM that varies widely by country, and within country by health jurisdiction.

Recommendation-Specific Supportive Text

1. Given the fundamental differences in the healthcare financing across health systems, a single prototypic reimbursement model is unlikely suitable for all settings. More generally, however, implementation or reform of existing reimbursement should consider several cost categories: (a) costs associated with the RM system itself, such as hardware and industry service reimbursement; (b) physician fees for RM data interpretation; and (c) clinic overhead costs including allied health professionals, administrative and non-clinical personnel. In particular, reimbursement models should account for the added indirect workload when managing a RM clinic, that is not reflected by in-clinic patient evaluations. This additional work may include triaging and reviewing frequent remote transmissions, and timely management of alerts.
Reimbursement will also need to be adaptable to the potentially evolving landscape of industry charges and ongoing expenses for RM infrastructure, data servers and technical support personnel. Ideally, reimbursement models are aligned with the broader goals of the healthcare system, which may include access, sustainability, quality, and equity. RM could decrease healthcare costs by reducing and shortening hospital stays if implemented properly. Innovative models may be required to facilitate the goals of access and equity particularly among patients without cell phone coverage or internet access. Without focused policy efforts, there is a risk of exacerbating care disparities and excluding vulnerable patients from the potential benefits RM.
**Section 3 Administrative and Non-Clinical Staff**

As device clinics are burdened with the increased volume of remote transmissions sent from patient with CIEDs on RM, there is an opportunity to review responsibilities that could be completed by administrative and non-clinical staff to assist in optimizing prompt patient enrollment, patient follow-up and workflow efficiencies. This could include but is not limited to tasks such as assisting with patient enrollment, missed appointment notices, managing patient connectivity, ordering monitors, handling patient transfer requests, scheduling, and maintaining patient information on manufacturer web-based platforms. It is important to define the scope of practice when evaluating appropriate duties for administrative and non-clinical staff.

### 3.1 Patient Enrollment Techniques

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**Synopsis**

The concept of RM should be discussed as part of patient education before CIED implantation, allowing assessment of the preferred connection method which may affect device selection in certain circumstances. There is significant variability in practice regarding the timing of patient enrollment in RM. Ideally, patients would enrolled prior to discharge, with chosen RM equipment. For same-day discharge this would assure additional safety by providing immediate remote surveillance replacing what was previously hospital-based surveillance. There are challenges and limitations to this model. Patients may need time to process the life change a CIED implementation could represent. Technical limitations (eg, lack of hardware availability) and patient characteristics (eg, absence of primary caregivers) could also limit the opportunity to initiate RM prior to discharge. In these circumstances, patients should be enrolled virtually or at the first post-implantation in-office visit. Both enrollment options have been used in clinical trials without direct comparison for any clinical outcome. As up to 50% of patients fail to activate their RM receiver, the use and confirmation of a successful “handshake transmission” can minimize the proportion of patients who fail to activate RM. In-office setup with pairing of the CIED and the RM receiver has shown to be feasible and increased the proportion of patients with a successful first RM transmission after discharge.

**Recommendation-Specific Supportive Text**

1. As implantable loop recorders have daily diagnostic data available, RM is a crucial part of their management and should be initiated prior to discharge to capture and transmit events starting the moment the patient is no longer monitored in hospital.
2. It can be beneficial to enroll patients with a CIED in a RM program within 2 weeks of CIED implantation, and ideally prior to discharge if feasible. In a randomized trial comparing RM with conventional follow-up, enrollment in RM before discharge was associated with earlier detection of actionable events without increasing unnecessary in-patient evaluations. RM enrollment within 3 months of implant was associated with improved survival in all CIED types, but the survival benefit was greatest in patients with CRT-D devices.

3.2 Managing & Updating Manufacturer Websites

**Recommendations for Managing & Updating Manufacturer Websites**

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<td>C-EO</td>
<td>1. For the care of patients with CIEDs on RM who undergo device change or upgrade, have a change in vital status, or request clinic transfer, it is recommended that there is a process to update patient information on the manufacturer web-based platform in a timely manner to avoid gaps in RM.</td>
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**Synopsis**

In patients with CIEDs on RM, timely updates of device manufacturer web-based platform is needed to avoid gaps when patients undergo device change or upgrade, or when a patient is deceased or with requested clinic transfers. For continuous optimal care of patients with CIEDs on RM with these circumstances, updating baseline trend information on the manufacturer web-based platform is essential to avoid clinical or demographical gaps with ongoing use of RM. This information updating process also contributes to maintaining a more accurate roster of patients being followed by device clinic staff, thus improving workflow efficiency.

**Recommendation-Specific Supportive Text**

1. RM staffs in clinic or hospital-based programs need to update patient information on the manufacturer web-based platform for those who undergo device change or upgrade before discharge to ensure ongoing monitoring and compatibility of new device with existing RM equipment. These updates on the manufacturer website are also required in the case of a change in vital status (such as patient death), or in the case of patient transfer from or into another clinic. Workflows should be established to address whether administrative or clinical staff should address these updates.

3.3 Techniques to Optimize Patient Connectivity

**Recommendations for Techniques to Optimize Patient Connectivity**

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<td>C-EO</td>
<td>1. For the care of patients with CIEDs on RM who lose connectivity, it is recommended that clinics have an</td>
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established process that includes dedicated clinic staff to facilitate reconnection.

Synopsis

Established processes for overcoming challenges with connectivity increases efficiency, thereby reducing response time necessary to address patients’ concerns as well as minimizing time that patients remain disconnected.

Recommendation - Specific Supportive Text

Patient connectivity to RM is critical for the success of a RM program and most importantly for the patient to realize the known benefits of RM. Rapid management of disconnected patients is imperative. This responsibility ultimately falls on the device clinic. Manufacturers as collaborative partners can assist by providing an alert directly to the patient to notify disconnection. This time-intensive process that includes contacting the patient and trouble-shooting the issue/s can be accomplished by adequately trained non-clinical or clinical staff with adequate time budgeted for this important task.
Section 4 Staffing of Remote Monitoring Clinics

The 2015 HRS Expert Consensus Statement on remote interrogation and monitoring for CIEDs identified the roles and responsibilities of the RM team members. The document identified the following as members of the team: physician, advanced practice provider, allied professional and ancillary staff. In addition, the original document clearly stipulated that an event detected by RM can trigger a full interrogation, office visit, or even an emergency department evaluation, each of which would be associated with the appropriate communication with the patient’s additional healthcare providers.

Inherent to RM is the work effort needed to consistently operate and maintain an effective and efficient RM clinic. Furthermore, several important developments have transpired since the initial 2015 HRS Expert Consensus Statement document was published. These include an increase in the number of patients undergoing RM, the availability of ILRs that transmit data daily for years at a time, the continued absence of a national coverage determination that provides a uniform reimbursement model for RM and the proliferation of multiple operational models to conduct a RM program. These developments require us to reconsider the appropriate staffing requirements for RM clinics.

4.1 Recommended Staffing Requirements for Remote Monitoring

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<th>Recommendations for Staffing Requirements for Remote Monitoring</th>
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Synopsis

The 2015 HRS Expert Consensus Statement assigned a Class 1 recommendation to RM in all CIED patients. The adoption of RM was further facilitated by the COVID-19 pandemic, which prompted adoption of digital and virtual technologies to provide safe, uninterrupted monitoring and care for CIED patients. However, staffing challenges are multi-faceted, inter-related and continue to persist (Figure 4.1). The value of RM and its benefits may not be widely known or accepted, which can affect
resourcing, reimbursement and ultimately allocation of staffing for RM monitoring within an institution.\textsuperscript{110-112} CIED RM work hours are incorporated into a “virtual” space; while the patient may not be physically in the clinic, the work-burden related to managing CIED RM patients still exists on multiple levels.\textsuperscript{112} The success of CIED RM programs is directly related to the ability to absorb and complete this workload in an efficient manner. This requires organizational models and infrastructure, with policies and procedures to govern operations and workflow and dedicated time, space and equipment.\textsuperscript{6,9-16} Critical to this organizational model is a team of CIED RM personnel with clearly defined roles—physicians and advanced allied professionals, nurses and/or cardiac physiologists, technicians, and administrative support staff.\textsuperscript{1,6,9-13} 

Recommendation-Specific Supportive Text

1. The continued uptake of RM has led to a deluge of data from scheduled and unscheduled RM transmissions. Some institutions report receiving >100,000 transmissions annually.\textsuperscript{10,17} Although RM transmission volume can be extremely high, RM transmission review can be highly efficient, as long as staff, workflow and decision-trees are in place (Figure 4.1).\textsuperscript{10-12,18} The Italian HomeGuide Registry structured organizational model of a primary nurse and physician team to review RM transmissions and manage RM patients was found to be highly effective, safe and efficient.\textsuperscript{11,12} Subsequent observational studies have corroborated the use of structured organizational models with dedicated staff, workflows and decision-trees, showing improvements in patient management, timely detection of actionable events and gains in clinic efficiencies.\textsuperscript{10,15,16,19} Structured workflow with dedicated RM staff (a central monitoring unit) and duties (RM transmission review with forwarding of events to clinical teams), may have contributed to improved outcomes in patients on RM in the Implant-based multiparameter telemonitoring of patients with heart failure (IN-TIME) randomized controlled trial.\textsuperscript{20} These data led to a position paper from the Italian Association of Arrhythmology and Cardiac Pacing calling for RM organizational model standardization and formally recommending the use of dedicated, trained teams to manage RM transmissions in CIED patients.\textsuperscript{13} 

2. The growth of RM and RM transmissions has been accompanied by an exponential increase in workload.\textsuperscript{6,9,10,17} In addition to reviewing RM transmissions, other RM-related tasks must be completed to appropriately manage CIED patients on RM.\textsuperscript{6,10,21-25} While review of RM transmissions is rapid, the total RM-related work burden is high.\textsuperscript{21,25} The Euro-ECO trial showed that total staff time required to manage home monitoring “on” vs home monitoring “off” groups was similar (176 vs 178 min, P=NS).\textsuperscript{24} In 2021, an international RM time-motion workflow study\textsuperscript{6} found that for each RM transmission, at least 15 tasks needed completion, including transmission review and diagnosis, patient communication and clinical action, and electronic charting and billing. Furthermore, there were 17 additional tasks, including triage and scheduling, technology and connectivity troubleshooting, and telephone work, to completely manage a CIED patient on RM.\textsuperscript{6} Without investment in infrastructure and personnel with dedicated time for RM, the benefits of RM on clinic efficiencies, patient adherence, satisfaction and QoL, and most importantly, on patient morbidity and mortality, cannot be realized, and systems become overwhelmed.\textsuperscript{5,7,9,14,15,17,22,23} Lack of formalized policies to perform the “invisible work” of RM prevents personnel from performing at the top of their license, especially if also tasked with other non-RM responsibilities. This leads to job-dissatisfaction, burnout, and high staff turn-over in under-resourced teams.\textsuperscript{5,14,21-23}
3. Clinical trials have highlighted the efficiencies and time saved by a RM scheduled follow-up versus in-clinic follow-up.\textsuperscript{12,21} However, many patients will have unscheduled transmissions in addition to their scheduled follow-ups and each of these require triage, data review and documentation with an associated time cost\textsuperscript{17}. Unscheduled remote transmissions comprise 27-40\% of clinic workload and as such, sufficient staff resources will need to be provided to review this data.\textsuperscript{18,12} Additionally unscheduled transmissions have more actionable events which require longer time for clinical management; this also needs to be taken into consideration when calculating the number of staff required.\textsuperscript{1136} When integrating this evidence into clinical practice, the actual remote clinic workload may be underestimated and thus staffing has become an important issue for many clinics as the number of patients followed by RM continues to increase.

4. CIED RM is comprised of multiple tasks; these include patient education and enrollment, connectivity and troubleshooting, data triage and review, alert management, and final sign-off, which includes documentation, communication, and billing (Figure 4.2). Requirements for documentation and communication vary extensively from region to region. Each of these tasks is best performed by a different member of the RM team, which includes physicians, advanced practice providers, registered nurses, physiologists, device technicians, and ancillary staff. It is important to understand how many staff members are required to manage RM, keeping in mind that RM does not exist in a vacuum, but rather adds to the workload inherent to ongoing in-person device evaluations. A recent analysis attempted to quantify the mean cumulative staff time required per remote transmission and in-person clinic visit.\textsuperscript{6,26} They determined the average staff time required to review a transmission and the number of scheduled and unscheduled transmissions per year, stratifying data for device type (PM, ICD, CRT, and ILR) and location (United States versus Europe). Workload varied based on device type, ranging from 0.8 hours per patient with a PM to 8.4 hours per patient with an ILR. An analysis of a large multicenter cohort of patients undergoing RM and using proprietary patient management software reported the following breakdown of devices: 46.7\% PMs; 18.8\% non-CRT ICDs; 18.7\% CRT-Ds; and 15.7\% ILRs.\textsuperscript{17} Based on these two datasets, an estimated 33.5 hours a week in Europe and 40.5 hours a week in the United States are required to manage 1000 patients on RM. As the proportion of patient with ILRs monitored remotely increases, the associated workload increases in a disproportionate manner.\textsuperscript{9,17} Furthermore, institutions need to account for time away from the office as well as the additional RM-related tasks and personnel as shown in Figure 4.1. Thus, we estimate that 3 full-time equivalents (FTEs) are required to support the RM of 1000 patients with varying proportions of the type of personnel (clinical versus non-clinical) depending on individual clinic workflows. This staffing ratio includes in-person staff and use of third-party staffing resources.
Figure 4.1. Staffing challenges with remote monitoring.

Figure 4.2. 2015 HRS Expert Consensus Statement versus 2023 HRS Expert Consensus Statement.
**4.2 Staff Credentialing & Qualifications for Remote Monitoring**

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<th>COR</th>
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<th>Recommendations</th>
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<tr>
<td>1</td>
<td>C-EO</td>
<td><strong>1.</strong> For the care of patients with CIEDs on RM, it is recommended that clinical providers who independently prescribe, interpret, and document for RM results possess appropriate education and/or certification.</td>
<td></td>
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<tr>
<td>1</td>
<td>C-EO</td>
<td><strong>2.</strong> For the care of patients with CIEDs on RM, it is recommended that clinics regularly conduct quality improvement reviews to support current evidence-based standards.</td>
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**Synopsis**

Similar to the 2015 HRS Expert Consensus Statement, this document upholds the recommendation that providers who oversee or independently review, manage, or document and bill for CIED RM demonstrate specific expertise in CIED management by holding appropriate education and/or certification.\(^1\) Certification and education should be supported by the institution/center of employment. Quality improvement review is essential for maintaining high quality care. All members of the RM team should receive training and continuing education specific to RM. All staff/personnel involved with CIED RM should engage in quality improvement review to support current evidence-based standards. All related complications should be reviewed at these meetings, and a process should be in place for reporting outcomes and complications with a goal of continuous improvement.

**Recommendation-Specific Supportive Text**

1. The International Board of Heart Rhythm Examiners (IBHRE) – Certified Cardiac Device Specialist (CCDS) or Certified Cardiac Device Remote Monitoring Specialist (CDRMS) – or American Board of Internal Medicine (ABIM) are currently recognized options for certification of CIED clinic personnel.\(^1\) For AHPs performing initial review and/or triage of RM who do not possess appropriate certification, final remote interpretation should be completed by an appropriately trained professional with such certification. AHPs are eligible for the IBHRE certified CCDS certification, which focuses on comprehensive clinical knowledge pertinent to CIED management, or CDRMS certification, which focuses specifically on RM technology and interpretation of remote CIED transmissions. Additional details and eligibility requirements for these examinations are listed on the IBHRE website (www.ibhre.org). The 2020 HRS Educational Framework for Clinical Cardiac Electrophysiology (reference?) recommends continuing education for both physicians and AHPs who provide clinical care for heart rhythm patients.\(^1\) It provides a topical framework for education for all professionals delivering heart rhythm care and are used to structure existing or new education through the Heart Rhythm Society. The IBHRE supports continuing education through IBHRE-C3—a program providing up to date Accredited Continuing Education (ACE) options for maintenance of certification. Additional options for RM continuing education are available through various entities such as the Heart Rhythm Society’s online learning platform, HRS 365 (heartrhythm365.org), or Heart Rhythm Society Scientific Sessions.
2. Quality improvement is an important part of healthcare delivery and has been the focus of many international and multidisciplinary collaborations such as the IMPACT registry (Improving Pediatric and Adult Congenital Treatments)\textsuperscript{116} and Pediatric Cardiac Critical Care Consortium (PC4).\textsuperscript{117} These registries support the review and transparency of internal data which then can be compared to other similar programs with the goal of improving care. The Intersocietal Accreditation Commission (IAC) accredits facilities meeting high standards of process and now has accreditation for the CIED clinic which focuses on post-procedural onsite and longitudinal RM of implantable cardiac devices. IAC accreditation requires programs to perform regular quality improvement review.\textsuperscript{118}

Section 5 Technical Considerations in Remote Monitoring

RM technology differs widely by manufacturer. Some RM technologies offer continuous monitoring capabilities, and others offer non-continuous monitoring capabilities. “Continuous monitoring” involves continuous data collection within the device with automatic transmission using manufacturer-specific transmission frequency, which often occurs once daily. This assures ongoing surveillance of device and lead parameters with the potential of rapid communication when there is a problem. These monitors are not transmitting on a minute-by-minute, or even hourly, basis. This transmission frequency should be communicated to patients, their caregivers, and their other healthcare providers. They are not substitutes for an emergency medical system. “Non-continuous monitoring” involves non-continuous data collection and requires manual efforts for transmission to occur. This can be either scheduled by the clinic or initiated by the patient. Whereas continuous monitoring may be preferred as it expedites transmission of actionable events, intermittent monitoring should at least meet the recommended frequency of in-person device interrogation. Some centers may be without on-site device interrogation capabilities but still need for acute device surveillance. In these instances, site-based RM and an established workflow to connect with device experts may help to reduce time to getting diagnostic information from the device.

5.1 Devices with Continuous vs. Non-Continuous Remote Monitoring

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<th>Recommendations for Continuous vs. Non-Continuous Monitoring</th>
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Synopsis

Remote device management may consist of multiple types of transmissions. First, full remote device interrogation at scheduled intervals which mimic in-office visits. Second, automatic unscheduled RM transmission consists of continuous monitoring with ongoing, real-time assessment of device function
following pre-defined alert events. Finally, patients can initiate a remote transmission when they experience an event.\textsuperscript{1} Evidence regarding the frequency of remote follow-up interrogations and transmissions is lacking. In general, transmissions for ICDs should be more frequent than for PM due to the increased complexity of their function as well as the in general, sicker population. There will be some circumstances (e.g., if a patient is pacemaker-dependent) where the transmission frequency for PM may match or exceed that for some ICDs.

**Recommendation-Specific Supportive text**

1. In patients without continuous monitoring, the frequency of remote device transmissions should be based on the recommendations for in-office visits of devices that are not monitored remotely. This approach uses a remote platform to mimic traditional in-office visits, and do not offer ongoing monitoring and timely communication of any potential problem between visits. We have not altered the previously recommended interval between visits for these patients based on the prior guidelines and expert consensus statements.\textsuperscript{16, 17, 78, 119} Patients may need to be seen more frequently in specific circumstances. These circumstances could include patients who are pacemaker dependent, whose device is under safety advisory, or if they have other medical conditions that warrants closer assessment.

2. Recommendations for the frequency of devices in RM that approach elective replacement due to battery depletion, and that are not monitored continuously, match those recommendations for the frequency of follow-up of cardiac devices without RM, if the device is not under “continuous monitoring”.\textsuperscript{1–3} As the CIED battery depletes, more frequent monitoring is needed due to the unpredictable risk of more rapid falls in battery voltage as the CIED approaches end of life. As a patient gets closer to their elective replacement indicator, or beyond it, monitoring monthly will likely be needed. We have not altered the recommended interval between visits for these patients generated in the prior expert statements.\textsuperscript{16, 17, 119}

### 5.2 Site-Based Remote Monitoring

| Recommendations for Site-based Remote Monitoring |
|---|---|---|---|
| COR | LOE | Recommendations | References |
| 2a | C-EO | For patients with CIEDs in centers without onsite device interrogation capability, it may be reasonable to use site-based remote interrogation technology to facilitate access to care. |  |
| 2a | C-EO | For patients with CIEDs, in centers with onsite device interrogation capability, it may be reasonable to use site-based remote interrogation technology to provide expedited care. |  |

**Synopsis**

CIED patients frequently encounter situations whereby an immediate, unscheduled device interrogations is clinically necessary. The most common settings for these encounters are the Emergency Department (ED) or peri-operative areas (OR) where the patient may have presented with cardiac or CIED-related symptoms such as perceived shocks or unrelated conditions, for urgent surgical
interventions, MRI scans or unplanned hospitalizations. In the past, a device physician, trained allied
health professional, or a manufacturer representative would be notified. That person would then travel
to perform the interrogation and discuss the findings with the attending clinician or implanting
electrophysiologist. This arrangement is costly, time consuming and associated with significant delays to
clinical decision-making. A more recent alternative is site-based RM. In this is a type of RM, a special
manufacturer-specific monitor is provided to a clinical site and can be used to interrogate CIEDs
belonging to the associated manufacturer, even if the patient is not individually enrolled in RM. These
monitors have no ability to reprogram the device. This tool can be used to expedite CIED device
interrogation and patient care, when onsite CIED interrogation is not immediately available.

**Recommendation-Specific Supportive Text**

1. To leverage the capabilities of RM, most device manufacturers have developed site-based
   (rather than individual-based) remote transmission systems. These can be placed in clinical
   areas with the largest need for unscheduled interrogations, including from patients not enrolled
to a RM system. This could include hospital and urgent care centers without on-site device
   interrogation capabilities. These transmitters can perform manual download of device data onto
   the manufacturers’ proprietary web portal. They can be downloaded by trained technical staff
   through a CIED clinic or a third-party monitoring service for review and interpretation by an
   expert device clinician. This could be used to extend the reach of RM into rural, isolated,
inaccessible, or other underserved areas. Device re-programming is not possible using these
   monitoring devices.

2. Using the Medtronic Carelink Express system to handle 7044 transmissions from the ED and OR,
time to device interrogation / interpretation was reduced by 78% to a mean of 22 ± 14 minutes,
compared to calling for the local device representative to physically attend the patient’s
location. Only 9.1% of interrogations were clinically actionable. In the overwhelming majority
of cases, the device was functioning normally, no device or arrhythmia concerns were found
after an expert technical review of the transmitted data, and the attending clinician can be
notified and provided with a report of the interrogation. In the minority of cases where there
are concerns about device function or reprogramming is required, an in-person evaluation by
trained electrophysiology staff with a programmer can be arranged immediately or non-urgently
when clinic reopens. Similarly, using a Boston Scientific Latitude Consult Communicator installed
in 42 hospital facilities to evaluate 509 discreet unscheduled transmissions, device evaluation
was completed in less than 15 minutes for 89% of cases and only 10% of transmissions were
classified as urgent. These site-based RM workflows provide a time-efficient and cost-
effective strategy to manage unscheduled device interrogations, even when there is on-site
device interrogation capabilities.
**Figures**

**Figure 5.1** - Illustrative example of unscheduled CIED interrogation using a Non 1:1 (site-based) remote monitoring transmitter.

**Figure 5.2** – Traditional 1:1 versus Site-Based 1:Many Remote Monitoring. With traditional 1:1 RM, each patient is individually enrolled into the RM program and the RM data is routed to the patient’s home clinic. With site-based 1:Many RM, multiple patients can use the system, even if they are not individually enrolled into the RM program, and the RM data is routed to that facility’s clinic.
Section 6 Programming Considerations for Optimal Remote Monitoring

RM of CIEDs have facilitated effective surveillance of device function as well as follow-up for arrhythmic events that require clinical intervention, regardless of CIED types.\(^{17}\) RM reduced significant volume of in-person evaluation (IPE) and can decrease the delay from arrhythmia onset to clinical decision, without undermining safety concerns.\(^{19, 20, 23, 51}\) To optimize the efficient use of RM, both optimal device programming and an infrastructure of trained clinicians, who can interpretate massive information derived from RM, are required. Although the programming details might vary by platform, preferred programming strategies are those that enable the most accurate detection of arrhythmia or problems, earlier detection of arrhythmia or problems, and facilitates subsequent therapeutic measures. All types of CIEDs should be programmed to alert for intrinsic change of device function that needs attention. CIEDs that are capable of monitoring atrial arrhythmia should be programmed to improve detection rate of sustained atrial arrhythmia and its burden. Since CIEDs are utilized by different patient populations with distinct cardiovascular needs, RM should be programmed and stratified according to the indications for the CIED. Patients with ICD or CRT often have underlying heart failure, which necessitates specific monitoring for signs of heart failure aggravation. In contrast monitoring for right ventricular pacing burden may be of interest in patients without CRT pacing. In addition, CIEDs that are indicated for diagnostic purpose rather than therapeutic indication (such as ILR) should be programmed to optimize diagnostic accuracy and reduce false-positive events caused by undersensing or oversensing.

In patients in whom certain clinical conditions are already known (e.g., chronic atrial fibrillation or complete heart block with 100% RV pacing), these circumstances should be considered when programming alerts to minimize clinic burden for non-actionable events (see recommendation 11.2).

6.1 Manufacturer and Device Specific Knowledge

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Synopsis

Proper management of patients with CIEDs on RM essentially depends on specific knowledge of the system in use. This knowledge is not restricted to the differences in layout and presentation of the various information displayed, but mainly related to the programmability of parameters and alerts. It is essential that the team that will remotely monitor the patient has a full understanding about the specific system that will be used. This should be considered even before implanting the device, since specific device-related differences may make one CIED/RM system preferable to another system for a particular patient. Manufacturers’ support for training staff about their systems is imperative.
**Recommendation Specific Supportive Text**

1. Although the different RM systems share common principles, they differ significantly in philosophy and practical application, the type and number of programmable alerts, and some proprietary algorithms. The programming and information display screen itself differs considerably among different manufacturers. The capabilities and limitations of the different RM systems should be understood when considering the best CIED system for an individual patient. Some examples of these differences between manufacturers are outlined in **Table 6.1**.

**Tables**

**Table 6.1 Remote Monitoring System Differences Between Manufacturers.**

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<tr>
<th>Manufacturer</th>
<th>Abbott</th>
<th>Biotronik</th>
<th>Boston Scientific</th>
<th>Medtronic</th>
<th>MicroPort</th>
</tr>
</thead>
<tbody>
<tr>
<td>RM system</td>
<td>Merlin.net™</td>
<td>Home Monitoring™</td>
<td>Latitude™</td>
<td>CareLink™</td>
<td>SmartView™</td>
</tr>
<tr>
<td>Home monitor</td>
<td>Merlin@Home™</td>
<td>CardioMessenger</td>
<td>Latitude™ NXT Communicator</td>
<td>MyCareLink™</td>
<td>SmartView™ SmartView Connect™ (Bluetooth®-enabled CIED)</td>
</tr>
<tr>
<td>Smartphone-based RM applications</td>
<td>myMerlin™ mobile app (ILR) myMerlinPulse™ mobile app (ICD and CRT-D)</td>
<td>No</td>
<td>No</td>
<td>MyCareLink Smart™ patient monitor (Bluetooth®-enabled PMs)</td>
<td>Yes; limited to a dedicated smartphone delivered to the patient</td>
</tr>
<tr>
<td>Patient smartphone applications without RM</td>
<td>No</td>
<td>Biotronik patient app (Biomonitor III or IIIm)</td>
<td>MyLatitude™ patient app</td>
<td>No</td>
<td>No</td>
</tr>
<tr>
<td>Transmitter</td>
<td>Stationary</td>
<td>Stationary or mobile</td>
<td>Stationary</td>
<td>Stationary or mobile</td>
<td>Stationary or mobile</td>
</tr>
<tr>
<td>Connectivity</td>
<td>Bluetooth®; Mobile Network; Wi-Fi; analogue phoneline</td>
<td>Mobile Network; analogue phoneline</td>
<td>Mobile Network; Wi-Fi; Ethernet; Analogue phoneline</td>
<td>Bluetooth®; Mobile Network; Wi-Fi; analogue phoneline</td>
<td>Bluetooth®; Mobile Network</td>
</tr>
<tr>
<td>Frequency of transmissions</td>
<td>Scheduled FU; daily FU; alert events</td>
<td>Scheduled FU; daily FU; alert events</td>
<td>Scheduled FU; daily FU; alert events</td>
<td>Scheduled FU; alert events</td>
<td>Scheduled FU; daily FU; alert events</td>
</tr>
<tr>
<td>Programmability of frequency of transmissions</td>
<td>Yes</td>
<td>No</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>Programmability of alerts and parameters</td>
<td>Alerts fully configurable online (Settings, such as alert notifications, report settings and data export settings can be done online. Adjustments to the patient’s device settings must be done in person).</td>
<td>Alerts can be customized by users into High, Medium, and Low priorities according to their preferences. Some alerts and parameters can be programmed online. Certain life-threatening alerts cannot be changed as a safety feature.</td>
<td>RM alerts and parameters can be programmed online through the LATITUDE website.</td>
<td>BlueSync Devices: parameters and alerts are configurable via in-clinic programming; notifications for alerts are remotely configurable BlueSync Device (LINQ II Only): parameters, alerts, and notifications are configurable remotely Conexus Devices parameters and alerts are configurable via in-clinic programming; notifications for alerts are configurable remotely; alerts may be manually reset remotely (Awaiting approval)</td>
<td>Alerts can be programmed</td>
</tr>
<tr>
<td>------------------------------------------</td>
<td>-------------------------------------------------------------------------------------------------</td>
<td>-------------------------------------------------------------------------------------------------</td>
<td>---------------------------------------------------------------------------------</td>
<td>---------------------------------------------------------------------------------</td>
<td>---------------------------------------------------------------------------------</td>
</tr>
<tr>
<td>Patient-initiated transmission</td>
<td>Yes</td>
<td>No</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>Recommended distance from transmitter</td>
<td>&lt; 2 meters</td>
<td>&lt; 2 meters</td>
<td>&lt; 3 meters</td>
<td>&lt; 3 meters</td>
<td>&lt; 2 meters</td>
</tr>
<tr>
<td>Real-time IEGM at remote follow-up</td>
<td>30 seconds</td>
<td>30 seconds</td>
<td>10 seconds</td>
<td>10 seconds</td>
<td>7 seconds</td>
</tr>
<tr>
<td>IEGM of arrhythmic episodes</td>
<td>All memorized</td>
<td>All memorized</td>
<td>All memorized</td>
<td>All memorized</td>
<td>All memorized</td>
</tr>
<tr>
<td>Provider communication method</td>
<td>E-mail, SMS, Fax</td>
<td>E-mail, SMS, Fax</td>
<td>E-mail, SMS, Fax</td>
<td>E-mail, SMS, Website</td>
<td>E-mail, SMS, Pager, Voicemail, Mobile App</td>
</tr>
<tr>
<td>FDA and CE Mark approved</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>Additional features</td>
<td>CoRVUE fluid status alert; Automatic lead thresholds; Patient callback feature; Integrated HF Website with correlation between PA pressures and AF burden, heart rate trends, and pacing burden for patients with both CardioMEMS and SJM CIED</td>
<td>Automatic lead thresholds; Impedance and sensing measurements; Patient callback feature; Electronic health record export compatibility</td>
<td>Configurable red and yellow alerts; Electronic health record export compatibility; Optional Bluetooth weight scales and BP cuffs; Configurable data transmission to associated caregivers</td>
<td>Configurable red and yellow alerts; Electronic health record export compatibility; Optivol thoracic impedance alert; Available for ILR; PDF exports of patient reports; Cardiac compass HF report</td>
<td>Patient initiated transmissions; Alert reports</td>
</tr>
</tbody>
</table>

---

### 6.2 Programming for Clinical Indications with Different Types of CIEDs

<table>
<thead>
<tr>
<th>COR</th>
<th>LOE</th>
<th>Recommendations</th>
<th>References</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>B-R</td>
<td>1. In patients with CIEDs on RM, it is recommended that alert parameters be customized to clinical indications.</td>
<td>53, 102, 105, 113, 123</td>
</tr>
<tr>
<td>1</td>
<td>C-LD</td>
<td>2. In patients with ICDs on RM, it is recommended that the ICD be programmed to alert the clinic for all ventricular shock therapies.</td>
<td>23, 24, 27, 53, 113, 124</td>
</tr>
<tr>
<td>2a</td>
<td>B-R</td>
<td>3. In patients with CIEDs on RM, it is reasonable to remotely monitor heart failure diagnostics to detect incident heart failure and/or progression.</td>
<td>66, 68, 125, 8, 51-61, 126-128</td>
</tr>
<tr>
<td>2a</td>
<td>C-LD</td>
<td>4. In patients with CIEDs on RM with CRT, it is reasonable that the CIED be programmed to alert the clinic when there is a low percentage of biventricular pacing.</td>
<td>53, 124</td>
</tr>
<tr>
<td>2a</td>
<td>C-LD</td>
<td>5. In patients with CIEDs on RM with atrial arrhythmia monitoring capabilities, it is reasonable for the CIED to be programmed to alert the clinic of the first episode, a prolonged episode, or a high burden of atrial arrhythmia.</td>
<td>19, 48, 50, 124</td>
</tr>
<tr>
<td>2a</td>
<td>C-LD</td>
<td>6. In patients with ICDs on RM, it is reasonable that the CIED be programmed to alert the clinic for all ventricular anti-tachycardia pacing therapies.</td>
<td>124</td>
</tr>
</tbody>
</table>
For the care of patients with CIEDs on RM, it is reasonable that the CIED be programmed to alert the clinic for excessive percentage of right ventricular pacing.

**Synopsis**

The programming of the devices that will be remotely monitored must be customized based on the capabilities of the system and according to the type of device itself, the clinical characteristics of each patient, and the expectation of the occurrence of clinically relevant outcomes. Some information is important regardless of device type, such as battery longevity and atrial fibrillation occurrence. In contrast, diagnostics related to heart failure, risk of life-threatening ventricular arrhythmias triggering shock or ATP therapies, percentage of ventricular or biventricular pacing are parameters that will not be relevant for all patients. Furthermore, ILRs have only rhythm registration as target.

**Recommendation Specific Supportive Text**

1. RM alerts should be programmed at a minimum to monitor battery status, lead integrity, and arrhythmic events in virtually all scenarios. Beyond those basic parameters, the patient’s clinical profile and needs will drive a customized pool of programming. Examples include the use of LV/BiV pacing in a patient with a CRT device.

2. The clinic needs to quickly know about significant CIED events that may indicate the necessity of reprogramming or system revision (e.g., battery status; increasing pacing threshold; AF and VT/VF detection and shock therapy). Shock therapy is usually related to a high-risk event, or a device sensing problem, and the cause of the shock discharge should be checked and appropriately managed. True VT/VF (risk of death), unnecessary (NSVT) or inappropriate therapy (AF, oversensing) and noise interference (lead failure) all can result in harm to the patient. Likewise, electrical storm and recurrent discharge can result in adverse physical and psychological effect, in addition to draining the battery.

3. CIEDs are currently able to monitor several parameters such as heart rate and rhythm, daily activity, and transthoracic impedance for estimating fluid status that can help to identify patient’s clinical status. RM-based risk stratification of heart failure patients can indicate the possibility of clinical decompensation. A recent meta-analysis of three randomized controlled trials (TRUST, ECOST, IN-TIME) demonstrated improved survival, and reduced the composite endpoint of all-cause mortality or heart failure hospitalizations.\(^{55}\)

4. One important reason for CRT non-response is inadequate biventricular pacing. A direct correlation between CRT response and maintenance of high percentage of biventricular pacing (CRT%) has been well proven. The relation between optimal CRT% and clinical outcomes has been studied on different cut-off values (from >80% to >98.47%). Daily based RM seems to be the best tool for early identification of those patients at risk for CRT% loss and the cut-off >95% should be the target. This strategy of using alerts based on CRT% makes it possible to restore optimal biventricular pacing as quickly as possible. \(^{53, 62, 130, 131}\)

5. Early detection of AF may help to prevent clinical complications, such as the prevention of inappropriate ICD therapies (the ECOST trial showed a 74% reduction in the number of inappropriate shocks related to SVT in the RM arm compared with standard follow-up). \(^{31}\) AF
may trigger hemodynamic instability and worsen congestive heart failure, both directly and via
the loss of adequate CRT%. The InTIME study showed more favorable outcomes and survival in
patients with heart failure and RM of their ICD ([1] patients with a history of AF benefited more
from RM than did the patients without AF; and [2] AF was the RM alert that most often led to
patient contact). Early detection of AF may lead to initiation of anticoagulation therapy after
appropriate risk stratification. A large proportion of AF episodes are asymptomatic, and RM
shortens the time to its detection (1 to 5 months earlier). Furthermore, an EGM of an AF episode
that has been initially stored in the device, but not yet transmitted, may be absent from the ICD
records if overwritten by more recent episodes. If the patient is known to have a high
burden of atrial fibrillation such that further transmissions will not alter management, then
these alerts can be turned off (see recommendation 9.2).

6. Non-shocked ventricular therapy episode alerts allow reduction in time to medical evaluation
for VT and VF events, as shown in the TRUST trial. Such episodes may relate to SVT, P/R/T-
wave oversensing, noise oversensing, or lead dysfunction. RM systems that generate alerts
following ATP delivery could reduce emergency presentations for ICD shock by 24%.
Asymptomatic cancelled shock therapy (whether for actual VT or noise) may reduce battery
longevity. Their early identification provides an opportunity for prevention of therapy and
battery preservation. Early RM notification of ventricular arrhythmia episodes enables
preemptive action to avoid further inappropriate shock therapy and/or aborted shocks.

7. Conventional pacing from the right ventricle (RV) results in altered electromechanical
ventricular activation which can have detrimental effects on myocardial perfusion and
metabolism. This can lead to progressive ventricular remodeling, function deterioration and
heart failure (pacing-induced cardiomyopathy). Even though only a subset of patients with RV
pacing develop cardiomyopathy (9 to 19.5%), the MOST and DAVID trials suggested a
threshold of RV pacing of more than 40% for the development of pacing-induced
cardiomyopathy. Other study identified a RV pacing burden >33% as a risk factor. Early
knowledge of high RV pacing burdens could lead to mitigation strategies that could lower the
rate of RV pacing. Conduction system pacing (His area or left bundle branch area), with its
advantage of minimizing or eliminating electromechanical dyssynchrony, is emerging as an
attractive alternative and this concern may not apply. If the clinic is aware that the patient is
chronically paced in the right ventricle 100% of the time, then this alert is not required.
Figure 6.2 - Alert recommendations by device type. Color corresponds to the class of the Recommendation Table 1.1
6.3 Special Programming Considerations for Implantable Loop Recorders (ILRs)

<table>
<thead>
<tr>
<th>COR</th>
<th>LOE</th>
<th>Recommendations</th>
<th>References</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>B-NR</td>
<td>1. In patients with ILRs on RM, it is recommended that clinic staff confirm an actionable event transmission by reviewing the electrograms to exclude misdiagnoses.</td>
<td>9, 89, 143, 144</td>
</tr>
<tr>
<td>1</td>
<td>B-NR</td>
<td>2. In patients with ILRs on RM, it is recommended that programmed alerts be tailored to the clinical indication.</td>
<td>9, 89, 143</td>
</tr>
<tr>
<td>1</td>
<td>B-NR</td>
<td>3. In patients with ILRs on RM and frequent undersensing and/or oversensing, reprogramming is recommended.</td>
<td>9, 89, 143, 144</td>
</tr>
<tr>
<td>1</td>
<td>B-NR</td>
<td>4. In patients with ILRs on RM for unexplained syncope, it is recommended to emphasize to the patient the need to perform a manual transmission immediately following syncope to obtain a symptom-rhythm correlation.</td>
<td>9, 143</td>
</tr>
<tr>
<td>2a</td>
<td>B-NR</td>
<td>5. In patients with ILRs on RM for cryptogenic stroke, it is reasonable to adjust the sensitivity to improve detection of atrial fibrillation.</td>
<td>9, 143</td>
</tr>
</tbody>
</table>

Synopsis

ILRs can have some unique challenges when implementing RM. These include a high burden of transmissions, frequent misdiagnoses, and the need for a symptom-rhythm correlation in some cases. Due to the relatively high false-positive rate for both atrial fibrillation and for sinus pauses with ILRs, clinical staff must confirm putative dysrhythmias by manually reviewing electrograms of individual events to exclude misdiagnosis. The sensitivity of detection of atrial dysrhythmia could be increased in patients with cryptogenic stroke, to improve detection of symptomatic or asymptomatic atrial fibrillation. Conversely, this might not be desired when the ILR is implanted for unexplained syncope. In this group, educating the patient about the importance of a manual activation at the time of syncope is critical to obtain a symptom-rhythm correlation.

Recommendation-Specific Supportive Text

1. In a recent study of RM with nominal setting on Medtronic Reveal LINQ™, incidence of false-positives was high at 71% in patients with syncope. Factors for false-positives in bradycardia episodes with ILR may include under-sensing of small R wave amplitude, variable signal amplitude, non-physiologic flatline from loss of electrode contact, and/or in saturated sense amplifiers. The incidence of false-positive detections of AF during RM has been reported in 46-86% patients, although this might improve with newer devices and newer algorithms. When monitoring for tachycardia episodes, low detection and false-positives from under
sensing and over sensing due to noise may cause frequent false-positives. To avoid misdiagnosis and potential errors in clinical management, device clinic staff needs to confirm an actionable event transmission by reviewing the electrograms.  

2. Programming of alert setting on RM should be optimized for different clinical indications. In unexplained syncope patients, alert transmission is essential for patient’s symptom-rhythm correlation. In patients with symptomatic atrial fibrillation, programmed alert transmission should be set based on rate, frequency, duration, or AF burden. In cryptogenic stroke patients, it important to detect correctly for symptomatic or asymptomatic AF. Careful and tailored programming will help maximize the diagnostic benefit of ILRs.  

3. Primary causes of false-positives in ILR transmissions are signal drop out, undersensing, as well as atrial and ventricular ectopy. More recent ILR algorithms use a combination of R-R variability, beat variation, ventricular scatter, heart rate density index, and in addition QRS morphology, noise discrimination and/or pattern detection provide additional filters to reject false-positives. This advancement of technologies may reduce the false-positive transmissions with ILRs and may help to avoid misdiagnosis. Clinical staff still need to confirm each transmission by reviewing the electrogram for accuracy. If the presence of a false-positive transmission is confirmed after review, reprogramming the ILR could help to minimize future false-positive transmissions.  

4. The purpose of an ILR in the setting of unexplained syncope is to determine if the syncope is due to a dysrhythmia. Many patients can have a dysrhythmia that is incidental to their syncope. A symptom-rhythm correlation is critical to establish that the dysrhythmia is truly causing syncope. The patient needs to be instructed to initiate a manual transmission directly following the event to communicate the symptoms to the clinic.  

5. ILRs allow clinics to alter their sensitivity to make it more likely, or less likely, to detect atrial fibrillation. For patients in whom the ILR was implanted for cryptogenic stroke, it is of paramount importance that episodes of atrial fibrillation are not missed. In these patients, the sensitivity of the ILR for atrial fibrillation should be maximized, even if this is at the cost of reduced specificity.  

Section 7 Pediatric Considerations with Remote Monitoring

As in the adult population RM in pediatric (defined as < 18 years or followed by a pediatric provider) patients has significant benefit allowing the medical team to detect and intervene on CIED issues, such as battery depletion, lead or device malfunction, or arrhythmic issues. RM can be useful to identify acute lead malfunction after new implants. Younger age was associated with an increase in lead/device malfunction. Although the overall likelihood of an actionable event in pediatric patients is low, RM is recommended for early detection and management of device or arrhythmia concerns as the patient may be asymptomatic. Tachyarrhythmia is the most common abnormality found on RM transmissions in younger patients. A pediatric study showed the median time between RM interrogations was every 91 days and the median time between last follow up and occurrence of actionable events was 46 days. Pediatric studies support every 3–12-month RM for PM and every 3–6 months for ICDs. Frequency of RM non-continuous devices should be increased as the device...
reaches elective replacement as device replacement is an actionable event and needs clinical attention.\textsuperscript{146}

The recommendations outlined in this document for the adult population are applicable to the pediatric population. Recommendations detailing indications, management, and timing/frequency for pediatric patients with CIEDs on RM were outlined in the \textit{2021 Expert Consensus Statement on the Indications and Management of CIEDs in Pediatric Patients}.\textsuperscript{114} Additional considerations for pediatric patients include the importance of engaging the patient early in their life to promote independence, and compliance as they reach adulthood. Transition, defined as the active process that focuses on the medical, psychosocial, and educational/vocational needs of adolescents as they move towards adulthood, to adult CIED care should be the eventual goal. The transition process is dynamic, and duration of transition can vary from patient to patient. Shared medical decision making which promotes open dialogue and exchange of medical information between the child, parents, and provider can also help to support compliance, transition to adult care and better outcomes.\textsuperscript{114, 149} Implementation of focused patient education to adolescent patients has been shown to increase self-management and knowledge of medical condition in a recent clinical trial.\textsuperscript{150} At each follow up visit, pediatric CIED providers should evaluate transition readiness and provide targeted education on device care and importance of RM beginning in the young adolescence period.

\section*{Section 8 Remote Monitoring Reporting}

A report of the results of RM must offer detailed information on device functioning and clinical status of the patient. RM device transmissions include continuous or non-continuous, alert-based and patient-activated manual transmissions. Each transmission includes comprehensive data on device technical functioning and data related to arrhythmias and heart failure. All data should be stored in the medical record.

\subsection*{8.1 Communication of the Remote Monitoring Report to Patients}

\begin{table}[h]
\centering
\begin{tabular}{|c|c|p{10cm}|}
\hline
\textbf{COR} & \textbf{LOE} & \textbf{Recommendations} & \textbf{References} \\
\hline
2a & C-EO & 1. For the care of patients with CIEDs on RM, it is reasonable for the results of all remote device transmissions to be shared with patients, based on patient preferences for content and mode of communication, and clinic workflows. & \textsuperscript{112, 149} \\
\hline
\end{tabular}
\end{table}

\textbf{Synopsis}

Patient awareness of RM transmissions is critical to improve compliance and maximize clinical benefits. Sharing results of patient transmissions should take into account patient preference, considering culture, psychological and social status, as well as clinic workflow to avoid work overload.

\textbf{Recommendation Specific Supportive Text}

1. Timing and mode of communication of transmission results to patients depends on clinical relevance and actionability of detected events. Actionable events should be promptly communicated, and clinical reaction performed with a timely plan. Routine transmission and
non-actionable event reports, as well as billing, may be delivered periodically (see section 5.1). According to patient preference and clinic workflow, reports may be delivered by mail, secure e-mail, patient portal or directly during in-person visits. Patient health information privacy should be emphasized. Incorporating device reports into the Electronic Health Record is crucial for data availability to all hospital services. This may include routinely to the primary care provider or urgently during emergency needs, to maintain optimal patient care.

8.2 Components of a Comprehensive Report

Similar to reports generated from in-clinic device visits, the content of a RM report will depend on clinical and technical factors as well as the type of CIED. An additional consideration for RM is the context of remote transmission (ie, scheduled versus automatic/alert-driven). Suggestions for the components of a comprehensive remote follow-up/interrogation report are provided in Table 8.2.

### Tables

Table 8.2. Suggested Components of Remote Monitoring Report.

<table>
<thead>
<tr>
<th>Category</th>
<th>Data Element*</th>
<th>PM</th>
<th>ICD</th>
<th>CRT</th>
<th>ILR</th>
<th>Scheduled</th>
<th>Alert-Driven</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Patient Information</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Clinical indication</td>
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<td>✓</td>
<td>✓</td>
<td>✓</td>
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<td>✓</td>
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<tr>
<td></td>
<td>Presenting rhythm</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
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<tr>
<td><strong>Battery</strong></td>
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<td>Voltage</td>
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<tr>
<td></td>
<td>Battery impedance</td>
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<td>✓</td>
<td>✓</td>
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</tr>
<tr>
<td></td>
<td>Capacitor charge time</td>
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<td>✓</td>
<td>✓</td>
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<tr>
<td><strong>Leads – Sensing</strong></td>
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<td></td>
<td></td>
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<td></td>
</tr>
<tr>
<td></td>
<td>Sensing thresholds for all leads</td>
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<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Serial trend in sensing threshold(s)</td>
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<td>✓</td>
<td>✓</td>
<td>✓</td>
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<tr>
<td></td>
<td>Oversensing / Undersensing</td>
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<td>✓</td>
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</tr>
<tr>
<td><strong>Leads – Pacing</strong></td>
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<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Pacing thresholds for all leads</td>
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<td>✓</td>
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<tr>
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<td>Serial trend in pacing threshold(s)</td>
<td>✓</td>
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<tr>
<td><strong>Leads – Impedance</strong></td>
<td></td>
<td></td>
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<td>Lead Impedance(s) for all leads</td>
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<td>Shock impedance</td>
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<td>Shock Impedance Out of Range</td>
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<tr>
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<td>Polarity Switch</td>
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<td>✓</td>
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</tbody>
</table>
### Heart Rate

<table>
<thead>
<tr>
<th></th>
<th>% Atrial pacing</th>
<th>% Ventricular pacing</th>
<th>✓</th>
<th>✓</th>
<th>✓</th>
<th>✓</th>
<th>✓</th>
<th>✓</th>
</tr>
</thead>
<tbody>
<tr>
<td>% Atrial pacing</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
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</tr>
<tr>
<td>Characterize atrial and/or ventricular rate histograms (Optional)</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
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### Arrhythmia(s)

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<tr>
<th></th>
<th>AF / AT (% burden, maximum duration)</th>
<th>✓</th>
<th>✓</th>
<th>✓</th>
<th>✓</th>
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<tbody>
<tr>
<td>Mode switches (Optional)</td>
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<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
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<tr>
<td>Ventricular high-rate events episodes (number and duration)</td>
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<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
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</tr>
<tr>
<td>Therapies required for VT /VF termination (Appropriate versus Inappropriate)</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
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<tr>
<td>Electrogram morphology template (for VT discrimination algorithm) (Optional)</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
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### Heart Failure

<table>
<thead>
<tr>
<th></th>
<th>% Biventricular or LV pacing</th>
<th>✓</th>
<th>✓</th>
<th>✓</th>
<th>✓</th>
<th>✓</th>
<th>✓</th>
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</thead>
<tbody>
<tr>
<td>Thoracic Impedances (Optional)</td>
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<td>✓</td>
<td>✓</td>
<td>✓</td>
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<td>✓</td>
<td></td>
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<tr>
<td>Heart Failure Algorithms (Optional)</td>
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<td>✓</td>
<td>✓</td>
<td>✓</td>
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### Programming

<table>
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<td>Tachycardia settings</td>
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### Other

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<th>✓</th>
<th>✓</th>
<th>✓</th>
</tr>
</thead>
<tbody>
<tr>
<td>Patient Activated (Symptom rhythm correlation)</td>
<td>✓</td>
<td>✓ (ICD)</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td></td>
</tr>
</tbody>
</table>

---

910 *Additional manufacturer specific features can be added if these data will influence patient care / management and used by the local device clinic (e.g., activity monitor, heart rate variability, heart failure algorithms). Listed data elements would be considered the mandatory minimal dataset for a remote monitoring report, unless otherwise denoted.

913 †Availability of alerts are manufacturer specific. These may include but are not limited to: RV lead integrity alert, RV lead noise, lead impedance out of range, AT/AF daily burden (as per user set threshold), excessive charge time, low battery voltage. Alert programming should balance patient safety and actionable clinical information with the burden of non-actionable alerts that device clinics may encounter with undiscerning programming.
8.3 Techniques for Incorporating Reports into Electronic Health Records

<table>
<thead>
<tr>
<th>COR</th>
<th>LOE</th>
<th>Recommendations</th>
<th>References</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>C-EO</td>
<td>1. For patients with CIEDs on RM, it is recommended that patient health information privacy be maintained when incorporating reports into electronic health records.</td>
<td></td>
</tr>
<tr>
<td>2a</td>
<td>C-EO</td>
<td>2. For the care of patients with CIEDs on RM, it can be beneficial to use universally accepted data element definitions and exchange formats when incorporating reports into electronic health records.</td>
<td></td>
</tr>
<tr>
<td>2b</td>
<td>C-LD</td>
<td>3. For the care of patients with CIEDs on RM, it may be beneficial to use patient management software to incorporate reports into electronic health records.</td>
<td>96</td>
</tr>
</tbody>
</table>

Synopsis

RM information must be private but also should be available in the patient’s health record. The element definitions and report formats should be universally accepted, regardless of the manufacturer, to be compatible with management software that can be incorporated into electronic health records. Manual or automatic capability for populating databases is essential for both, the regular follow-up and for unscheduled transmission including those site-based interrogations as can occur in emergency departments, intensive care units, or even for long distance service.

Recommendation Specific Supportive Text

1. Solutions for data management continue to evolve. The goal is to be able to access data stored in CIEDs in a timely fashion, review the data for clinically valuable information, and present this information in a contextual and relevant format in the EHR system for the physician following the patient with a CIED. Device data downloads need to be accessible to, for example, operating rooms and emergency departments for interpretation by trained technical staff. With accessibility, however, comes challenges to maintaining the privacy of patient health information as well as potential issues related to liability when using RM-related services.151

2. Patient device data is regarded as a part of their patient file and should be stored in the hospital information system (HIS). The manufacturer’s web-based platform provides data in a protected environment that are suitable for incorporation into the HIS. However, the diversity and incompatibility of sources for current device data is a barrier to high-quality patient care. Universally accepted data element definitions and exchange formats facilitate accurate and efficient data transfer (regardless of manufacturer) from RM servers and programmers to electronic health record (EHR) and other data repositories, thereby increasing clinical and
3. For both remote transmission review and in-person clinic visits, time saving protocols are driven by steps for documentation in EHRs. The staff time required per remote and in-person device check is less when a vendor-neutral CIED management software is used. A recent publication demonstrated that sites using management software, reduced, on average, the total staff time to review a remote transmission by 2.1 minutes (11.5 vs 13.6 minutes) and an in-clinic visit by 2.2 minutes (50.4 vs 52.6 minutes). When extrapolated to an average clinic size of 5758 patients, the use of such software was associated with an estimated 10.1 cumulative staff hours saved during a clinic day (50.7 hours per week) based on 171 weekly clinic visits and 1335 weekly remote transmissions. Annually, this translates to 2639 hours of staff time saved, equivalent to 1.4 annual full-time equivalents.  

Section 9 Managing Alerts

RM of CIEDs allows both scheduled remote follow-up and automatic unscheduled transmissions of data for pre-specified alerts. There is clear evidence of a significant reduction in the time to diagnosis and clinical decision making for unscheduled actionable events, compared to in-clinic follow up alone. Early notification of actionable events is associated with improved outcomes, reductions in hospitalizations and health care costs. A significant reduction in all-cause mortality for systems with daily RM has been reported in systematic reviews and meta-analyses. Unscheduled transmissions generate a significant incoming data workload for clinics, since all transmissions require triage, review, and documentation. The number of alert transmissions received by clinics will vary depending on the programming practices of each individual clinic, patient education, and the device indication. Some manufacturers provide auditory or vibratory alerts to the patient directly, and the use of RM of these alerts can allow the clinics to advise the patients as to the nature of the alert. Given there are fundamental differences between manufacturers in the number and type of programmable alerts, and how and when these are communicated, this introduces further complexity for clinics in RM alert management. Remote clinics will require robust organizational models and processes in place to safely manage alerts and workload.

9.1 Defining High-Priority Alerts

<table>
<thead>
<tr>
<th>COR</th>
<th>LOE</th>
<th>Recommendations</th>
<th>References</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>B-R</td>
<td>1. In patients with CIEDs on RM, it is recommended that for concerns related to critical device or lead function, high-</td>
<td>19, 28, 53, 102, 133</td>
</tr>
</tbody>
</table>
priority alerts be programmed to promptly notify the clinic.

Synopsis

The definition of high-priority alerts, and of the response to them, is crucial for organization of care pathways, prioritization of review of alerts, and definition of acceptable response timelines. A significant percentage, if not the majority, of alerts transmitted from remotely monitored CIED are non-actionable alerts (such as detection of known atrial fibrillation) and concern events that do not require immediate action. In contrast, and as demonstrated in randomized studies, reaction to alerts concerning battery capacity, lead integrity and therapies delivered by ICDs for ventricular tachyarrhythmias, has been shown to reduce adverse outcomes. Arrhythmic events such as shock therapies or anti-tachycardia pacing therapies delivered by the ICD do not only indicate an increased risk for subsequent therapies, but may also indicate lead integrity issues. Reaction to these alerts may reduce adverse clinical events.

Recommendation-Specific Supportive Text

1. Alerts related to impedance or pacing threshold may indicate lead failure leading to adverse clinical events, similar to alerts related to battery capacity, as shown in randomized trials. These alerts should be considered high-priority alerts. Shock therapies may indicate clinical deterioration requiring corrective action but may also indicate lead failure and should be considered high-priority alerts. Evidence for the high-priority character of anti-tachycardia pacing therapies delivered by the ICD is weaker than for shock therapies. Nevertheless, observational studies indicate that review of alerts related to anti-tachycardia pacing may be associated with reduced consequent adverse events such as shocks and emergency presentations. Therefore, it is reasonable to consider such alerts high-priority alerts.

Figures & Tables

<table>
<thead>
<tr>
<th>Red Alerts (Critical Alerts)</th>
<th>Yellow Alerts</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>PACEMAKER ALERTS</strong></td>
<td></td>
</tr>
<tr>
<td><strong>Device Integrity Alerts:</strong></td>
<td></td>
</tr>
<tr>
<td>Device</td>
<td>Low battery voltage</td>
</tr>
<tr>
<td></td>
<td>Device reset or in safety mode</td>
</tr>
<tr>
<td></td>
<td>Recommended replacement MRI mode</td>
</tr>
<tr>
<td>Lead</td>
<td>RV pacing impedance out of range</td>
</tr>
<tr>
<td></td>
<td>RA/RV/LV pacing impedance out of range</td>
</tr>
<tr>
<td></td>
<td>RA/RV/LV pacing threshold out of range</td>
</tr>
<tr>
<td><strong>Clinical Alerts:</strong></td>
<td></td>
</tr>
<tr>
<td>Atrial arrhythmia</td>
<td>Atrial burden &gt; programmed value</td>
</tr>
<tr>
<td>High ventricular rate in atrial arrhythmia</td>
<td>Ventricular rate in atrial arrhythmia &gt; programmed value</td>
</tr>
<tr>
<td>RV pacing %</td>
<td>RV pacing &gt; programmed value</td>
</tr>
<tr>
<td>CRT</td>
<td>CRT pacing &lt; programmed value</td>
</tr>
<tr>
<td>----------------------</td>
<td>-------------------------------</td>
</tr>
<tr>
<td>NSVT</td>
<td>In selected patients</td>
</tr>
</tbody>
</table>

**ICD ALERTS**

**Device Integrity Alerts:**

<table>
<thead>
<tr>
<th>Device</th>
<th>VF detection/therapy off</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>End of service/low battery voltage</td>
</tr>
<tr>
<td></td>
<td>Device reset / safety mode</td>
</tr>
<tr>
<td></td>
<td>Long charge time</td>
</tr>
<tr>
<td></td>
<td>Recommended replacement MRI mode</td>
</tr>
<tr>
<td>Lead</td>
<td>Shock impedance out of range</td>
</tr>
<tr>
<td></td>
<td>RV pacing impedance out of range</td>
</tr>
<tr>
<td></td>
<td>Noise episode</td>
</tr>
<tr>
<td></td>
<td>RA/RV/LV pacing impedance out of range</td>
</tr>
<tr>
<td></td>
<td>RA/RV/LV pacing threshold out of range</td>
</tr>
</tbody>
</table>

**Clinical Alerts:**

| Shock                  | Shock delivered             |
|                        | ATP delivered               |
| Atrial arrhythmia      | Atrial burden > programmed value |
|                        | Ventricular rate in atrial arrhythmia > programmed value |
| RV pacing percentage   | RV pacing > programmed value |
| CRT                    | CRT pacing < programmed value |
| NSVT                   | In selected patients        |

Table 9.1 Red and yellow alerts for PM and ICDs. Red alerts are “critical alerts”, whereas yellow alerts are important alerts that do not rise to the level of a critical alert. MRI – magnetic resonance imaging; RA – right atrial; RV – right ventricular; LV – left ventricular; CRT – cardiac resynchronization therapy; VF – ventricular fibrillation; ATP – anti-tachycardia pacing.
998
999
Figure 9.1 RM alerts that should be considered “high-priority”.

1000
1001
9.2 Programming Considerations to Minimize Inappropriate Alerts

| Recommendations for Programming Considerations to Minimize Inappropriate Alerts |
|---------------------|---------------------------------|-----------------------------|
| COR | LOE | Recommendations | References |
| C | C-EO | 1. In patients with CIEDs on RM from whom sufficient clinical data have been received, it is recommended that alert parameters be reprogrammed to avoid non-actionable alerts. | |

1002
1003 Synopsis

1004 Unscheduled alert transmissions and the associated workload are an ongoing concern for RM clinics. Alerts for arrhythmias that are already known, and where further alerts will not lead to any clinical action, can contribute to this workload. In an observational study by Morimoto et al. (2019), two-thirds of transmissions were reported to have shown at least one abnormal event with the majority requiring no clinical action. Most non-actionable alerts occur for known arrhythmias. Individualizing RM alerts to suit the patients’ individual clinical circumstances can improve clinic efficiency. Ideally, optimized alert programming would occur at the time of implantation based on individual clinical circumstances.
1. Once sufficient information has been gathered regarding a particular alert, and there is no further requirement to receive this information, it is recommended that RM settings should be adjusted to receive only those alerts that will result in a clinical action and minimize further non-actionable alerts. (Figure 9.2) The ongoing triage and review of unscheduled alerts has a significant impact on clinic workload and productivity. In one study many unscheduled alert transmissions were not clinically relevant as the information was already known, and action had already been taken. Alert transmissions occur more frequently in patients with known AF. Alert settings could be adjusted based on the patient’s clinical situation, to minimize unnecessary alerts. In addition, Morimoto et al. describe a high abnormal event rate (63-16.7%) in remotely monitored patients, but a low “critical-event” rate (4.1%). One method to reduce the volume of incoming transmissions is by reprogramming alert criteria from the CIED default settings to allow only critical events to be received. These may include turning off alerts for a high burden of ventricular pacing in patients with known AV block, or turning off atrial fibrillation alerts in patients known to have a high burden of chronic atrial fibrillation.
Figures 9.2. Minimizing alerts for non-actionable events. CIED - cardiac implantable electrical device.

Each CIED transmission alert is critically reviewed by a credentialed clinician. If the event is a known clinical event that has been previously addressed, the specific alert may be programmed OFF and it is no longer considered an actionable event. If this is NOT a known clinical event, more information is needed about the patient’s status. Based on the review of additional information, the alert may be adjusted or programmed OFF.

9.3 Timeline Recommendations for Alert Management

<table>
<thead>
<tr>
<th>COR</th>
<th>LOE</th>
<th>Recommendations</th>
<th>References</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>C-EO</td>
<td>1. For the care of patients with CIEDs on RM, it is recommended that patients and their caregivers be</td>
<td></td>
</tr>
</tbody>
</table>
informed that automatic alerts transmitted by RM do not substitute for an emergency management system.

2a  C-EO  2. For the care of patients with CIEDs on RM, it is reasonable for clinics to review and react to high-priority alerts within one business day.

Synopsis

Management of alerts is a crucial part of the workflow in each remote device clinic. Reaction to critical alerts and to non-critical alerts needs to be tailored to the individual patient. Reaction to alerts transmitted during non-business hours are frequently a particular concern for RM clinics. These concerns include potential liability for non-immediate response to incoming high priority alerts. Nevertheless, there is no evidence for the need of an immediate response to alerts outside of the working hours. Most RM sites are not able to provide an immediate response. For this reason, it is crucial that patients and their care providers realize that RM should not be misinterpreted as a replacement for an emergency system.

Recommendation-Specific Supportive Text

1. For logistical and organizational reasons, the vast majority of RM sites operates during normal working hours and are not able to provide review and response to these alerts and outside of their normal business hours. The benefit of reaction to alerts outside of the normal business hours has not been investigated. It is important that patients and their caregivers have an emergency management plan for a device problem in addition to RM.

2. Timely review and appropriate reaction to high-priority alerts are considered crucial. The definition of the term “timely” regarding RM is unclear, as there are no direct comparisons of clinical outcomes based on differing reaction times to critical alerts. Prompt review of alerts is important. Indirect evidence shows that daily transmission has better patient outcomes than with less frequent transmissions. A workflow based on review of transmissions within one business day was highly effective for detection and management of clinical events without overwhelming manpower and resource consumption.

Section 10 Alert-Based Remote Monitoring

The follow-up and management of increasing numbers of patients with CIEDs is generating larger workloads for clinical staff. Advances in telecommunication technologies can minimize this burden by monitoring chronic conditions during ambulatory care, thus creating more efficient healthcare systems. In the 2015 HRS Expert Consensus Statement, the recommendation was to interrogate CIEDs every 3 months, either in-person or remotely. In clinical practice, this regimen requires significant effort from both patients and clinic staff. These scheduled visits miss interim events until the next scheduled visit, delaying treatment of actionable alerts. RM systems are evolving to continuous RM, where device and disease-related alerts are generated as and when they occur and transmitted often within 1 day. Continuous RM may facilitate the implementation of alert-based RM, which is a combination of continuous RM with clinic visits that are prompted only by the detection of actionable events.

Recommendations for Alert-Based Remote Monitoring

<table>
<thead>
<tr>
<th>COR</th>
<th>LOE</th>
<th>Recommendations</th>
<th>References</th>
</tr>
</thead>
</table>

46
1. In patients with CIEDs and a component with a safety advisory, it is recommended that continuous monitoring be added to scheduled remote or in-person interrogation to enable early detection of actionable events.  

2. In patients with PM on RM with consistent and continuous connectivity, and in the absence of recent alerts or other cardiac comorbidity, it is reasonable to schedule in-person visits every 24 months.

3. In patients with ICDs on RM with consistent and continuous connectivity, and in the absence of recent alerts or other cardiac comorbidity, it is reasonable to schedule in-person visits every 24 months.

Synopsis
The implementation of continuous RM extends remote patient management beyond periodic calendar-based follow-up. In randomized clinical trials, RM was associated with a reduction of hospital use, staff workload, and a shorter time to clinical decisions. “Alert-based RM” was increasingly used during the COVID-19 pandemic out of necessity. The practice was effective and yielded a positive experience. This form of remote management has the potential to replace structured intermittent device follow-up (whether in-person or remote). This could minimize low-value effort, optimize clinic visits for actionable events, and could decrease healthcare costs. For Alert-based RM to be effective, there must be near-perfect connectivity, robust systems to assure connectivity from the manufacturers, and excellent patient compliance.

Recommendation-Specific Supportive Text

1. During the last few decades, the number of safety advisories for CIED components has increased due to the increasing complexity of the technology. Monitoring compromised CIED system integrity is challenging due to the unpredictability of CIED malfunction and the need for immediate action. The addition of continuous monitoring to regularly scheduled remote or in-person follow-up has been shown to allow for more rapid detection of, and response to actionable events, including system malfunction.

2. In randomized trials, alert-based RM in patients with PM was a safe, cost-effective, and an efficient substitute for conventional follow-up reducing hospital visits, staff workload, and facilitating early detection of actionable events. If there is consistent and continuous connectivity and the absence of recent CIED alerts or cardiac comorbidities requiring shorter follow-up durations, if the aforementioned conditions cannot all be met, more frequent in-person visits might be necessary.

3. Randomized trials comparing alert-based RM with conventional follow-up in patients with ICDs have shown a reduction in in-person visits, staff workload, almost immediate detection of actionable events, and improved patient retention, adherence and quality of life with continuous RM. If there is consistent and continuous connectivity and in the absence of recent CIED alerts or concomitant cardiac comorbidities requiring shorter follow-up
If the aforementioned conditions cannot all be met, more frequent in-person visits might be necessary.

Section 11 Patient Education for Remote Monitoring

Device implantation represents the beginning of a lifelong relationship between patients and their device clinic care providers. It requires communication and trust between patients and providers. Anticipating patients’ concerns before and after device implantation as well as adapting to their changing needs over time increases the likelihood that patients understand and adhere to the quality-improving and life-saving implications of RM. Evidence to support specific algorithms for timing and methodologies of patient education is sparse. Available evidence is confounded by technology complexity, including different transmission platforms supported by the various device companies. In-person instruction after device implantation is optimal, especially in the early follow-up period, to establish personal relationships with device clinic staff. This is often not possible based on a patient’s geographic distance from a device clinic. Also, patients may be overwhelmed by the experience of device implantation, so their retention of in-hospital education may be sub-optimal. There are different phases of patient education on RM; (1) BEFORE device implantation which promotes shared decision making, (2) SHORTLY AFTER device implantation which increases patient satisfaction and adherence and, (3) ONGOING education that adapts to the changing needs of the patient over time.

11.1 Patient Education for Participation & Compliance

<p>| Recommendations for Patient Education for Participation &amp; Compliance |
|-----------------------------|------------------|</p>
<table>
<thead>
<tr>
<th>COR</th>
<th>LOE</th>
<th>Recommendations</th>
<th>References</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>C-LD</td>
<td>1. In patients with CIEDs on RM, patient education should be delivered in plain language, at a basic reading level, and be individualized to support patient communication preferences and educational needs throughout the continuum of care.</td>
<td>183, 184</td>
</tr>
<tr>
<td>1</td>
<td>C-EO</td>
<td>2. In patients with CIEDs on RM, comprehensive patient education about RM is recommended for patients, families, and caregivers prior to device implantation to guide shared decision-making regarding device selection.</td>
<td></td>
</tr>
<tr>
<td>1</td>
<td>C-EO</td>
<td>3. In patients with CIEDs on RM, it is recommended that patient education start before implant and include the importance of ensuring ongoing connectivity to improve post implant patient compliance and monitoring effectiveness.</td>
<td></td>
</tr>
<tr>
<td>2a</td>
<td>C-LD</td>
<td>4. In patients with CIEDs on RM, providing a hands-on education session with the RM device can be beneficial.</td>
<td>185</td>
</tr>
</tbody>
</table>
Synopsis

High-quality patient education is delivered when patient’s level of comprehension and dynamic communication preferences are considered. To promote maximal engagement of the patient in decision making, family members should be included, and ideally the educational process should begin prior to device implantation. An initial in-person hands-on education session can promote trust and engagement.

Recommendation-Specific Supportive Text

1. In a study that assessed the readability of patient education materials on ICDs from a variety of sources (including industry, hospital resources, and patient support organizations), it was determined that 95% of the materials exceeded the recommended 8th grade reading level. Accordingly, this may explain the acknowledged disparity that patients with a preference for RM tend to have higher educational attainment. As part of identifying patients’ individual needs for optimal comprehension, information should be adapted to address personal and cultural preferences that will optimize communication. Beyond patients’ reading skills, additional factors that may limit their comprehension and should be considered when personalizing education include the following: age, language barriers, learning preferences for written versus auditory information, and sociodemographic factors and physical limitations such as visual or auditory impairment. It is also relevant to acknowledge that an individual’s educational preferences may change over time as individuals age.

2. Shared decision-making, especially for non-urgent procedures, ensures patient understanding and that their choices align with their goals and values. Sensitivity to this topic is essential in acknowledging the impact this may have on a patient’s decision to proceed with a CIED implantation. With a focus on patient-centered care, the Centers for Medicare and Medicaid Services (CMS) mandated documentation of an evidence-based patient decision aid for individuals receiving primary prevention ICDs for systolic heart failure. The engagement of patients’ family members and caregivers supports this process to promote the highest level of understanding possible. An additional factor regarding shared decision making for a CIED implant can be the manufacturer. What best aligns with an individual patients’ preferences for RM interaction, such as app-based software should be considered.

3. Formalized education on RM is an opportunity to enhance the understanding of practical device function and alert management. For non-urgent device implants, patients may be overwhelmed by hospital events surrounding the device implantation procedure. It is recommended that these educational efforts begin prior to implantation, preferably during the discussion for indication of the device. As ongoing connectivity is paramount for appropriate monitoring, the importance of its maintenance should be included in standardized education.

4. Survey-based studies have demonstrated that patients feel they receive less information and interact less with providers when they are remotely monitored than if they had in-person care. Doing an in-person, hands-on demonstration of the manufacturer-specific transmitter, or software that the patient will use for RM can provide an opportunity to answer all questions about the system. While this is not feasible for all patients all of the time, it should
be considered as part of the initial educational process to establish trust. Increased knowledge and understanding may improve patient adherence and connectivity to RM.

### 11.2 Patient Education of Clinic-Specific Policies

<table>
<thead>
<tr>
<th>COR</th>
<th>LOE</th>
<th>Recommendations</th>
<th>References</th>
</tr>
</thead>
<tbody>
<tr>
<td>2a</td>
<td>C-EO</td>
<td>1. In patients with CIEDs on RM, it is reasonable to communicate clinic-specific policies associated with RM to the patient.</td>
<td></td>
</tr>
</tbody>
</table>

#### Synopsis

The monitoring of patients with a CIED is a partnership between patients and their device clinic staff. When providing patient education, dialogue on clinic-specific policies sets clear expectations for patients who will be remotely monitored by that device clinic.

#### Recommendation-Specific Supportive Text

1. Clinic-specific policies should be established and presented to patients. In addition to verbal communication, this could also include an educational brochure or a patient/clinic agreement form. This information may include hours of clinic operation, remote scheduling, billing information, communication preference for device transmission report, and commitment to maintaining follow-up. The importance of updated and current contact information for the patient should be emphasized. It is critical to clarify that remote transmissions do not replace emergent care. Patients should develop an emergency plan in advance of a crisis situation. Instructions will be provided to the patient regarding who to contact for home monitoring troubleshooting including the manufacturers’ technology service phone numbers.

#### Section 12 Manufacturer Responsibilities with Remote Monitoring

Industry has a central role in the development of technology, and in ensuring its safety and effectiveness. These include: (1) informing clinic staff and patients about any disruption in the RM service; (2) communication about recalls and advisories to CIED clinic providers and patients in a transparent and timely manner; and (3) refraining from direct patient care (either within the clinic or at home). Although manufacturer representatives can play an important role in training clinic staff, it is not their role to perform, collect, or triage data on behalf of the clinic staff or be used as a staffing resource in lieu of local qualified personnel. It is the responsibility of industry to ensure RM systems function across varying geographies. This includes a need to overcome problems related to the telephone network, communication evolution, and the impossibility of using the electromagnetic spectrum band of the CIED already assigned for other uses. As the data resides on servers owned and managed by the manufacturers, the onus lies with the manufacturers to maintain the servers in a secure and encrypted environment. Privacy is of paramount consideration. The minimal standard is to maintain privacy in accordance with local and national laws. The data pooled from the servers are important to industry for quality assurance purposes (e.g., tracking device performance and watching for early signs of device trouble) and for making improvements to the CIED technology. The data are also of value to individual CIED programs for improving the quality of the processes. Finally, these data are essential to
investigators, independent of industry, and so it is important for manufacturers to have in place a procedure to process requests for an independent scientific review.

12.1 Manufacturers Role to Optimize Individual Patient Care

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<th>Recommendations</th>
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<tbody>
<tr>
<td>1</td>
<td>C-EO</td>
<td>1. For the care of patients with CIEDs on RM, manufacturers should provide clinic staff with adequate training, education, and technical support to optimize individual patient connectivity.</td>
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</tr>
<tr>
<td>1</td>
<td>C-EO</td>
<td>2. In patients with CIEDs on RM, the manufacturer should provide a RM system that is reliable, safe, accurate, and meets the needs of the patient.</td>
<td>179</td>
</tr>
<tr>
<td>1</td>
<td>C-EO</td>
<td>3. For the care of patients with CIEDs on RM, manufacturers should include key stakeholders in the design and development of technologies for RM.</td>
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<tr>
<td>1</td>
<td>C-EO</td>
<td>4. For the care of patients with CIEDs on RM, manufacturers should provide prompt notification of disconnection to the clinic, and to the patient to restore connectivity.</td>
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</tbody>
</table>

Synopsis

Successful and ongoing connectivity of individual patients is associated with challenges for RM clinics. Industry plays an important role in supporting clinics to provide and maintain this connectivity. This starts with the design and development of RM technology and continues through providing education to clinic staff and to patients directly. Patient care can benefit from the early notification of critical events, and this requires good compliance with RM. Including patient partners and clinic staff in the development and design of RM products will ensure that the technology will continue to evolve and meet stakeholder needs from the perspectives of ease of use, flexibility and reliability. Systems designed to clearly indicate, to both patients and the clinics, when connectivity has been interrupted will allow for the timely resumption of monitoring. Recent studies have highlighted the large workloads for RM clinics associated with maintaining connectivity. Technology that empowers patients to independently troubleshoot their RM systems would be optimal.

Recommendation Specific Supportive Text

1. Ensuring optimal connectivity of remotely monitored CIED patients, enhances patient safety, and can aid in clinical decision making. Manufacturer representatives are important partners in the training and education of RM clinic staff. This may take the form of onsite support (such as enrolling patients into a RM platform) or suggesting manufacturer specific programming settings or alert parameters. This manufacturer support also extends to providing online or in person technical help when troubleshooting connectivity concerns of individual patients.
2. As new devices and RM platforms are developed and upgraded, it is important to remember that no single RM transmitter technology will be suitable for all patients. Fraiche et al. recently highlighted a lack of understanding by patients about how RM works.\textsuperscript{188} Timmermans et al. found patients with negative RM experiences will opt for in-clinic follow-up.\textsuperscript{189} Manufacturer partners should consider having alternate systems available for those patients who have limited mobile connectivity or digital literacy. Mobile device applications should allow compatibility with all smartphone manufacturers, recognizing the financial burden that technology upgrades can have on a patient. Ideally, the RM transmitter will match the lifetime of the implanted device. Security concerns, including cybersecurity, are important to ensure both patient safety and the safety of their personal health information.

3. There are workload implications for clinics when there are high volumes of alerts and calls with patients to troubleshoot connectivity.\textsuperscript{112,160} The involvement of key stakeholders, including patients and clinic staff, in the development of RM technology will ensure that ongoing product designs will meet needs as technology rapidly evolves and changes. In addition, this collaborative approach with industry will lead to increased efficiency and satisfaction for stakeholders.

4. Studies have demonstrated that patient outcomes are directly correlated to RM adherence.\textsuperscript{7,190} Clinics need to be notified about disconnected patients in a prompt manner. Manufacturer monitors, or mobile applications, should provide a clear indication to patients about transmission status, and should provide easy to follow instructions to re-establish connection when connectivity is lost. Dechert et al. have found that when patients perceive a lack of device feedback (lack of recognition that the device is transmitting), patient-initiated transmissions increase, resulting in more extraneous data for the RM teams to review.\textsuperscript{191} If patients are able to troubleshoot and resolve connectivity issues unassisted, patient will spend less time disconnected, clinic work load will decrease, and clinical care will improve.\textsuperscript{96}

12.2 Manufacturers Role in the Management of Patient Safety Advisories via Remote Monitoring

As the implantation of CIEDs have become more commonplace, there have been more device hardware and software errors or failure, leading to manufacturer safety advisory or recalls. Data from as early as the 1990s and early 2000s found escalating numbers of recalls and advisories\textsuperscript{192} with a subsequent review of Food and Drug Administration (FDA) Enforcement Reports from 2000-2008 revealing a 26.4% recall alert of either device generator or leads. Though there were no major complications attributed to these alerts, the patient burden related to extra visits or procedures did lead to an increased cost burden.\textsuperscript{193} Additional studies confirmed the high volume of patients affected, though there continued to be no evidence of associated of increased mortality.\textsuperscript{194} Acknowledging these challenges, in 2005 the Heart Rhythm Society and the FDA convened a conference on pacemaker and ICD performance. The resulting taskforce called for improved communication from manufacturers to physicians and patients regarding recalls and advisories, and generally “more cooperation among industry, the FDA and the physician community.”\textsuperscript{195,196} Industry was asked to use the Patient Device Advisory Notification letter format to communicate with physicians and use patient registration information found at the time of implant to communicate with patients. The HRS Task Force on Lead Performance Policies and Guidelines (2009) further recommended that “manufacturers should develop and adapt RM technology to monitor
longitudinal lead performance.” The increased number of advisories have had a significant impact on provider workflow, financial costs, patient anxiety and patient safety. Patients can experience a range of emotions, including outrage, if such information is learned through media outlets and not from their clinical team. The clinical team requires early access to recall and advisory information to preserve trust in the patient-provider relationship.

### Recommendations for Manufacturers Role in the Management of Patient Safety Advisories via Remote Monitoring

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<tr>
<td>1</td>
<td>C-E0</td>
<td>1. For the care of patients with CIEDs on RM, manufacturers should contact the managing clinics with details of a safety advisory and assist in identifying affected patients both immediately and on a regular basis.</td>
<td></td>
</tr>
<tr>
<td>1</td>
<td>C-E0</td>
<td>2. For the care of patients with CIEDs with an advisory and on RM, manufacturers should provide guidance to clinics on optimal alert settings to manage the safety advisory.</td>
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**Synopsis**

Manufacturers and industry representatives play a vital role in the management of patients affected by CIED safety advisories by providing timely patient reports to the clinical team when devices meet advisory conditions. To help navigate vendor specific nuances, manufacturer guidance is critical for the clinical team to best manage the advisory through device reprogramming or reprogramming alert settings. Ongoing support to the clinical team with updated patient lists and safety advisory details should be routinely provided.

**Recommendation-Specific Supportive Text**

1. Manufacturers should directly contact the clinical team as soon as device safety advisories or recalls are issued. This should include a list of affected patients and specific system components involved in the advisory. Industry representatives should continue to contact clinical providers using different modalities (email, certified mail, or in person communication) until confirmation of communication is received. Updates to the safety advisories should be ongoing.

2. As part of advisory and recall communication, manufacturers or industry representatives should provide detailed guidance about how to manage the safety advisory through device reprogramming or alert settings. This may include changing the frequency of remote transmission or modifying details of critical alerts, or the development of novel advisory-specific alerts. Manufacturer representatives should also share planned or suggested long-term solutions to the safety advisory such as software updates, or potential lead or device removal.
12.3 Manufacturers Support Surrounding Implantation

### Recommendations for Manufacturers Support Surrounding Implantation

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<tr>
<td>1</td>
<td>C-EO</td>
<td>1. For patients undergoing CIED implantation, it is recommended that manufacturer’s provide adequate resources, including personnel, to ensure enrollment and connectivity to RM platforms before discharge or within two weeks of implantation.</td>
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<tr>
<td>1</td>
<td>C-EO</td>
<td>2. For the care of patients undergoing CIED implantation, it is recommended that manufacturer representatives provide the clinic staff with adequate training to properly program remote alerts specific to the clinical indication to minimize inappropriate alerts and need for consequential reprogramming.</td>
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**Synopsis**

RM platforms and device programming across manufacturers continue to have many distinct differences between manufacturers. Each manufacturer has a different RM interface that processes and reports alerts differently. Manufacturers vary in what is considered a red vs. yellow alert, and when these data get transmitted to the clinics. For example, some devices provide continuous monitoring RM, while others provide only non-continuous monitoring RM. Some device RM systems are connected to a mobile transmitter, while others utilize a stationary transmitter. This impacts the speed and frequency with which information can be shared with the clinical team. Each manufacturer uses unique CIEDs algorithms and software (and sometimes multiple algorithms/systems within a manufacturer), which can make it challenging for an implanter to recall the nuances of each system and device. Guidance on optimal manufacturer specific alert parameters relevant to a clinical scenario can minimize inappropriate alerts and need for immediate future reprogramming.

**Recommendation-Specific Supportive Text**

1. Manufacturers should provide either personnel (in-person manufacturer representatives), or adequate support of clinic staff through education, or “on-demand” off-site support to ensure that patients are properly enrolled into the manufacturer’s RM platform. This should ideally be accomplished prior to discharge, but no later than two weeks after discharge. This includes confirming that the chosen RM interface matches the patient’s technology literacy and ability. For example, connecting a patient living in a rural area with poor internet or cellular service, to a cellular based/wireless device may prevent successful remote transmissions and result in poor patient care.

2. CIEDs manufacturer-specific algorithms and software can pose challenges for implanters or clinic staff related to the nuances of each system and device. For example, criteria for a red (critical) alert can differ between manufacturers. Industry support during and immediately after implant can help ensure optimal device programming to meet the clinical indications. This guidance on optimal manufacturer specific alert parameters relevant to a clinical scenario can minimize
inappropriate alerts. Industry support during and immediately after implant can help ensure timely and optimal device programming.

Section 13 Third-Party Resources for Remote Monitoring

There is a high volume of data captured through remoting monitoring systems. The amount of these data can make it challenging to manage these data without adequate clinical staff and administrative support. To address this challenge, some hospitals and clinics have turned to third-party resources to aid in RM (Figure 13.1). Third-party resources refer to hiring an outside service to help with any of the tasks described later in this section. The use of third-party resources has potential clinical, financial and workflow benefits, but also has drawbacks. The goal is to ease the workload on overwhelmed staff in order to improve timeliness of remote transmissions review and enhance patient communication. Risks of using third-party resources include exposing private patient data to maleficence (hacking). Adoption of third-party resources into a RM program requires careful thought and consideration to ensure patient safety and optimize communication between the patient and medical team.

Third-party resources may be task specific (e.g., only reviewing CIED alerts) or encompass the entire RM process. Third-party resources should not include professional decision making. Some third-party providers act as a “middleware services”, centralizing data from multiple manufacturers. Others offer comprehensive services that include facilitating patient enrollment in RM, assessing and addressing compliance to transmission, providing review of routine and acute CIED transmissions with accompanying report, notifying medical team of actionable data, generating a service charge, and integrating report data with the electronic medical record to support patient communication. They can assist with troubleshooting, patient feedback and billing. These third parties may use either cloud based or server-based services to store patient data.

13.1 Use of Third-Party Resources in Remote Monitoring

<p>| Recommendations for Use of Third-Party Resources in Remote Monitoring |
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<tr>
<td>2a</td>
<td>C-EO</td>
<td>1. For the care of patients with CIEDs on RM, it is reasonable to use third-party resources for the initial review and triage of remote transmissions to alleviate RM data burden on local staff.</td>
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<tr>
<td>2a</td>
<td>C-EO</td>
<td>2. For the care of patients with CIEDs on RM, it is reasonable to inform patients about the use of third-party resources to facilitate patient care.</td>
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Synopsis

Relying on a third-party resource may assist programs with under-sized staffing resources to meet the standards of care expected for an efficient RM program. The use of third-party resources poses many challenges, including cybersecurity risks, dependency on data processors to share clinical information, and potential financial burden. Third party personnel should be well-trained in device interrogation management and ideally have credentials that verify this training. Many third-party resources are cloud-
based and rely on cloud data storage. This can introduce a risk for data breach or loss, that may affect patient data privacy and safety. It is important for patients to be informed that the institution utilizes third party services. Furthermore, institutions can become dependent upon the third-party resources to initially review and triage patient clinical information in an accurate and timely manner. Third-party resource workforce shortages or novice employees may risk missing actionable event transmissions thus affecting patient care and safety.\(^{200, 201}\) The costs of such third-party resources can become a financial burden for smaller institutions as third-party resources collect a technical fee for each transmission.\(^ {152}\) One less technical concern is that the use of a third-party service may change the patient’s perception of the patient-medical team relationship. The loss of a more personal connection with the clinic team may decrease patient compliance and satisfaction.

**Recommendation-Specific Supportive Text**

1. Third-party resources have created the infrastructure to manage high volume data. Offloading administrative tasks from clinical personnel (nurses, advanced practitioners, and physicians) can improve staff efficiency with resulting financial benefits. Furthermore, redistribution of administrative tasks can help alleviate burnout associated with such burdensome tasks.\(^ {202}\) Quality of care and communication between providers and patients may improve when outsourcing to third-parties if more data can be reviewed and results communicated in a timely manner.\(^ {200, 201}\)

2. RM is a communication process that transmits patient data between data controllers and data processors.\(^ {203}\) Institutions have traditionally been the data controllers with manufacturers or third-party resources acting as data processors. Using third-party resources for their monitoring or reporting services, adds an additional layer between the processor and controller (Figure 13.1). Each additional interface between the processor and controller introduces the opportunity for potential maleficence (hacking). Traditional data processors (device manufacturers) use either their own secure servers or engage the hosts’ servers through a virtual private network connection. The legal and regulatory implications of outsourcing patient data must also be considered.\(^ {203}\) For example, the General Data Protection Regulation (GDPR) in the European Union was implemented in 2018 and provides a legal framework for participating countries. This requires patient consent for the transfer of data to a third party. Other countries across the globe are working to emulate this landmark regulation. CIED patients need to be aware of the use of third-party services in order to properly provide their informed consent for enrolling in a RM program.
Section 14 Geographic Differences with Remote Monitoring Practices

Despite near global availability of RM by a limited number of manufacturers, there is significant geographic variability in the uptake of RM, both within countries and between countries and regions.\textsuperscript{7} Significant variability also exists as to how RM is conducted, including the frequency of scheduled transmissions, enrollment criteria for RM, and the technologies used for RM.\textsuperscript{204} Disparity exists due to a multitude of barriers that includes insufficient reimbursement for patients and care teams, a lack of manpower resources, and inadequate infrastructure for RM.\textsuperscript{83,89}

Figure 13.1 Remote monitoring outsourcing circuit by third-party resources. CIED – cardiovascular implantable electrical device.
14.1 Availability of Remote Monitoring

### Recommendations for Availability of Remote Monitoring

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<tr>
<td>1</td>
<td>C-EO</td>
<td>1. For the care of patients with CIEDs, health systems should identify local barriers, and develop strategies to optimize the successful use of RM globally.</td>
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**Synopsis**

RM has been developed to address limitations with in-office follow-up, such as late detection of medical or technical actionable events, by providing need-based care and continuous surveillance of CIED devices. In 2013 an update on the use of RM in the Asia-Pacific region reported a global availability of RM, but the actual use of RM was highly variable. While utilization was very limited in South East Asia, India and Hong Kong, up to 50% of patients with an ICD or CRT in Japan were provided with RM. Availability is a necessary prerequisite, but it does not necessarily lead to adequate use and patient compliance. Real-world data from 2014 on the RM of ICDs and CRT-Ds illustrated large geographical variability in the compliance of RM within the US with noncompliance rates ranging between 8.5% and 19.5%.

**Recommendation Specific Supportive Text**

1. There are very limited data available on geographical disparities in RM availability, use, and compliance. Future research should focus on identifying barriers to RM adoption and compliance, as well as their respective solutions. Examples of these barriers include geographical and socio-economic disparities. The optimal approach to this research would involve a collaboration between patients, health systems, and RM providers.

**Section 15 Knowledge Gaps and Future Needs**

The innovations in RM technologies over the last few decades have greatly contributed the advancement in the “standard of care” for patients with CIEDs. The vast potential of these technologies is just starting to be harnessed. Advances are still needed on many fronts—technology development, policy leadership, payment reform, and patient-centered communications. Seven important challenges related to remote care of patients are enumerated below. If these can be adequately addressed in the coming years, there is great potential to improve the quality of care that we can deliver to our patients.

**15.1 Remote Monitoring Can “Shorten” Large Geographic Distances**

While some countries are geographically small with a high population density, other countries are large with areas of very low population density. Examples of the latter in North America might be in parts of the central regions of the United States or in the Canadian North. Patients may need to travel great distances in order to receive CIED care. RM might be able to address this problem. It is likely not be feasible to set up CIED clinics with trained staffed in every small town. One could imagine, however, a site-based remote monitor in smaller towns that could be interpreted remotely by trained CIED staff. A network of these monitors could be deployed which could decrease the costs for staffing, costs to the
patients, and inconveniences to patients living in these communities. If the CIED interrogation is reassuring, then no further action would be required.

15.2 Remote Programming

One of the great benefits of RM is the ability to provide high quality care to patients who are not near a CIED clinic (or a programmer). Currently, these benefits accrue primarily to those patients in whom the programmed settings are optimal. If the remote interrogation provides actionable information necessitating reprogramming, the patient needs to travel to a CIED clinic (or at least to a physical CIED programmer) for care. Fortunately, this applies only to a minority of interrogations.

The next frontier will not only encompass RM of patients with CIEDs, but true “remote programming”. In the future, care needs to be delivered to the patient where the patient lives—ideally in the patient’s home. There have been tests of remote programming from over 20 years ago (Personal Communication with Dr. AM Gillis). More recently, remote programming has been reported in a case series from China, in the context of reprogramming a CIED before and after a magnetic resonance imaging scan, and there is a study testing this in Bordeaux, France (https://clinicaltrials.gov/ct2/show/NCT05366660). Each of these have used a model of remote programming that requires a programmer near the patient. These small forays into remote programming need to be expanded to the point that they do not require the patient to be in a healthcare facility. Only then will this be a readily available treatment for our patients. The engineering challenges are likely easily surmountable. It is critical that this technology be deployed in a manner that instills confidence in both patients and providers about the safety and security of RM.

15.3 Inequitable Access to CEID Remote Monitoring

RM was strongly recommended for most CIED patients in the 2015 HRS Expert Consensus Statement. Across the world in 2022, most CIED patients do not have access to RM. There are huge disparities in the utilization of RM both between countries and within counties. There are different reasons for these disparities. In some cases, they relate to the cost burden on some national health systems. In other cases, the telecommunications infrastructure might not be able to provide a stable backbone for RM. In some smaller city-states, the value proposition has not been clear to the payers given the short distances between the citizens and the CEID clinics. Within the United States, patients are often required to make a monthly co-payment for their RM. Without obvious benefits that are tangible to the patient, many patients decline further RM.

There are many different problems leading to this variability in access to RM, so there need to be many different solutions. In some cases, the solutions are changes to government policy, in other cases technological solutions are needed, and in some cases novel reimbursement models are required. Efforts will be required on multiple fronts to decrease these disparities.
15.4 Reimbursement Reform for Remote Monitoring

There are currently many challenges with the reimbursement model for RM. First, there is a large variability in what the Medicare program pays for RM visits across the United States. This variability makes RM financially challenging in some parts of the United States. This makes little sense, especially since the background structural costs of RM are likely similar for central monitoring services.

Second, the co-payments required for RM (mentioned above) serve as a barrier to optimal patient care. In the United States, while co-payments are often required for diagnostic care and for treatments, co-payments can be waived for preventative care and screening tests. Most CIED RM could be considered a form of preventative care. The remote visits are to ascertain whether there is a problem that might be treated, even in the absence of symptoms, to prevent progression to more serious and potentially life-threatening problems.

Third, there is significant worldwide heterogeneity in the reimbursement for RM. In Europe, many clinics receive no reimbursement for RM, and this has been identified as a major barrier to the use and expansion of RM. Uptake of RM has slowed in parts of the Asia-Pacific regions, with a lack of reimbursement identified as a barrier in many locales.

Finally, a larger shift may be needed in how we think about RM of CIEDs. Currently, most remote visits are scheduled in advance at a pre-specified interval. This is a relic from the CIED clinic visits that were used exclusively prior to RM. Most of these visits (both remote and in person) conclude that the CIED is working properly and that no further action is needed. One could argue that those visits are of “low-value” to the patients, but they still require a significant effort from trained clinic staff (with the related costs). While clinic reimbursements are tied to these visits, this “low value care” will continue. To shift efforts to an “alert-based” model of care that focuses on clinic visits for actionable event will require a restructuring of CIED clinics and their reimbursement models. The reimbursement would need to shift from the current model of reimbursement on a per visit basis, to a model of reimbursement for care over a window of time (e.g., annually). We need a model where the system of reimbursement is designed to match the optimal care for the patient, instead of the care of the patient being designed to match the system of reimbursement.

15.5 Move from “Remote Monitoring (RM)” to “Remote Patient Monitoring (RPM)”

This document has been focused on RM from prescribed CIED devices. Increasingly, our patients are using consumer-based wearable monitors that can collect and transmit large volumes of data to healthcare providers. An emerging challenge is how to manage these data. The issues include how to incorporate these data into electronic health records, who should review these data, and how should they be compensated for these reviews. Many wearables provide disparate information in addition to heart rate. These could include heart failure diagnostics, blood pressure, and temperature. While CIED clinics are currently best equipped to deal with remote information, it might be optimal to have specific information delivered to the most appropriate providers, with some data coming to the CIED clinic, some data going to the heart function clinic, and other data going to the primary care physician. Using
this “team care” approach, we can shift from remotely caring for the device to remotely caring for the
patient.

15.6 Better Information...Not More Information

RM has generated a lot of information. CIED providers are already suffering from “information overload”
with frequent transmissions, especially from ILRs. The increasing use of wearable technologies with
transmission capabilities will only make this problem worse.

The problem is that while some of these data are valuable, most of these data are not useful. It can be
very labor intensive (and costly) to manually review all these data to find the important bits. This is
where Artificial Intelligence (AI) might prove to be particularly valuable. There have already been some
early publications about AI models improving the classification accuracy of diagnoses by ILRs. There are also studies assessing whether AI could be used to predict ventricular arrhythmia events and IC therapies. If these algorithms could be used to enrich the quality of the data that requires manual review by staff, this would enhance patient care.

15.7 Direct Patient Access to Device Information

Some patients want to know about all their CIED parameters, while other patients just want to know
that everything is okay. Both types of patients are entitled to information about the function of their
CIED in their desired manner. This must be approached from the viewpoint that the patient “owns” their
health information. Some jurisdictions have laws in place mandating this, such as the General Data
Protection Regulation (https://gdpr-info.eu/art-20-gdpr/) in the European Union. Whether or not it is
the local law, this is correct approach to take using a patient-centric perspective. The challenge is in
presenting this information in a way that conveys information effectively and efficiently to the patient,
in accordance with their preferences. Manufacturers need to provide clinics with better tools to aid in
this communication. This is critical if our goal is to care for the patient and not just care for the device.

15.8 Summary: Past, Present, and Future

RM has already enhanced the care of CIED patients which is why the use of RM is a class I
recommendation in this 2015 HRS Expert Consensus Statement. The early models of care with RM
followed the same pattern as the prior clinic visits, with the sessions scheduled and planned. This is still
the pattern with non-continuous monitoring. Most of these visits confirm that the device is working
appropriately, and do not require any intervention from the clinic staff. The current schedule of RM
visits is often driven by the reimbursement schedule for RM visits. For example, if reimbursement for
RM is provided every 91 days, then clinics are incentivized to schedule these RM visits every 91 days.

Increasingly, we are seeing RM platforms with continuous monitoring of devices that can transmit to the
clinic information about the lead function, device function and the patient’s clinical status (e.g.,
development of atrial fibrillation) shortly after problems develop. This could allow for the transition to
alert-based care. In this model, there would be fewer routinely scheduled “low-value visits” (and
perhaps eventually none), with visits scheduled based on device alters suggesting that device
reprogramming or other intervention is needed for patient care ("high value visits"). We can move to a model of care driven by optimizing care for the patient.

For this to happen, all stakeholders need to participate. Manufacturers need to transition more completely to RM platforms that offer reliable continuous monitoring. Healthcare facilities need to staff their clinics properly to address both the volume of RM transmissions and the unpredictable nature of alter-based RM. Payers need to develop novel payment schemes that are provide payment to clinics for managing the patient with CIED for a duration of time (e.g., annually), and not only for a visit.

This paradigm shift has the potential to reduce the requisite clinic resources, to decrease healthcare costs, to save time and money for patients, and to improve patient satisfaction.

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