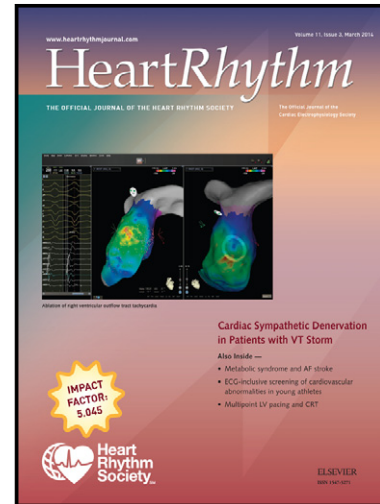


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HRS Expert Consensus Statement on Remote Interrogation and Monitoring for Cardiovascular Electronic Implantable Devices

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Keywords: Cardiac resynchronization therapy-defibrillator, Cardiac resynchronization therapy-pacemaker, Implantable cardioverter defibrillator, Pacemaker, Remote monitoring.

Abbreviations: ABIM=American Board of Internal Medicine, CIED=cardiac implantable electronic devices, CRT-D=cardiac resynchronization therapy devices, resynchronization Defibrillator, IBHRE=International Board of Heart Rhythm Examiners, IPE=In-person evaluation, RM=remote monitoring

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Introduction

Cardiovascular implantable electronic devices (CIEDs) have evolved significantly since the publication of the 2008 Heart Rhythm Society (HRS) Consensus Statement outlining recommended monitoring strategies.¹ Novel embedded technologies have created the ability for devices to monitor their own function, record arrhythmias, and other physiological parameters, and communicate this information to health care providers without the active participation of the patient. CIEDs with wireless remote monitoring (RM) capabilities stand at the forefront of a new class of medical devices that will unobtrusively acquire vital data beyond the walls of health care facilities and seamlessly transmit the information back to health care providers. This document focuses on implantable devices for managing heart rhythm disorders.

The 2008 recommendations were, by necessity, consensus driven, without objective evidence to inform clinical practice. The document recognized that contemporary CIED follow-up has been neglected and that many patients were not receiving the recommended follow-up care. This deficiency was subsequently confirmed; patient follow-up has been erratic, with only 22% of patients seen in person during the first year.² The 2008 document advocated for structured follow-up that employs a system of regular in-person evaluations (IPEs). Remote interrogation (RI) and RM technologies (defined below) were developed as complementary tools to replace some of the routine follow-up appointments during the long-term phase of CIED management, while maintaining an IPE schedule of at least 6–12 months.³

Since 2008, randomized controlled trials have compared IPE vs remote management strategies for the follow-up care of patients with CIEDs. Various trials have also explored the ability of RM to detect problems early, thereby improving patient outcomes. The trials have employed a variety of proprietary technologies in various health care models, and have collectively shown the superiority of RI and RM for achieving the follow-up goals of patient adherence to structured follow-up protocols and improvement in

device clinic workflow efficiency. The advent of automatic wireless RM has been critical to these results, a change in paradigm that forms the basis for the new recommendations.

The current document was developed from the foundations established by the 2008 HRS Consensus Statement¹ and the 2012 Expert Consensus Statement on Remote Monitoring of CIED by the International Society for Holter and Noninvasive Electrocardiography and the European Heart Rhythm Association.⁴ The goals for the follow-up, hardware definitions, and personnel remain the same and will not be covered in this document, except for cases in which remote technologies and responsibilities have evolved. The current document provides new recommendations based on data published since 2008, endorses the need to maintain consistent follow-up, and outlines the limitations of strictly in-person methods. We focus on the organizational changes required to most effectively implement RI and RM, from the occasional replacement of routine appointments (for patient and clinician convenience) to a system of nearly continuous monitoring, with most IPEs initiated in response to alert notifications communicated by RM, thereby improving the quality and efficiency of patient care.

Remote Interrogation vs Remote Monitoring

The terms RI and RM are often used interchangeably, with RM the colloquially accepted term for both. RI and RM, however, refer to different and complementary tools, which we will define below and address separately throughout the text.

RI refers to the routine, scheduled, remote device interrogations structured to mirror in-office check-ups.⁴

⁵ Practically all information obtained during an in-office device check-up can now be obtained remotely.

An important exception to this is the data for measuring the pacing capture threshold, which is available only for devices capable of automatically measuring the capture threshold.

RM refers to the automated transmission of data based on pre-specified alerts related to device functionality and clinical events.⁴ This provides the ability for rapid detection of abnormal device function and/or arrhythmia events.^{6,7}

Methodology of Document Preparation

The writing group was comprised of content experts representing the following organizations: the Heart Rhythm Society (HRS), the Latin American Society of Cardiac Pacing and Electrophysiology (SOLAECE), the American College of Cardiology (ACC), the European Heart Rhythm Association (EHRA), the Pediatric and Congenital Electrophysiology Society (PACES), and the Asia Pacific Heart Rhythm Society (APHRS). The members of the writing group performed a comprehensive literature search, developed a series of recommendations, and provided explanations for the reasoning and research used to make each recommendation outlined in the document text.[♦] The recommendations were voted on, with the vote threshold for inclusion set at 80%. The Classification of Recommendation and Level of Evidence followed the recently updated American College of Cardiology/American Heart Association standard.⁸ Class I is a strong recommendation, denoting a benefit greatly exceeding risk. Class IIa is a somewhat weaker recommendation, with a benefit probably exceeding risk, and class IIb denotes a benefit equivalent to or possibly exceeding risk. Class III is a recommendation against a specific treatment because there is either no net benefit or there is net harm. Level of Evidence A denotes the highest level of evidence, usually from multiple randomized clinical trials or from a single randomized clinical trial and a high-quality registry. Level of evidence B indicates a moderate level, either from randomized trials (B-R) or well-executed nonrandomized trials (B-NR). Level of evidence C is from

[♦] A review of relevant data was performed including evidence conducted in human subjects and that were published in English from PubMed, EMBASE, Cochrane, and the Agency for Healthcare Research and Quality Reports. Key search terms included but were not limited to the following: pacemaker, implantable defibrillator, cardiac resynchronization therapy device, remote monitor, remote interrogation, transtelephonic, randomized controlled trial, meta-analysis, registry, and observational trials.

weaker studies with significant limitations, and level of evidence E is from consensus opinions in the absence of credible published evidence.

Industry Forum

The writing committee believes that the problems faced by patients with heart rhythm disorders cannot be addressed if clinicians, scientists, and industry work in isolation and that the value of this document would be enhanced by a structured dialogue with industry to address technical questions and gain an understanding of the challenges faced by industry in advancing this technology. Due to the potential for actual or perceived bias, strict parameters had to be established for information sharing. It is the policy of HRS that industry may participate in the development of clinical documents in an advisory capacity but not in its authorship. To this end, manufacturers of cardiac rhythm management devices and related industries were invited to join the writing committee at a forum on emerging technologies. The forum provided a venue for sharing important research and innovation and helped inform the writing committee's recommendations for future developments in the field.

Section 1: History and Description of Remote Monitoring Technology

The remote evaluation of CIEDs began with the transtelephonic monitoring (TTM) of pacemakers, which was first introduced in 1971. Soon after its adoption, the supplementation of in-office visits with TTM for pacemaker follow-up became common in North America. TTM is still in use, and its function remains essentially unchanged.¹ The technology delivers limited data on pacemaker function via analog transmission over a telephone landline; the information includes sensing, capture, and battery longevity data, as well as a real-time electrocardiogram (Figure 1). TTM requires coordination with the clinical staff to receive and interpret the data. Verbal communication between the patient and the nurse or technician who performs the TTM is necessary, allowing real-time assessment of the patient's clinical status. TTM technology is not capable of retrieving diagnostic data from the device's memory and can provide only

rudimentary data on the pacemaker's function. RI and RM technologies, which are now incorporated in all CIEDs, are recommended over TTM because of the additional diagnostic data they provide.⁹

Despite its limitations, TTM remains an important tool for places where more advanced technological solutions have not or cannot be instituted.

In the late 1990s, inductive technology was incorporated into CIED RI systems (Figure 1).^{10, 11} These systems use a wand-based radiofrequency platform to transfer data between the patient's device and a transceiver. The remote inductive interrogation procedure is similar to that performed at a typical IPE. Once the wand is placed over the device, the programmed, stored, and measured data are sent via real-time radiofrequency transmissions from the patient's device to a home transceiver. The patient receives feedback regarding the success or failure of the transmission. The data are then sent from the transceiver by telephone to a central repository where they are stored and processed securely. Communication between the in-home transceiver and the central storage repository can be conducted using either analog phone lines or a cellular wireless data network. The data are then available via a secure dedicated Internet site for the provider to retrieve and review. Inductive systems can be time consuming and cumbersome to operate, can create challenges for compliance, and do not automatically transmit asymptomatic events.^{11,}

¹²

In 2001, the first fully automatic platform for RM was introduced.¹³ Currently, multiple such platforms are in use. Automatic RM offers the advantage of independence from patient or physician scheduling. Although there are proprietary differences, essentially the implanted device initiates transmissions periodically at set frequencies (ranging from 3 weekly to daily) and additionally if certain abnormal criteria are detected. Symptomatic patients may also initiate the interrogations. Radiofrequency transmissions are sent wirelessly to a transceiver located close to the patient, typically in the patient's bedroom (Figure 1). Using either analog landlines or wireless data networks, the transmitted data are sent

to the manufacturer's central repository for storage and retrieval. Physicians or designees typically access the patient data by logging onto a secure, dedicated Internet website.

Section 2: Evidence supporting Remote Interrogation and Monitoring

Most large-scale randomized trials of remote follow-up paradigms have employed both RI and RM as complementary tools; however, several important early studies have examined RI alone.

Remote Interrogation: Clinical Benefits

RI technology was first implemented for managing patients with implantable cardioverter defibrillators (ICDs) to reduce the frequency of scheduled in-person follow-up visits. Two prospective studies evaluated the technology from the perspective of the patient and clinician.^{10, 14} Patients reported high satisfaction and acceptance of the technology, and clinicians found the data to be reliable and sufficient for evaluating device function and detecting arrhythmias, while reducing the frequency of IPEs.

The Pacemaker Remote Follow-up Evaluation and Review study examined the hypothesis that frequent scheduled RIs of pacemakers might be superior to routine IPEs by providing early identification of significant findings such as ventricular arrhythmias, atrial fibrillation, device/lead malfunction, and battery voltage elective replacement indicator (ERI) status (i.e., clinically actionable events).⁹ This prospective randomized trial enrolled 980 patients who were assigned in a 2:1 ratio to undergo RI vs a control group assigned to IPE and TTM-based follow-up. Over the 12-month study, clinically actionable events were detected significantly sooner among the patients randomized to RI compared with IPE+TTM (mean time of 5.7 months and 7.7 months, respectively; $P < .0001$). Among the patients undergoing RI, 446 of 676 events were detected (66%) compared with only 3 of 190 (2%) events for patients undergoing IPE+TTM.

These early clinical trials of RI validated its safety, effectiveness, and patient and clinician satisfaction.

Remote Interrogation Combined with Remote Monitoring: Clinical Benefits

The combination of RI and wireless RM allows for nearly continuous monitoring, providing daily self-testing and event notification for out-of-bounds parameters, which are not possible for wanded telemetry systems. These complementary follow-up tools form the basis of the clinical trials discussed below.

Follow-up Optimization and Patient Safety

The 2008 transatlantic consensus recommendations advocated a regular calendar-based follow-up system of either IPE or RI, although their comparative efficacy and ideal ratio was unknown at that time.¹ Since then, the Lumos-T Safely Reduces Routine Office Device Follow-Up (TRUST) trial in 2010 (Table 1) compared and contrasted the 2 methods, with results showing that RI combined with RM more effectively and durably attained the follow-up goals of timely scheduled follow-up and patient retention (Figure 2).^{15,16} Moreover, replacement of many IPEs with RI follow-up evaluations created efficiencies for both patients and clinics.^{15, 17, 18}

Abbreviations: CONNECT = Clinical Evaluation of Remote Notification to Reduce Time to Clinical Decision; TRUST = Lumos-T Safely Reduces Routine Office Device Follow-Up Trial.

CIED evaluation at prescribed intervals (every 6–12 months for pacemakers and every 3–6 months for ICDs and resynchronization devices¹ can be facilitated by RI and RM. Several studies that have demonstrated this are listed chronologically in Table 1. Results consistently show that replacing IPE follow-up visits with RI for at least 1 year can reduce the volume of IPEs by approximately 50% for patients with all types of CIEDs, without compromising safety and improving the early detection of clinically significant events (Table 1 and Figure 2).^{15, 16, 19-21} In the TRUST trial, RM reduced the number of scheduled and unscheduled hospital evaluations by almost 50%, with no increase in the incidence of death, strokes, or events requiring surgical intervention. RM also shortened the time to detection of

arrhythmic events to a median of 1 day, compared with the more than 30 days with quarterly conventional care (Table 1).^{21, 22} The CONNECT study showed that the median time from clinical event to clinical decision per patient was reduced from 22 days in the in-office arm to 4.6 days in the remote arm ($P < .01$) (Table 1).²¹ The Effectiveness and Cost of ICD Follow-Up Schedule with Telecardiology (ECOST) study endorsed the safety of RM extended over a period of 24 months (Table 1).²³ The Evolution of Management Strategies of Heart Failure Patients With Implantable Defibrillators (EVOLVO) study showed that the rate of emergency department or urgent in-office visits was 35% lower in the RM arm than in the IPE arm. Furthermore, there was a 21% reduction in the rate of total health care visits for heart failure, arrhythmias, or ICD-related events.⁹ The REFORM trial showed that ICD follow-up using adjunct RM can reduce the number of IPEs by 63.2%, with no difference in the hospitalization or mortality rates.¹⁹ Although most patients in the above trials had ICDs and cardiac resynchronization therapy devices (CRT-Ds), the PREFER and COMPARative follow-up Schedule with home monitoring (COMPAS) trials demonstrated similar results for early event detection and the reduction of outpatient clinic loads for patients with pacemakers followed with RM.^{9, 24}

In summary, several large randomized prospective trials conducted with different proprietary RM technologies (including pacemakers, ICDs, and CRT-Ds) in various countries have consistently shown that the replacement of most routine IPEs with RI and RM reduces the number of health care visits, provides earlier detection of actionable events, and does not compromise safety.

Table 1: Remote Follow-up: Clinical Evidence *

Study Name or author	Year	Study Type	Study Size	Inclusion Criteria	Endpoints	Results	Findings	Statistical Values
Randomized Trials – Pacemakers								
PREFER⁹	2009	Randomized, prospective, multicenter	897 pts	VVI/DD D PMs Medtronic CareLink RM	Mean time to first diagnosis of CAEs comparing RM arm vs control arm.	FU: 375±140 days. Mean time to first diagnosis of CAE was 5.7 months in RM arm vs 7.7 months in the control arm.	Mean time to first diagnosis of CAE was shorter in the RM arm.	$P = .0001$
COMPAS²⁵	2011	Randomized, multicenter	538 pts	DDD PMs indications, no PM dependencies. Biotronik HM	MAE: hospitalization for PM-related complications, CV events, and death. Incidence of each MAE. RM reduction of in-office visits.	FU: 18 months. MAE: 17.3% in RM arm vs 19.1% in control arm. Hospitalization due to PM complications (0.4%) in RM arm vs control arm (2.8%) Mean number of unscheduled FUs per pt per year: 56% lower in RM arm.	RM was safe and reduced the number of in-office visits. RM enabled earlier detection of clinical and device-related adverse events.	OR: 0.90 OR: 0.14 $P = .01$
Randomized Trials – ICDs								

* Table summarizes clinical trials discussed in the document text.

TRUST ^{6, 15, 16, 26}	2010	Randomized, prospective, multicenter	1339 pts	VVI/DD D ICDs, no PM dependent. Biotronik HM	Total in-hospital device evaluations. Overall adverse event rate. Time from event onset to physician evaluation.	In-hospital device evaluation was 2.1 per pt per year in the RM arm vs 3.8 per pt per year in the control arm. Overall adverse event rate was 10.4% in both groups at 12 months. RM reduced event detection delay by >30 days	RM was safe in supplanting 'routine' in-office visits, enabling early event detection in ICD recipients.	$P = .001$ $P = .005$ Noninferiority
CONNECT ²¹	2011	Randomized, prospective, multicenter.	1997 pts	ICDs and CRT-D. Medtronic Carelink	Time from a clinical event to a clinical decision. Evaluated hospitalization on LOS.	22 days (in-office arm) vs 4.6 days (RM arm). Health care use for CV reasons: 4 days (in-office arm) vs 3.3 days (RM arm). LOS per hospitalization was 3.2 days in RM arm vs 4.3 days for in-office arm.	RM reduced the time to a clinical decision. RM reduced the mean LOS	$P = .001$ $P = .007$
ECOST ²³ Clinical aspects	2012	Randomized, prospective, multicenter.	433 pts	ICDs. Biotronik HM	Incidence of MAE (all-cause and CV death). Procedure-related	FU: 24.2 months MAE: 40.3% vs 43.3% in the RM and control	RM was as safe as standard FU. RM reduces appropriate	HR: 0.90. (noninfer.) $P = .02$ $P < .005$

					complications and device-related adverse events.	arm, respectively. Appropriate and inappropriate shocks delivered were 71% lower in the RM arm. 76% reduction of capacitor charges.	and inappropriate shocks. Battery longevity increased in RM arm.	
Economic aspects	2014		310 pts		Economic impact of RM in ICD pts.	Nonhospital costs: RM €1695±1131 Conventional €1952±1023 Hospital costs: RM €2829±6382 conventional €3549±9714. Adding the ICD to the nonhospital costs, the savings were increased to €494 or, when the monitoring system was included, to €315 per pt per year.	RM reduced mean nonhospital costs per pt per year. RM did not significantly reduce the hospital costs per pt per year.	$P < .04$ $P = .46$ $P < .005$ $P < .05$
EVOLVO 27	2012	Randomized	200 pts	LVEF ≤35%.	Rate of emergency	FU:16 months	RM reduced the	$P < .005$

Clinical aspects		prospective, multicenter		Medtronic ICD or CRT-D with thoracic impedance measurement capabilities (OptiVol)	department or urgent in-office visits for heart failure, arrhythmias or ICD-related events.	Total events: 0.59 in RM vs 0.93 events per pt per year in control arm. Number of urgent visits per pt per year for heart failure, arrhythmias, or ICD-related: 4.4 in RM vs 5.7 in control. Time from ICD alert to review: 1.4 days in RM vs 24.8 days in control	number of emergency department or urgent in-office visits and health care use. RM increased the efficiency of health care.	$P < .001$ $P < .001$
Economic aspects	2013				Economic impact of RM in ICD pts with HF.	Costs: €1962 vs €2130 Costs for pts: €291 versus €381 Cost-utility: pts in RM had a cost saving of €888 per pt and gained 0.065 QALYs more over 16 m.	No significant annual cost savings for the health care system. Significant reduction of the annual cost for the pts and gained QALYs in the RM arm.	$P = .8$ $P < .01$
REFORM (2nd analysis) ¹⁹	2013	Randomized, Parallel Quarterly clinic visits	155 pts	ICD implanted according to MADIT II	Scheduled and unscheduled ICD visits.	FU: 24 months FU visits reduced by 58% (3.8	RM safely reduces the ICD FU burden for 27 months after	$P = .001$ $P = .03$

		(Q-arm) vs yearly clinic visits (Y-arm)		criteria.	<p>Difference in quality of life scores at baseline and after 27 months.</p> <p>Total and CV mortality.</p> <p>Rate and length of all-cause and CV hospitalizations.</p>	<p>Q-arm to 1.6 Y-arm per pt per year.</p> <p>Unscheduled FU per pt year was 0.27 in Q-arm vs 0.64 in Y-arm.</p> <p>All-cause mortality was not different between groups.</p> <p>Y-group did not exceed one additional visit per pt-year</p>	<p>implantation.</p> <p>Favorable impact of RM on quality of life.</p> <p>No impact on mortality and hospitalization rate.</p>	<i>P</i> = ns
Calo ²⁸	2013	Prospective, randomized	233 pts	Biotronik, Boston Scientific, Medtronic, and St. Jude	<p>Assess current direct costs of 1-year ICD follow-up based on RM compared with conventional quarterly in-hospital follow-up from the hospital and patient perspective.</p>	<p>FU required 47 min per pt per year in the RM arm vs 86 min in the control arm.</p> <p>The costs associated with RM FU vs standard FU was USD 103±27 vs 154±21 per pt per year.</p> <p>Overall cost-savings for RM vs standard FU: USD 97±121 per pt per year</p>	<p>RM significantly reduced:</p> <p>The time spent by hospital staff.</p> <p>The costs for the hospital and pt.</p>	<p><i>P</i> = .03</p> <p><i>P</i> = .01</p> <p><i>P</i> = .0001</p>

						vs 287±160 per pt per year.		
INTIME²₉	2014	Randomized, parallel	716 pts	ICDs/ CRT-Ds with Biotronik HM; NYHA II/III LVEF ≤35%	Primary outcome measure was a composite clinical score combining all-cause mortality, overnight hospital admission for heart failure, change in NYHA class, and change in patient global self- assessment. Secondary outcome measures were all- cause mortality, hospital admission, and heart failure admissions.	At the 1- year follow up, 18.9% patients in the HM group vs 27.2% in the control group had worsened symptoms. 1-year all- cause mortality in the telemonito ring group was 3.4% vs 8.7% in the control group. RM did not affect HF admissions	Patients on HM less likely to reach composite endpoint. Patients on HM had lower mortality. HM did not reduce heart failure admissions .	$P = 0.013$ $P = .004$ $P = .38$
Registries, MEGA COHORT observational studies								
AWARE₂₄	2007	Retrospectiv e analysis.	11,624 pts	PM, ICD, and CRT-D Biotronik HM	Time to detection of events and impact on physician workload, comparing the RM vs the standard care arm.	Mean time from last FU to detection of an event was 26 days in RM group compared with the usual FU.	RM improved safety and optimized the allocation of health resources.	

ALTITUDE³⁰	2010	Nonrandomized networked patients	185,778 pts	ICDs/CRT-Ds with Latitude Boston Scientific	Patient Survival	1- and 5-year survival rates were 50% reduced in non-RM patients	RM improves survival	$P < .0001$
MERLIN³¹	2015	Nonrandomized networked patients	Consecutive 269,471 pts	PPMs, ICDs/CRT-Ds with MERLIN	Survival according to level of adherence to RM and device type.	>75% adherence to RM promoted best survival. PM pts gained similar survival advantage with >75% adherence to RM.	RM-mediated survival is dose-dependent on the degree of adherence but not on CIED complexity.	$P < .001$ $P < .001$
Observational Studies								
Fauchier³²	2005	Nonrandomized. Database analysis	502 pts	ICDs Biotronik HM	Calculation of costs related to ICD follow-up, including medical services and transportation compared with the expected costs of RM.	RM was associated with a \$2149 saving per pt in 5 years. Even considering an extra cost of \$1200 for acquiring the technology, break-even could be reached after 33.5 months.	RM reduces medical and transportation costs compared with standard ICD follow-up	
Raatikainen³³	2008	Observational study	41 pts	ICDs Medtronic Carelink	Assess whether RM offers a safe, practical, and cost-effective alternative to the in-office follow-up	To complete the follow-up RM required: Less time from patients (6.9±5.0 vs 182±148	RM reduces costs compared with standard ICD follow-up (saving of 524 € per pt per year,	$P < .001$ $P < .001$

					of pts with ICD.	min). Less time from physicians (8.4±4.5 vs 25.8±17.0 min).	41% of the cost of standard follow-up).	
Home Guide Registry ^{17, 18}	2013 2014	Multicenter, prospective registry	1650 pts	PM, ICD, and CRT-D Biotronik HM	To estimate clinical effectiveness in event detection and management of devices with RM. To analyze outpatient clinic workload and the impact on resource consumption. To test a specific nurse-based workflow model.	Clinical events: RM sensitivity, 84.3%; PPV, 97.4%. RM detected 95% of asymptomatic and 73% of AEs. RM incremental utility +0.56 Manpower of 55.5 minutes per health personnel per month every 100 pts. 15.4 min per pt to detect 0.43 AEs (remote arm) vs 60.5 min per pt to detect 0.16 AEs (in-person) Nurses reviewed 70% of transmissions (15% submitted	RM effectively detected and managed clinical events. The nurse-based workflow model was safe, effective, and efficient.	$P < .0001$ $P < .01$

						to the physician).		
Patient Satisfaction								
Marzegalli³⁴	2008	Observational study	67 pts	ICDs	Assess the ease of use of the system and patient and clinician acceptance and satisfaction.	78% of the patients preferred remote FU to in-clinic visits; 100% found it easy to use.	RM reduces follow-up time compared with standard in-hospital visits.	
Ricci³⁵	2010	Observational study	119 pts	PMs, ICDs, and CRTs in RM after 1 year of FU	To evaluate patient acceptance and satisfaction through a self-administered questionnaire (HoMASQ)	The mean scores were (range 0–4): 3.0±0.9 for relationship, 3.4±0.6 for ease of use, 3.4±0.9 for psychological aspects, 3.4±0.8 for clinical implication, and 3.4±0.8 for overall satisfaction.	Patients showed a high level of acceptance and satisfaction for all investigated areas.	
Petersen³⁶	2012	Observational study	474 pts	Medtronic ICD or CRT-D, and successful Carelink transmissions	To evaluate patient satisfaction with remote follow-up.	385 of 474 (81.2%) patients responded to the questionnaire. 25% of patients made unscheduled transmission	95% were very content or content with remote follow-up. 84% expressed desire for clear and prompt communication	

						ns (for shock, alarm, palpitation, or other reasons)	tion from the monitoring center.	
Morichelli ³⁷	2014	Observational study	163 pts	Recipients of ICDs in RM after 20 months	To evaluate patient acceptance and satisfaction through a self-made questionnaire (HoMASQ) with another proprietary system.	The mean scores were (range 0–4): 3.3±0.7 for relationship, 3.5±0.5 for ease of use, 3.5±0.4 for psychological aspects, 3.4±0.6 for clinical implication, and 3.8±0.3 for overall satisfaction.	Patients showed a high level of acceptance and satisfaction for all investigated areas.	

Abbreviations: AEs = actionable events; CAEs = clinically actionable events; CRT-Ds = cardiac resynchronization therapy with defibrillators; CV = cardiovascular; DDD = dual-chamber; FU = follow-up; HF = heart failure; HM = home monitoring; HoMASQ = Home Monitoring Acceptance and Satisfaction Questionnaire; ICD = implantable cardioverter defibrillator, LOS = length of stay; LVEF = left ventricle ejection fraction; MADDIT II = Multicenter Autonomic Defibrillator Implantation Trial II; MAE = major adverse event; NYHA = New York Heart Association; PM = pacemaker; pts = patients; PPMs = permanent pacemakers; PPV = positive predictive value; QALYs = quality-adjusted life years; RM = remote monitoring; USD = United States dollar; VVI = Ventricle paced, ventricle sensed, pacing inhibited if beat sensed.

Patient Satisfaction and Quality of Life

Patient acceptance of remote follow-up is critical to successful implementation. In the few studies of patient satisfaction that are available, a number have reported no difference in the quality of life and patient satisfaction when comparing remote and conventional follow-up strategies.^{28, 38} Other authors have reported a high rate of patient satisfaction for diverse aspects such as the patient's perceived relationship with their health care providers, ease of use, psychological impact, and the ability to maintain follow-up compliance, even with nonwireless transceivers.^{21, 36, 39, 40} Remote follow-up reduces IPE costs such as travel, time off from work, and the interruption of daily activities.⁴¹ Only a minority of patients do not accept RM, for reasons that include privacy concerns, fear of technology, and concern about the risk of losing human contact with nurses and physicians. The majority of patients surveyed in a single-center observational study expressed a strong desire for prompt and clear communication of the interrogation findings, by phone, email, or letter.³⁶ None of the patients assigned to RI/RM in the TRUST trial crossed over during the study, and 98% elected to retain this follow-up model at the end of the trial, indicating patient acceptance and confidence in this technology. Patient-clinician communication improved, and patients were more compliant with the scheduled IPEs when required.¹⁶ In contrast, conventional care was characterized by follow-up attrition, suggesting that IPEs could be perceived as a relative inconvenience. Nevertheless, the overall attrition rates among the patients in the TRUST trial were high for conventionally and remotely managed patients (unrelated to distance from the receiving facility), which aligns with the results from contemporary US practice.² Similarly, the 17.4% attrition rate (withdrawal, moving, lost to follow up) over 27 months in the European REFORM trial occurred under study conditions.¹⁹ This is an under-appreciated challenge in CIED patient follow-up, and although this may be alleviated by remote management, its causes require further investigation.

Device Surveillance

RM alerts practitioners to changes in lead or device function that would otherwise go undetected until the next scheduled IPE or RI, which can sometimes take place months after the change.²⁶ Trends in lead impedances, the number of mode switch events, ventricular arrhythmias, and changes in R-wave and P-wave amplitudes can presage device and non-device problems before they manifest clinically. In addition to detecting device failure, RM is able to alert practitioners to possible human programming errors such as the failure to activate tachyarrhythmia therapies.

Although malfunction rates are generally infrequent (even for devices on advisory), they require prompt identification and action. Early battery depletion, high-voltage circuitry disruption, and unexpected lead failures can lead to potentially life-threatening complications. Their onset can be unpredictable and sudden, and their detection can be challenging. Although many CIED devices have built-in audible or vibrating alarms that alert the patient to important issues, these alarms are often missed, especially by children or the elderly who tend to be less communicative⁴². RM provides an additional mechanism for communicating with care providers, enabling surveillance of CIED system integrity with improved temporal resolution. This mechanism can assist in prompt detection and early intervention when compared with routine in-office monitoring. The advantages of this mechanism have been demonstrated in large randomized trials (e.g., TRUST²⁶) and supported by observational data in mega-cohort analyses (e.g., ALTITUDE and MERLIN^{30, 31}).

RM has become the modality of choice for the surveillance of patients with CIEDs who are under advisory status.⁴³⁻⁴⁵ Although the increased frequency of in-person surveillance would eventually detect adverse events, the majority of patients remain unaffected. A system of increased IPE might therefore be onerous and inefficient. In contrast, RM accurately, efficiently, and quickly identifies abnormal parameter values (providing these are tagged to event notifications via the device and home monitor), yielding better use of patient, device, and clinical resources.

Shock Reduction

The early detection function of remote monitoring for clinical events such as atrial fibrillation with rapid ventricular response rates^{26, 46, 47}, T-wave oversensing or EMI or device malfunction, enables faster intervention to reduce the risk of unnecessary ICD shocks²⁵. Even when appropriate ICD therapy has been delivered, remote monitoring may lead to early intervention and possible reduction in total number of therapies.

The ECOST study^{23, 46} evaluated ICD therapy events as a pre-specified secondary endpoint and reported a significant reduction in inappropriate therapy for patients assigned to the RM arm. Over 27 months, the incidence of inappropriate shocks was 5.0% in the patients randomized to RM compared with 10.4% for the standard group ($P = .04$). This was largely mediated by preemptive action initiated by early RM notification. Overall, 14.5% of shocks were inappropriate in the remote group compared with 43% in the control group ($P < .001$). All causes of inappropriate shocks, including supraventricular tachycardia, noise oversensing, lead dysfunction, and T wave oversensing, were lower for the RM arm.

It is important to note that no study to date has shown a reduction in *appropriate* ICD shocks with remote follow-up compared with conventional follow-up. Even in the ECOST study^{23, 46}, in which the number of patients with appropriate shocks was more than twice the number with inappropriate shocks, the number of patients who were administered appropriate shocks was similar in both the remote follow-up and control arms of the study (16.7% vs 17.5%; $P = .84$).

Optimization of Device Longevity

Enabling RM can affect battery life, especially in regard to the frequency of scheduled wireless transmissions (e.g., daily vs every 3 months). However, the battery drain varies appreciably among the proprietary systems. Experience from the clinical use of one of these devices has shown preserved and sometimes improved battery life from the use of the RM function in ICDs and pacemakers.^{23, 48} Other

proprietary systems can promote battery drain when the frequency of transmissions is increased.⁴⁹ Data on the impact of RM on battery life should be transparently available to clinicians so that management can be optimized to balance the benefits of RM against premature battery depletion. Before using RM for an individual patient, the CIED specialist should be aware of the individual differences in RM systems and balance the relative benefits for an individual patient.

The potential roles of RM in facilitating CIED battery conservation include the earlier identification of conditions that drain battery voltage, such as frequent capacitor charging.^{23, 46, 50} Automatic output algorithms can also falsely detect an elevated capture threshold condition, thereby pushing the device output to unnecessarily high levels. Similarly, the early detection of anti-tachycardia pacing or PVC burden could indicate ventricular arrhythmias that could herald the administration of shocks. Patients could be brought in for visits sooner so as to change their medications or ablative therapy. Alternatively, therapy zones or time to detection can be changed so that slower, shorter episodes of unsustained VT are not treated, preserving treatment for truly life-threatening arrhythmias and avoiding unnecessary shocks. Early detection of rapid atrial arrhythmias can also enable treatment and programming changes to avoid inappropriate shocks. Frequent aborted shocks can significantly impact battery life, and their notification by RM and prevention by reprogramming can improve battery life.

Disease Management

Atrial Fibrillation

Early Detection of Atrial Fibrillation by Remote Monitoring

RM has been shown to facilitate the early detection and quantification of atrial fibrillation episodes and arrhythmia burden.^{7, 15, 21, 51} In the worldwide Home Monitoring database analysis,²⁴ 3,004,763 transmissions were sent by 11,624 patients with pacemakers, ICDs, and CRT-D devices. Atrial fibrillation was responsible for more than 60% of alerts in pacemakers and CRT-D devices and for nearly 10% of

alerts in dual-chamber ICDs. RM has a sensitivity of nearly 95% for true atrial fibrillation detection,⁵² and as many as 90% of atrial fibrillation episodes that trigger alerts are asymptomatic.⁵¹ Even when using an inductive RM system (without automatic alerts), remote follow-up performed better than standard follow-up for patients with pacemakers in detecting atrial fibrillation.⁹ Compared with the standard scheduled follow-up arm, the remote follow-up arm detected atrial fibrillation 1 to 5 months earlier. Patients with CIEDs have an incidence of previously unrecognized atrial fibrillation ranging from 30%–60%.⁵³⁻⁵⁶ Early detection of atrial fibrillation by RM can enable preemptive intervention to avoid inappropriate therapy, heart failure, and loss of CRT. The early detection also helps provide sufficient time to consider whether to initiate anticoagulation therapy.

Stroke Risk Associated with Device-detected Atrial Fibrillation

Several large clinical trials have consistently shown an association between CIED-detected atrial fibrillation episodes and thromboembolic events.⁵⁶⁻⁶¹ The risk of thromboembolic events is increased above normal with even brief atrial fibrillation episodes (5 minutes), and the risk increases with the increasing duration of the episodes.⁶¹ However, in the majority of study patients, recordings made up to 30 days prior to the thromboembolic events showed no evidence of atrial fibrillation, indicating no temporal relationship between atrial fibrillation and the thromboembolic event.^{60, 62} A combination of atrial fibrillation burden and clinical risk scores can help identify patients at lower/higher risk.⁵⁶ There are very few data to guide anticoagulation strategies for atrial fibrillation detected by the RM of CIEDs. The risk/benefit ratio for starting anticoagulation in response to an atrial fibrillation event of any specific duration is uncertain. Although a benefit might be predicted with RM-mediated early notification and quantification of atrial fibrillation burden, this benefit remains to be seen. An interventional trial by Martin et al⁶³ failed to show any difference in stroke or all-cause mortality despite accounting for the severity of CHADS scores. Another study (COMPAS)²⁵ suggested a benefit but was relatively underpowered.

The management of atrial fibrillation, whether detected by RM or other modalities, should be guided by the 2014 AHA/ACC/HRS Guidelines for the Management of Patients with Atrial Fibrillation.⁶⁴

Heart Failure

There is significant interest in the use of recorded data from implantable CRM devices for predicting (and thus preemptively treating) episodes of acute decompensated heart failure. Transthoracic impedance calculated between the CIED's endocardial lead and pulse generator has yielded mixed clinical results. Multicenter trials have calculated positive predictive values ranging from 38.1% to 60% for the worsening of systolic heart failure.⁶⁵⁻⁶⁹ Chest infection, anemia, and pleural effusion can generate false positive detections. Although intrathoracic impedance-guided HF treatment seemed to provide benefit in nonrandomized/case-control studies^{70, 71, 78, 79} HF-related hospitalizations actually increased when this treatment was tested in a randomized trial.⁷² Other diagnostic factors, such as asymptomatic atrial fibrillation, patient activity, mean resting heart rate, right ventricular pacing percentage, and CRT pacing percentage, might help. Combined heart failure device diagnostics have been demonstrated to improve the identification of patients at higher risk of subsequent heart failure hospitalizations^{69, 77}. Recently, the Implant-based Multiparameter Telemonitoring of Patients with Heart Failure⁷³ randomized clinical trial demonstrated that daily automatic RM enabled early action to be taken in response to the warning signs of acute decompensated heart failure, resulting in lower all-cause mortality and hospital admission rates for heart failure.²⁹ A remotely monitored implantable pulmonary artery hemodynamic sensor tested in a large randomized trial has shown that preemptive medical intervention taken in responses to elevated pulmonary artery pressure reduced HF hospitalization by 37%.⁷⁴

Channelopathies

Inherited electrical syndromes are rare indications for ICD implantation^{75, 76}; however, device management can be challenging because the devices are often implanted in younger patients (who are less likely to attend follow-ups). Electrical abnormalities can occur in these diseases (particularly intermittent T-wave oversensing in channelopathies and cardiomyopathies), which predispose patients to unnecessary shock therapy and require careful programming.⁷⁷⁻⁸¹ The risk of component failure is also considerable due to the length of service for patients who undergo the transplantation at a young age and to the increased strain from higher levels of physical activity. The pediatric population, which frequently have epicardial leads implanted, is more vulnerable. RM might therefore have particular utility in such patients for surveillance, early detection, and preemptive programming²⁶. In the multicenter Brugada registry, the number of outpatient visits was significantly lower in the RM group than in the control group ($P < .001$), and there was a trend suggesting that the number of inappropriate shocks was also reduced ($P = NS$).⁸²

Implantable Loop Recorders

Implantable loop recorders (ILRs) serve an important role in detecting infrequent arrhythmias and evaluating syncope. Storage capacity is limited, however, and the data are prone to be overwritten, erasing potentially important diagnostic data. RM-enabled ILRs overcome these limitations and facilitate early diagnosis by providing daily automatic and patient-activated transmissions. Interventional strategies based on the RM function of ILRs have yet to be evaluated.

Mega-cohort Analysis

A large cohort analysis of consecutive patients with RM-enabled CIEDs has provided insights into disease epidemiology, such as the interaction between atrial fibrillation and CRT device function.^{83, 84} The analysis could also yield opportunities for optimizing device programming (e.g., reducing the number of inappropriate shocks). Studies with 2 separate proprietary systems indicated that patient survival

improved when pacemakers, ICDs or CRTs are coupled to RM. Moreover, gain was amplified with higher levels of RM utilization, indicating a “dose-dependent” effect.^{30, 31}

RM generates an enormous quantity of data containing the device’s long-term longitudinal performance and lead data, which can help guide classification for advisory notifications and enhance future product design.

Section 3: Indications, Paradigms, Frequency, and Content of CIED Follow-up

Technological advances in RI and RM are altering the relative value of IPE vs remote CIEDs evaluations. Up to now, IPEs have served as the primary tool for evaluating device function and disease management, with RI and RM supplementing the evaluation when available. As noted in the introduction, the rate of compliance with recommended follow-ups is low, with only 42% of eligible U.S. patients who underwent CIED implantation between 2005 and 2009 actually participating in an initial IPE within the recommended 2–12 week post-implantation timeframe and only a trivial number of patients undergoing quarterly RI consistently.²

Based on the evidence supporting RI and RM and the disappointingly low rates of adherence to in-person follow-up, the issue is whether RM and RI should become routine, with in-office visits limited to the initial postimplantation period and then annually, unless alerts are triggered indicating a need for IPE by either the electrophysiologist or heart failure specialist.⁸⁵ This event-based paradigm of CIED monitoring and follow-up is illustrated in Figure 3. A more efficient and patient centric paradigm for CIED follow-up could ultimately improve the ability of patients and providers to adhere to the recommended follow-up

protocol. This paradigm holds particular value for patients who are geographically isolated or otherwise unable to travel for IPEs, as well as for adolescents transitioning from home to independent living.*

Although the benefit of RI and RM is likely greater for patients with ICDs or CRT-Ds than for a nonpacemaker-dependent patient who has a single-chamber pacemaker, a consistent follow-up paradigm for all CIEDs reduces the number of different workflows, thereby simplifying management strategies and facilitating adherence by the patient and CIED clinician to the recommended follow-up paradigm.

Timing of Patient Education and Enrollment

The concept of remote follow-up should be presented to the patient prior to CIED implantation as part of the patient education and informed consent process. This should also determine the nature of telephone access (wireless vs. landline (itself digital/analog)) which may govern selection of appropriate device.

There is no standard practice for when to initiate RI and RM. One option is to discuss and initiate RI and RM at the patient's post-implantation office visit. An alternative is to enroll the patient prior to discharge and send the patient home with an RM transceiver (Figure 4). Once at home, the patient connects the hardware and initiates the handshake transmission; receipt of the transmission is confirmed at the first in-office visit. (Table 2). Technical circumstances (e.g., ability of the remote transceiver to be paired to a CRM device in the field) and patient characteristics (e.g., the patient's ability to follow and act upon instructions) can limit the opportunity to initiate RM prior to hospital discharge.

Abbreviations: CIED = cardiac implantable electronic devices.

* CIEDs with epicardial leads were not included in clinical trials of RI and RM. This, along with the fact that autocapture algorithms do not function reliably for epicardial leads should be taken into consideration when determining the appropriate frequency of IPE for individual patients with epicardial leads.

Remote Interrogations

Following the acute 2–12 week post-implantation interrogation, reprogramming, and wound check, the device's function and stored arrhythmia events can be obtained by quarterly or semiannually scheduled RI sessions (Figure 3). The frequency of RIs should be determined based upon CIED type and the patient-specific indications outlined in the 2008 HRS/EHRA Expert Consensus on the Monitoring of CIEDs: every 3–12 months for pacemakers and every 3–6 months for ICDs.¹ We recommend that all patients undergo an IPE at least annually. This provides an opportunity for the medical records to be updated with interim events and medication changes. It also provides an opportunity to check pacing thresholds (for devices that do not have autocapture algorithms), to verify that automatic sensing and pacing capture algorithms are functioning correctly, to adjust other programmed parameters, and to provide the patient with the opportunity to ask questions. Annual visits for device therapy should not supplant visits required with other health care providers for overall disease management.

Remote Monitoring

RM provides periodic alert notifications based upon clinician-configured settings and manufacturer-specific communication intervals between the CIEDs and RM transceiver. Alerts should be programmed at a minimum to monitor battery status, lead integrity, and arrhythmic events. There are many internal and external factors that can hinder, delay, or prevent acquisition and delivery of device and patient information as intended by the clinician. Examples include the technical failure of the transceiver setup at home, a communication failure between the CIED and transceiver, clinical system failures (such as patients not being informed that their transceiver has failed to communicate), and practices that fail to inform the appropriate clinician of an alert. Robust practice systems are necessary to ensure that patients remain connected to RM, that data are transmitted at the desired frequency, and that relevant findings are

communicated to the patient and corresponding health care providers (see section 4: Roles and Responsibilities).

The safe and effective replacement of the bulk of routine in-clinic evaluations (as demonstrated in the TRUST trial) has many potential implications for resource utilization.¹⁵ Although RM demands a restructuring of workflow patterns, especially for alert notifications, this is balanced by the reduction of routine nonactionable IPEs. However, systems that require any form of patient operation (whether inductive or wireless) are associated with erratic compliance. This affects the clinical workflow efficiency, mainly because missed remote transmissions must be rescheduled by contacting each patient.¹²

Communication

The technological advances in RM and interrogation, along with the diagnostic capabilities of CIEDs that are advancing beyond the boundaries of arrhythmia management, present complex challenges to the sharing of information with the patient, referring physician(s), and heart failure specialists. Regularly scheduled IPEs provide real-time feedback with the patient and discrete time intervals for creating summary reports that can be shared with the relevant health care providers. RIs should be used to create similar reports at the recommended interrogation frequency (Table 3). 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 health care providers. Heart failure diagnostic data will, for some patients, warrant more frequent and individualized communication.

Table 2: Goals of the Initial Education Process, Prior to CIED Implantation

- Explain the clinical utility of CIED follow-up.
- Differentiate between in-office and remote follow-up.
- Outline the desired frequency of CIED follow-up.
- Discuss the differences between RM and RI.
- Understand the health care providers involved in the patient's care and determine who will be responsible for CIED follow-up.
- Assess the suitability of the patient as a candidate for RM (e.g., are analog phone lines present, does the patient have an adapter to connect using cable or voice over Internet protocols (VOIP), is the patient willing to pay for cellular-based monitoring).
- Determine the patient's desire to access their RM data (when available).

Abbreviations: CIED = cardiac implantable electronic devices.

Table 3: The Remote Monitoring Process

- Enrollment to connection
 - Enroll patient into an RM system.
 - Ensure patient receives RM system.
 - Consider pairing the patient's device to a transceiver prior to hospital discharge.
 - Ensure that the patient establishes a successful connection with the RM system (i.e., handshake transmission).
- Connection to transmission
 - Obtain monthly data from heart failure patients and patients with an implantable cardiac monitor.
 - Obtain quarterly data from patients with pacemakers and defibrillators.
 - Identify patients whose transceivers are not communicating.
- Transmission to communication
 - Notify electrophysiologist of any alert notifications.
 - Present clinically significant data to the electrophysiologist for review.
 - Generate summary document for health care providers involved in the patient's care.

Section 4: Roles and Responsibilities of the Remote Monitoring Team Members

The implementation of RM in clinical practice requires changes in the organizational model of CIEDs clinical follow-up and clearly defined roles and responsibilities for patients, physicians, allied professionals, and manufacturers.

Patient Responsibilities

Patient enrollment represents a crucial point for the medical team to establish a clear and open strategy for communicating with patients and their caregivers and providing detailed information on the benefits and limitations of RM. A frequently misunderstood limitation of RM is its inability to act as an emergency response system. Patients and caregivers should be made aware that there is a delay between an episode or alert and the transmission of that alert to the CIED clinic. The CIED clinical organizational model should also not be constructed to immediately interpret and act on alerts, rather it should do so within an acceptable timeframe (such as the next business day). Information on the expected reaction times should be carefully explained to patients, and they and their caregivers should be instructed on how to react in an emergency situation. Key topics to be covered during the informational process are listed in Table 4.

Documentation indicating that the patient education has been completed should be included in the medical record. A number of institutions have formalized the process and ask patients to sign agreements. These serve as documentation of the patient education process and reinforce patient expectations. Patients should also be given explicit instructions on how to interface with the CIED follow-up clinic when experiencing symptoms.

Once they have received the patient education, only a minority of patients will object to RM, once technical and cost issues have been factored out (e.g., lack of landline, usage cost). The reasons for objecting to RM typically include fear of the technology, loss of privacy, and loss of human contact with caregivers. These concerns can often be alleviated, if not eliminated, by educating patients on the benefits of RM. Demonstrations of how to set up the monitor and how transmissions work should be performed at

enrollment. A review of anticipated connectivity issues (e.g., landline, cable/internet, phone service, and cellular access) and the providing of connectivity solutions will enhance the patient's or caregiver's success. Clear explanations of what data are transmitted, where they are transmitted to, under what circumstances, and how the data are to be used often assuage patients' privacy concerns. Patients should also understand that RM is not a substitute for contact with the clinic but can actually enhance communication with the clinic. Each clinic varies in how they ensure ongoing communication with patients, but personal knowledge of the allied professionals who actually call the patient in case of trouble can considerably strengthen the human relationship. In an RM program, the clinic will expect patients to communicate important information to their monitors, such as up-to-date phone and mail contacts and any travel plans. Patients should also inform the clinic of any clinical events, hospitalizations, and changes in drug therapy.

The timing for starting RM depends upon patient-specific conditions and the institutional organization. The system should be delivered as early as possible after implantation; however, the implantation of a CIED device represents a major change in a patient's life, which can have a profound effect on their psychological status. Patients therefore might need some time to accept the implanted device and process the immediate postsurgical information before trying to learn about RM. For this reason, many programs implement RM at the 1-week or 1-month visit. Failure to engage patients in the RM process can undermine any efficacy or benefits that RM can provide.¹² For example, missed scheduled or duplicate transmissions (and the resulting additional phone calls) can impair the clinical efficiency of CIEDs.¹²

Table 4 provides guidelines for the potential topics to discuss in the initial patient education and patient agreement/contract.

Overview of RM	<ul style="list-style-type: none"> • Explain the benefits and limitations. • Explain the frequency and types of monitoring.
What to Expect	<ul style="list-style-type: none"> • Frequency of remote RI and RM. • RI and RM are not meant to be an emergency response system. • Indicate the hours of operation and the expected delay in responding to alerts (e.g., next business day), as well as the operation (if any) during evenings, weekends, and holidays. • Expectations for in-person follow-up. • Expectations for the responsibilities of and the communication with CIED clinic staff.
Patient Responsibilities	<ul style="list-style-type: none"> • Keep all contact information up to date- • Keep the clinic informed of other health care providers to whom reports should be communicated. • Inform the CIED clinic about extended travel. • Keep the clinic up to date on the medical condition and drug changes. • Maintain the function of the transceiver and appropriate landline/cellular communications. • Understand how to interface with RM equipment. • Show up for an IPE when an alert is triggered and when advised by clinic staff.
Privacy	<ul style="list-style-type: none"> • All patient health data are kept private in accordance with local/national laws. • De-identified, aggregate data may be used for quality assurance and/or research purposes.
Consent	<ul style="list-style-type: none"> • Patient agrees to RM.

Abbreviations: CIED = cardiac implantable electronic devices; IPE = in-person evaluation; RI = remote interrogation; RM = remote monitoring.

Physician Responsibility

Physicians who ultimately prescribe RM have the overarching responsibility for patient monitoring. The remote system is linked to the implanted CIED; RM should therefore be thought of as an extension of the CIED's diagnostic capabilities. The operation of an RM program can vary among medical centers, hospitals, and private practice groups. Some physicians might have the responsibility for reviewing, interpreting, documenting, and billing for the entire remote report, while others might review data that

have first been screened by an allied professional. Regardless of the process, physician interpretation and documentation remain the final step.

Physicians who oversee RI and RM programs should have the skills to interpret all CIED data and intracardiac electrograms, as well as troubleshoot and treat CIED-related problems. They should also be familiar with the capabilities and limitations of the systems in use by their clinic. It is recommended that the physician responsible for supervising and reviewing RI and RM data possess a board certification from either the American Board of Internal Medicine (ABIM) Clinical Cardiac Electrophysiology, American Board of Pediatrics Cardiology certification or the International Board of Heart Rhythm Examiners (IBHRE) device certification.

Mid-level Provider Responsibilities

Mid-level practitioners are nurse practitioners or physician assistants who function as independent practitioners and work under the supervision of a licensed physician. When responsible for supervising the RI and RM of CIEDs, these individuals must have the same training, qualifications, and experience as is required to perform IPEs. The practitioners should be able to interpret CIED and basic intracardiac electrogram data and understand CIED troubleshooting and the management of CIED-related problems. These practitioners should also be supervised by an individual who possesses ABIM Clinical Cardiac Electrophysiology or IBHRE device certification.

The mid-level providers' role can vary greatly within an RM program. Typically, they provide oversight of the allied health professionals in the CIED clinic. They might also be called upon to assist with remote alerts and/or patients who have undergone device therapy. The providers typically interact with the patient, obtain a relevant history, review the transmissions, and make recommendations for management. This might require consultation with the patient's attending or collaborating physician. CIED clinics should have guidelines in place that outline the mid-level providers' scope of practice with regard to

decision making and physician consultation. Mid-level providers can also take on roles including patient enrollment and education, interpretation of routine transmissions, documentation, and billing.

Allied Professional Responsibilities

The allied professional who is responsible for reviewing RM transmissions needs to have adequate training in the full scope of device follow-up and interpretation. It is therefore recommended that these professionals possess either an IBHRE Device Specialist certification or experience on par with such certification. In the absence of this experience, all downloaded data need to be reviewed by an appropriately trained professional, such as a physician who is ABIM certified in clinical cardiac electrophysiology or a mid-level provider who possesses an IBHRE device certification or its equivalent.

The roles and responsibilities of the allied professional with respect to the scope of practice for RM should be clearly identified. Allied professionals should know the expectations for data review, the criteria for referral to another professional (mid-level provider or physician), what the disposition of the information should be, and the expectations for contacting the patient. Clear lines of communication should be available to the allied professional to ensure that a timely overview can be provided when required. A Standards of Care document for the clinic should clearly outline the scope of practice and expectations of the allied professional.

Most importantly, RM requires dedicated allied professional resources to ensure the timely and complete review of transmitted information. This can be accomplished by a dedicated resource person or by assigning CIED clinic allied professionals to RM, with clear accountability for data review. It is not advisable to simply add RM to the usual CIED clinic schedule without assigning a dedicated human resource because this risks overlooking urgent alert information from the RM. Maintaining higher levels of adherence to RM was associated with a higher survival benefit in CIEDs.³¹

Ancillary Staff Responsibilities

RM can potentially increase the strain on CIED clinic resources. In many cases, the efficiency gained by reducing the volume of IPEs can provide for the added resource requirements of RM. For some clinics, alternative models (such as third-party providers and the addition of ancillary staff) can help accommodate the added resource requirements. Ancillary staff can take the form of clerical staff or RM technicians who are accountable for the nonclinical portions of the RM service. This can include reminding patients of scheduled transmissions, patient education in connectivity and troubleshooting, acting as the technology expert/customer support for the clinic, and collecting data for review by allied professionals and physicians. These additional human resources can reduce the nonclinical burden on the clinic staff, but clear expectations regarding the scope of practice must be identified for this group to ensure the safety and reliability of the information review.

Institution/Clinic Responsibilities

Practices that provide RI and RM services should establish the responsibilities of each member in the CIED clinic, the day-to-day functioning of the program (such as the use of alerts), patient-specific programming, hours of operation, and guidelines for timeliness of review. To set realistic and appropriate expectations, clinics should determine the patient communication strategy to ensure that RM and RI policies are openly communicated to the patient. The monitoring of missed transmissions, connectivity, and patient support should be determined and assigned to the resource that fits the clinic model. It is critically important that a mechanism be established to reliably determine whether a patient's transceiver has stopped communicating. Checking this failure and troubleshooting its cause requires collaboration between the institution responsible for monitoring the data and the CIED manufacturer. The data can be documented in the device clinic database, the electronic health record, or both, with critical information available to the entire care team. Asymptomatic atrial fibrillation is perhaps the most frequent abnormality detected by RM and is a trigger for the clinic staff to assess patients' risk of thromboembolic events. Operational efficiency and quality of care can be greatly enhanced by establishing, in advance, a

clear strategy for documenting anticoagulation considerations and lines for communicating this information between allied professionals and physicians.

Finally, we recommend that clinics develop a guidance document for patients and families to facilitate their engagement in the RM process by clearly defining the roles and responsibilities of each party. Some clinics have elected to implement this in the form of a signed patient-clinician agreement, while others have chosen to document (in the medical record) that the patient and/or family have received appropriate education. As long as the proper information has been effectively communicated to the patient and/or family, either approach is reasonable.

Third-party Provider Responsibilities

For some providers, setting up the required infrastructure for RI and RM might prove daunting and prevent the use of the technology. To meet these setup needs, several for-profit companies have started offering services to assist in remote follow-up. These services can potentially provide RI and RM to large numbers of patients whose providers might otherwise not be able to support these services. It is important to ensure that well-trained and qualified interpreters with credentials appropriate to their level of responsibility (i.e., ABIM clinical cardiac electrophysiology, IBHRE certification, or equivalent) are in place so that important findings can be recognized and brought to the attention of the patients' providers.

CIED Industry Responsibilities

CIED manufacturers play a critical role in developing RI and RM technology and ensuring that adequate evidence is gathered to support the safety and effectiveness of the technology. The collected data includes proprietary industry data regarding device function and clinical data of interest to health care providers. Manufacturers are responsible for informing clinic staff and patients about any disruptions in the RM service. For example, device recalls and advisories must be communicated to CIED clinic providers and patients in a transparent and timely manner. Industry should refrain from direct patient care, either within

the clinic or with the patient at home. Although industry representatives might be qualified to train clinic staff, they should not perform, collect, or triage data on behalf of the clinic staff and should not be employed as a staffing resource in lieu of local qualified personnel. Certain countries face particular challenges when implementing RI and RM. In Japan, for example, the use of analog telephone landlines limits the use of some RM technology. In a number of countries, the electromagnetic spectrum band used by CIED to communicate with the transceiver has been previously assigned to other uses (such as emergency services communications).

This document also acknowledges that RI and RM data currently reside on servers that are owned and managed by the manufacturers. Given the privileged information stored on these servers, it is critical that the industry maintains secure and encrypted data repositories. The de-identified data pooled from the servers are of significant value to the industry for quality assurance purposes (e.g., tracking device performance and watching for early signs of device trouble, which warrant advisories) and for making improvements to the CIED technology. The data from these repositories are also of value to individual CIED programs for improving the quality of the processes. Finally, this data may also play an important role in answering important research questions initiated by investigators independent of industry. Manufacturers should have a procedure for an independent scientific review in place that can process requests made by independent investigators for the use of these data.

Section 5: Data Management

Diversity of Data Repositories

The volume, granularity, and diversity of the repositories in which the device data are stored present opportunities and challenges for RM of CIEDs. These data repositories include manufacturer device registration databases, vendor device programmers, commercial manufacturer RM services, commercial CIED practice management software systems, practice and/or hospital medical records (which can include hard copy and electronic records), and registries (including the American College of Cardiology

National Cardiovascular Data Registry's ICD Registry and vendor post-approval studies). Data integrity and accessibility are essential to the usefulness of a data set. 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 records and other data repositories.

Data Elements: Definitions and Interoperability

The Heart Rhythm Society has led a multi-stakeholder collaboration between CIED manufacturers and standards development organizations to identify and define the data elements and exchange protocols required to manage data from pacemakers, ICDs, and CRT devices.⁸⁶ These data elements and definitions have been formally recognized and approved by the Institute of Electrical and Electronics Engineers, the standards development organization governing CIED nomenclature.^{87, 94} Data exchange across proprietary vendor environments (e.g., from a CIED programmer or RM server to an electronic medical record) is made possible by the implementation of the Implantable Device Cardiac Observations profile, a vendor-neutral standards-based exchange profile created under the technical framework of Integrating the Healthcare Enterprise, a standards development organization created by health care professionals and industry to improve how computer systems in health care share information through the use of basic standards such as Digital Imaging in Medicine and Health Level-7.⁸⁸ The Implantable Device Cardiac Observations profile is now being incorporated in market release products by all CIED manufacturers. Repositories such as electronic medical records that choose to implement this profile will enable its users to access and share CIED data in a vendor-neutral environment.

Rationale for a Coherent Data Management Strategy

Developing an organized, secure and coordinated approach to data management is an essential component of caring for patients with CIEDs. The diversity and incompatibility of current data sources is a barrier to high-quality patient-centered care. Broad support among stakeholders for the nomenclature and interoperability profile described above, particularly when coupled with the U.S. Food and Drug

Administration Universal Device Identifier initiative, will lay the groundwork for data exchange among multiple CIED data repositories, thereby increasing clinical and administrative efficiency, patient safety, regulatory postmarketing surveillance, product advisory/recall management, and clinical research.

Section 6: Reimbursement, Legal, and Privacy Considerations

Reimbursement

Despite the scientific data supporting the cost effectiveness of RI and RM, reimbursement for physician and practice expenses is lacking in many countries.^{33, 89} Payers have taken different approaches to this new model of health care delivery, with only the U.S. and Germany recognizing full reimbursement for services rendered remotely. Even in countries that do not provide reimbursement, many health care providers have adopted the technology due to the resulting efficiency. In this regard, RI and RM have become essential tools for managing the increasing number of patients with CIEDs. Italy and Canada are 2 such examples, where creative strategies have been developed to leverage the efficiency produced by RM to reduce the number of in-clinic visits, building on the ability of a single provider to provide service to more patients with RM than with IPE. Patient costs associated with IPE have seldom been measured. The patient-centric paradigm of RI and RM minimizes the disruption and cost to patients who would otherwise be required to take time off from work.

The RI and RM of CIEDs has been established as a cost-effective modality for managing patients. Early small studies based on cost estimates or models based on review of the literature suggested this was indeed the case, and this has recently been substantiated in a prospective study based on actual costs.^{38, 89} The ECOST study evaluated 310 patients randomly assigned to RM (plus 1 annual visit, unless RM dictated otherwise) vs outpatient follow-ups every 6 months. Costs within the French health insurance system were evaluated and included outpatient visits and transportation, cardiovascular treatments, and hospitalization for managing cardiac events. Over a 2-year follow-up, there were substantial savings in

the RM group, largely reflecting device management. Significant predictors of cost savings included costs related to ICD-related outpatient visits, direct nonhospital costs related to device management, and direct nonhospital costs. The European Health Economic Trial on Home Monitoring in ICD Patients prospectively gathered cost data on 312 patients assigned to remote monitoring either turned on or off.⁸⁹ Patients receiving RM had fewer scheduled IPEs, and despite the fact that they had more unscheduled IPEs the total number of IPE was still significantly lower than for patients not receiving RM ($(3.79 \pm 1.67$ vs. 5.53 ± 2.32 , $p < 0.001$). While patients receiving RM had a trend toward fewer cardiovascular hospitalizations and shorter lengths of stay overall provider costs were similar for both groups.

Manufacturers bundle the cost of the transceiver, maintenance of remote servers, technical support, and increasingly the wireless data service into the upfront cost of the CIED. This substantial cost is borne by the purchasing institution, which is not necessarily the entity that will provide the patients' ongoing follow-up care. In order to increase their competitive advantage, manufacturers can offer purchase options that exclude the cost of the remote transceivers and monitoring services. The present costs model creates a potential conflict of interest for both the manufacturer and the device purchaser that can potentially exclude state-of-the-art RM technology in order to reduce the up-front cost of the device. Health care providers should ensure that the patients' long-term interests are met. Alternative reimbursement strategies that recognize the ongoing expense of RI and RM wireless data transmission, data servers, and technical and clinical support might help ensure that patients have access to state-of-the-art remote follow-up technology and services.

Legal Considerations

The possible consequences of delayed action or inaction in response to alerts transmitted by RI and RM represent the most commonly cited concern on the part of caregivers. This fear has contributed to the reluctance of many practices to adopt RM. Current RM technology can warn of significant clinical problems within minutes, and most medical practices cannot respond immediately. Nonetheless, RM is becoming the standard of care, and as such there is risk of liability for not informing patients of the technology and its proven benefits. Patients should be educated about the limitations of the technology (delay in transmission, practice schedule for data review, etc.), what they can reasonably expect from it, and the fact that it is not an emergency alert system. Critical alerts, such as lead malfunction or sustained ventricular arrhythmia, should be communicated to the patient and acted upon in a timeframe commensurate with the clinical significance of the finding, recognizing that clinics will be staffed during normal business hours. While it is clear that this paradigm creates a potential delay between the detection of an event and patient notification, it is far superior to the alternative of *not* implementing RM for fear of litigation, thus leaving the patient vulnerable to a recorded event not being detected until the next IPE, which could be several months into the future.

Third-party vendors offering RM services assume the responsibility and liability for services they are contracted to perform. Thus, if they fail to perform such service or if an employee misinterprets or fails to act appropriately on information they have agreed to be responsible for, the vendor can be held liable.

The patient (or, particularly in the pediatric setting, the responsible caregiver) is an integral part of any RM scheme and has to assume some responsibility. Keeping contact information up to date and notifying changes of address is critical to this role. Patients can jeopardize their health and safety if they fail to return to the office for scheduled in-person follow-up visits or fail to respond to requests from clinicians for an urgent evaluation of an RM-detected abnormality. This issue needs to be addressed at the outset in the patient agreement given that it affects the agreed-upon responsibilities.

A vocal minority of patients have requested full and direct access to data obtained from their CIEDs.⁹⁰ Most patients, however, prefer that the data first be screened, vetted, and interpreted by health care providers. Could patients be harmed by having direct access to the data? Although well-intended paternalism can be cited as a reason for limiting patient access, the most reasonable answer is that patients should have access to all of their data, although it is strongly encouraged that they access the data under their health care providers' guidance. Beyond this, patients must have the right to determine which practices receive their RM data.

Cardiac rhythm management devices have differing RM capabilities, particularly in pacemaker technology. Although the data showing the benefit of RM are derived predominantly, although not exclusively, from the ICD population, discussions with patients should be conducted in advance as to whether to implant a pacemaker with RM capability, a conversation similar to that for the pros and cons of implanting a magnetic resonance imaging conditional device.

Privacy

Privacy remains a paramount concern. In the United States, the security and privacy of protected health information has been addressed by state and federal laws, which include the Health Insurance Portability and Accountability Act of 1996 and the Health Information Technology for Economic and Clinical Health Act. The relationships between health care providers and organizations involved with RM are governed by a terms-of-use agreement between the CIED vendor and the health care provider.⁴ International privacy laws are complex and beyond the scope of this document. Nonetheless, vendors should be encouraged to put into place a process whereby such data are made available in an aggregate de-identified format for the purposes of research, safety and efficacy surveillance, epidemiology, and regulation.

An ongoing concern is the question as to who owns the data obtained through RM and to what extent manufacturers should be compelled to release data available in their registries when medically warranted.

Another concern is how to protect patient privacy when such data are made available for other purposes, whether regulatory or research. The manufacturer of the RM data system has, by definition, custody of the RM data because it is collected on their servers. Patient medical records, by analogy, are in the custody of a practice or hospital.

Fears have been raised regarding security breaches by hackers who are able to directly access wireless devices.⁹¹ Recent cyberterrorism events have alerted the public to the vulnerability of virtually any and all electronic data systems and repositories. Although the current risk of unauthorized access to data involving CIEDs (let alone the ability to remotely reprogram device settings) is considered to be exceedingly low, the importance of ensuring the highest level of security against malicious activity cannot be overstated. The public perception of the integrity of such systems is critical to their acceptance and thus their ability to reach and serve patients around the world.

Conclusions

This consensus document reflects the wealth of recent clinical data generated by large randomized prospective trials from around the world that included patients with pacemakers, ICDs, and cardiac resynchronization therapy devices from various manufacturers. These consistently show meaningful patient benefits from the early detection capabilities of automatic RM. Incorporation of RM into follow-up practice, integrating this technology with a modified frequency of conventional IPE ensures greater patient retention and improves adherence to scheduled evaluations. These data form the basis of our recommendations that RM represents the new standard of care for patients with CIEDs, with alert-driven IPE replacing most routine office interrogations.

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HRS Remote Monitoring Consensus Statement Recommendations

Device Follow-up Paradigm	Class of Recommendation	Level of Evidence
A strategy of remote CIED monitoring and interrogation, combined with at least annual IPE, is recommended over a calendar-based schedule of in-person CIED evaluation alone (when technically feasible).	I	A
All patients with CIEDs should be offered RM as part of the standard follow-up management strategy.	I	A
Before implementing RM, it is recommended that each patient be educated about the nature of RM, their responsibilities and expectations, potential benefits, and limitations. The occurrence of this discussion should be documented in the medical record.	I	E
It is recommended that all CIEDs be checked through direct patient contact 2–12 weeks postimplantation.	I	E
It might be beneficial to start RM within the 2 weeks following CIED implantation.	IIa	C
All patients with an implantable loop recorder with wireless data transfer capability should be enrolled in an RM program, given the daily availability of diagnostic data.	I	E
It is recommended that allied health care professionals responsible for interpreting RM transmissions and who are involved in subsequent patient management decisions have the same qualifications as those performing in-clinic assessments and should ideally possess IBHRE certification for device follow-up or equivalent experience.	I	E
It is recommended that RM programs develop and document appropriate policies and procedures to govern program operations, the roles and responsibilities of those involved in the program, and the expected timelines for providing service.	I	E

Abbreviations: CIED = cardiac implantable electronic devices; IBHRE = International Board of Heart Rhythm Examiners; IPE = in-person evaluation; RM = remote monitoring.

Device and Disease Management	Class of Recommendation	Level of Evidence
RM should be performed for surveillance of lead function and battery conservation.	I	A
Patients with a CIED component that has been recalled or is on advisory should be enrolled in RM to enable early detection of actionable events.	I	E
RM reduces the incidence of inappropriate ICD shocks.	I	B-R
RM is useful for the early detection and quantification of atrial fibrillation.	I	A
The effectiveness of RM for thoracic impedance alone or combined with other diagnostics to manage congestive heart failure is currently uncertain.	IIb	C

Abbreviations: CIED = cardiac implantable electronic devices; ICD = implantable cardioverter defibrillator; RM = remote monitoring.

Appendix: Author Disclosure Table

Writing Group Member	Institution	Consultant / Advisory Board/ Honoraria	Speakers' Bureau	Research Grant	Fellowship Support	Stock Options/Partner	Board Mbs/ Other
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Taya Glotzer, MD, FHRS, FACC	Hackensack University Medical Center	1: Medtronic Inc., St. Jude	1: Medtronic Inc.	None	None	None	None

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Appendix: Peer-Reviewers Disclosure Table

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Harry G. Mond, MD, FHRS, CCDS	Royal Melbourne Hospital, Camberwell, Australia	0; St. Jude Medical	0; St. Jude Medical	None	0; St. Jude Medical	None	None
Jonathan P. Piccini, Sr. MD, MHS, FHRS	Duke University Medical Center, Durham, North Carolina	1; Spectranetics Corporation; Johnson and Johnson	None	5; Janssen Pharmaceuticals; ARCA Biopharma Inc.; Boston Scientific Corp.; ResMed; GE Healthcare	None	None	None
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		Pharmaceuticals; Bristol Meyers Squibb; ScottCare Inc; Boston Scientific Corp.; AliveCor		Biosense Webster, Inc.; St. Jude Medical			
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Gaurav A. Upadhyay, MD	University of Chicago Medical Center, Chicago, Illinois	None	None	None	None	None	None
Michele K. Young, BS, BSN, CCDS	Walter Reed National Military Medical Center – Bethesda, Maryland	None	None	None	None	None	Salary or position funding: 2; Rhythm Management Group PLLC

Number Value: 0 = \$0; 1 = < \$10,000; 2 = > \$10,000 to < \$25,000; 3 = > \$25,000 to < \$50,000; 4 = > \$50,000 to < \$100,000; 5 = > \$100,000

Figure 1: Technologies in Use

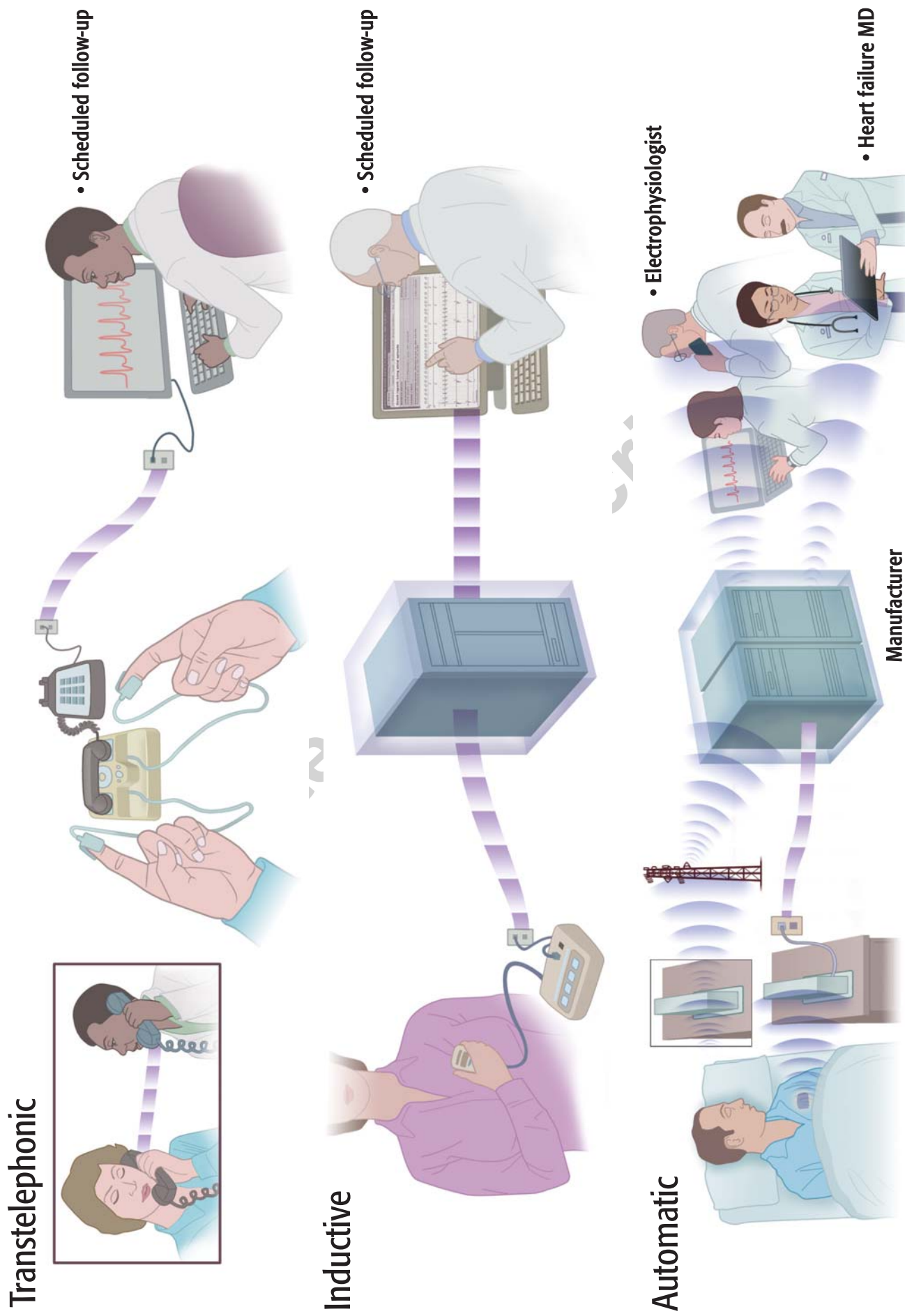


Figure 2: Benefits of Remote Monitoring

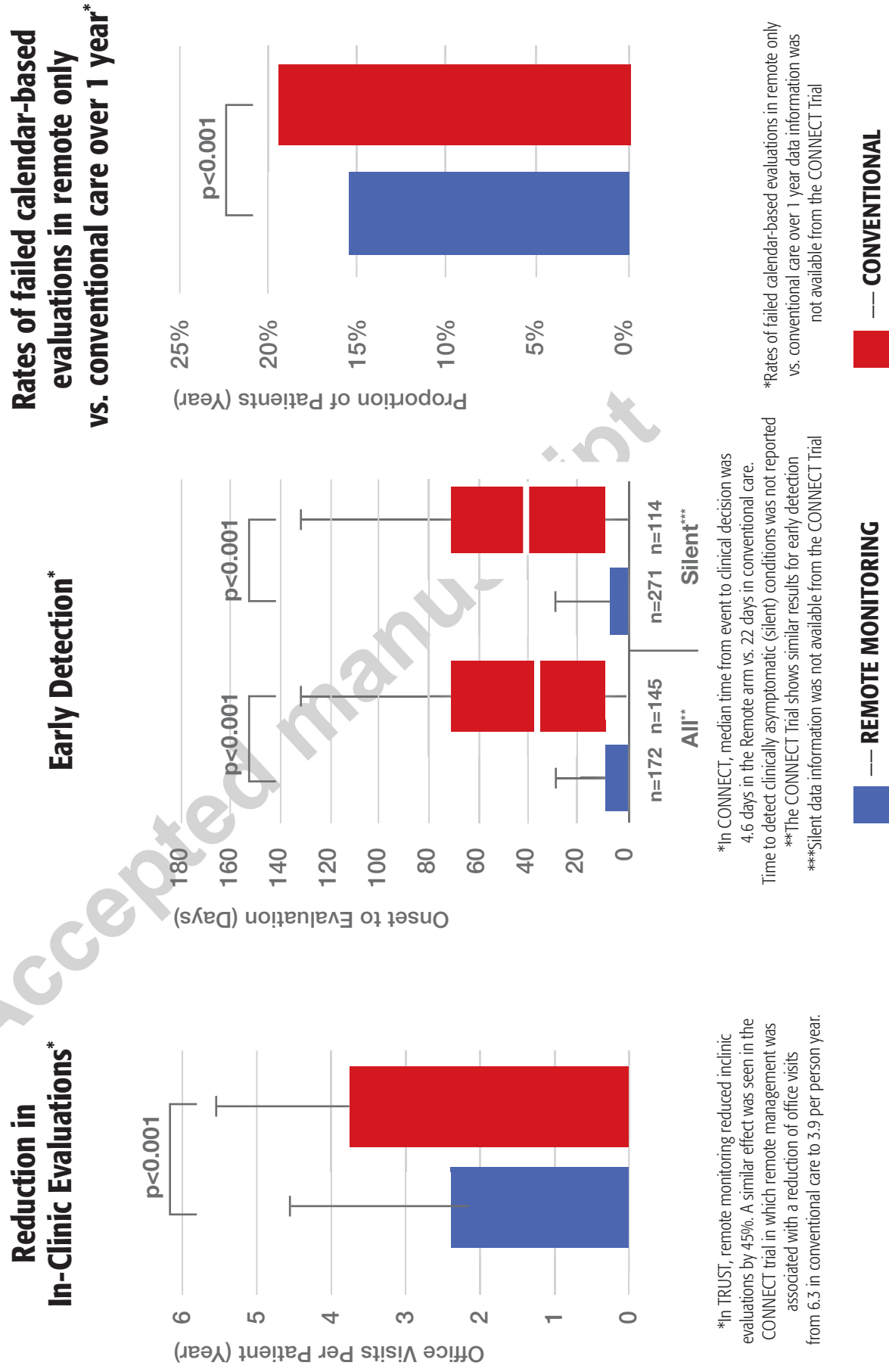
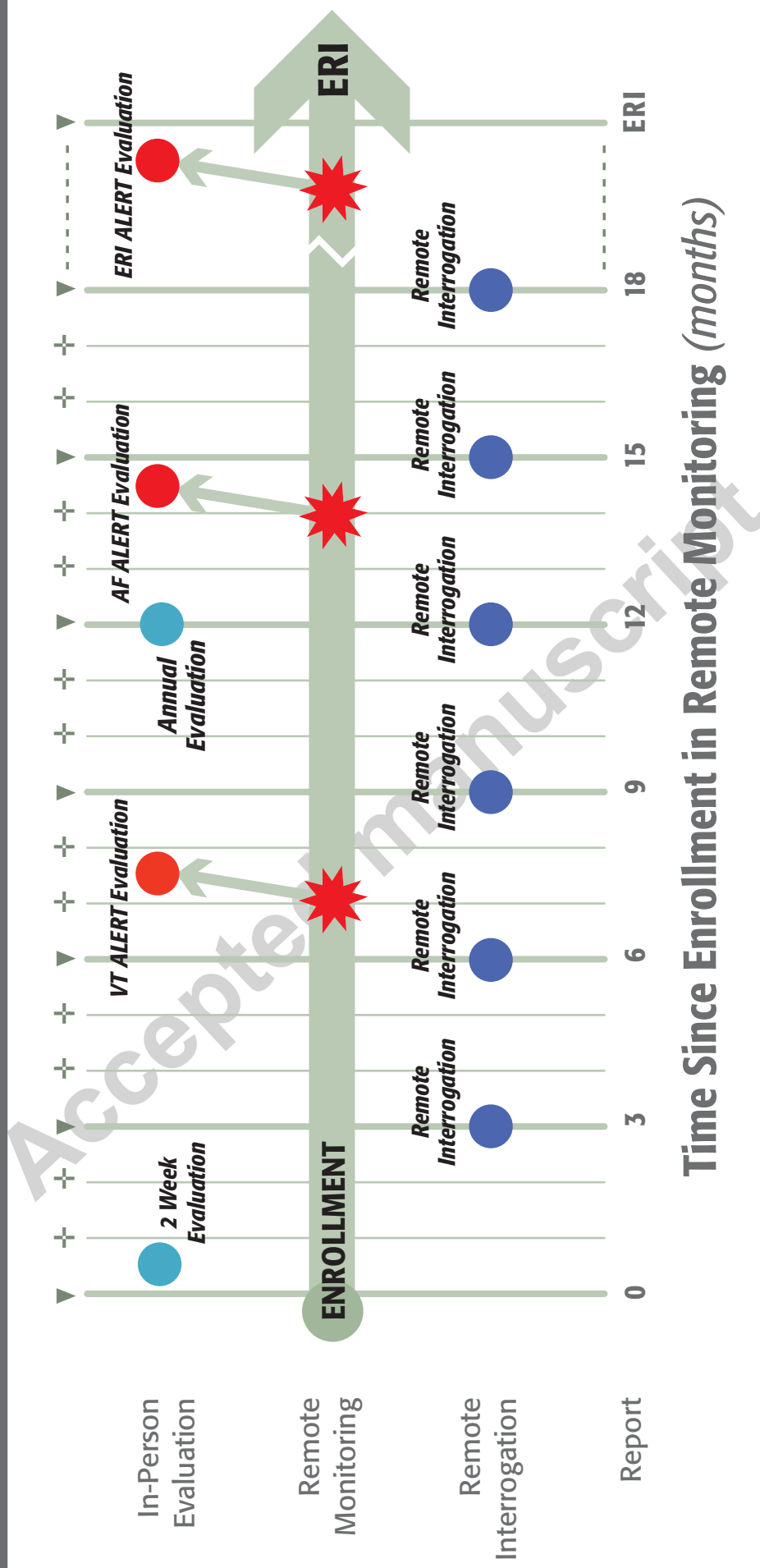
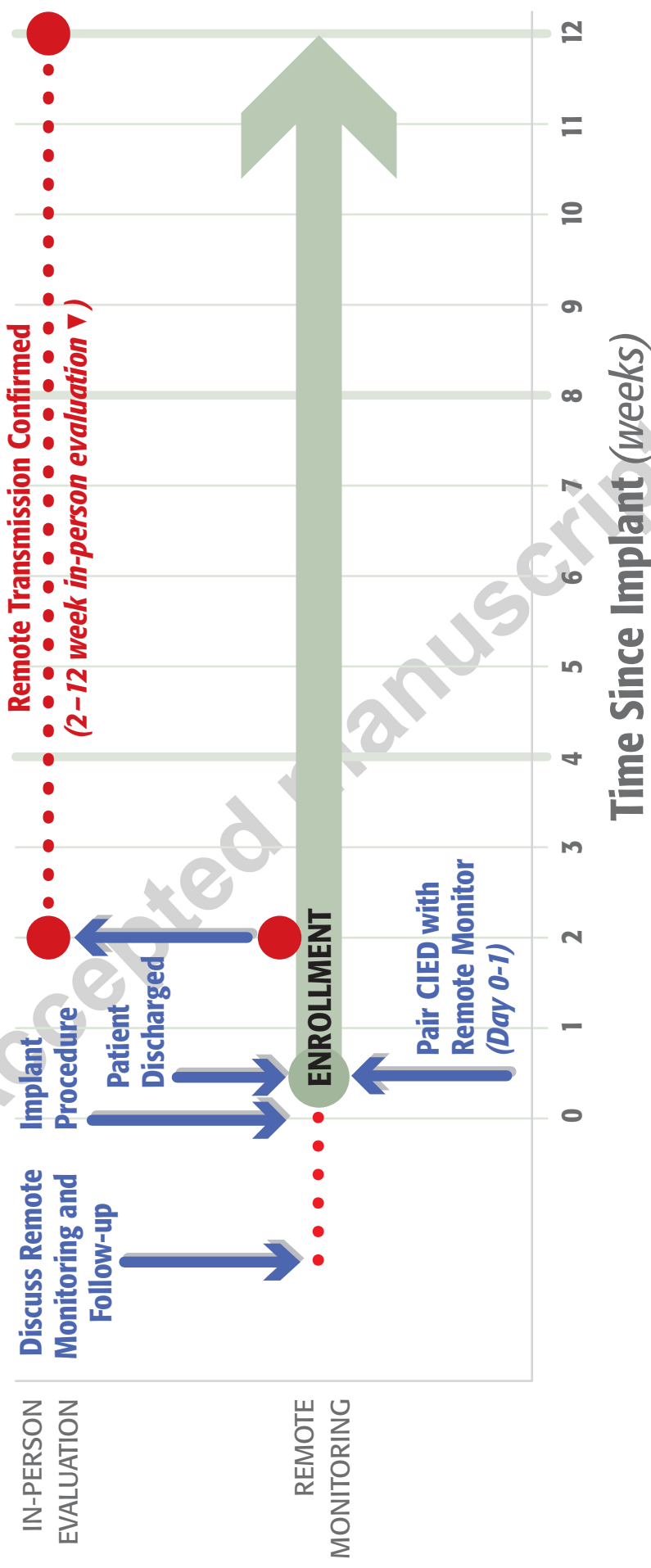


Figure 3: Event-Based Model of CIED Follow-up*



- * Any wireless PM, ICD, CRT device with auto thresholds and auto-sensing algorithms
 - ▼ Interim report generation & communication with other health care providers, including heart failure data
 - + Interim (monthly) remote monitoring heart failure report
- ABBREVIATIONS: AF = atrial fibrillation; CHF = congestive heart failure; ERI = elective replacement indicator.

Figure 4: Initiation of Remote Monitoring



▼ Interim report generation & communication with other health care providers, including heart failure data.