HRS Expert Consensus Statement on remote interrogation and monitoring for cardiovascular implantable electronic devices

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ABBREVIATIONS **ABIM** = American Board of Internal Medicine; **CIED** = cardiac implantable electronic device; **CRT-D** = cardiac resynchronization therapy with defibrillator; **IBHRE** = International Board of Heart Rhythm Examiners; **IPE** = in-person evaluationn; **RM** = remote monitoring (Heart Rhythm 2015;12:e69–e100)

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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[1] outlining recommended monitoring strategies. Novel embedded technologies have created the ability of the 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 almost a quarter of patients not seen in person in the year following implant.[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 and remote management strategies for 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 of new recommendations.

The present document was developed from the foundations laid by the 2008 HRS consensus statement[1] and the 2012 expert consensus statement on remote monitoring of CIEDs by the International Society for Holter and Noninvasive Electrocardiography and the European Heart Rhythm Association.[4] The goals for 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 present 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 being 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 routine, scheduled, remote device interrogations structured to mirror in-office checkups.[4,5] Practically all information obtained during an in-office device checkup 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 prespecified 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 HRS, the Latin American Society of Cardiac Pacing and Electrophysiology (SOLAECE), the American College of Cardiology (ACC), The American Heart Association (AHA), 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 the level of evidence follow the recently updated ACC/AHA 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 either there is no net benefit or there is net harm. Level of evidence A denotes the highest level of evidence, usually from multiple randomized controlled 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 or well-executed nonrandomized trials. Level of evidence C is from weaker studies with significant limitations, and level of evidence E is from consensus opinions in the absence of credible published evidence.

*A review of relevant data was performed including evidence from studies conducted in human subjects and 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*.

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. Because of the potential for actual or perceived bias, strict parameters had to be established for information sharing. It is the policy of the 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 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 CIEDs for the purpose of RI (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

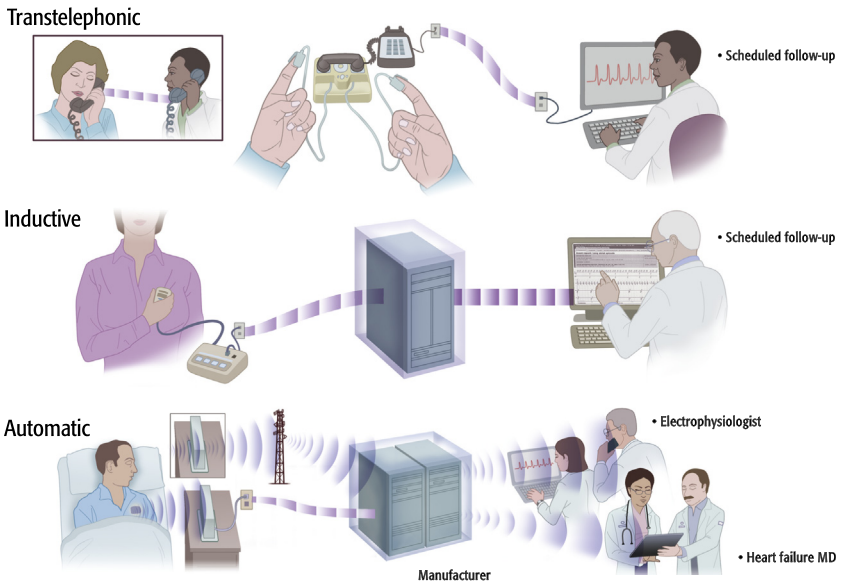


Figure 1 Technologies in use.

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 website 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 every 3 weeks 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 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 status (ie, 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 patients randomized to RI compared to IPE+TTM groups (mean time 5.7 and 7.7 months, respectively; $P < .0001$). Among patients undergoing RI, 446 of 676 events (66%) were detected as compared with only 3 of 190 events (2%) in patients undergoing IPE+TTM.

These early clinical trials of RI validated its safety and effectiveness, as well as 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-bound 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 goals of timely scheduled follow-up and patient retention (Figure 2).[15,16] Moreover, replacement of many IPEs with RI follow-up evaluations resulted in increased efficiency for both patients and clinics".[15,17,18]

CIED evaluation at prescribed intervals (every 6–12 months for pacemakers and every 3–6 months for ICDs and resynchronization devices[1]) 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 follow-up visits 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 reduced the time to detection of arrhythmic events to a median of 1 day as compared with more than 30 days with quarterly conventional care (Table 1).[21,22] The Clinical Evaluation of Remote Notification to Reduce Time to Clinical Decision (CONNECT) study showed that the median time from the 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 Remote Follow-Up for ICD-Therapy in Patients Meeting MADIT II Criteria (REFORM) trial showed that ICD follow-up using adjunct RM can reduce the number of IPEs by 63.2%, with no difference in hospitalization or mortality rates.[19] Although most patients in the above trials had ICDs and cardiac resynchronization therapy with defibrillators (CRT-Ds), the Pacemaker REmote Follow-up Evaluation and Review (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 using 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.

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 of studies[28,38] have reported no difference in the quality of life and patient satisfaction when comparing remote and conventional follow-up strategies. Other authors[21,36,39,40] 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, even with nonwireless transceivers. Remote follow-up reduces IPE costs such as travel, time off from work, and the interruption of daily activities.[41] 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, e-mail, 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 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 underappreciated 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

Table 1 Remote Follow-Up: Clinical Evidence*

Study Name/ Author	Year	Study Type	Study Size (No. of Patients)	Inclusion Criteria	End Points	Results	Findings
Randomized trials—PMs							
PREFER[9]	2009	Randomized, prospective, multicenter	897	VVI/DDD PMs Medtronic CareLink RM	Mean time to first diagnosis of CAE, comparing the RM arm and the control arm	FU: 375 ± 140 d Mean time to first diagnosis of CAE was 5.7 mo in the RM arm vs 7.7 mo in the control arm $P < 0.001$	Mean time to first diagnosis of CAE was shorter in the RM arm
COMPAS[25]	2011	Randomized, multicenter	538	DDD PMs indications, no PM dependents Biotronik HM	MAE: hospitalization for PM-related complications, CV events, and death Incidence of each MAE RM reduction of in-office visits	FU: 18 mo MAE: 17.3% in the RM arm vs 19.1% in the control arm ($P < 0.01$ for non-inferiority Hospitalization due to PM complications in the RM arm (0.4%) vs the control arm (2.8%) $P < 0.05$ Mean number of unscheduled FUs per patient per year: 56% lower in the RM arm $p < 0.001$	RM was safe and reduced the number of in-office visits RM enabled earlier detection of clinical and device-related adverse events
Randomized trials—ICDs							
TRUST[6,15,16,26]	2010	Randomized, prospective, multicenter	1,339	VVI/DDD 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 patient per year in the RM arm vs 3.8 per patient per year in the control arm $p < 0.001$ Overall adverse event rate was 10.4% in both groups at 12 mo $p = 0.005$ for non-inferiority RM reduced event detection delay by >30 d $p < 0.001$	RM was safe in supplanting "routine" in-office visits, enabling early event detection in ICD recipients

Table 1 (*continued*)

Study Name/ Author	Year	Study Type	Study Size (No. of Patients)	Inclusion Criteria	End Points	Results	Findings
CONNECT[21]	2011	Randomized, prospective, multicenter.	1,997	ICDs and CRT-Ds Medtronic Carelink RM	Time from a clinical event to a clinical decision Evaluated hospitalization LOS	22 d (in-office arm) vs 4.6 d (RM arm) $p < .001$ Health care use for CV reasons: 4 d (in-office arm) vs 3.3 d (RM arm) $p < .001$ LOS per hospitalization was 3.2 d in the RM arm vs 4.3 d in the in-office arm $p = .002$	RM reduced the time to a clinical decision RM reduced the mean LOS
ECOST[23]							
Clinical aspects	2012	Randomized, prospective, multicenter	433	ICDs Biotronik HM	Incidence of MAE (all-cause and CV death) Procedure-related complications and device-related adverse events	FU: 24.2 mo MAE: 40.3% vs 43.3% in the RM arm vs in the control arm $p < 0.05$ (non inferiority) Appropriate and inappropriate shocks delivered were 71% lower in the RM arm $p < 0.05$ Battery longevity increased in the RM arm $p < 0.02$ 76% reduction of capacitor charges	RM was as safe as standard FU RM reduces appropriate and inappropriate shocks
Economic aspects	2014		310		Economic impact of RM on patients with ICD	Nonhospital costs: RM: €1695 ± 1131 $p < 0.04$ Conventional: €1952 ± 1023 Hospital costs: RM: €2829 ± 6382 Conventional: €3549 ± 9714 $p = .46$ Savings were increased to €494 by adding the ICD to nonhospital costs or to €315 per patient per year by adding the monitoring system	RM reduced mean nonhospital costs per patient per year RM did not significantly reduce the hospital costs per patient per year

Table 1 (*continued*)

Study Name/ Author	Year	Study Type	Study Size (No. of Patients)	Inclusion Criteria	End Points	Results	Findings
EVOLVO[27]							
Clinical aspects	2012	Randomized, prospective, multicenter	200	LVEF $\leq$35% Medtronic ICDs or CRT-Ds with thoracic impedance measurement capabilities (OptiVol)	Rate of the emergency department or urgent in-office visits for heart failure, arrhythmias, or ICD-related events Economic impact of RM on patients with ICD and heart failure	FU: 16 mo Total events: 0.59 vs 0.93 events per patient per year in the RM arm vs in the control arm $p = 0.005$ Number of urgent visits per patient per year for heart failure, arrhythmias, or ICD-related: 4.4 in the RM arm vs 5.7 in the control arm $p < 0.001$ Time from ICD alert to review: 1.4 d in the RM arm vs 24.8 d in the control arm $p < 0.001$	RM reduced the number of emergency department or urgent in-office visits and health care use RM increased the efficiency of health care No significant annual cost savings for the health care system
Economic aspects	2013					Costs: €1962 vs €2130 $p = 0.8$ Costs for patients: €291 vs €381 $p < 0.01$ Cost utility: patients in the RM arm had a cost saving of €888 per patient and gained 0.065 QALYs more over 16 months	Significant reduction in the annual cost for patients and gained QALYs in the RM arm

Table 1 (*continued*)

Study Name/ Author	Year	Study Type	Study Size (No. of Patients)	Inclusion Criteria	End Points	Results	Findings
REFORM[19] (second analysis)	2013	Randomized, parallel Quarterly clinic visits (Q arm) vs yearly clinic visits (Y arm)	155	ICD implanted according to MADIT II criteria	Scheduled and unscheduled ICD visits Difference in quality of life scores at baseline and after 27 mo Total and CV mortality Rate and length of all-cause and CV hospitalizations	FU: 24 mo FU visits reduced by 58% (3.8 vs 1.6 visits per patient per year in the Q arm vs in the Y arm) $p < 0.001$ Unscheduled FU per patient year was 0.27 in the Q arm vs 0.64 in the Y arm $p = 0.03$ All-cause mortality was not different between groups Y group did not exceed 1 additional visit per patient per year	RM safely reduces the ICD FU burden for 27 mo after implantation Favorable impact of RM on the quality of life No impact on mortality and hospitalization rate
Calò et al[28]	2013	Prospective, randomized	233	Biotronik, Boston Scientific, Medtronic, St Jude Medical	Assess current direct costs of 1-y ICD FU based on RM compared with conventional quarterly in-hospital FU from the hospital and patient perspective	FU required 47 min per patient per year in the RM arm vs 86 min per patient per year in the control arm $p < 0.03$ The costs associated with RM FU vs standard FU was \$103 $\pm$ 27 per patient per year vs \$154 $\pm$ 21 per patient per year $p < 0.01$ Overall cost savings for RM vs standard FU: \$97 $\pm$ 121 per patient per year vs \$287 $\pm$ 160 per patient per year $p < 0.001$	RM significantly reduced: The time spent by hospital staff The costs of the hospital and pt

Table 1 (*continued*)

Study Name/ Author	Year	Study Type	Study Size (No. of Patients)	Inclusion Criteria	End Points	Results	Findings
IN-TIME[29]	2014	Randomized, parallel	716	ICDs/CRT-Ds Biotronik HM, NYHA class II/III, LVEF $\leq 35\%$	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 1-y FU, 18.9% of patients in the HM group vs 27.2% in the control group had worsened symptoms $p = 0.013$ 1-y all-cause mortality in the telemonitoring group was 3.4% vs 8.7% in the control group $p = .004$ RM did not affect heart failure admissions $p = .38$	Patients on HM less likely to reach the composite end point Patients on HM had lower mortality HM did not reduce heart failure admissions
Registries, Mega-cohort observational studies							
AWARE[24]	2007	Retrospective analysis	11,624	PMs, ICDs, CRT-Ds Biotronik HM	Time to detection of events and impact on physician workload, comparing the RM arm vs the standard care arm	Mean time from the last FU to detection of an event was 26 d in the RM group compared with the usual FU period	RM improved safety and optimized the allocation of health resources.
ALTITUDE[30]	2010	Nonrandomized networked patients	185,778	ICDs/CRT-Ds with LATITUDE (Boston Scientific)	Patient survival	1- and 5-y survival rates were 50% reduced in non-RM patients $p < 0.001$	RM improves survival
MERLIN[31]	2015	Nonrandomized networked patients	269,471 (consecutive)	PPMs, ICDs/CRT-Ds with MERLIN	Survival according to the level of adherence to RM and device type	$>75\%$ adherence to RM promoted best survival $p < .001$ Pts with PM gained similar survival advantage with $>75\%$ adherence to RM $p < 0.001$	RM-mediated survival is dose dependent on the degree of adherence but not on CIED complexity

Table 1 (*continued*)

Study Name/ Author	Year	Study Type	Study Size (No. of Patients)	Inclusion Criteria	End Points	Results	Findings
Observational studies							
Fauchier et al[32]	2005	Nonrandomized database analysis	502	ICDs Biotronik HM	Calculation of costs related to ICD FU, including medical services and transportation compared with the expected costs of RM	RM was associated with a $2149 saving per patient in 5 y. Even considering an extra cost of $1200 for acquiring the technology, a breakeven point could be reached after 33.5 mo	RM reduces medical and transportation costs compared with standard ICD FU
Raatikainen et al[33]	2008	Observational	41	ICDs Medtronic Carelink RM	Assess whether RM offers a safe, practical, and cost-effective alternative to the in-office FU of patients with ICD	To complete FU, RM required: Less time from patients: 6.9 ± 5.0 min vs 182 ± 148 min $p < 0.001$ Less time from physicians: 8.4 ± 4.5 min vs 25.8 ± 17.0 min $p < 0.001$	RM reduces costs compared with standard ICD FU (saving of €524 per patient per year, 41% of the cost of standard FU)

Table 1 (*continued*)

Study Name/ Author	Year	Study Type	Study Size (No. of Patients)	Inclusion Criteria	End Points	Results	Findings
HomeGuide Registry[17,18]	2013 2014	Multicenter, prospective registry	1650	PMs, ICDs, CRT-Ds 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 incremental utility: 0.56 RM detected 95% of asymptomatic events and 73% of AEs Manpower of 55.5 min per health personnel per month for every 100 patients 15.4 min per patient to detect 0.43 AEs (RM arm) vs 60.5 min per patient to detect 0.16 AEs (in-person arm) Nurses reviewed 70% of transmissions (15% submitted to the physician)	RM effectively detected and managed clinical events $p < 0.001$ The nurse-based workflow model was safe, effective, and efficient
Patient satisfaction							
Marzegalli et al[34]	2008	Observational study	67	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 FU time as compared with standard in-hospital visits

Table 1 (*continued*)

Study Name/ Author	Year	Study Type	Study Size (No. of Patients)	Inclusion Criteria	End Points	Results	Findings
Ricci et al[35]	2010	Observational	119	PMs, ICDs, and CRTs in RM after 1 y 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
Petersen[36]	2012	Observational	474	Medtronic ICD or CRT-D and successful Carelink transmissions	To evaluate patient satisfaction with remote FU	385 of 474 (81.2%) patients responded to the questionnaire 25% of patients made unscheduled transmissions (for shock, alarm, palpitation, or other reasons)	95% were very content or content with remote FU 84% expressed desire for clear and prompt communication from the monitoring center
Morichelli et al[37]	2014	Observational	163	Recipients of ICDs in RM after 20 mo	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

AE = actionable event; CAE = clinically actionable event; CRT-D = cardiac resynchronization therapy with defibrillator; CV = cardiovascular; DDD = dual-chamber; FU = follow-up; HM = home monitoring; HoMASQ = Home Monitoring Acceptance and Satisfaction Questionnaire; HR = hazard ratio; ICD = implantable cardioverter-defibrillator; LOS = length of stay; LVEF = left ventricle ejection fraction; MADIT II = Multicenter Autonomic Defibrillator Implantation Trial II; MAE = major adverse event; NYHA = New York Heart Association; OR = odds ratio; PM = pacemaker; PPM = permanent pacemaker; PPV = positive predictive value; QALY = quality-adjusted life year; RM = remote monitoring; VVI = ventricle paced, ventricle sensed, pacing inhibited if beat sensed.

*The table summarizes clinical trials discussed in the text.

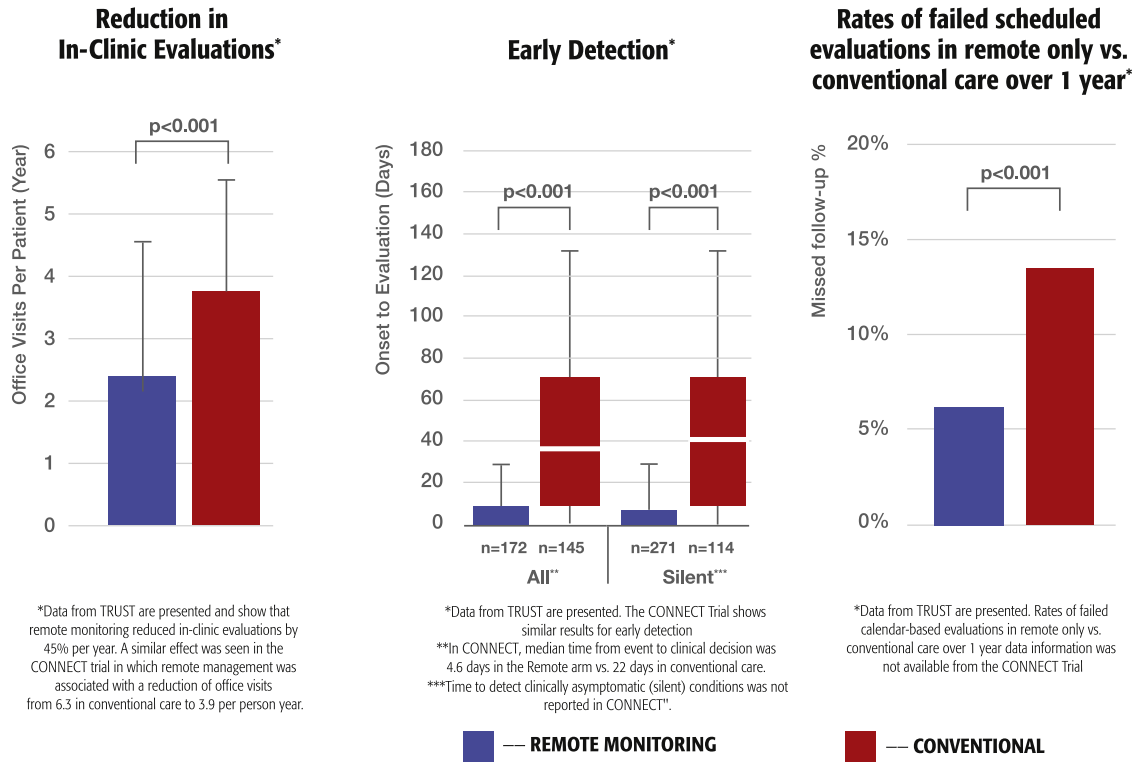


Figure 2 Benefits of remote monitoring. CONNECT = Clinical Evaluation of Remote Notification to Reduce Time to Clinical Decision; TRUST = Lumos-T Safely Reduces Routine Office Device Follow-Up.

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 CIEDs 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 communicative.[42] 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 (eg, TRUST trial[26]) and supported by observational data in mega-cohort analyses (eg, ALTITUDE trial[30] and MERLIN trial[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 RM for clinical events such as atrial fibrillation with rapid ventricular response rates,[26,46,47] T-wave oversensing or electromagnetic interference, or device malfunction, enables faster intervention to reduce the risk of unnecessary ICD shocks.[25] Even when appropriate ICD therapy has been delivered, RM may lead to early intervention and possible reduction in the total number of therapies.

The ECOST study[23,46] evaluated ICD therapy events as a prespecified secondary end point 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 the RM group compared with 10.4% in 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 in 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 of patients 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 (eg, daily vs every 3 months). However, the battery drain varies appreciably among the proprietary systems. Experience from the clinical use of one of these has shown preserved and sometimes improved battery life with its use 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 antitachycardia pacing or premature ventricular contraction 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 nonsustained ventricular tachycardia 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,[50] 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.[7,15,21,51,92] In the worldwide Home Monitoring database analysis,[24] 3,004,763 transmissions were sent by 11,624 patients with pacemakers, ICDs, and CRT-Ds. Atrial fibrillation was responsible for more than 60% of alerts in pacemakers and CRT-Ds 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 1–5 months earlier. Patients with CIEDs have an incidence of previously unrecognized atrial fibrillation ranging from 30% to 60%.[53–56] Early detection of atrial fibrillation by RM can enable intervention to avoid ICD inappropriate therapy, heart failure, and avoid loss of biventricular pacing. Early detection also provides additional 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 and thromboembolic events.[56–61] The risk of thromboembolic events is increased with even brief atrial fibrillation episodes (5 minutes), and the risk increases with increasing duration of the episodes.[61] However, in the majority of study patients, recordings made up to 30 days before the thromboembolic events showed no atrial fibrillation episodes, indicating temporal relationship between atrial fibrillation and the thromboembolic event may not always exist.[60,62] A combination of atrial fibrillation burden and clinical risk scores can be used to identify patients at lower/higher risk.[56] There are very few data to guide anticoagulation strategies for atrial fibrillation detected by RM of CIEDs. The risk/benefit ratio of initiating anticoagulation therapy in response to an atrial fibrillation event of any specific duration is uncertain. Although benefit might be predicted from RM-mediated early notification and quantification of atrial fibrillation burden, this benefit remains to be seen. An interventional trial of starting and stopping oral anticoagulation based on RM detected AF burden by Martin et al[63] failed to show any difference in stroke rates or all-cause mortality despite accounting for the severity of CHADS2 scores. Another study (COMPAS trial)[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 guideline for the management of patients with atrial fibrillation.[64]

Heart Failure

There is significant interest in the use of recorded data from implantable cardiac rhythm management 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 a higher risk of subsequent heart failure hospitalizations.[69,77] Recently, the Implant-based Multiparameter Telemonitoring of Patients with Heart Failure[73] 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 (not including thoracic impedance), 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 response 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 because of the length of service for patients who undergo the transplantation at a young age and because of the increased strain from higher levels of physical activity. The pediatric population, who frequently has epicardial leads implanted, is more vulnerable. RM might therefore have particular utility in such patients for surveillance, early detection, and preemptive programming.[26] 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.[82]

Implantable Loop Recorders

Implantable loop recorders (ILRs) play 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. Among patients with cryptogenic stroke, a diagnostic strategy of an implantable loop recorder coupled with RI technology has been demonstrated to detect atrial fibrillation more frequently than a conventional electrocardiogram monitoring approach.[92] 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-D function.[83,84] The analysis could also yield opportunities for optimizing device programming (eg, 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.

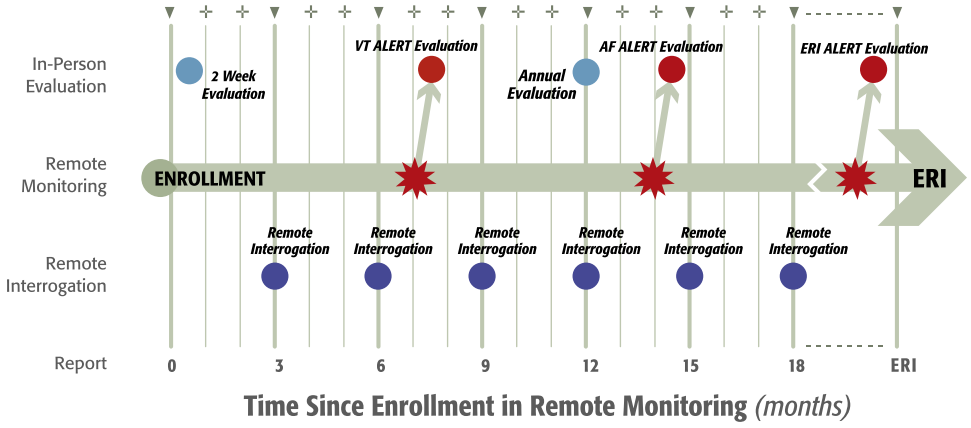
Section 3: Indications, Paradigms, Frequency, and Content of CIED Follow-Up

Technological advances in RI and RM are altering the relative value of IPEs vs remote CIED 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 US patients who underwent CIED implantation between 2005 and 2009 actually participating in an initial IPE within the recommended 2–12 week postimplantation time frame 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 the 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 non–pacemaker-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.

[†]CIEDs with epicardial leads were not included in the 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.



* 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 3 Event-based model of cardiac implantable electronic device follow-up.

Timing of Patient Education and Enrollment

The concept of remote follow-up should be presented to the patient before 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]) that may govern the 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 postimplantation office visit. An alternative is to enroll the patient before 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 (eg, ability of the remote transceiver to be paired to a CRM device in the field) and patient characteristics (eg, the patient's ability to follow and act on instructions) can limit the opportunity to initiate RM before hospital discharge.

Remote Interrogations

After the acute 2–12-week postimplantation 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 on CIED type and the patient-specific indications outlined in the 2008 HRS/EHRA Expert Consensus on the Monitoring of Cardiovascular Implantable Electronic Devices[1]: every 3–12 months for pacemakers and every 3–6 months for ICDs. 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 on clinician-configured settings and manufacturer-specific communication intervals between the CIED and the 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 the 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).

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]

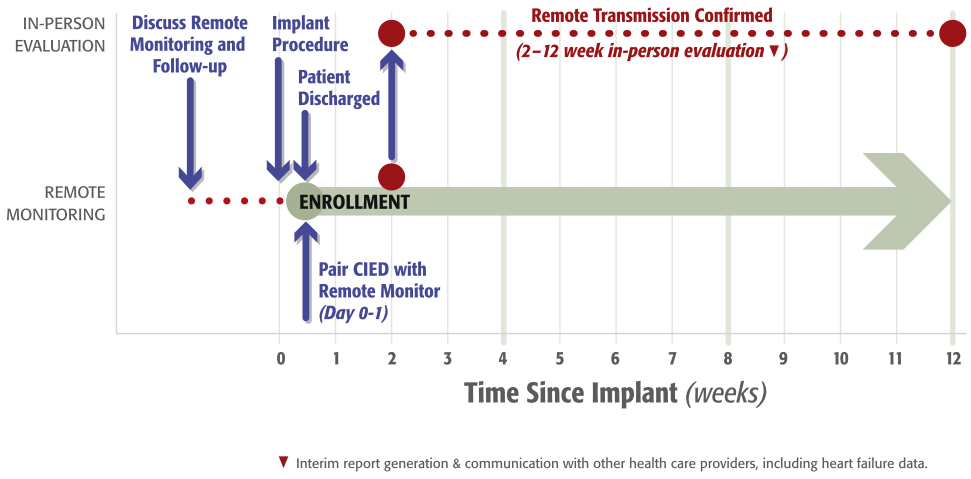


Figure 4 Initiation of remote monitoring. CIED = cardiac implantable electronic device.

Communication

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.

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 CIED clinical follow-up and clearly defined roles and responsibilities of patients, physicians, allied professionals, and manufacturers.

Table 2 Goals of the Initial Education Process Before 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 patient's care and determine who will be responsible for CIED follow-up.
- Assess the suitability of the patient as a candidate for RM (eg, are analog phone lines present, does the patient have an adapter to connect using cable or Voice over Internet protocols, and is the patient willing to pay for cellular-based monitoring).
- Determine the patient's desire to access their RM data (when available).

CIED = cardiac implantable electronic device; RM = remote monitoring.

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, but rather it should do so within an acceptable time frame (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 (eg, lack of landline and 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

Table 3 The RM Process

- Enrollment to connection
  - Enroll patient into an RM system.
  - Ensure patient receives an RM system.
    - Consider pairing the patient's device to a transceiver before hospital discharge.
  - Ensure that the patient establishes a successful connection with the RM system (ie, handshake transmission).
- Connection to transmission
  - Obtain monthly data from patients with heart failure 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 the electrophysiologist of any alert notifications.
  - Present clinically significant data to the electrophysiologist for review.
  - Generate summary document for health care providers involved in patient's care.

CIED = cardiac implantable electronic device; RM = remote monitoring.

(eg, 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 initiating RM depends on patient-specific conditions and the institutional organization. The system should be delivered as early as possible after implantation; however, the implantation of a CIED 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.

Physician Responsibilities

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.

Table 4 Potential Topics to Cover in the Initial Patient Education and Patient Agreement/Contract

Overview of RM	• Explain the benefits and limitations. • Explain the frequency and types of monitoring.
What to expect	• 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 (eg, 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	• 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 the clinic staff.
Privacy	• 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	• Patient agrees to RM.

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

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 certification, 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 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 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. The 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 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 increased 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 clinical 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 (ie, ABIM Clinical Cardiac Electrophysiology certification, IBHRE device certification, or equivalent) are in place so that important findings can be recognized and brought to the attention of the patient's 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 on 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 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 the CIED to communicate with the transceiver has been previously assigned to other uses (such as emergency service 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 (eg, 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, these 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 hardcopy and electronic records), and registries (including the American College of Cardiology National Cardiovascular Data Registry's ICD Registry and vendor postapproval 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 HRS[86] has led a multistakeholder 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-Ds. 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] Data exchange across proprietary vendor environments (eg, from a CIED programmer or an RM server to an electronic medical record) is made possible by the implementation of the Implantable Device Cardiac Observation Profile, a vendor-neutral standards-based exchange profile created under the technical framework of the 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 Observation 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 US Food and Drug Administration's 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 United States 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 because of 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 the 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 have 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 non-hospital costs related to device management, and direct nonhospital costs. The European Health Economic Trial on Home Monitoring in ICD Patients[89] prospectively gathered cost data on 312 patients assigned to RM either turned on or off. Patients undergoing RM had fewer scheduled IPEs, and despite the fact that they had more unscheduled IPEs, the total number of IPEs was still significantly lower than for patients not undergoing RM (3.79 ± 1.67 vs 5.53 ± 2.32; $P < .001$). While patients undergoing 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 cost 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 upfront 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. The 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 on in a time frame 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 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, though not exclusively, from the ICD population, discussions with patients 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, should be conducted in advance.

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 about 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.

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 may be beneficial to initiate RM within the 2 weeks of 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

CIED = cardiac implantable electronic device; HRS = Heart Rhythm Society; 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 is useful to reduce 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

B-R = level of evidence B indicates a moderate level from randomized trials; CIED = cardiac implantable electronic device; ICD = implantable cardioverter-defibrillator; RM = remote monitoring.

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 CRT-Ds 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 the 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.

Appendix 1

See Tables A1 and A2.

References

1. Wilkoff BL, Auricchio A, Brugada J, et al. HRS/EHRA Expert Consensus on the Monitoring of Cardiovascular Implantable Electronic Devices (CIEDs): description of techniques, indications, personnel, frequency and ethical considerations: developed in partnership with the Heart Rhythm Society (HRS) and the European Heart Rhythm Association (EHRA); and in collaboration with the American College of Cardiology (ACC), the American Heart Association (AHA), the European Society of Cardiology (ESC), the Heart Failure Association of ESC (HFA), and the Heart Failure Society of America (HFSA). Endorsed by the Heart Rhythm Society, the European Heart Rhythm Association (a registered branch of the ESC), the American College of Cardiology, the American Heart Association. Heart Rhythm 2008;5:907–925.
2. Al-Khatib SM, Mi X, Wilkoff BL, Qualls LG, Frazier-Mills C, Setoguchi S, Hess PL, Curtis LH. Follow-up of patients with new cardiovascular implantable electronic devices: are experts' recommendations implemented in routine clinical practice? Circ Arrhythm Electrophysiol 2013;6:108–116.
3. Halimi F, Clementy J, Attuel P, Dessenne X, Amara W; OEDIPE Trial Investigators. Optimized post-operative surveillance of permanent pacemakers by home monitoring: the OEDIPE trial. Europace 2008;10:1392–1399.
4. Dubner S, Auricchio A, Steinberg JS, et al. ISHNE/EHRA expert consensus on remote monitoring of cardiovascular implantable electronic devices (CIEDs). Ann Noninvasive Electrocardiol 2012;17:36–56.
5. Burri H. Remote follow-up and continuous remote monitoring, distinguished. Europace 2013;15:i14–i16.
6. Varma N, Pavri BB, Stambler B, Michalski J; TRUST Investigators. Same-day discovery of implantable cardioverter defibrillator dysfunction in the TRUST remote monitoring trial: influence of contrasting messaging systems. Europace 2013;15:697–703.
7. Varma N, Stambler B, Chun S. Detection of atrial fibrillation by implanted devices with wireless data transmission capability. Pacing Clin Electrophysiol 2005;28:S133–S136.
8. Jacobs AK, Anderson JL, Halperin JL. The evolution and future of ACC/AHA clinical practice guidelines: a 30-year journey: a report of the American College of Cardiology/American Heart Association Task Force on Practice Guidelines. J Am Coll Cardiol 2014;64:1373–1384.
9. Crossley GH, Chen J, Choucair W, Cohen TJ, Gohn DC, Johnson WB, Kennedy EE, Mongeon LR, Serwer GA, Qiao H, Wilkoff BL. Clinical benefits of remote versus transtelephonic monitoring of implanted pacemakers. J Am Coll Cardiol 2009;54:2012–2019.
10. Schoenfeld MH, Compton SJ, Mead RH, Weiss DN, Sherfesee L, Englund J, Mongeon LR. Remote monitoring of implantable cardioverter defibrillators: a prospective analysis. Pacing Clin Electrophysiol 2004;27:757–763.
11. Al-Khatib SM, Piccini JP, Knight D, Stewart M, Clapp-Channing N, Sanders GD. Remote monitoring of implantable cardioverter defibrillators versus quarterly device interrogations in clinic: results from a randomized pilot clinical trial. J Cardiovasc Electrophysiol 2010;21:545–550.
12. Cronin EM, Ching EA, Varma N, Martin DO, Wilkoff BL, Lindsay BD. Remote monitoring of cardiovascular devices: a time and activity analysis. Heart Rhythm 2012;9:1947–1951.
13. Theuns DA, Res JC, Jordaens LJ. Home monitoring in ICD therapy: future perspectives. Europace 2003;5:139–142.
14. Joseph GK, Wilkoff BL, Dresing T, Burkhardt J, Khaykin Y. Remote interrogation and monitoring of implantable cardioverter defibrillators. J Interv Card Electrophysiol 2004;11:161–166.
15. Varma N, Epstein AE, Irimpen A, Schweikert R, Love C; TRUST Investigators. Efficacy and safety of automatic remote monitoring for implantable cardioverter-defibrillator follow-up: the Lumos-T Safely Reduces Routine Office Device Follow-up (TRUST) trial. Circulation 2010;122:325–332.
16. Varma N, Michalski J, Stambler B, Pavri BB; TRUST Investigators. Superiority of automatic remote monitoring compared with in-person evaluation for scheduled ICD follow-up in the TRUST trial—testing execution of the recommendations. Eur Heart J 2014;35:1345–1352.
17. Ricci RP, Morichelli L, D'Onofrio A, Calò L, Vaccari D, Zanotto G, Curnis A, Buja G, Rovai N, Gargaro A. Effectiveness of remote monitoring of CIEDs in detection and treatment of clinical and device-related cardiovascular events in daily practice: the HomeGuide Registry. Europace 2013;15:970–977.
18. Ricci RP, Morichelli L, D'Onofrio A, Calo L, Vaccari D, Zanotto G, Curnis A, Buja G, Rovai N, Gargaro A. Manpower and outpatient clinic workload for remote monitoring of patients with cardiac implantable electronic devices: data from the HomeGuide Registry. J Cardiovasc Electrophysiol 2014;25:1216–1223.
19. Hindricks G, Elsner C, Piorkowski C, Taborsky M, Geller JC, Schumacher B, Bytesnik J, Kottkamp H. Quarterly vs. yearly clinical follow-up of remotely monitored recipients of prophylactic implantable cardioverter-defibrillators: results of the REFORM trial. Eur Heart J 2014;35:98–105.
20. Boriani G, Da Costa A, Ricci RP, et al. The MOnitoring Resynchronization dEvices and CARdiac patiEnts (MORE-CARE) randomized controlled trial: phase 1 results on dynamics of early intervention with remote monitoring. J Med Internet Res 2013;15:e167.
21. Crossley G, Boyle A, Vitense H, Chang Y, Mead RH. The CONNECT (Clinical Evaluation of Remote Notification to Reduce Time to Clinical Decision) trial: the value of wireless remote monitoring with automatic clinician alerts. J Am Coll Cardiol 2011;57:1181–1189.
22. Varma N. Rationale and design of a prospective study of the efficacy of a remote monitoring system used in implantable cardioverter defibrillator follow-up: the Lumos-T Reduces Routine Office Device Follow-Up Study (TRUST) study. Am Heart J 2007;154:1029–1034.
23. Guedon-Moreau L, Lacroix D, Sadoul N, Clementy J, Kouakam C, Hermida JS, Aliot E, Boursier M, Bizeau O, Kacet S. A randomized study of remote follow-up of implantable cardioverter defibrillators: safety and efficacy report of the ECOST trial. Eur Heart J 2012;34:605–614.
24. Lazarus A. Remote, wireless, ambulatory monitoring of implantable pacemakers, cardioverter defibrillators, and cardiac resynchronization therapy systems: analysis of a worldwide database. Pacing Clin Electrophysiol 2007;30:S2–S12.
25. Mabo P, Victor F, Bazin P, Ahres S, Babuty D, Da Costa A, Binet D, Daubert JC; COMPAS Trial Investigators. A randomized trial of long-term remote monitoring of pacemaker recipients (the COMPAS trial). Eur Heart J 2012;33:1105–1111.
26. Varma N, Michalski J, Epstein AE, Schweikert R. Automatic remote monitoring of implantable cardioverter-defibrillator lead and generator performance: the Lumos-T Safely RedUceS RouTine Office Device Follow-up (TRUST) Trial. Circ Arrhythm Electrophysiol 2010;3:428–436.
27. Landolina M, Perego GB, Lunati M, Curnis A, Guenzati G, Vicentini A, Parati G, Borghi G, Zanaboni P, Valsecchi S, Marzegalli M. Remote monitoring reduces healthcare use and improves quality of care in heart failure patients with implantable defibrillators: the evolution of management strategies of heart failure patients with implantable defibrillators (EVOLVO) study. Circulation 2012;125:2985–2992.
28. Calò L, Gargaro A, De Ruvo E, Palozzi G, Sciarra L, Rebecchi M, Guarracini F, Fagagnini A, Piroli E, Lioy E, Chirico A. Economic impact of remote monitoring on ordinary follow-up of implantable cardioverter defibrillators as compared with conventional in-hospital visits: a single-center prospective and randomized study. J Interv Card Electrophysiol 2013;37:69–78.
29. Hindricks G, Taborsky M, Glikson M, et al. Implant-based multiparameter telemonitoring of patients with heart failure (IN-TIME): a randomised controlled trial. Lancet 2014;384:583–590.
30. Saxon LA, Hayes DL, Gilliam FR, Heidenreich PA, Day J, Seth M, Meyer TE, Jones PW, Boehmer JP. Long-term outcome after ICD and CRT implantation and influence of remote device follow-up: the ALTITUDE survival study. Circulation 2010;122:2359–2367.
31. Varma NPJ, Snell J, Fischer A, Dalal N, Mittal S. The relationship between level of adherence to automatic wireless remote monitoring and survival in pacemaker and defibrillator patients. J Am Coll Cardiol. In press. Available at: http://dx.doi.org/10.1016/j.jacc.2015.04.033.
32. Fauchier L, Sadoul N, Kouakam C, Briand F, Chauvin M, Babuty D, Clementy J. Potential cost savings by telemedicine-assisted long-term care of implantable cardioverter defibrillator recipients. Pacing Clin Electrophysiol 2005;28:S255–S259.
33. Raatikainen MJ, Uusimaa P, van Ginneken MM, Janssen JP, Linnaluoto M. Remote monitoring of implantable cardioverter defibrillator patients: a safe, time-saving, and cost-effective means for follow-up. Europace 2008;10:1145–1151.
34. Marzegalli M, Lunati M, Landolina M, et al. Remote monitoring of CRT-ICD: the multicenter Italian CareLink evaluation—ease of use, acceptance, and organizational implications. Pacing Clin Electrophysiol 2008;31:1259–1264.
35. Ricci RP, Morichelli L, Quarta L, Sassi A, Porfili A, Laudadio MT, Gargaro A, Santini M. Long-term patient acceptance of and satisfaction with implanted device remote monitoring. Europace 2010;12:674–679.
36. Petersen HH, Larsen MC, Nielsen OW, Kensing F, Svendsen JH. Patient satisfaction and suggestions for improvement of remote ICD monitoring. J Interv Card Electrophysiol 2012;34:317–324.
37. Morichelli L, Porfili A, Quarta L, Sassi A, Ricci RP. Implantable cardioverter defibrillator remote monitoring is well accepted and easy to use during long-term follow-up. J Interv Card Electrophysiol 2014;41:203–209.
38. Guédon-Moreau L, Lacroix D, Sadoul N, Clémenty J, Kouakam C, Hermida JS, Aliot E, Kacet S; ECOST Investigators. Costs of remote monitoring vs. ambulatory follow-ups of implanted cardioverter defibrillators in the randomized ECOST study. Europace 2014;16:1181–1188.

39. Zanaboni P, Landolina M, Marzegalli M, Lunati M, Perego GB, Guenzati G, Curnis A, Valsecchi S, Borghetti F, Borghi G, Masella C. Cost-utility analysis of the EVOLVO study on remote monitoring for heart failure patients with implantable defibrillators: randomized controlled trial. J Med Internet 2013;15:e106.
40. Burri H, Sticherling C, Wright D, Makino K, Smala A, Tilden D. Cost-consequence analysis of daily continuous remote monitoring of implantable cardiac defibrillator and resynchronization devices in the UK. Europace 2013;15:1601–1608.
41. Ricci RP, Vicentini A, D'Onofrio A, et al. Impact of in-clinic follow-up visits in patients with implantable cardioverter defibrillators: demographic and socio-economic analysis of the TARIFF study population. J Interv Card Electrophysiol 2013;38:101–106.
42. de Asmundis C, Ricciardi D, Namdar M, Chierchia G-B, Sarkozy A, Brugada P. Role of home monitoring in children with implantable cardioverter defibrillators for Brugada syndrome. Europace 2013;15:i17–i25.
43. Neuzil P, Taborsky M, Holy F, Wallbrueck K. Early automatic remote detection of combined lead insulation defect and ICD damage. Europace 2008;10:556–557.
44. Varma N. Remote monitoring for advisories: automatic early detection of silent lead failure. Pacing Clin Electrophysiol 2009;32:525–527.
45. Spencker S, Coban N, Koch L, Schirdewan A, Muller D. Potential role of home monitoring to reduce inappropriate shocks in implantable cardioverter-defibrillator patients due to lead failure. Europace 2009;11:483–488.
46. Guedon-Moreau L, Kouakam C, Klug D, MarquiÉ C, Brigadeau F, BoulÉ S, Blangy H, Lacroix D, ClÉMenty J, Sadoul N, Kacet S, on behalf of the EtI. Decreased delivery of inappropriate shocks achieved by remote monitoring of ICD: a substudy of the ECOST trial. J Cardiovasc Electrophysiol 2014;25:763–770.
47. Ricci RP, Pignalberi C, Landolina M, et al. Ventricular rate monitoring as a tool to predict and prevent atrial fibrillation-related inappropriate shocks in heart failure patients treated with cardiac resynchronisation therapy defibrillators. Heart 2014;100:848–854.
48. Ricci RP, Morichelli L, Quarta L, Porfili A, Magris B, Giovene L, Torcinaro S, Gargaro A. Effect of daily remote monitoring on pacemaker longevity: a retrospective analysis. Heart Rhythm 2015;12:330–337.
49. Medtronic. Clinician Manual Supplement ProtectaTM XT/ProtectaTM Projected service life information related to remote monitoring. EVERA™ XT VR DVBB1D1. Manual No: M945739A001A.
50. Varma N, Johnson MA. Prevalence of cancelled shock therapy and relationship to shock delivery in recipients of implantable cardioverter-defibrillators assessed by remote monitoring. Pacing Clin Electrophysiol 2009;32:S42–S46.
51. Ricci RP, Morichelli L, Santini M. Remote control of implanted devices through Home Monitoring technology improves detection and clinical management of atrial fibrillation. Europace 2009;11:54–61.
52. Ricci RP, Morichelli L, D'Onofrio A, Calo L, Vaccari D, Zanotto G, Curnis A, Buja G, Rovai N, Gargaro A. Effectiveness of remote monitoring of CIEDs in detection and treatment of clinical and device-related cardiovascular events in daily practice: the HomeGuide Registry. Europace 2013;15:970–977.
53. Orlov MV, Ghali JK, Araghi-Niknam M, Sherfesee L, Sahr D, Hettrick DA; Atrial High Rate Trial Investigators. Asymptomatic atrial fibrillation in pacemaker recipients: incidence, progression, and determinants based on the atrial high rate trial. Pacing Clin Electrophysiol 2007;30:404–411.
54. Cheung JW, Keating RJ, Stein KM, Markowitz SM, Iwai S, Shah BK, Lerman BB, Mittal S. Newly detected atrial fibrillation following dual chamber pacemaker implantation. J Cardiovasc Electrophysiol 2006;17:1323–1328.
55. Bunch TJ, Day JD, Olshansky B, Stolen KQ, Mullin CM; INTRINSIC RV Study Investigators. Newly detected atrial fibrillation in patients with an implantable cardioverter-defibrillator is a strong risk marker of increased mortality. Heart Rhythm 2009;6:2–8.
56. Botto GL, Padeletti L, Santini M, et al. Presence and duration of atrial fibrillation detected by continuous monitoring: crucial implications for the risk of thromboembolic events. J Cardiovasc Electrophysiol 2009;20:241–248.
57. Glotzer TV, Hellkamp AS, Zimmerman J, et al. Atrial high rate episodes detected by pacemaker diagnostics predict death and stroke: report of the atrial diagnostics ancillary study of the MOde Selection Trial (MOST). Circulation 2003;107:1614–1619.
58. Capucci A, Santini M, Padeletti L, et al. Monitored atrial fibrillation duration predicts arterial embolic events in patients suffering from bradycardia and atrial fibrillation implanted with antitachycardia pacemakers. J Am Coll Cardiol 2005;46:1913–1920.
59. Glotzer TV, Daoud EG, Wyse DG, Singer DE, Ezekowitz MD, Hilker C, Miller C, Qi D, Ziegler PD. The relationship between daily atrial tachyarrhythmia burden from implantable device diagnostics and stroke risk: the TRENDS study. Circ Arrhythm Electrophysiol 2009;2:474–480.
60. Shanmugam N, Boerdlein A, Proff J, Ong P, Valencia O, Maier SK, Bauer WR, Paul V, Sack S. Detection of atrial high-rate events by continuous home monitoring: clinical significance in the heart failure-cardiac resynchronization therapy population. Europace 2012;14:230–237.
61. Healey JS, Connolly SJ, Gold MR, et al. Subclinical atrial fibrillation and the risk of stroke. N Engl J Med 2012;366:120–129.
62. Brambatti M, Connolly SJ, Gold MR, et al. Temporal relationship between subclinical atrial fibrillation and embolic events. Circulation 2014;129:2094–2099.
63. Martin DT, Bersohn MM, Waldo AL, Wathen MS, Choucair WK, Lip GYH, Ip J, Holcomb R, Akar JG, Halperin JL, on behalf of the IMPACT Investigators. Randomized trial of atrial arrhythmia monitoring to guide anticoagulation in patients with implanted defibrillator and cardiac resynchronization devices. Eur Heart J. In press. Available at: http://eurheartj.oxfordjournals.org/content/ehj/early/2015/04/22/eurheartj.ehv115.full.pdf.
64. January CT, Wann LS, Alpert JS, et al. 2014 AHA/ACC/HRS guideline for the management of patients with atrial fibrillation: executive summary: a report of the American College of Cardiology/American Heart Association Task Force on Practice Guidelines and the Heart Rhythm Society. J Am Coll Cardiol 2014;64:2246–2280.
65. Vollmann D, Nägele H, Schauerte P, Wiegand U, Butter C, Zanotto G, Quesada A, Guthmann A, Hill MR, Lamp B; EISOS Investigators. Clinical utility of intrathoracic impedance monitoring to alert patients with an implanted device of deteriorating chronic heart failure. Eur Heart J 2007;28:1835–1840.
66. Conraads VM, Tavazzi L, Santini M, Oliva F, Gerritse B, Yu CM, Cowie MR. Sensitivity and positive predictive value of implantable intrathoracic impedance monitoring as a predictor of heart failure hospitalizations: the SENSE-HF trial. Eur Heart J 2011;32:2266–2273.
67. Perego GB, Landolina M, Vergara G, et al. Implantable CRT device diagnostics identify patients with increased risk for heart failure hospitalization. J Interv Card Electrophysiol 2008;23:235–242.
68. Small RS, Wickemeyer W, Germany R, Hoppe B, Andrulli J, Brady PA, Labeau M, Koehler J, Sarkar S, Hettrick DA, Tang WH. Changes in intrathoracic impedance are associated with subsequent risk of hospitalizations for acute decompensated heart failure: clinical utility of implanted device monitoring without a patient alert. J Card Fail 2009;15:475–481.
69. Whellan DJ, Ousdigian KT, Al-Khatib SM, Pu W, Sarkar S, Porter CB, Pavri BB, O'Connor CM. Combined heart failure device diagnostics identify patients at higher risk of subsequent heart failure hospitalizations: results from PARTNERS HF (Program to Access and Review Trending Information and Evaluate Correlation to Symptoms in Patients With Heart Failure) study. J Am Coll Cardiol 2010;55:1803–1810.
70. Catanzariti D, Lunati M, Landolina M, et al. Monitoring intrathoracic impedance with an implantable defibrillator reduces hospitalizations in patients with heart failure. Pacing Clin Electrophysiol 2009;32:363–370.
71. Maines M, Catanzariti D, Cemin C, Vaccarini C, Vergara G. Usefulness of intrathoracic fluids accumulation monitoring with an implantable biventricular defibrillator in reducing hospitalizations in patients with heart failure: a case-control study. J Interv Card Electrophysiol 2007;19:201–207.
72. van Veldhuisen DJ, Braunschweig F, Conraads V, et al. Intrathoracic impedance monitoring, audible patient alerts, and outcome in patients with heart failure. Circulation 2011;124:1719–1726.
73. Hindricks G, Taborsky M, Glikson M, et al. Implant-based multiparameter telemonitoring of patients with heart failure (IN-TIME): a randomised controlled trial. Lancet 2014;384:583–590.
74. Abraham WT, Adamson PB, Bourge RC, et al. Wireless pulmonary artery haemodynamic monitoring in chronic heart failure: a randomised controlled trial. Lancet 2011;377:658–666.
75. Epstein AE, DiMarco JP, Ellenbogen KA, et al. 2012 ACCF/AHA/HRS focused update incorporated into the ACCF/AHA/HRS 2008 guidelines for device-based therapy of cardiac rhythm abnormalities: a report of the American College of Cardiology Foundation/American Heart Association Task Force on Practice Guidelines and the Heart Rhythm Society. J Am Coll Cardiol 2013;61:e6–e75.
76. Gussak I, Brugada P, Brugada J, Antzelevitch C, Osbakken M, Bjerregaard P. ECG phenomenon of idiopathic and paradoxical short QT intervals. Card Electrophysiol Rev 2002;6:49–53.
77. Antzelevitch C, Brugada P, Borggrefe M, et al. Brugada syndrome: report of the second consensus conference: endorsed by the Heart Rhythm Society and the European Heart Rhythm Association. Circulation 2005;111:659–670.
78. de Asmundis C, Ricciardi D, Namdar M, Chierchia GB, Sarkozy A, Brugada P. Role of home monitoring in children with implantable cardioverter defibrillators for Brugada syndrome. Europace 2013;15:i17–i25.
79. Schwartz PJ, Spazzolini C, Priori SG, et al. Who are the long-QT syndrome patients who receive an implantable cardioverter-defibrillator and what happens to them? Data from the European Long-QT Syndrome Implantable Cardioverter-Defibrillator (LQTS ICD) Registry. Circulation 2010;122:1272–1282.

80. Berul CI, Van Hare GF, Kertesz NJ, Dubin AM, Cecchin F, Collins KK, Cannon BC, Alexander ME, Triedman JK, Walsh EP, Friedman RA. Results of a multicenter retrospective implantable cardioverter-defibrillator registry of pediatric and congenital heart disease patients. J Am Coll Cardiol 2008;51:1685–1691.
81. Maron BJ, Spirito P, Shen WK, et al. Implantable cardioverter-defibrillators and prevention of sudden cardiac death in hypertrophic cardiomyopathy. JAMA 2007;298:405–412.
82. Sacher F, Probst V, Bessouet M, et al. Remote implantable cardioverter defibrillator monitoring in a Brugada syndrome population. Europace 2009;11:489–494.
83. Hayes DL, Boehmer JP, Day JD, Gilliam FR III, Heidenreich PA, Seth M, Jones PW, Saxon LA. Cardiac resynchronization therapy and the relationship of percent biventricular pacing to symptoms and survival. Heart Rhythm 2011;8:1469–1475.
84. Gilliam FR, Hayes DL, Boehmer JP, Day J, Heidenreich PA, Seth M, Jones PW, Stein KM, Saxon LA. Real world evaluation of dual-zone ICD and CRT-D programming compared to single-zone programming: the ALTITUDE REDUCES study. J Cardiovasc Electrophysiol 2011;22:1023–1029.
85. Heart Rhythm Society. Resource—Specifications for HRS-developed Measures. 2015.A HRS-developed physician-level performance measure "In-Person Evaluation Following Implantation of a Cardiovascular Implantable Electronic Device (CIED)" is available as a tool to measure adherence to in-person follow-up. www.hrsonline.org/hrs/Practice-Guidance/Quality-Outcomes-Reporting/Physician-Quality-Reporting-Systems-PQRS/Resource-Specifications-for-HRS-Measures. Accessed April 8, 2015.
86. Winters SL, Kusumoto FM, Miller JM, Slotwiner DJ. The role of the Heart Rhythm Society in integrating the healthcare enterprise. Heart Rhythm 2007;4:122–124.
87. IEEE. 11073-10103-2012—Health informatics–Point-of-care medical device communication Part 10103: Nomenclature–Implantable device, cardiac. http://standards.ieee.org/findstds/standard/11073-10103-2012.html. Accessed April 8, 2015.
88. Integrating the Healthcare Enterprise. Patient Care Device Technical Framework. 2014. http://www.ihe.net/Technical_Frameworks/pcd. Accessed April 8, 2015.
89. Heidbuchel H, Hindricks G, Broadhurst P, et al. EuroEco (European Health Economic Trial on Home Monitoring in ICD Patients): a provider perspective in five European countries on costs and net financial impact of follow-up with or without remote monitoring. Eur Heart J 2015;36:158–169.
90. Amy Dockser Marcus CW. Heart gadgets test privacy—law limits. Wall St J. Available at: http://www.wsj.com/articles/SB10001424052970203937004578078820874744076.
91. Halperin D, Heydt-Benjamin TS, Ransford B, Clark SS, Defen B, Morgan W, Fu K, Kohno T, Maisel WH. Pacemakers and implantable cardiac defibrillators: software radio attacks and zero-power defenses. security and privacy. In: Proceedings of the IEEE Symposium on Security and Privacy. 2008:129–142.
92. Sanna T, Diener H-C, Passman RS, Di Lazzaro V, Bernstein RA, Morillo CA, et al. Cryptogenic stroke and underlying atrial fibrillation. New England Journal of Medicine 2014;370(26):2478–2486.

Table A1 Author Disclosure Table

Writing Group Member	Institution	Consultant/Advisory Board/Honoraria	Speakers' Bureau	Research Grant	Fellowship Support	Stock Options/ Partner	Board Mbs/Other
David Slotwiner, MD (Chair)	Hofstra School of Medicine, North Shore-Long Island Jewish Health System	None	None	None	None	None	None
Niraj Varma, MD, PhD (Co-chair)	Cleveland Clinic	1: Boston Scientific, Biotronik, Medtronic, Sorin Group 2: St Jude Medical	None	None	None	None	None
Atul Verma, MD, FRCPC, FHRS	Southlake Regional Health Centre	1: Boehringer Ingelheim, Bayer HealthCare	None	1: Medtronic, Biosense Webster, Boehringer Ingelheim	None	None	None
Charles J. Love, MD, FHRS, FACC, FAHA, CCDS	New York University Langone Medical Center	0: Cook Medical 1: Lake Region Medical 2: Medtronic, St Jude Medical, Spectranetics	None	None	None	None	None
Cheuk-Man Yu, MD, FACC, FRCP, FRACP (APHRS representative)	The Chinese University of Hong Kong	None	None	None	None	None	None
George Annas, JD, MPH	Boston University School of Public Health	None	None	None	None	None	None
Gerald A. Serwer, MD (PACES representative)	University of Michigan Congenital Heart Center, University of Michigan Health System	1: Medtronic	None	None	None	None	None
John Rickard, MD, MPH	Johns Hopkins University	None	None	None	None	None	None
Joseph G. Akar, MD, PhD	Yale University School of Medicine	None	None	None	None	None	None
Julie Shea, MS, RNCS, FHRS, CCDS	Brigham and Women's Hospital	1: Medtronic, Heart Rhythm Society	None	None	None	None	None
Kristen Patton, MD	University of Washington	None	None	None	None	None	0: American College of Cardiology, American Heart Association
Loredana Morichelli, RN, MSN	Department of Cardiovascular Diseases, San Filippo Neri Hospital	1: Medtronic	None	None	None	None	None
Marianne Beardsall, MN/NP, CCDS, FHRS	Southlake Regional Health Centre	1: Medtronic, St Jude Medical	None	None	None	None	None
Mark Schoenfeld, MD, FACC, FAHA, FHRS, CCDS	Yale University School of Medicine, Yale-New Haven Hospital,	1: United Health Care	None	None	None	None	None

Table A1 (*continued*)

Writing Group Member	Institution	Consultant/Advisory Board/Honoraria	Speakers' Bureau	Research Grant	Fellowship Support	Stock Options/ Partner	Board Mbs/Other
	Saint Raphael Campus						
Merritt H. Raitt, MD, FHRS	VA Portland Medical Center, Oregon Health & Science University, Knight Cardiovascular Institute	None	None	None	None	None	None
Nestor O. Galizio, MD (SOLAECE representative)	Favaloro Foundation, University Hospital	0: Biotronik, Boston Scientific 1: Biomedica Argentina, Medtronic, Bayer	None	None	None	None	None
Paul Varosy, MD, FACC, FAHA, FHRS	VA Eastern Colorado Health Care System, University of Colorado	None	None	1: National Institutes of Health 2: Patient-Centered Outcomes Research Institute	None	None	0: National Cardiovascular Data Registry, American College of Cardiology Foundation
Renato Pietro Ricci, MD (EHRA representative)	Department of Cardiovascular Diseases, San Filippo Neri Hospital	1: Medtronic Italia, Biotronik	None	None	None	None	None
Rhondalyn McLean, MD	University of Pennsylvania Health System	None	None	None	None	None	None
Richard I. Fogel, MD	St Vincent Medical Group	None	None	None	None	None	Officer: St Vincent Medical Group Ownership: St Vincent Heart Center of Indiana
Robin Leahy, RN, BSN, FHRS, CCDS	Sanger Heart & Vascular Institute, Carolinas HealthCare System	None	None	None	None	None	None
Suneet Mittal, MD, FHRS	Valley Hospital Arrhythmia Institute	1: St Jude Medical, Greatbatch Technologies, Biotronik, Sorin Group, Boehringer Ingelheim 3: Boston Scientific 4: Medtronic	None	2: TyRx	None	None	Equity, 5: Topera Medical
Taya Glotzer, MD, FHRS, FACC	Hackensack University Medical Center	1: Medtronic, St Jude Medical	1: Medtronic	None	None	None	None

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.

Table A2 Peer-Reviewers Disclosure Table

Writing Group Member	Institution	Consultant/Advisory Board/Honoraria	Speakers' Bureau	Research Grant	Fellowship Support	Stock Options/ Partner	Board Mbs/Other
Haran Burri, MD	University Hospital of Geneva	1: Boston Scientific, Medtronic, St Jude Medical	1: Sorin Group, Medtronic	2: St Jude Medical	None	None	None
Michele Brignole, MD	Ospedali del Tigullio	None	None	None	None	None	None
López Cabanillas Néstor, MD	Hospital Presidente Peron	None	None	None	None	None	None
Jim Cheung, MD, FHRS	Weil Cornell Medical College	None	1: Biotronik, Medtronic 2: St Jude Medical	5: Biotronik	3: Biosense Webster, Boston Scientific, Medtronic, St Jude Medical	None	None
Mina K. Chung, MD, FHRS	Cleveland Clinic	0: Zoll Medical Corporation, Amarin, Biotronik 1: National Institutes of Health, Japanese Society of Electrocardiography	1: American College of Cardiology Foundation	5: National Institutes of Health	None	None	Royalty Income, 1: *UptoDate*, Jones & Bartlett
Mitchell I. Cohen, MD, FHRS, CCDS	Phoenix Children's Hospital, University of Arizona School of Medicine-Phoenix, Arizona Pediatric Cardiology Consultants/Mednax	None	None	None	None	None	None
Edmond E. Cronin, MBChB, FHRS, CCDS, CEPS	Hartford Hospital	None	None	None	None	None	None
Andrei Dan, MD	University Hospital Colentina	None	None	None	None	None	None
Andrew E. Epstein, MD, FAHA, FACC, FHRS	University of Pennsylvania	1: Biotronik, Medtronic, Zoll Medical Corporation, Daiichi, Boehringer Ingelheim 2: Boston Scientific, St Jude Medical	None	4: Biosense Webster 5: Biotronik, Boston Scientific, Medtronic, St Jude Medical	4: Boston Scientific, Medtronic, St Jude Medical, Biotronik	None	None
Bulent Gorenek, MD, FACC, FESC	Eskisehir Osmangazi University	None	None	None	None	None	None
Edmund Keung, MD	VA Medical Center	None	None	None	None	None	None
Kousik Krishnan, MD, FHRS	Rush University Medical Center	1: St Jude Medical, Biosense Webster	0: Boehringer Ingelheim 1: Pfizer, Bristol-Myers Squibb,	None	2: Boston Scientific 3: Medtronic 4: St Jude Medical	None	None

Table A2 (*continued*)

Writing Group Member	Institution	Consultant/Advisory Board/Honoraria	Speakers' Bureau	Research Grant	Fellowship Support	Stock Options/ Partner	Board Mbs/Other
			Janssen Pharmaceuticals				
Chu-Pak Lau, MD, FHRS	Department of Medicine, University of Hong Kong	None	None	None	None	None	None
Christophe I. Leclercq, MD	CHRU Pontchaillou	1: Medtronic 2: St Jude Medical	None	None	None	None	None
Gregory Lip, MD	University of Birmingham	None	None	None	None	None	None
Harry G. Mond, MD, FHRS, CCDS	Royal Melbourne Hospital	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	1: Spectranetics, Johnson & Johnson	None	5: Janssen Pharmaceuticals, ARCA Biopharma, Boston Scientific, ResMed, GE Healthcare	None	None	None
Brian Olshansky, MD, FHRS, CCDS	The University of Iowa Hospitals	1: Boston Scientific, Boehringer Ingelheim, Medtronic, BioControl Medical, Sanofi Aventis, Amarin, Daiichi Sankyo, Biotronik, On-X, Lundbeck	None	None	None	None	None
Jonathan S. Steinberg, MD, FHRS	Arrhythmia & Cardiovascular Associates of NY/NJ	1: Medtronic, St Jude Medical, Stereotaxis, Topera Medical, Biosense Webster, Cameron Health, Sanofi Aventis, Janssen Pharmaceuticals, Bristol-Myers Squibb, Scott Care, Boston Scientific, AliveCor	1: Bristol-Myers Squibb, Pfizer, Janssen Pharmaceuticals, Sanofi Aventis	2: Biosense Webster, Boston Scientific, Medtronic 3: Medtronic, Biosense Webster 5: Biosense Webster, St Jude Medical	None	None	None
Martin K. Stiles, MBCHB, PhD	Waikato Hospital, Cardiology	1: Boston Scientific, Medtronic	None	None	2: St Jude Medical, Medtronic, Johnson & Johnson	None	None
Charles D. Swerdlow, MD, FHRS	Cedars-Sinai Medical Center	1: St Jude Medical, Sorin Group 2: Medtronic	2: Medtronic	None	None	None	Intellectual Property Rights, 3: Medtronic
Cynthia M. Tracy, MD		None	None	None	None	None	None

Table A2 (*continued*)

Writing Group Member	Institution	Consultant/Advisory Board/Honoraria	Speakers' Bureau	Research Grant	Fellowship Support	Stock Options/ Partner	Board Mbs/Other
	George Washington University Medical Center						
Wendy S. Tzou, MD, FHRS	University of Colorado Denver	None	None	None	None	None	None
Gaurav A. Upadhyay, MD	University of Chicago Medical Center	None	None	None	None	None	None
Michele K. Young, BS, BSN, CCDS	Walter Reed National Military Medical Center	None	None	None	None	None	Salary or position funding, 2: Rhythm Management Group

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.