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Remote Monitoring of Cardiac Implantable Electronic Devices (CIED)

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Abstract

With increasing indications and access to cardiac implantable electronic devices (CIEDs) worldwide, the number of patients needing CIED follow up continues to rise. In parallel, the technology available for managing these devices has advanced considerably. In this setting, remote monitoring (RM) has emerged as a complement to routine in-office care. Rigorous studies, randomized and otherwise, have demonstrated advantages to CIED patient management systems which incorporates RM resulting in authoritative guidelines from relevant professional societies recommending RM for all eligible patients. In addition to clinical benefits, CIED management programs that include RM have been shown to be cost effective and associated with high patient satisfaction. Finally, RM programs hold promise for the future of CIED research in light of the massive data collected through RM databases converging with unprecedented computational capability. This review outlines the available data associated with clinical outcomes in patients managed with RM with an emphasis on randomized trials; the impact of RM on patient satisfaction, cost-effectiveness and healthcare utilization; and possible future directions for the use of RM in clinical practice and research.

Keywords

cardiac implantable electronic device; remote monitoring; implantable cardioverter defibrillator; pacemaker; cardiac resynchronization therapy

Background

Cardiac implantable electronic devices (CIEDs) including pacemakers, implantable cardioverter defibrillators (ICDs), cardiac resynchronization therapy (CRT) devices, and implanted rhythm monitors have evolved significantly over the past few decades in a number of ways. First and foremost, indications for their use have expanded, and access to these

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technologies has improved such that CIEDs have become increasingly prevalent all over the world. (1, 2)

Secondly, CIEDs have an ever-improving capability for remote monitoring (RM) of device function and patient health. By leveraging existing communication technologies (e.g., cellular, satellite, etc.), the tremendous wealth of information recorded and stored by CIEDs has become increasingly available to health care providers without face-to-face interaction. In the early days of RM, portions of a traditional visit were essentially replaced by remote methods including, for example, assessment of remaining battery life. These types of interactions are more specifically identified as “remote interrogation” or “remote follow up”. As technologies progressed, true remote *monitoring* has become possible which denotes automatic data acquisition on a frequent basis (e.g., daily) with unscheduled transmission of any pre-defined alerts to the CIED provider (Figure 1). These alerts can include information and warnings about device integrity (e.g., lead impedance), programming issues (e.g., insufficient safety margins for sensing or capture), or medical data (e.g. arrhythmia events, change in thoracic impedance). This review will focus on the implementation, utilization, and value of contemporary RM for pacemakers, defibrillators, and cardiac resynchronization therapy devices.

Logistics of Remote Monitoring

Despite RM having become a common feature among device manufacturers, differences between RM systems remain – some of which are clinically relevant (Table 1). Therefore, in order to establish a successful RM relationship between patient and provider, the logistics of the system must be well understood including those tasks that are the responsibility of patients versus providers versus those of the health system. In addition, despite increasing similarities between manufacturers, differences remain including whether transmissions are hands-free versus “wanded”, automatic versus “patient triggered”, and daily versus less frequent to name a few, and these differences should be considered at the time of hardware selection based on patient characteristics and preferences as well as provider and health system capabilities. For example, while all RM systems are capable of daily transmissions, only the Home Monitoring™ system sends automatic, hands-free daily transmissions which significantly reduces time between transmissions for this system and time to evaluation of an alert event compared with other RM platforms. (3) Importantly, RM platforms have not been directly compared for effectiveness.

The role played by the local telecommunications infrastructure is not trivial. For example, some legacy CIEDs and associated home transceivers require an analogue landline for transmission of RM data. As some telecommunications providers switch landlines from analogue to digital technology, the remote monitoring of these CIEDs may no longer be possible.

In another example, until recently, Boston Scientific’s Latitude™ and Medtronic’s CareLink™ systems required an analogue phone line for data transmission. Now these systems are moving towards a mobile communications based systems that is an alternative and/or replacement for landline-based RM depending on the manufacturer. Unfortunately, in

some cases, this switch to a mobile communications platform results in additional charges to the patient they would not otherwise incur, which represents an additional barrier to RM participation.

Patient participation

As with any healthcare interaction, patient engagement plays an important role, and in the case of RM, active patient participation is essential. While high quality data have demonstrated RM to be acceptable to patients (4–7), convenient (7, 8), and associated with good quality of life (9) compliance with RM can be challenging. Patients must actually use the RM systems and comply with transmission schedules and other responsibilities (e.g., maintaining up to date contact information with the following physician) for an RM-based system of management to be successful. Some evidence suggests that there is significant room for improvement in regard to patient adherence to RM responsibilities. (10, 11) In one study of RM-eligible patients, 21% of patients were not compliant with RM. Some of the reasons for this appear to be patient-related (e.g., age >80 was associated with poorer compliance), while others suggest systems-based challenges (e.g., increased RM enrollment at a clinic site was associated with improved compliance at the patient level) and still others suggest device related reasons (e.g., patients with wireless devices had better compliance compared to those requiring use of a “wand”). These findings underscore the complexities of patient-device-provider-institution interactions in RM utilization.

Some approaches to patient engagement in RM have resulted in improvements in compliance. For example, Ren and colleagues showed that in-office set up of RM equipment for pacemakers significantly improved compliance in the early months following implantation (odds ratio of successful transmission for the in-office group: 114.5; 95% CI 32.1–408.4, $p<0.0001$). (10) Another strategy to improve compliance is the establishment of an RM patient agreement/contract, which is endorsed by the Heart Rhythm Society. (12) Such a tool is attractive because it can be implemented relatively easily and at low cost.

Responsibilities of Physicians and Other Providers

As the group with the ultimate responsibility for managing CIED patients, physicians are adapting to the needs of CIED patients managed with RM which begins with educating patients about RM options and facilitating enrollment. In large cohorts of CIED patients, RM enrollment rates are mediocre. (13, 14) Reasons for low enrollment are not entirely clear but at least part of the deficiency is explained by institutional variation. For example, Akar and colleagues demonstrated that 13.3% of US hospitals enroll no patients and 10.5% of hospitals enroll all eligible patients despite controlling for differences in relevant patient characteristics. Other barriers to enrollment may be due to real or perceived patient barriers including access to a telephone landline (when one is needed), insurance status, and geographic distance to a CIED clinic to name a few.

Adaptations to facilitate RM depend on the available infrastructure at the health system level, but invariably include modifications to patient and information flow as well as reorganization of or additions to office personnel. Regardless of the specific configuration, physicians must provide final evaluation of any RM transmission.

Mid-level providers (nurse practitioners or physician assistants) as well as allied professionals trained in CIED management can effectively serve as the “first contact” for CIED patients; they can review RM transmissions or troubleshoot clinical events in collaboration with the supervising physician. (15) In addition, physicians and other providers collaboratively engaged in a CIED RM program can develop and implement effective patient education programs at the time of CIED implant, revision, or upgrade as well as along the course of treatment as technology and clinical status change. Finally, physicians and other providers have the shared responsibility to document patient interactions – remote or otherwise – in the medical record.

Some providers may be deterred from implementing an RM system out of concern for creating an influx of data that must be reviewed and evaluated putting them at medicolegal risk. However, avoiding RM programs may result in an alternative medico-legal vulnerability as the evidence favoring such programs mounts. Some experts have proposed that one way to address physician concerns about medicolegal liability is to better engage patients and more clearly outline expectations. Concern regarding “data overload” has led CIED manufacturers that facilitate RM programs to provide some data processing before releasing the data to providers (e.g., eliminating duplicated alerts). Moreover, the role of “first contact” played by nurses and other members of a CIED management team can help reduce the burden of data on physicians.

Health System and Infrastructure

As described, RM relies on interoperability between the implanted CIED, the home transmitting device, existing telecommunications technology, and servers that communicate with physician offices typically through web-based platforms. In some cases, technological limitations of the health system and/or the infrastructure may not support RM for a particular patient. (14) For example, in the absence of an available landline or reliable cellular service, some CIEDs cannot be followed remotely. In addition, changes in monitoring and/or telecommunications technology after implant may periodically make it impossible to follow some devices remotely. In these cases, transtelephonic monitoring may be a best alternative until incompatibilities are resolved or the device is replaced. Thoughtful hardware selection accomplished through understanding device and infrastructure limitations is part of optimal CIED patient management. Additionally, health system(s) must provide a supportive environment for RM, including reimbursement for activities that do not involve direct patient interaction. Unfortunately, coverage and reimbursement structures are not always consistent or adequate across regions or even within the same healthcare system. (16, 17)

Review of Clinical Evidence

RM has been studied extensively in regard to a wide range of important outcomes including mortality, health care utilization, incidence of inappropriate shocks, and others. Because of the nature of RM, data collected by device manufacturers lends itself well to observational registry-based studies. In some cases, the sheer numbers of patients included in these

registries makes the evidence compelling. However, in other cases, high quality randomized data are available demonstrating improved outcomes.

Mortality

The influence of RM on all-cause mortality has been analyzed in several randomized studies. While not designed or powered to detect differences in mortality, the COMPAS trial was one of the first of these, which randomized pacemaker patients to active RM versus usual care found no difference in survival between groups (13 versus 18 patient deaths, $p=0.37$). (18)

In a 2014 study of heart failure patients with high voltage devices (ICD or CRT-D), those randomized to Home Monitoring™ (Biotronik, Berlin, Germany) which incorporates daily, automatic monitoring to complement in-office visits had reduced mortality compared to those receiving quarterly in-office visits only with 1-year Kaplan Meier estimates of all-cause mortality of 3.4% in the RM group and 8.7% in the control group ($p=0.004$). (19) When combined with two other randomized studies using the same RM system (The Effectiveness and Cost of ICDs Follow-up Schedule with Telecardiology [ECOST] and The Lumos-T Safely Reduces Routine Office Device Follow-Up [TRUST] trials), a reduction in mortality with RM was observed (OR: 0.65; 95% CI: 0.45–0.94; $p=0.021$). (20–22) In contrast, four additional randomized studies using a different RM platform, found no mortality benefit from RM over usual care. (23–26) When the effects from these six randomized studies were combined in a 2015 meta-analysis representing nearly 5000 randomized patients, the odds ratio for mortality with RM was not statistically significant from in-office follow up alone (OR: 0.83; 95% CI: 0.58–1.17; $p=0.285$; $I^2=34.8\%$). (20) Data from observational studies support a survival benefit from RM as was seen from the ALTITUDE survival study (50% survival benefit) (27) and the survival analysis from the Merlin database (reduction in mortality incidence rate from greatest to least RM use) (28).

Healthcare Utilization

At the point of care, a single center study from the Cleveland Clinic demonstrated that follow up via RM was much less resource intensive than an in office visit (11.5 versus 27.7 minutes, $p<0.01$). (29) A number of studies have evaluated the differences in other aspects of healthcare utilization between patients managed with RM versus not. In the 2010 TRUST trial, a significant reduction in health care utilization (scheduled and unscheduled office and hospital visits) was observed among ICD patients randomized to RM over usual care (2.1 visits per patient-year compared with 3.8, $p<0.001$). (22) However, six other randomized studies failed to show any decrease in inpatient hospitalizations among RM patients compared to those receiving usual care. (18, 23–26, 30)

While hospitalizations are more resource-intensive than an office visit, the effect of RM on office visits also has implications for efficiency and sustainability of RM programs. To that end, six randomized investigations have examined this question specifically. From the COMPAS trial, those pacemaker patients in the RM group had 56% fewer ambulatory visits compared with the RM group ($p<0.001$). (18) In ICD patients, the impact of RM on unscheduled in-office visits has been examined in five randomized studies. (21, 22, 24–26)

The findings from these five studies are inconsistent: three showed an increase in unscheduled visits in RM patients (21, 22, 24); one showed a decrease (26); and one showed no difference (25). Meta-analysis of these studies concluded that there was no difference in unscheduled in office visits when patients are managed with RM versus standard care. (20) Notably, however, in the TRUST and Clinical Evaluation of Remote Notification to Reduce Time to Clinical Decision (CONNECT) trials, despite an increase and no change in unscheduled office visits, respectively, both studies demonstrated a decrease in overall office visits for RM patients. (22, 25) The Remote Follow-Up for ICD-Therapy in Patients Meeting MADIT II Criteria (REFORM) trial is another example of the impact of RM on reduction in overall healthcare utilization; RM patients were randomized to yearly versus quarterly in-office visits, and those with yearly follow up had significantly fewer total in-office visits (1.60 vs 3.85 per patient-year, $p<0.001$) without any significant decrease in safety as measured by mortality, rate of hospitalization, or length of hospitalization. (9) Overall healthcare utilization (hospitalization, emergency department visits, and office visits) was similarly reduced in The Evolution of Management Strategies of Heart Failure Patients With Implantable Defibrillators (EVOLVO) Study in the RM arm. (26)

Time to Clinical Decision Making

Related to unscheduled hospitalizations and in-office visits, remote monitoring is expected to compress the time between the occurrence of an ICD alert (e.g., arrhythmia) and a clinical decision or change in clinical management. Randomized data support this hypothesis. For example, in the CONNECT study of 1997 patients from 136 sites with a Medtronic ICD or CRT-D randomized to RM versus standard care those patients receiving RM had a reduction in time to a clinical decision from a median of 22 days to 4.6 days ($p<0.001$). (25) Importantly, however, 45% of automated alerts were not transmitted primarily because the home monitor was not set up and initiated to send transmissions. This underscores the importance of patient engagement and education at the time of RM initiation. Other randomized investigations have shown similar benefit of RM in time to clinical decision making. (22, 24, 26)

Inappropriate Shocks

The significance of inappropriate and unnecessary ICD shocks on both quality of life and cardiovascular outcomes has become increasingly recognized. Thus, there is an increased focus on the avoidance of inappropriate and all-cause shocks in CIED management through tailored software algorithms and programming related to atrial fibrillation, electromagnetic interference, and T-wave oversensing to name a few. In other cases, inappropriate shocks may be caused by device or lead malfunction. (31) In either case, RM offers the potential to identify these risks earlier and intervene to avoid inappropriate shocks. The ECOST study illustrated this principle by demonstrating that patients randomized to an RM management program had less than half the incidence of inappropriate shocks compared with those patients with standard in-office follow up (5.0% vs 10.4%, $p=0.04$). Notably, RM reduced inappropriate shocks from all causes: supraventricular tachycardia, oversensing secondary to noise, lead dysfunction, and T-wave oversensing.

RM has a particular important role to play in patients with CIED generators, device components, or leads under advisory or recall. For example, in a two relatively recent and high profile ICD lead recalls of the Riata defibrillator lead (St. Jude Medical, St. Paul, MN) and the Sprint Fidelis lead (Medtronic, Minneapolis, MN), some parameters available through RM can identify lead defects (e.g., rapid change in lead impedance) that may place patients at risk for inappropriate shocks. Evidence generated in the wake of this recall and others, led the Heart Rhythm Society to issue a specific Class I recommendation that patients with a CIED component under advisory or recall be enrolled in RM in addition to the general recommendation to use RM in all patients in whom it is technically feasible.(12)

Heart Failure Disease Management

Since the proportion of CIED patients with heart failure has grown considerably over the past few decades, the impact of RM on this population is particularly important. The Implant-based multiparameter telemonitoring of patients with heart failure (IN-TIME) study assessed whether RM would improve outcomes in this specific population using a single RM platform. Mortality was greater in the conventionally managed patients (no RM) as discussed above. However, there was no effect on heart failure specific endpoints including hospital admissions, hospital length of stay, worsening of NYHA class, or worsening of self-assessed condition. (19)

Aside from standard mechanisms of monitoring, the CIED-based technologies available to monitor events specific to heart failure have improved. For example, transthoracic impedance can be calculated by many CIEDs, and following trends in these values can alert providers to an impending or active heart failure exacerbation which may reduce hospitalizations and improve other clinical outcomes. (32) However, randomized data do not support this finding. (33) As such, using these device functions in isolation to diagnose and treat heart failure exacerbations is not strongly supported(12) but may be an important component in a comprehensive assessment of a given heart failure patient. For example, the value of thoracic impedance in combination with other heart failure diagnostics (e.g., heart rate variability and patient activity) was associated with a 5.4-fold increased risk of heart failure hospitalization (95% CI 3.2–9.0, $p < 0.0001$) within the subsequent month in a population of patients with an implanted CRT-D. (34) In the right context, consideration of these heart failure diagnostics may allow clinical intervention to avoid hospitalization or other bad outcomes.

Atrial Fibrillation Disease Management

Besides heart failure disease management, RM allows for earlier detection of atrial fibrillation (35, 36) over standard follow up. The Cryptogenic Stroke and Underlying AF (CRYSTAL AF) study in 2014 clearly demonstrated that in patients with cryptogenic stroke, RM with an implantable monitor identified significantly more patients with atrial fibrillation within 6 months compared with standard follow up (8.9% vs 1.4%, HR 6.4, 95% CI 1.9–21.7, $p < 0.001$). (37) This is important because even brief (6 minutes) subclinical episodes of AF can significantly increase the risk of stroke. (38) In addition, consistent with findings above related to time to clinical decision making, the median time to detection of atrial fibrillation in the RM group was 32 days compared with 41 days in the control group. Early

detection of atrial fibrillation by RM has important implications for stroke prevention and device management (e.g. improve percent biventricular pacing). Furthermore, since even brief episodes of atrial fibrillation can appreciably increase stroke risk (38), better detection can help guide physicians in discussions with patients about anticoagulation for stroke prevention.

Cost Effectiveness

Apart from primary analyses focused on cardiovascular outcomes and other endpoints, several randomized studies have embedded cost-effectiveness studies including ECOST and EVOLVO. (39, 40) In the former case, cost savings of €315 per patient year were accrued to the French healthcare system in patients randomized to RM versus usual care ($p=0.05$). In EVOLVO, RM proved to be cost-effective within the Italian healthcare system with savings of €888.10 per patient. Findings from these contemporary randomized studies are consistent with earlier findings from a 2010 meta-analysis which found cost savings per RM patient to be €300 to €1000 when compared with usual care. (41) A subsequent examination of cost-effectiveness of RM in six European countries demonstrated no significant difference in cost for patients randomly assigned to RM versus not. Notably, cost effectiveness between countries varied considerably depending on whether there was specific reimbursement for RM services. (42)

In summary, these and other stand-alone cost-effectiveness studies have found a program of CIED management that includes RM to be no worse than cost neutral in a variety of settings. (43–46) In addition, other studies underway or planned will address the question of cost-effectiveness of RM including one in the United States. (47, 48)

Mega-cohorts

One consequence of RM programs and the improving availability to store, handle, and analyze “big data” is the development of “mega-cohorts”. Each CIED manufacturer has developed an RM system specific to its devices (Table 1) that can act as a repository for all of the CIED data that are collected, stored, and transmitted. In turn, these data collection and transmission systems can be leveraged to provide important longitudinal information including device integrity data and clinical information about patients with CIEDs. Indeed, some of the largest studies of CIEDs come from these sources. For example, in an analysis of nearly 270,000 patients with CIEDs an association was found between RM use and improved survival across all device types. Patients who used RM with high intensity or low intensity had an associated survival advantage over patients who did not use RM at all, with the greater advantage associated with more intense use (HR 2.10; 95% CI 2.04–2.16; $p<0.001$ and HR 1.58; 95% CI 1.54–1.62; $p<0.001$, respectively) – suggesting a dose-response relationship between RM utilization and outcomes. Indeed, high intensity RM users had an associated survival advantage over low intensity users (HR 1.32; 95% CI 1.27–1.36; $p<0.001$). (28) Another strikingly large cohort study of >185,000 patients with defibrillators (ICDs and CRT-Ds) also demonstrated that RM utilization was associated with improved outcomes including 50% greater survival at 1 and 5 years ($p<0.001$) compared with patients followed in traditional in office visits only. (27)

Relevant Guidelines and Recommendations

In the past 3 years, as clinical evidence related to RM has grown significantly, some relevant professional society groups have produced guidelines and recommendations for the integration of RM in the care of CIED patients.(12, 16, 49, 50) Most recently, HRS has published an expert consensus statement on RM for CIEDs (12) which builds on a 2008 expert consensus document by HRS and the European Heart Rhythm Association. (51) The newer guidelines leverage the extensive body of evidence developed since the 2008 consensus document recognizing that RM technology is moving closer to a paradigm in which monitoring is nearly continuous and in-office evaluations are primarily initiated as a response to alerts generated by RM. Based on a comprehensive review of the available literature by topic experts, the 2015 document includes eleven class I recommendations for CIED patient management, some of which overlaps with other professional societies (Table 2), and none of which were present in the 2008 iteration due to insufficient data.

While the randomized evidence for each individual benefit of RM (e.g., mortality, reduction in unscheduled hospitalizations/office visits) is not completely consistent, the summation of all the evidence – randomized or otherwise – strongly favors the use of RM for all CIED patients when technically feasible. Thus, the 2015 expert consensus includes a Class I recommendation to offer RM as part of standard CIED follow-up management combined with at least annual in person evaluation to all patients in whom it is technically feasible (Table 2).

Outside of recommendations for establishing and maintaining a program of RM, the HRS consensus document specifically identifies some areas of disease management in which RM is particularly effective. For example, implementing RM for the early detection and quantification of atrial fibrillation is a Class I recommendation (LOE A) as is the recommendation to enroll CIED patients with a component that has been recalled or is under advisory (LOE E). However, while device functions aimed at monitoring thoracic impedance or other signs of heart failure exacerbation can be effectively incorporated into the management of heart failure patients, the effectiveness of these functions in isolation are uncertain (Class IIb, LOE C).

Future Directions

RM technologies continue to evolve. To date, RM has been a one-way street: patients connect to a system that allows transmission of stored CIED information to a provider. If technological barriers and privacy concerns can be adequately addressed, there may be opportunity to program CIEDs remotely. This may be particularly important for patients in remote geographic locations, those with urgent/emergent need based on a clinical event, and for the administration of software upgrades or execution of advisories and recalls amenable to reprogramming.

Direct to consumer marketing of medical devices, in particular wearable technologies, has increased significantly in recent years. Patients have the ability to track peripheral oxygen saturation, serum glucose, and heart rate through a smartphone just to name a few. There

may be similar potential for CIED patients to interact with their CIED. As above, rational safety and privacy concerns make this a distant goal, but the opportunity to more fully engage patients in their healthcare through sharing CIED generated and stored information could enhance patient satisfaction, patient-provider interactions, and clinical outcomes.

Finally, the sheer number of patients and amount of data involved in RM have facilitated tremendous data collection and produced compelling evidence through mega-cohorts as described above. However, high quality randomized data remain the standard. Accordingly, a key sea-change innovation would be the development of RM platforms to facilitate the conduct of randomized clinical trials that may include remote programming or other interventions.

Conclusion

Supported by high quality clinical evidence and endorsed by authoritative guidelines and recommendations from professional societies, RM now plays a central role in the management of many patients with CIEDs. This role includes an expanding range of capabilities which requires that patients, providers, and health systems adapt to get the maximum benefit. With thoughtful interaction of CIED patients, providers, and healthcare systems, the utilization of RM holds tremendous potential to improve outcomes.

References

1. Zhan C, Baine WB, Sedrakyan A, Steiner C. Cardiac device implantation in the United States from 1997 through 2004: a population-based analysis. *J Gen Intern Med.* 2008; 23(Suppl 1):13–9. [PubMed: 18095038]
2. Mond HG, Proclemer A. The 11th world survey of cardiac pacing and implantable cardioverter-defibrillators: calendar year 2009—a World Society of Arrhythmia's project. *Pacing Clin Electrophysiol.* 2011; 34(8):1013–27. [PubMed: 21707667]
3. de Ruvo E, Sciarra L, Martino AM, Rebecchi M, Iulianella RV, Sebastiani F, et al. A prospective comparison of remote monitoring systems in implantable cardiac defibrillators: potential effects of frequency of transmissions. *J Interv Card Electrophysiol.* 2015
4. 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(3):203–9. [PubMed: 25256800]
5. 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(3): 317–24. [PubMed: 22418649]
6. Ricci RP, Morichelli L, Quarta L, Sassi A, Porfili A, Laudadio MT, et al. Long-term patient acceptance of and satisfaction with implanted device remote monitoring. *Europace.* 2010; 12(5): 674–9. [PubMed: 20200019]
7. Schoenfeld MH, Compton SJ, Mead RH, Weiss DN, Sherfese L, Englund J, et al. Remote monitoring of implantable cardioverter defibrillators: a prospective analysis. *Pacing Clin Electrophysiol.* 2004; 27(6 Pt 1):757–63. [PubMed: 15189530]
8. Marzegalli M, Lunati M, Landolina M, Perego GB, Ricci RP, Guenzati G, et al. Remote monitoring of CRT-ICD: the multicenter Italian CareLink evaluation—ease of use, acceptance, and organizational implications. *Pacing Clin Electrophysiol.* 2008; 31(10):1259–64. [PubMed: 18811805]
9. Hindricks G, Elsner C, Piorkowski C, Taborsky M, Geller JC, Schumacher B, et al. 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(2):98–105. [PubMed: 23868932]

10. Ren X, Apostolakis C, Vo TH, Shaw RE, Shields K, Banki NM, et al. Remote monitoring of implantable pacemakers: in-office setup significantly improves successful data transmission. *Clin Cardiol.* 2013; 36(10):634–7. [PubMed: 24105924]
11. Rosenfeld LE, Patel AS, Ajmani VB, Holbrook RW, Brand TA. Compliance with remote monitoring of ICDS/CRTDS in a real-world population. *Pacing Clin Electrophysiol.* 2014; 37(7): 820–7. [PubMed: 24484075]
12. Slotwiner D, Varma N, Akar JG, Annas G, Beardsall M, Fogel RI, et al. HRS Expert Consensus Statement on remote interrogation and monitoring for cardiovascular implantable electronic devices. *Heart Rhythm.* 2015; 12(7):e69–100. [PubMed: 25981148]
13. Akar JG, Bao H, Jones P, Wang Y, Chaudhry SI, Varosy P, et al. Use of remote monitoring of newly implanted cardioverter-defibrillators: insights from the patient related determinants of ICD remote monitoring (PREDICT RM) study. *Circulation.* 2013; 128(22):2372–83. [PubMed: 24043302]
14. Mittal S, Movsowitz C, Varma N. The modern EP practice: EHR and remote monitoring. *Cardiol Clin.* 2014; 32(2):239–52. [PubMed: 24793800]
15. Ricci RP, Morichelli L, D'Onofrio A, Calo L, Vaccari D, Zanolto G, et al. 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(7):970–7. [PubMed: 23362021]
16. Dubner S, Auricchio A, Steinberg JS, Vardas P, Stone P, Brugada J, et al. ISHNE/EHRA expert consensus on remote monitoring of cardiovascular implantable electronic devices (CIEDs). *Europace.* 2012; 14(2):278–93. [PubMed: 22232544]
17. Slotwiner D, Wilkoff B. Cost efficiency and reimbursement of remote monitoring: a US perspective. *Europace.* 2013; 15(Suppl 1):i54–i8. [PubMed: 23737232]
18. Mabo P, Victor F, Bazin P, Ahres S, Babuty D, Da Costa A, et al. A randomized trial of long-term remote monitoring of pacemaker recipients (the COMPAS trial). *Eur Heart J.* 2012; 33(9):1105–11. [PubMed: 22127418]
19. Hindricks G, Taborsky M, Glikson M, Heinrich U, Schumacher B, Katz A, et al. Implant-based multiparameter telemonitoring of patients with heart failure (IN-TIME): a randomised controlled trial. *Lancet.* 2014; 384(9943):583–90. [PubMed: 25131977]
20. Parthiban N, Esterman A, Mahajan R, Twomey DJ, Pathak RK, Lau DH, et al. Remote Monitoring of Implantable Cardioverter-Defibrillators: A Systematic Review and Meta-Analysis of Clinical Outcomes. *J Am Coll Cardiol.* 2015; 65(24):2591–600. [PubMed: 25983009]
21. Guedon-Moreau L, Lacroix D, Sadoul N, Clementy J, Kouakam C, Hermida JS, et al. A randomized study of remote follow-up of implantable cardioverter defibrillators: safety and efficacy report of the ECOST trial. *Eur Heart J.* 2013; 34(8):605–14. [PubMed: 23242192]
22. Varma N, Epstein AE, Irimpen A, Schweikert R, Love C, Investigators T. 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(4):325–32. [PubMed: 20625110]
23. 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(5):545–50. [PubMed: 20021522]
24. Boriani G, Da Costa A, Ricci RP, Quesada A, Favale S, Iacopino S, 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(8):e167. [PubMed: 23965236]
25. Crossley GH, Boyle A, Vitense H, Chang Y, Mead RH, Investigators C. 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(10):1181–9. [PubMed: 21255955]
26. Landolina M, Perego GB, Lunati M, Curnis A, Guenzati G, Vicentini A, et al. 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(24):2985–92. [PubMed: 22626743]
27. Saxon LA, Hayes DL, Gilliam FR, Heidenreich PA, Day J, Seth M, et al. Long-term outcome after ICD and CRT implantation and influence of remote device follow-up: the ALTITUDE survival study. *Circulation*. 2010; 122(23):2359–67. [PubMed: 21098452]
 28. Varma N, Piccini JP, 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*. 2015; 65(24):2601–10. [PubMed: 25983008]
 29. 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(12):1947–51. [PubMed: 22864266]
 30. Perl S, Stiegler P, Rotman B, Prenner G, Lercher P, Anelli-Monti M, et al. Socio-economic effects and cost saving potential of remote patient monitoring (SAVE-HM trial). *Int J Cardiol*. 2013; 169(6):402–7. [PubMed: 24383121]
 31. Hauser RG, Kallinen LM, Almquist AK, Gornick CC, Katsiyannis WT. Early failure of a small-diameter high-voltage implantable cardioverter-defibrillator lead. *Heart Rhythm*. 2007; 4(7):892–6. [PubMed: 17599673]
 32. Catanzariti D, Lunati M, Landolina M, Zanotto G, Lonardi G, Iacopino S, et al. Monitoring intrathoracic impedance with an implantable defibrillator reduces hospitalizations in patients with heart failure. *Pacing Clin Electrophysiol*. 2009; 32(3):363–70. [PubMed: 19272067]
 33. van Veldhuisen DJ, Braunschweig F, Conraads V, Ford I, Cowie MR, Jondeau G, et al. Intrathoracic impedance monitoring, audible patient alerts, and outcome in patients with heart failure. *Circulation*. 2011; 124(16):1719–26. [PubMed: 21931078]
 34. Whellan DJ, Ousdigian KT, Al-Khatib SM, Pu W, Sarkar S, Porter CB, et al. 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(17):1803–10. [PubMed: 20413029]
 35. Crossley GH, Chen J, Choucair W, Cohen TJ, Gohn DC, Johnson WB, et al. Clinical benefits of remote versus transtelephonic monitoring of implanted pacemakers. *J Am Coll Cardiol*. 2009; 54(22):2012–9. [PubMed: 19926006]
 36. 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(1):54–61. [PubMed: 19011260]
 37. Sanna T, Diener HC, Passman RS, Di Lazzaro V, Bernstein RA, Morillo CA, et al. Cryptogenic stroke and underlying atrial fibrillation. *N Engl J Med*. 2014; 370(26):2478–86. [PubMed: 24963567]
 38. Healey JS, Connolly SJ, Gold MR, Israel CW, Van Gelder IC, Capucci A, et al. Subclinical atrial fibrillation and the risk of stroke. *N Engl J Med*. 2012; 366(2):120–9. [PubMed: 22236222]
 39. Guedon-Moreau L, Lacroix D, Sadoul N, Clementy J, Kouakam C, Hermida JS, et al. Costs of remote monitoring vs. ambulatory follow-ups of implanted cardioverter defibrillators in the randomized ECOST study. *Europace*. 2014; 16(8):1181–8. [PubMed: 24614572]
 40. Zanaboni P, Landolina M, Marzegalli M, Lunati M, Perego GB, Guenzati G, et al. Cost-utility analysis of the EVOLVO study on remote monitoring for heart failure patients with implantable defibrillators: randomized controlled trial. *J Med Internet Res*. 2013; 15(5):e106. [PubMed: 23722666]
 41. Klersy C, De Silvestri A, Gabutti G, Raisaro A, Curti M, Regoli F, et al. Economic impact of remote patient monitoring: an integrated economic model derived from a meta-analysis of randomized controlled trials in heart failure. *Eur J Heart Fail*. 2011; 13(4):450–9. [PubMed: 21193439]
 42. Heidbuchel H, Hindricks G, Broadhurst P, Van Erven L, Fernandez-Lozano I, Rivero-Ayerza M, 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(3):158–69. [PubMed: 25179766]

43. Fauchier L, Sadoul N, Kouakam C, Briand F, Chauvin M, Babuty D, et al. Potential cost savings by telemedicine-assisted long-term care of implantable cardioverter defibrillator recipients. *Pacing Clin Electrophysiol.* 2005; 28(Suppl 1):S255–9. [PubMed: 15683509]
44. Calo L, Gargaro A, De Ruvo E, Palozzi G, Sciarra L, Rebecchi M, et al. 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(1):69–78. [PubMed: 23515883]
45. 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(11):1601–8. [PubMed: 23599169]
46. 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(10):1145–51. [PubMed: 18703585]
47. Zabel M, Muller-Riemenschneider F, Geller JC, Brachmann J, Kuhlkamp V, Dissmann R, et al. Rationale and design of the MONITOR-ICD study: a randomized comparison of economic and clinical effects of automatic remote MONITORing versus control in patients with Implantable Cardioverter Defibrillators. *Am Heart J.* 2014; 168(4):430–7. [PubMed: 25262251]
48. Ricci RP, D'Onofrio A, Padeletti L, Sagone A, Vicentini A, Vincenti A, et al. Rationale and design of the health economics evaluation registry for remote follow-up: TARIFF. *Europace.* 2012; 14(11):1661–5. [PubMed: 22544910]
49. Yee R, Verma A, Beardsall M, Fraser J, Philippon F, Exner DV. Canadian Cardiovascular Society/ Canadian Heart Rhythm Society joint position statement on the use of remote monitoring for cardiovascular implantable electronic device follow-up. *Can J Cardiol.* 2013; 29(6):644–51. [PubMed: 23465345]
50. de Cock CC, Elders J, van Hemel NM, van den Broek K, van Erven L, de Mol B, et al. Remote monitoring and follow-up of cardiovascular implantable electronic devices in the Netherlands : An expert consensus report of the Netherlands Society of Cardiology. *Neth Heart J.* 2012; 20(2):53–65. [PubMed: 22249958]
51. Wilkoff BL, Auricchio A, Brugada J, Cowie M, Ellenbogen KA, Gillis AM, et al. HRS/EHRA expert consensus on the monitoring of cardiovascular implantable electronic devices (CIEDs): description of techniques, indications, personnel, frequency and ethical considerations. *Heart Rhythm.* 2008; 5(6):907–25. [PubMed: 18551743]

Figure 1. General schema for automatic remote monitoring technology

Transmitter circuitry integrated within the pulse generator transmits stored data to a mobile communicator in the patient's home. The data are relayed to a service center. The service center receives incoming data and automatically generates a customized summary, available to the physician online via secure Internet access. (*With permission: Varma N, Ricci RP. Eur Heart J. 2013 Jul 1;34(25): 1885–95.*)

Table 1

Comparison of available RM systems by device manufacturer

Feature	Biotronik	Boston Scientific	Medtronic	Sorin	St. Jude Medical
RM system name	Home Monitoring™	Latitude™ NXT	CareLink™	SMARTVIEW™	Merlin.net™
Data transmission	Analogue phoneline and GSM network	Analogue or Digital, Cellular adapter, Wired Ethernet adapter, Wireless Internet Adapter	Analogue phone line; GSM network; Ethernet; mobile cellular network & wifi (pacemakers only)	Analogue phoneline and GSM network	Analogue, GSM, or broadband
Transmitter	Mobile or stationary	Stationary	Mobile or stationary	Stationary	Stationary
Provider communication method	SMS, email, fax	Email, SMS, website	SMS, email, voicemail, pager, mobile app	Fax, email, SMS	Fax, email, SMS
FDA clearance	Yes	Yes	Yes	Yes	Yes
CE Mark	Yes	Yes	Yes	Yes	Yes
Special Features	Automatic RV and LV thresholds, impedance and sensing measurements; configurable red and yellow alerts fully configurable online; patient callback feature; electronic health record export compatibility	Optional blue tooth weight scales and BP cuffs; Configurable data transmission to associated caregivers; Configurable red and yellow alerts; Electronic health record data export capability, hands-free automatic data transmissions, iPhone App available.	Optivol thoracic impedance alert (CE mark only); configurable red and yellow alerts; RM available for ILR; pdf exports of patient reports; Cardiac Compass HF report; 99% of implanted device are able to be RM; electronic health record data export capability; supports IDCO profile	7 seconds real-time IECGM for scheduled follow ups, alerts reports, and PPT (patient initiated transmissions)	Alerts fully configurable online; Send phone calls to patients; CoRVUE fluid status alert; Automatic RA, RV, and LV pacing thresholds; Integrated Heart Failure Website showing correlation between Pulmonary Artery Pressures and Device Diagnostics such as AF Burden, Percent Pacing, Day/Night HR when patient is implanted with both CardiomEMS PA Sensor and SJM CIED
Default alert assessment frequency	Daily	Daily	Immediate (when device within range of monitor)	Daily	Daily

Table 2

Comparison of recent professional society guidelines

Domain	Heart Rhythm Society(12)		Canadian Cardiovascular Society(49)	
	Recommendation	Strength	Recommendation	Strength
Eligibility and application of RM for CIED patients	All patients with CIEDs should be offered RM as part of standard management	Class I, LOE [†] A	Integrate RM into routine care functions of CIED patients	Strong Recommendation, moderate-quality evidence
	RM combined with annual follow up is favorable over in person evaluation alone	Class I, LOE A	Routine follow up of CIED patients (after 3 months post-implant) should include alternating RM and in-clinic in 1:1 ratio	Conditional Recommendation, low-quality evidence
			RM should be used to supplement in-person monitoring in clinical circumstances warranting more intensive surveillance	Strong recommendation, low-quality evidence
Patient education	Before implementing RM, patients should be education regarding their responsibilities and expectations; this should be documented in medical record	Class I, LOE E	RM should only be implemented after explicit consent and proper patient education including medico-legal implications and effects on patient privacy and confidentiality	Strong recommendation, very low-quality evidence
Frequency and initiation of RM	All CIEDs should be checked in person 2–12 weeks post implantation	Class I, LOE E	Follow up of CIED patients should be done in person until 3 months post-implantation	Conditional Recommendation, low-quality evidence
	It may be beneficial to initiate RM within 2 weeks of implant	Class IIa, LOE C		
Role of allied health care professionals	Allied health care providers responsible for interpreting RM should have same qualifications as those performing in-clinic assessments	Class I, LOE E	health professionals responsible for RM interpretation and subsequent patient management decisions have the same qualifications, training, and experience as those performing in-clinic assessments	Strong recommendation, low-quality evidence
RM program management	Develop and document appropriate policies and procedures to govern program operations, roles and responsibilities of those involved and expected timelines for providing service	Class I, LOE E	Develop infrastructure, resources, policies and procedures to optimally support an RM program analogous to in-clinic assessment	Develop infrastructure, resources, policies and procedures to optimally support an RM program analogous to in-clinic assessment
Recalls/Advisories	Patients with a CIED component under advisory or recalls should be enrolled in RM	Class I, LOE E	N/A	
Role of industry representatives	Industry should refrain from direct patient care, either within the clinic or at home	Not a recommendation; noted in HRS text	Representatives of private industry involved in RM can provide support but should not be involved in RM-related patient care	Strong recommendation, very low quality evidence

[†] LOE =level of evidence