Implementation and reimbursement of remote monitoring for cardiac implantable electronic devices in Europe: a survey from the health economics committee of the European Heart Rhythm Association

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Remote monitoring (RM) of cardiac implantable electronic devices (CIEDs) permits early detection of arrhythmias, device, and lead failure and may also be useful in risk-predicting patient-related outcomes. Financial benefits for patients and healthcare organizations have also been shown. We sought to assess the implementation and funding of RM of CIEDs, including conventional pacemakers (PMs), implantable cardioverter defibrillators (ICDs), and cardiac resynchronization therapy (CRT) devices in Europe. Electronic survey from 43 centres in 15 European countries. In the study sample, RM was available in 22% of PM patients, 74% of ICD patients, and 69% of CRT patients. The most significant perceived benefits were the early detection of atrial arrhythmias in pacemaker patients, lead failure in ICD patients, and worsening heart failure in CRT patients. Remote monitoring was reported to lead a reduction of in-office follow-ups for all devices. The most important reported barrier to the implementation of RM for all CIEDs was lack of reimbursement (80% of centres). Physicians regard RM of CIEDs as a clinically useful technology that affords significant benefits for patients and healthcare organizations. Remote monitoring, however, is perceived as increasing workload. Reimbursement for RM is generally perceived as a major barrier to implementation.

Keywords
- Telemonitoring
- Remote monitoring
- Cardiac resynchronization therapy
- Implantable cardioverter defibrillator
- Pacemaker
- Heart failure

Introduction

Remote monitoring (RM) of cardiac implantable electronic devices (CIEDs) was addressed in a joint European and American Expert Consensus Statement¹ and is now a class IIa recommendation of the 2013 ESC guidelines on cardiac pacing and cardiac resynchronization therapy (CRT).² Prominent among the potential benefits of RM are the early detection of arrhythmias and safety issues, including lead fracture, insulation defects, or premature battery depletion.³ – ⁶ Recent studies have also explored the role of device-based sensors in the detection of worsening heart failure and risk stratification. It has been proposed that avoidance of traditional, in-office visits for CIED monitoring translates into financial benefits for patients and healthcare organizations.⁷,⁸

This survey was undertaken by the Health Economic Committee of the European Heart Rhythm Association to assess the implementation and reimbursement of RM for CIEDs, including conventional pacemakers (PMs), implantable cardioverter defibrillators (ICDs), or CRT devices. We have also assessed the demands on workload relating to the implementation of RM, as perceived by clinicians at these centres.

Methods

This survey is based on an electronic questionnaire sent electronically to 152 centres participating in the EHRA Electrophysiology research network. Responses were received from 43 (28%) centres from the wide European geographical area, including Austria, Belgium, Brazil,
Bulgaria, Estonia, France, Georgia, Germany, Greece, Italy, Norway, Romania, Serbia, Spain, and United Kingdom. Responding centres were university hospitals (69%), regional hospitals (22%), and local hospitals (9%). The survey assessed the frequency of surveillance of RM and the effect of RM on in-office visits. Questions also focused on perceived benefits of and constraints to the use of RM.

**Statistics**

Continuous data were reported as mean and standard deviation (SD). Categorical data as counts and percent, exact binomial 95% confidence intervals (95%CI) were computed. The maximum margin of error (ME) was computed as the half width of the exact binomial 95%CI for a proportion of 50%. Stata (Stata Corp) was used for computation.

**Results**

During the calendar year prior to the survey in 2014, participating hospitals implanted 263 (200–372) (median, IQR 25–75) single or...
dual-chamber PMs, 115 (60–150) single- or dual-chamber ICDs and 60 (43–110) CRT devices (CRT-P or CRT-D) (new implants and replacements).

Implementation of remote monitoring
Remote monitoring was set up for pacemakers in 63% of responding centres and adopted in 22 ± 23% (mean ± SD) of pacemaker patients (range 1–80%, adoption rate 14%). For ICDs, RM was set up in more centres (74%) and was also adopted in a greater proportion of patients (69 ± 25%, range 10–100, adoption rate 51%). For CRT, RM was set up in 69% of centres and adopted in 71 ± 25% of patients (range 5–100, adoption rate 49%).

Maximum margin of error
The maximum ME expected if all 152 centres were responding, and centres in the network were a representative sample of the EU centres, is 8.2%. With 43 centres responding, the observed maximum ME increases to 15.6%.

Remote monitoring events
Reported RM events varied according to the CIED type (Figure 1). In PM patients, the most important reported benefit was the early detection of sustained atrial fibrillation (39%), followed by early detection of lead failure, ventricular arrhythmias, battery depletion, or inadequate device settings. In ICD patients, the most important reported benefit was the early detection of lead failure (41%), followed by the early detection of ventricular arrhythmias, atrial fibrillation, inappropriate shocks, battery depletion, or inadequate device settings. In contrast, for CRT patients, the most important reported benefit was the early detection of worsening heart failure (31%), followed by the early detection of lead failure, ventricular arrhythmias, loss of biventricular capture, atrial fibrillation, and battery depletion.

Remote monitoring checks
As shown in Figure 2, 24 h/7 days RM cover was available for pacemakers and ICDs in very few centres (4.4% and 3.5%, respectively), and no such cover was provided for CRT devices. Most centres (52.2–69%) provided RM cover at least once every working day.

Effect of remote monitoring on in-office follow-up
For pacemakers 61% of centres reported that RM had led to reductions in in-office follow-ups (Figure 3). In 22%, these were reduced to less than one per year. For ICDs, 62% reported that RM had led to reductions in in-office follow-ups. In 10%, these were reduced to less than one per year. For CRT, 54% of centres reported that RM was had led to reductions in in-office follow-ups. In 8%, these were reduced to less than one per year.

Barriers to implementation
As shown in Figure 4, most centres, ranging from 83% for pacemakers to 88% for CRT devices, reported that no reimbursement for RM was available. Barriers to the implementation of RM were similar across the device types (Figure 5). The most frequently reported barrier to implementation for all device types was the lack of reimbursement, ranging from 57.7 to 72.4% of centres.

Discussion
This survey indicates that there is interest in RM of CIEDs among the European Cardiology Community, particularly for the follow-up of patients with ICDs and CRT devices. Physicians report that RM has clinically significant applications and that its implementation has led to reductions in in-office visits. This, however, has been achieved at the expense of an increased workload without appropriate reimbursement.

Events reported by remote monitoring
Although this survey does not address the link between reported alerts and patient outcomes, alerts reported by physicians are those which are likely to influence clinical outcomes. These

![Figure 2](https://academic.oup.com/europace/article-abstract/17/5/814/2467048/figure2)

**Figure 2** Frequency of checks on RM alerts. Data are presented as percentage of centres in each category. ICD, implantable cardioverter defibrillators; CRT-P, cardiac resynchronization therapy pacing; CRT-D, cardiac resynchronization therapy defibrillation.
included early detection of atrial fibrillation, ventricular arrhythmias, lead failure, loss of biventricular capture, inappropriate shocks, and battery depletion. In this context, several studies have suggested that RM is associated with better patient outcomes. In the CONNECT trial, in which dual-chamber ICD and CRT-D patients were randomized to RM or usual care, RM was associated with 18% reduction in the length of stay for cardiovascular hospitalization.3 A reduction in the risk of hospitalization for atrial arrhythmias or stroke was observed in the COMPAS trial.6 In the ALTITUDE registry, involving 263 562 CIED patients, RM was associated with a 50% lower mortality, compared with usual care.9 In contrast, when implantable diagnostic tools are linked to an audible patient alert without connection to a RM system, the risk for hospitalization may increase.10 Early battery depletion was reported as less important alert in RM, compared with usual care. This probably relates to the fact that normal battery depletion can usually be predicted from in-office assessments, while sudden, unpredictable battery depletion, is now rare. On the other hand, lead failure was reported as a significant alert in ICD patients, perhaps because this is one in which RM has a clear advantage over usual care.

Barriers to implementation

Lack of reimbursement was the most frequently reported barrier to the implementation of RM, affecting over 80% of centres for all devices. While we have no data on the cost setting up RM and undertaking follow-ups, a recent EHRA survey indicated that in 53.5% of centres surveyed, the costs of RM were charged directly to the implanting centre.11 As long as this imbalance exists, it is unlikely that RM will be universally adopted. Health technology appraisals on clinical efficacy and cost-effectiveness are required.

Limitations

This survey applies to a minority of European centres across the EHRA Electrophysiology Research Network. Consequently, we cannot necessarily assume that our findings are generalizable to the whole European Community. It is likely that RM use in centres participating in the EHRA network is above European average.
Moreover, the low response rate increases the maximum expect ME from 8% to 16%, adding uncertainty to the estimates. In addition, we have not assessed patient outcomes and therefore, we cannot assume that the benefit perceived by physicians necessarily reflects a true benefit. An important distinction needs to be made between remote follow-up and RM. While the former involves scheduled automatic device interrogation that replaces an in-office follow-up, RM involves automatic, unscheduled transmission of alert events. Patient-initiated interrogations are non-scheduled follow-ups initiated manually by the patient as a result of a real or perceived clinical event. In this survey, we have not distinguished between these different modes of remote interrogation. However, the fact that most centres checked alerts on a daily basis, or at least once a week, suggests that RM is being undertaken.

Conclusions
This survey reveals that physicians regard RM of CIEDs as a clinically useful technology, which has led to significant benefits for patients and a reduction in in-office consultations. Importantly, however, RM is perceived as increasing workload. Moreover, reimbursement for RM is generally lacking and this is perceived as a major barrier to implementation.

Supplementary material
Supplementary material is available at Europace online.

Conflict of interest: Please see the supplementary material.

References

Figure 5 Barriers to the implementation of remote monitoring of CIEDs. Data are expressed as percentage of centres. ICD, implantable cardioverter defibrillators; CRT-P, cardiac resynchronization therapy pacing; CRT-D, cardiac resynchronization therapy defibrillation.