Europace Advance Access published March 23, 2015

Europace
doi:10.1093/europace/euv031

EDITORIAL

Remote monitoring of cardiac implantable electrical devices in Europe: *quo vadis*?

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This editorial refers to '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' by G.H. Mairesse *et al.*, doi:10.1093/europace/euu390.

Remote monitoring (RM) of cardiac implantable electrical devices (CIEDs) is the application of communication technology to patients carrying a pacemaker (PM), an implantable cardioverter-defibrillator (ICD) or a device for cardiac resynchronization therapy (CRT). As a matter of fact, while communication of data over distance is already a standard practice in many fields (manufacturing, banking, and business services), in the healthcare setting we are still at an early exploratory phase.

Remote monitoring of CIEDs has been the subject of pilot projects performed in leading centres, modelling studies, controlled trials, and economic studies. In general, these evaluations indicated that RM is an attractive technology and should be implemented and validated in 'real world' clinical practice.[1–9]

Follow-up of CIEDs using RM is already included in the Consensus Guidelines on cardiac pacing and resynchronization therapy issued by the European Society of Cardiology (ESC) in 2013,[10] which delivered the following recommendation: 'Device-based remote monitoring should be considered in order to provide earlier detection of clinical problems (e.g. ventricular tachyarrhythmias, atrial fibrillation) and technical issues (e.g. lead fracture, insulation defect)' and assigned it class IIa recommendation, with a level of evidence B. However, despite this amount of support, RM is not at present a fully accepted standard of care in patients with a CIED, within the heterogeneous organizational, financial, and regulatory settings in Europe.[11]

In this issue of *EP-Europace*, Mairesse *et al.*[12] present the result of a survey initiated by the Health Economics Committee of the European Hearth Rhythm Association. This was the first association within ESC to promote the institution of a dedicated committee for health economics and to address the topical issue of Health Technology Assessment (HTA), a multidisciplinary approach to innovative technology where cardiologists and arrhythmia specialists may have an important role as stakeholders.[13] The article presented here is an interesting contribution on the perspective of HTA, since it considers the current extent of implementation of RM, as well as its reimbursement. Data were collected through replies to a questionnaire distributed among a network of European centres implanting CIEDs.

The results show that among the selected group of 43 centres from 15 European countries, which participated in this survey, the current implementation of RM was substantial, with RM adopted on average in around 70% of ICD and CRT patients, but in only 22% of PM patients. However, apart from the availability of RM and the average implementation rate, the range of adoption of RM in the different centres varied considerably, from an implementation rate of around 5–10% (even lower for PMs) to 80–100%.[12] This finding underscores the fact that RM is currently perceived as an attractive technology, which makes it possible to reduce the number of scheduled in-hospital follow-up visits, but, on the other hand, encounters some barriers in becoming an established standard of care. The lack of reimbursement was reported as the most important barrier to full implementation of RM from around 58 to 72% of centres. The feedback from the respondents to this survey should be considered valuable and timely, with the possibility of generalizing it to most European countries, since the status of reimbursement policies for RM, as shown in *Table 1*, is quite discouraging, being characterized by delay, inertia, and unresponsiveness. As a matter of fact, the status of reimbursement tariffs in most countries has not changed too much in comparison with what was reported around 4 years ago.[14] There are no obvious reasons for this situation, in view of many studies demonstrating that RM can reduce the number of CIED follow-up visits[5–7,12] and of recent data from the IN-TIME (Implant-based Multiparameter Telemonitoring of Patients with Heart Failure) study showing the positive effect on survival in patients with NYHA II-III heart failure who were implanted with a ICD or CRT-D device.[8]

The clinical advantages of RM, as reported in the survey, are mainly related to improved surveillance of the leads and prompt reaction in the case of lead failure, battery depletion, inadequate device programming, or performance in the case of ventricular tachyarrhythmias. Remote transmission of this information characterizes the context of device follow-up. It should be stressed that an additional dimension of the clinical use of RM could be explored, i.e. disease

The opinions expressed in this article are not necessarily those of the Editors of *Europace* or of the European Society of Cardiology.

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Table 1 Reimbursement of in-clinic and remote CIED device checks in different European countries

	Available reimbursement tariff for in-clinic device check	Available reimbursement tariff for remote device check	Sufficient reimbursement for procurement of hardware and services for remote device check
Austria	X	No	No
Belgium	X	No	No
Czech Republic	X	X	X
Denmark	X	X	No
Finland	X	X	X
France	X	No	Price premium for ICD and PM devices with RM
Germany	X	X	No
Italy	X	No	No
Norway	X	No	No
Portugal	X	X	No
Spain	N/A	N/A	N/A
Sweden	X	X	No
Switzerland	X	No	No
The Netherlands	X	No	No
UK	X	X (locally negotiated)	No

CIED, cardiac implantable electrical device; ICD, cardioverter-defibrillator; PM, pacemaker; RM, remote monitoring.

management where evaluating, through remote transmission of data, the dynamic changes of a chronic disease affecting a patient becomes the focus. The onset and evolution of atrial fibrillation, and the onset, worsening, and evolution of heart failure are settings where RM can be proposed as part of disease management.[1–4] This implies a shift in post-implant follow-up objectives from a strictly device-centred perspective (proper functioning of the device) to perspectives centred on the patient–device interactions and on patient status (evolution or change from a stable to an unstable condition, suggesting prompt treatment adjustment or intervention).[1] The background of disease management is that patient care should benefit from automatic or periodic data transmission, coupled with alert features (when the device detects significant abnormalities in a series of functional parameters) transmitted to physicians and nurses at the follow-up clinic to induce corrective and preventive actions, if needed. At the present time, the challenge is to obtain the proof that this type of management is feasible, effective, and cost-effective, and dedicated studies are addressing these issues.[2,4,15,16]

The potential economic return on the adoption of RM should be separately assessed for remote follow-up of CIEDs and for RM for disease management. For remote follow-up of ICD and CRT devices, Burri *et al.*[5] reported on the basis of a cost-consequence economic study based on a Markov model that even in a conservative approach (no reduction in cardiovascular events considered) RM may be an attractive feature, associated with a reduction of inappropriate shocks, an extension of device longevity, and a reduction of in-hospital visits, with no extra costs in a National Health Service perspective. With regard to RM for disease management, the current challenge is to definitely demonstrate that the shortened time to decision for an actionable event[2–4] can induce appropriate patient management, resulting in lower use of healthcare resources. It is noteworthy that the reduction of in-hospital visits for patients followed with disease management through RM of a CIED seems to be confirmed by many studies.[3,4,6,7]

Measuring and proving the full potential benefit of RM is complicated by existing country differences in reimbursement practices[7,12,14] and by the characteristics of the different healthcare systems.[11,14] No specific tariff for disease management through RM of implanted CIEDs has been established until now in any European country, so the only available reimbursement is usually that of RM for device checks. As a general comment, the wider perspective of RM for disease management should be considered in all its potential and RM should not be minimized to a way of cutting costs. Remote monitoring for disease management should be approached as a change in the paradigm of care provision, moving from empiric and 'reactive' in-hospital treatments and interventions to personalized, out-of-hospital pro-active care, guided by continuous patient surveillance through RM. The increasing burden of chronic diseases demands new approaches for patient care and RM could be considered in this perspective.

The contribution by Mairesse *et al.*[12] shows the growing interest in wider implementation of RM, now combined with increasing evidence on a favourable impact on outcome, according to data from the IN-TIME trial.[8] This allows RM to be proposed as a 'win–win' solution,[17] where many stakeholders (physicians, patients, hospital managers, payers) may obtain some advantage. According to this scenario, the present survey suggests that it is time to move from the current stalemate, and that some form of reimbursement for RM should be provided in those countries where it is currently unavailable, in order to allow testing of communication technology (i.e. RM of CIEDs) as a standard practice, similarly to what happened in other fields. This paradigm shift will make it possible to obtain further information on the impact of RM on 'real world' practice, in line with the virtuous path of HTA,[13] creating further feedback for

improving delivery of care. Legal and organizational aspects have also to be considered and clarified, since RM is not an emergency system for urgent care. Hopefully, integration of RM with healthcare records will allow both personalization of care and continuity of care, two important targets to be achieved in the near future.

Conflict of interest: G.B. speaker fees (small amount) from Boston Scientific, Medtronic, and St Jude.

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