

Current status of reimbursement practices for remote monitoring of cardiac implantable electrical devices across Europe

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Abstract

Remote monitoring (RM) of cardiac implantable electrical devices (CIEDs) is currently proposed as a standard of care for CIEDs follow-up, as recommended by major cardiology societies worldwide. By detecting a series of relevant device and patient-related parameters, RM is a valuable option for early detection of CIEDs' technical issues, as well as changes in parameters related to cardio-respiratory functions. Moreover, RM may allow longer spacing between in-office follow-ups and better organization of in-hospital resources. Despite these potential advantages, resulting in improved patient safety, we are still far from a widespread diffusion of RM across Europe. Reimbursement policies across Europe still show an important heterogeneity and have been considered as an important barrier to full implementation of RM as a standard for the follow-up of all the patients with pacemakers, defibrillators, devices for cardiac resynchronization, or implantable loop recorders. Indeed, in many countries, there are still inertia and unresponsiveness to the request for widespread implementation of RM for CIEDs, although an improvement was found in some countries as compared to years ago, related to the provision of some form of reimbursement. As a matter of fact, the COVID-19 pandemic has promoted an increased use of digital health for connecting physicians to patients, even if digital literacy may be a limit for the widespread implementation of telemedicine. CIEDs have the advantage of making possible RM with an already defined organization and reliable systems for data transmissions that can be easily implemented as a standard of care for present and future cardiology practice.

Keywords

Cardioverter-defibrillator • Pacemaker • COVID-19 • Reimbursement • Remote monitoring • Telemedicine

Introduction

Remote monitoring (RM) of cardiac implantable electrical devices (CIEDs) encompasses the use of communication technology to monitor patients carrying a pacemaker (PM), an implantable cardioverter-defibrillator (ICD) device for cardiac resynchronization therapy (CRT) or an implantable loop recorder.¹ Even though RM was initially introduced for complementary evaluation of device function, it currently represents the standard of care for CIEDs follow-up and it is recommended by major cardiology societies worldwide.² Indeed, RM of PM is recommended in the recent (2021) European

Society of Cardiology (ESC) guidelines on cardiac pacing and CRT³(Table 1), and it was already encouraged in the earlier 2013 ESC guidelines.⁴

In the last years, it has been widely accepted that RM can provide a similar quality of data retrieval from implanted CIEDs as compared to conventional office visits, with favourable implications both for clinicians and patients.^{5,6} This applies to a series of clinically relevant parameters including a check of battery status, detection of abnormalities in sensing/pacing functions, evidence of new atrial fibrillation or of therapy delivered for ventricular tachyarrhythmia, as well as improved safety for the patients in case of device advisories.⁷

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What's new?

- Remote monitoring (RM) of cardiac implantable electronic devices (CIEDs) is a valuable option for early detection of CIEDs technical issues, as well as changes in parameters related to patient conditions.
- An appropriate implementation of RM may allow longer spacing between in-office follow-ups, with better use of in-hospital resources.
- The COVID-19 pandemic promoted an increased use of digital health for connecting physicians to patients.
- Despite its important potential advantages, RM of CIED is still not fully adopted in many countries.
- Reimbursement policies across Europe are considerably heterogeneous and remain an important barrier to full implementation of RM.

At present, for safety reasons, reprogramming of a CIED device through RM is not allowed and this is probably the main limitation from a clinical point of view.

Available RM systems include CareLink Network (Medtronic Inc., Minneapolis, MN, USA), Latitude Patient Management System (Boston Scientific, St Paul, MN, USA), Home Monitoring system (Biotronik GmbH, Berlin, Germany), Merlin.net (Abbott Inc., St Paul, MN, USA), and Smartview (MicroPort, Shanghai, China).⁸

RM and COVID-19 pandemic

RM is a valuable option for earlier detection of clinical problems and technical issues in CIED patients and may allow longer spacing between in-office follow-ups.³ Traditional in-office device checks require important resources in terms of time dedicated by specialized personnel thus, RM may allow to better organize in-hospital resources.⁹ Spacing of scheduled in-office visits is particularly convenient for elderly patients with limited mobility, but also for young or middle-aged patients with full-time jobs, family commitments, etc. and in specific situations such as during a pandemic.³ Indeed, the coronavirus disease 2019 (COVID-19) pandemic had a profound impact on the organisation of health care, with a drastic reduction in hospital access and traditional controls and widespread implementation of RM.^{10–12} The measures of physical distancing implemented in many countries during the COVID-19 created a broader and urgent need for wider adoption of digital solutions, and among them, RM.^{2,13,14} As a consequence, there was an acceleration in the development of telemedicine and the use of RM in order to follow cardiac patients at distance.^{10,11,15–17}

In a specific guidance document for the diagnosis and management of cardiovascular diseases during the COVID-19 pandemic, the ESC suggested that remote device interrogation (patient-initiated or automatic prescheduled transmissions) or RM (i.e. automatic daily or alert-triggered transmissions) should be utilized as much as possible to replace routine device interrogation visits to hospitals, clinics, and practices.¹⁸

Recently, Simovic *et al.*² reported the results of a survey assessing the influence of the COVID-19 pandemic on RM of CIEDs among European Heart Rhythm Association (EHRA) members and how it

Table 1 2021 ESC recommendation on RM³

Recommendation	Class of recommendation	Level of evidence
Remote device management is recommended to reduce the number of in-office follow-up in patients with pacemakers who have difficulties attending in-office visits (e.g. due to reduced mobility or other commitments or according to patient preference).	I	A
Remote monitoring is recommended in case of a device component that has been recalled or is on advisory, to enable early detection of actionable events in patients, particularly those who are at increased risk (e.g. in case of pacemaker dependency)	I	C
In-office routine follow-up of single- and dual-chamber pacemakers may be spaced by up to 24 months in patients on remote device management.	Ila	A
Remote device management of pacemakers should be considered in order to provide earlier detection of clinical problems (e.g. arrhythmias) or technical issues (e.g. lead failure or battery depletion).	Ila	B

ESC, European Society of Cardiology; RM, remote monitoring.

changed the current practice. Data were collected through replies to an online questionnaire distributed to the EHRA scientific research network members, national electrophysiology working groups, and social media platforms. The survey was completed by 160 participants from 28 countries, with 50% of respondents from France and Spain. Overall, the results of this survey suggest that the crisis caused by COVID-19 has led to a significant increase in the use of RM of CIEDs. In particular:

- The percentage of PM patients with RM increased significantly during the pandemic (from 24% to 40%, $P=0.002$).
- There was a trend for higher utilization of RM for ICDs, cardiac resynchronization therapy and defibrillator (CRT-D), and cardiac resynchronization therapy and pacing (CRT-P) (ICD: from 65% to 70%, $P=0.408$; CRT-D: from 65% to 69%, $P=0.513$; CRT-P: from

Table 2 Reimbursement of in-clinic and remote CIED device checks and for HF disease management in different European countries

Country	Reimbursement tariff for in-clinic device check	Reimbursement tariff for remote CIED management	Reimbursement specific for hardware and services for remote monitoring	Reimbursement tariff for HF disease management
Austria	Yes	No	No	Yes, from 2022
Belgium	Yes	No	No	No
Bulgaria	No	No	No	No
Czech Republic	Yes	Yes	Yes	No
Denmark	Yes	Yes	No	No
Finland	Yes	Yes	Yes	No
France	Yes	Yes ^a	Yes ^b	No
Germany	Yes	Yes ^c	Yes for some health insurance	No
Hungary	Yes	Yes	No	No
Italy	Yes	Yes (in 10 of 20 regional health services)	No	No
Norway	Yes	Yes	No	No
Poland	No	No	No	No
Portugal	Yes	Yes	No	Yes
Russia	No	No	No	No
Slovakia	No	No	No	No
Spain	Funded, no tariff	Funded, no tariff	N/A	No
Sweden	Yes	Yes	No	No
Switzerland	Yes	Yes	Yes	Yes
The Netherlands	Yes	Yes	No	Yes ^d
UK	Yes	Not at a national level, it is dependent on Clinical Commissioning Groups and NHS Trusts	Ordered by NHS Trusts	No

The data were collected from expert physicians of the European Heart Rhythm Association and data available from regulatory institutions.

CIED, cardiac implantable electronic device; CRT, cardiac resynchronization therapy; HF, heart failure; ICD, implantable cardioverter-defibrillator; PM, pacemaker; RM, remote monitoring.

^aFrench MoH pilot 2018–22: Expérimentations de Télémedecine pour l'Amélioration des Parcours en Santé programme.

^bPremium price for ICD and PM with RM.

^cOnly for ICDs and CRT devices.

^dSame as regular heart failure management.

44% to 55%, $P=0.063$) with nearly two-thirds of participants (65%) initiating new RM connections for CIEDs implanted before the pandemic.

The findings of Simovic *et al.*² have to be interpreted also taking into account the results of the 2015 EHRA survey on RM implementation across Europe, which already showed a very high rate of RM use in ICD and CRT devices (respectively, 74 and 69%).¹⁹ Moreover, the most recent EHRA survey asserted that a further increase in RM use after the pandemic was planned by most physicians.² It is noteworthy that lack of reimbursement was identified as the most common reason for the underutilization of RM both before and during the COVID-19 pandemic. A similar survey assessing the impact of the COVID-19 pandemic on the spread of RM of CIEDs and telecardiology was conducted in Italy by the Italian Association of Arrhythmology and Cardiac Pacing (AIAC).¹⁰ As for the EHRA

survey, the results showed that the COVID-19 pandemic has caused acceleration in the use of RM of CIEDs and the use of telemedicine in the clinical practice of cardiology. In a temporal perspective, this survey from AIAC showed an increase in the median number of patients per centre followed up by RM comparing the year 2012 to 2017, followed by an exponential increase from 2017 to 2020, thus including the effects of the COVID-19 pandemic, which markedly favoured the implementation of RM in Italy.¹⁰ It is noteworthy that in the AIAC survey on RM, 39.0% of centres reported during the COVID-19 pandemic an increase >30% in the number of CIED patients followed by RM.¹⁰

The rapid expansion of telehealth during the COVID-19 pandemic has been motivated by the need to maintain an adequate level of care despite the need to limit access to hospitals. This resulted in the potential advantage to continue using the various approaches of telehealth and telemedicine after the pandemic to increase efficiency

given the favourable cost-effectiveness profile that many telemedicine applications have in wide range of health care services.^{20–22} RM in patients with CIEDs has a great potential for reaching a high level of implementation and effectiveness, since it does not require complicated hardware (only the transmitter is needed which in addition is usually provided by the device manufacturer) and because the infrastructure is already available. In addition, patient involvement is minimal, thus overcoming the limitations of inadequate digital literacy.^{20,23}

RM and heart failure follow-up

Heart failure (HF) is one of the growing cardiovascular pandemics identified by the World Health Organization. Preventing hospital admissions by early identification of HF decompensating is a key. In patients with CIEDs affected by HF, RM using signals detected by implantable devices may be used for disease management, with the aim to predict and reduce HF exacerbations, consequent HF hospitalization and cardiovascular mortality.^{24,25} Indeed, the clinical role of RM has evolved by the trends to move the focus from the 'device carried by the patient' to the 'patient carrying a device', thus with the aim to detect signals suggesting the risk of worsening HF that could lead to appropriate clinical decisions and to reduce hospital admissions in patients with HF.^{5,26–30} Today, many physiologic variables can be monitored through CIEDs in patients with HF and with multi-parametric algorithms found to be more effective in assessing the risk of worsening or impending HF.^{29,31} The added value of monitoring multiple parameters may be linked to an enhanced sensitivity for HF events and studies are ongoing to prospectively validate this potential, with the result to reduce hospital readmissions in HF patients.^{1,32}

RM and reimbursement

Legal issues and compliance with the general data protection regulation, as well as lack of reimbursement and organizational issues have been traditionally the main factors limiting the widespread diffusion of RM across Europe, both for device checks and disease management.^{33,34} In accordance with the chain of processes that characterize health technology assessments (HTA), reimbursement policies for the activities related to RM are an important determinant of the successful implementation of a new technology.³⁵ Local policies and specifically the practice of reimbursement deserve a special focus, since in the survey promoted by EHRA and reported by Mairesse *et al.*¹⁹ in 2015 the lack of reimbursement was reported as the most important barrier to full implementation of RM from around 58% to 72% of centres. More recently, lack of reimbursement was still recognized as one of the main barriers to the adoption of RM in both European (in up to 40% of centres after COVID-19) and Italian surveys (in up to 73% of centres).^{2,10} Despite the improvement compared to the 2015 EHRA survey,¹⁹ there still was a high percentage of centres which consider lack of reimbursement for RM of CIEDs as a major issue limiting its widespread implementation. Moreover, these data may underestimate the implications of lack of reimbursement since the survey was based on a voluntary basis, with some underrepresentation of centres which had not adopted RM.

Major differences exist between Europe and the United States with regard to the way reimbursement codes are proposed and updated along with delay to implementation in daily practice of procedures

with proven effectiveness.^{36–38} It is noteworthy that in the United States a new regulation of reimbursement for applying RM to patients implanted with a CIED was released in 2022, in line with the changes in health care provision induced by the COVID-19 pandemic. According to this new regulation, a coverage of RM for CIEDs is provided by Medicare using detailed codes for specific procedures (such as device interrogation, data acquisition, receipt of transmissions and technical review, technical support, and distribution of results) performed remotely by a physician or other qualified health care professional in the out-patient setting. Billing is done for time periods that in the case of ICD and CRT devices correspond to 90 days.^{39,40} The granularity in describing the specific procedures related to RM is typical of the general approach to reimbursement of medical procedures applied in the United States.

The current status of reimbursement policies across Europe is shown in *Table 2* and continues to show some inertia and unresponsiveness, although with some improvement in the provision of reimbursement as compared to a similar assessment of reimbursement policies, published 7 years ago.⁴¹

The impact of the COVID-19 pandemic on all the health national systems in Europe has been enormous and it is undisputed that telemedicine had a crucial role in providing urgent responses to health care needs, both in specialized settings and in primary care, in order to manage patients with both acute and chronic diseases.⁴² As a matter of fact, the COVID-19 pandemic has promoted increased use of digital health for connecting physicians to patients, even if digital literacy may be a limit for widespread implementation of telemedicine.²³ CIEDs have the advantage of making possible RM with an already defined organization and reliable systems for data transmissions that can be easily implemented.^{26,43} In the setting of patients with CIEDs, RM allows limited in-person checks, providing new ways for monitoring both devices and patients, in integration with the new possibilities of interaction between patients and health professionals that the COVID-19 pandemic promoted. RM has a great potential of being cost-effective, in consideration of reduced direct costs and indirect costs, related to travel and work loss and this may be true both in the perspective of the health care system and of the society.^{42–45}

Despite the recent ESC recommendations and the spread of the technology, the cost-effectiveness of RM of CIEDs continues to be a matter of debate.⁴⁴ The Health Economics Evaluation Registry for Remote Follow-up (TARIFF; clinicaltrials.gov ID: NCT01075516) study was designed with the objectives of quantifying the costs and benefits of both RM and standard care.

The results of the TARIFF study showed that the RM of patients with CIEDs appears to be a cost-saving solution for the health care system vs. the conventional method of in-clinic visits.⁴⁶ Furthermore, RM is cost-saving for patients and caregivers as well.⁴⁶ An HTA conducted in Belgium has been recently published⁴⁷ and concluded that 'remote cardiac monitoring of ICDs and PMs is cost-effective compared to a monitoring exclusively based on in-clinic visits', but reimbursement in Belgium is still pending.

The new ESC recommendations strongly support RM as a standard way to perform the periodic checks of patients implanted with CIEDs and the surveys conducted in Europe indicate wider use of RM. This latter is also a consequence of COVID-19 pandemic, with advantages for both physicians and patients.³

Taking into account the profile of efficacy and safety of RM in the follow-up of CIED patients, the post-pandemic period should be characterized in our view by full implementation of RM as a standard of care for the follow-up of patients implanted with a CIED. It should become a complete alternative to in-office checks,^{48,49} limiting in-office patients checks only to cases with notification of an alarm, after appropriate triage.^{7,50} This should imply more homogeneous and adequate reimbursement policies thus eliminating some of the residual barriers to a re-organization of CIEDs follow-up based on RM as a standard of care, with potential advantages for all the stakeholders (patients, health care professionals, policymakers, and payers).

Introducing appropriate reimbursement in those countries where it is currently unavailable would make RM attractive even for the providers, while it would still be cost-saving for the healthcare system. Hopefully, complete integration of RM with healthcare records will allow both personalization of care and continuity of care.

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