REVIEW

Cardiac remote monitoring in France

Point sur la télécardiologie en France

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Summary The increase in number of implanted cardiac medical devices and the announced decrease in number of cardiologists have led to remote monitoring being considered as a pivotal tool for patient follow-up. For 10 years, remote monitoring has been the subject of multiple clinical studies. In these studies, reliability and clinical efficacy have been demonstrated, but the use of remote monitoring remains quite limited in France compared with other countries. To explain this delay in uptake, some organizational difficulties and the lack of reimbursement of remote monitoring are often mentioned. The results of medico-economic studies might provide answers about the value of remote monitoring and enable the supervisory authorities to define how its use will be financed. This review provides a global view of remote monitoring in France, and covers the principle, clinical efficacy, organizational and regulatory aspects, and medico-economic data.

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\textit{Abbreviations:} AF, atrial fibrillation; CAD, Canadian dollars; CRT, cardiac resynchronization therapy; GHS, homogeneous hospital stay groups (groupes homogènes de séjours); LPPR, List of Reimbursable Products and Services (Liste des Produits et Prestations Remboursables); RM, remote monitoring; USD, United States dollars.

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Background

The number of implantations of electronic implantable medical devices in the cardiovascular area has grown since their introduction in 1958 [1]. In France, 65,000 pacemakers are implanted every year. The number of implantable defibrillators rose from 2700 in 2003 to 13,000 in 2013. These medical devices require regular post-implantation follow-up of patients to ensure that an appropriate response to the patient’s condition is transmitted. Monitoring of battery status is also essential. Currently, conventional monitoring (face-to-face four times per year) does not allow real-time follow-up. Technological advances, with the development of implantable devices with automatic remote monitoring (RM) capability, allow constant surveillance.

RM involves the transmission of data on the status of the device, patient variables gathered by the device and, sometimes, disease-related data, over a network from the patient’s location via a central database to a hospital or physician’s office. RM could also be a solution to the decrease in the number of practitioners envisaged in the coming years as opposed to the predicted increase in the number of patients. The increase in patients can be explained by the ageing of the population and the widening of heart failure indications, thanks to the development of cardiac resynchronization therapy (CRT) devices [2].

Currently, five manufacturers offer monitoring interfaces, which provide follow-up of 20,000 patients in France [3]. These monitoring interfaces exhibit differences. The clinical and organizational impact of RM has already been supported by a large number of publications. Although the implantation of electronic medical devices is currently covered by health insurance, the deployment of RM remains subject to the supervisory authorities of the RM act itself in France, unlike in other countries. Validation of the act may evolve in the coming years and should be the subject of robust medico-economic studies.

This review firstly offers a reminder of the principle of RM. Secondly, the organizational and regulatory aspects of RM will be discussed, followed by medico-economic aspects inherent to RM.

The principle of cardiac remote monitoring

The principle of cardiac remote RM was first mentioned in the 1970s by Dreifus and Pennock [4]. With the recent progress in telecommunications, RM has rapidly become a powerful tool in the rhythmology department. Initially, active systems were developed but were soon replaced by automatic transmission, which increases patient observance naturally.

Implantable devices with automatic RM capability are equipped with an antenna circuit and transmit daily information as electromagnetic signals to a transmitter located in the patient’s home. The transmitter automatically transmits this information after encoding via the mobile phone or landline network to the secure server managed by the manufacturer. The analysis of information is then possible from the cardiology centre due to a secure internet portal. Two different types of data are transmitted to the implant centre. Firstly, data on the medical device integrity are available: battery status; recording and stimulation capacity; and measurement of impedance lead. Secondly, cardiac events in patients are transmitted (see later). All abnormalities are reported by e-mail, facsimile, telephone and/or short message service (SMS) to the health professional in charge of monitoring.

There are currently five manufacturers offering RM systems (Table 1), which operate differently (Table 2), especially in terms of location of data storage and encoding used. The notification of alerts, as well as the management of end of monitoring and registration of new patients, can be configured according to the needs of the rhythmology centre. The Home Monitoring® system does not allow the patient to activate the transmission. With the exception of Boston Scientific, all systems use the mobile network. As transmissions need energy from the device, RM reduces the lifetime of implants by 1–6 months, according to the prosthesis. The Latitude® system avoids this pitfall due to the transmitter querying the prosthesis that supplies the energy.

Data storage is not carried out in France, except for the systems developed by Sorin and Boston Scientific. All systems authorize access by the treating physician. Regarding the rules of confidentiality, many countries allow
Cardiac remote monitoring in France

<table>
<thead>
<tr>
<th>Supplier</th>
<th>Remote monitoring system</th>
<th>Compatibility</th>
<th>LPPR (with MD)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Biotronik</td>
<td>Home Monitoring® (Cardio Messenger)</td>
<td>Stimulators: Evia®, IAD: Lumax®</td>
<td>Registered (Lumax®)</td>
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<tr>
<td></td>
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</tr>
<tr>
<td>Boston Scientific</td>
<td>Latitude Patient Management System®</td>
<td>IAD: Teligen®, Cognis®, Incepta®</td>
<td>Registered (Teligen®, Cognis®, Incepta®)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Holter: Reveal®</td>
<td>Registered (Evera®/Protecta®/Viva®)</td>
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<tr>
<td></td>
<td></td>
<td>IAD: Evira®/Viva®/Secura®/Consulta®/Virtuoso®/Protecta®</td>
<td></td>
</tr>
<tr>
<td>Medtronic</td>
<td>Carelink Network®</td>
<td></td>
<td>Registered (Evera®/Protecta®/Viva®)</td>
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</tr>
<tr>
<td>St. Jude Medical</td>
<td>Merlin Patient Care System®</td>
<td>IAD: Ellipse®, Current®, Fortify®, Analyst®, Assura®, Atlas®, Unify®</td>
<td>Registered (Ellipse®, Current®, Fortify®, Analyst®)</td>
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<td></td>
<td></td>
<td></td>
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</tr>
<tr>
<td>Sorin</td>
<td>Smartview®</td>
<td>IAD: Paradym RF®, Intensia®</td>
<td>Not registered on 01/01/2014</td>
</tr>
</tbody>
</table>

IAD: implantable automatic defibrillator; LPPR: List of Reimbursable Products and Services; MD: medical device.

Initially, RM systems transmit data on the prosthesis and probe integrity, as well as on cardiac events in patients. The reports allow detection of:
- failure of the implants to charge and deliver appropriate therapy;
- inappropriate ventricular tachycardia and intermittent T-wave oversensing;
- a change in lead impedance that could reflect a lead fracture.

As a function of the medical devices implanted in patients, data are different, and the complexity of the implants increases the amount of data transmitted. With the development of CRT devices, new variables have been

manufacturers to dispose of the patient data; this is not the case in France, where patient data are confidential and can only be consulted by the rhythmology department.

The feasibility and reliability of RM has been demonstrated for a number of manufacturers across several publications [5—9]. In these studies (Biotronik, Medtronic, Boston Scientific), messages were received in their entirety and were delivered in < 1 minute to the rhythmology centre in > 90% of cases [7]. The correlation coefficient between the transmitted data and those collected by device querying was 95% [5]. Three manufacturers allow a wire-line transmission, which is useful in areas not covered by the Global System for Mobile Communications (GSM) network, covering 99% of the metropolitan area (Table 2).
Table 2  Comparison of intrinsic performance of remote monitoring systems.

<table>
<thead>
<tr>
<th>Supplier</th>
<th>Biotronik</th>
<th>Boston Scientific</th>
<th>Medtronic</th>
<th>St. Jude Medical</th>
<th>Sorin</th>
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<tbody>
<tr>
<td><strong>Transmission of data</strong></td>
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<tr>
<td>Manual</td>
<td>x</td>
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<td>x (for Holter &amp; stimulator)</td>
<td>x</td>
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<tr>
<td>Automatic</td>
<td>x</td>
<td>x</td>
<td>x (for DCI)</td>
<td>x</td>
<td>x</td>
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<tr>
<td>Scheduled</td>
<td>x</td>
<td>x</td>
<td>x (for DCI)</td>
<td>x</td>
<td>x</td>
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<tr>
<td><strong>Network used</strong></td>
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<tr>
<td>Landline</td>
<td>x</td>
<td></td>
<td>x</td>
<td></td>
<td>x (Orange ++++</td>
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<tr>
<td>Mobile</td>
<td>x</td>
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<td>x (Orange ++++</td>
<td>x</td>
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<tr>
<td>Internet</td>
<td>x</td>
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<td>x</td>
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<tr>
<td><strong>Data storage</strong></td>
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</tr>
<tr>
<td>Germanx</td>
<td>x (pending)</td>
<td>Franced</td>
<td>No, but agreement at European level</td>
<td>x (pending)</td>
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<tr>
<td><strong>Data encryption</strong></td>
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<tr>
<td>Germanx</td>
<td>x</td>
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<td>x</td>
<td></td>
<td>x</td>
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<tr>
<td><strong>Access to data</strong></td>
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<tr>
<td>Implant centre</td>
<td>x</td>
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<tr>
<td>Cardiologist</td>
<td>x</td>
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<td></td>
<td>x</td>
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<tr>
<td>Supplier</td>
<td>x</td>
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<tr>
<td><strong>Means of notifying alerts</strong></td>
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<tr>
<td>Telephone</td>
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<td>Fax</td>
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<td>Mail</td>
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<tr>
<td>SMS</td>
<td>x</td>
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<td>x</td>
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<tr>
<td><strong>Color code of alerts</strong></td>
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<tr>
<td>Red and yellow</td>
<td>x</td>
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<tr>
<td>Orange and white</td>
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</tbody>
</table>

ASIP: Agence des systèmes d’information partagés; DCI: data converter interface; SMS: short message service.

The proposed to follow-up patients with heart failure [10]. Weight and blood pressure are particularly useful for monitoring aggravation of heart failure. Pulmonary artery pressure is also followed up with these new devices and gives important information for rapid patient management. All the data downloaded from these increasingly complex devices need careful management and highlight the importance of a well-organized RM procedure.

**Identification of device defects**

Defects in pacemakers and defibrillators are rare but can be dramatic in patients without efficient escape rhythm [11]. The defibrillation leads are complex structures of multiple conductors associated with high-energy release systems. Major dysfunctions cause inappropriate shocks or potential loss of function. The clinical consequences are uncomfortable shocks for the patient or a pro-arrhythmic effect that can be life threatening [12]. In recent years, a growing number of medical device vigilance signals and alerts relating to active implantable cardiac medical devices, and more specifically to pacing and defibrillation leads, have been observed. Failure rates of 15% at 5 years and 40% at 8 years have been reported for defibrillators leads [13]. The use of RM appears to be adequate for the early detection of such failures. A study of 54 patients showed that monitoring by RM decreases the number of inappropriate shocks (19.2%) and allows earlier detection of failure (54 days) compared with traditional follow-up [14]. A prospective single-centre study (n = 69) demonstrated the feasibility and efficacy of RM for the detection of defibrillator failure [15]. A gain of 1.9 months in the detection of adverse events compared with traditional follow-up during the first year and of 5 months in the following years was observed [15]. At the same time as these studies, clinical cases demonstrated the value of RM in the early detection of defibrillator defects [16,17], allowing rapid patient management. A retrospective study (n = 169) concluded that RM identified 99.5% of arrhythmias and/or changes related to medical devices [5]. Taken together, these studies show that RM allows the early detection of abnormalities related to the device, thus improving quality and patient security. Identification of defects allows direct intervention to pre-empt shock delivery and to reduce patient morbidity and premature battery depletion [18].

**Clinical efficiency**

**Arrhythmias**

Atrial arrhythmias, particularly atrial fibrillation (AF), are major risk factors for ischemia, which may induce stroke. The detection of these rhythm abnormalities determines
therapeutic strategy, in terms of anticoagulation and adjustment of the implanted device. RM of 166 patients over a period of 16 months showed that 26% had an alert for AF [19]. For 78%, an unscheduled consultation was carried out, followed by the introduction/modification of medical treatment or of the medical device [19]. Compared with conventional monitoring, the duration of the first intervention was 50 days, which was a gain of 148 days [19]. The first publication of The Lumos-T Safely Reduces Routine Office Device Follow-Up (TRUST) study \((n = 1339)\) showed that arrhythmias were the leading cause of notification and that RM led to a mean time of a day for evaluation by the clinician compared with 35.5 days for traditional monitoring [20]. Furthermore, the detection time for AF was reduced from 40 days to 6 days [20].

**Heart failure progression**

New implantable devices have been developed by manufacturers to address the difficulties in managing heart failure. As a dynamic pathology, the process of heart failure decompensation is complex but behaves as a fluid congestion [10].

Currently, data are available to confirm that this pathophysiological process progresses over days to weeks before clinical presentation. With the development of CRT devices, the initial events of heart failure can be tracked. Specific variables, considered as essential, can be followed up: hemodynamic, pulmonary (pulmonary artery pressure), and thoracic (intrathoracic impedance). Thanks to the RM of heart failure, patients in decompensation can be rapidly detected and their therapy can be managed earlier. Results relating to this heart failure monitoring revolution are limited and controversial [21–23], but many studies are in progress to confirm the benefit of this new approach.

**Occurrence of severe adverse events and reduction in the number of hospital stays, morbidity and mortality**

The second publication from the TRUST study showed a 45% decrease in the number of consultations, without any impact on morbidity [24]. The COMPArative follow-up Schedule with home monitoring (COMPAS) study \((n = 538)\) demonstrated non-inferiority of RM in terms of occurrence of serious adverse events [25]. The management of notified events was 117 days earlier and a 66% decrease in hospital stays for AF was observed. The ECOST \((n = 433)\) and EVALuation of TELe follow-up (EVATEL) \((n = 1501)\) studies also showed non-inferiority compared with conventional follow-up in terms of risk of all-cause mortality [26,27]. A highly significant reduction in the number of inappropriate shocks was observed in the RM group in these two studies, with a 72% decrease in hospital stays related to these shocks in the ECOST study. Another study \((n = 379)\) showed, after pacemaker implantation, a reduction in adverse events (absolute risk reduction of 4.1%) and mean hospitalization duration (34%) [28]. Finally, a multicentre study \((n > 2000)\) showed that RM is associated with a lower mortality rate among patients with heart disease as well as a significant decrease in mean length of stay \(4 \text{ days for in-office visit versus } 3 \text{ days for RM follow-up}\) [29]. The authors concluded that RM has a protective clinical effect in these patients.

**Organizational aspects**

Efficient organization of RM is a prerequisite to allow its implementation in standard clinical practice. Currently, differences exist between countries. Organization, frequency of monitoring consultations and monitoring liability have to be defined if RM is to become the standard of care.

**Monitoring consultations**

In addition to early detection of adverse events, better monitoring of patients is possible with RM, while reducing the number of monitoring consultations with the cardiologist and making them more efficient. This reduction in the number of consultations has been demonstrated repeatedly in different studies, with a decrease in consultations of 45% and 56% in the TRUST [20] and COMPAS [25] studies, respectively; these decreases did not affect the rates of hospitalization or mortality. In another study the time required for a traditional monitoring visit compared with RM has been determined and showed substantial time saving (going from 25.8 minutes to 4.5 minutes in favor of RM) [6].

**Frequency of monitoring**

A consensus on the practice of RM and the competency of the person who carries it out has been proposed by European and American cardiology societies [33]. Face-to-face follow-up must be carried out within the 72 hours following implantation and 2–12 weeks after device implantation. Monitoring every 3–12 months for pacemakers and every 3–6 months for defibrillators can be carried out by RM. Whatever the type of implant, an annual face-to-face consultation with a cardiologist in an implant centre is recommended. Consultations for when the prosthesis reaches the end of its life and therefore needs to be replaced are planned, following the recordings obtained by RM.

**Monitoring liability and regulatory aspects**

While it seems clear from several studies that RM reduces the number of consultations and provides quicker analysis of cardiac events and implant defects, health professional liability is not yet well defined. RM is a medical procedure carried out by a trained cardiologist. However, part of the
concept of RM is carried out by allied professionals delegated by the cardiologist. Currently, important organizational differences exist between countries. The USA and Switzerland make use of RM-trained technicians. In the United Kingdom, monitoring is carried out by biomedical engineers, whereas nurses carry out monitoring in Italy. In France, the situation is heterogeneous, with variation according to centre; nurses or clinical research associates may be involved. In the French Telecardiology White Paper, the status of the technician specialized in rhythmology was discussed, but no decision was made for the moment [34]. Currently, some foreign teams have delegated the monitoring of uploaded data to independent telemedicine centers [35]. From a medical liability perspective, the practitioner has to organize the technical and human resources to carry out RM. Analysis of the uploaded data is a requirement in the days and hours of work (obligation of means) [36]. Interestingly, a multicentre Italian registry has been designed to analyze the manpower need for RM. Results reported in the HomeGuide Registry showed low manpower consumption, with 55.5 minutes per health-personnel unit per month per every 100 patients [37].

The information and patient consent sheet states that the physician is not required to keep a permanent record. The liabilities of patients and manufacturers have to be defined. The use of RM requires a contract to be drafted between the physician, the establishment concerned and the supplier, so that the role of each is perfectly defined. The supplier must provide permanent and secure access, allowing confidentiality and protection of patient data. The supplier must have a license for data storage, provide leadership in the event of failure and replace non-functional RM material. RM also shows its value in the management of medical device safety alerts, such that the offending device can be tracked early and material removed more quickly if the patient’s condition requires it. This new technology requires the cardiologist to provide a “clear, fair and appropriate” explanation to the patient in terms of the operating conditions of tele-monitoring (Article 35, Code of Ethics). Written consent is recommended. It should be emphasized that RM is not an alarm or emergency system and should not in any way replace conventional cardiac monitoring [38].

Medico-economic criteria and reflection

A number of studies have highlighted the economical advantage of RM. A theoretical evaluation of cost reduction conducted in a French study [39] showed a reduction of $2200 (United States dollars [USD]) per year and per patient if the number of visits is reduced from 4 to 2 and of $3300 (USD) for one visit per year. The important decrease in the overall cost is depicted by transportation cost. In the Franco-Belgian study QEDIPE, reducing the length of stay also brought about a medico-economic advantage for RM [28]. Another study estimated a cost reduction over 5 years of between $2100 and $3300 (USD) [6]. The prevention of acute events and the limitation of hospitalizations also decrease resource consumption with RM, as shown in the COMPAS trial, with fewer hospitalizations for atrial arrhythmias and strokes [25]. Other studies (ECOST, EVATEL, EUROECO, etc.) with cost analysis as primary or secondary endpoints should soon give consistent results. Interestingly, a recent statistical analysis using the Markov model showed that RM is cost neutral over 10 years compared with conventional follow-up [40]. In Italy, the TARIFF study is in progress and should provide some answers; the results of this study should be adapted to the specificities of each country [41].

These medico-economic data are important in showing the value of cardiac RM and in France they are also used by manufacturers to support their inclusion on the List of Reimbursable Products and Services (Liste des Produits et Prestations Remboursables [LPPR]). The difficulty in transposing these studies between countries must, nevertheless, be highlighted. Indeed, differences in health care systems are particularly important and reimbursement policies for RM vary extensively among different countries. Unlike many countries in Europe (Germany, Portugal, the United Kingdom, Netherlands, Sweden, Denmark and Finland), the complexity of the French hospital care system has resulted in important delays and aberrations.

In France, the economic and organizational environment of the hospital health system is based on activity-based tariffs. The first RM devices were registered on the list of invoiced products and included in homogeneous hospital stay groups (groups homogènes de séjours [GHS]) in September 2011. Ironically, a few months before, the management of defibrillators (not pacemakers !) was removed from inclusion in GHS. At present, the Home Monitoring® CareLink® et Latitude® systems receive an additional refund of €864 when they are associated with single- and double-chamber defibrillators and €972 for triple-chamber devices [42]. Today, only the Biotronik system has a specific registration for pacemakers; they are only paid when they are associated with implanted cardiac defibrillators (or a pacemaker for Biotronik), according to the directions specified by the LPPR (Table 3).

In France, a lack of financial compensation prevents cardiologists from wider deployment of RM. In addition to

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**Table 3: Indications for cardiac remote monitoring systems.**

<table>
<thead>
<tr>
<th>Indications</th>
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</thead>
<tbody>
<tr>
<td>Cardiac arrest by VF or VT, without acute or reversible cause</td>
</tr>
<tr>
<td>Coronary patients with or without symptoms of mild-to-moderate heart failure</td>
</tr>
<tr>
<td>Spontaneous sustained symptomatic VT on heart disease</td>
</tr>
<tr>
<td>Spontaneous sustained VT, poorly tolerated, in the absence of cardiac abnormalities, for which medical treatment or ablation cannot be carried out or failed</td>
</tr>
<tr>
<td>Syncope of unknown cause with sustained VT or inducible VF, in the presence of an underlying cardiac abnormality</td>
</tr>
<tr>
<td>Coronary patients with left ventricular dysfunction</td>
</tr>
<tr>
<td>Patient with dilated cardiomyopathy, primitive in appearance, with LVEF ≤ 30% and NYHA class II or III</td>
</tr>
<tr>
<td>Genetic disease at high risk of sudden death by VF, with no other known effective treatment</td>
</tr>
<tr>
<td>Sustained VT, poorly tolerated, in a patient waiting for a heart transplant</td>
</tr>
</tbody>
</table>

LVEF: left ventricular ejection fraction; NYHA: New York Heart Association; VF: ventricular fibrillation; VT: ventricular tachycardia.
the act of RM, reimbursement must take into account the structural costs incurred to ensure this activity: technical (hardware maintenance and security, high speed internet connection, etc.) and human resources (doctors and other health professionals trained in the practice of RM). An analysis of health services in Ontario (Canada) estimated the consultation fee as part of conventional (face-to-face) monitoring at approximately $140 (Canadian dollars [CAD]) and approximately $105 (CAD) for RM due to reduced consultation time and less use of transport by patients; this results in a health insurance gain of approximately $100 (CAD) per patient and per year [43]. The situation in Europe varies extensively. RM is paid for in Finland, Germany, Portugal and the Netherlands, but not in Italy, Belgium and Denmark. In France, discussions are ongoing and reflection is led jointly by the National Council of the College of Physicians, the National Professional Council of Cardiology and the French Society of Cardiology. The main areas are outlined in the report entitled ”Economic thinking for payment of ambulatory RM of patients with pacemakers and cardiac defibrillators”. One proposal is for an annual fee to cover RM; this fee would include payment of the health professional, the cost of RM installation in the patient’s home (technical and medical time) and costs relating to the structure housing the RM system and the premises necessary to carry out RM of patients. An annual fee for RM, paid by health insurance, of approximately €230 and €250 per year has been proposed for patients with a pacemaker or defibrillator, respectively. An additional reimbursement could be also proposed for the first year regarding RM installation and education of patient. Currently, the delivery of RM devices at the first consultation is subject to a fee of €12.60 for the administration of products and services in a hospital environment. In order to have a balanced model, it is necessary that the activity of RM is valued at a fair cost, without forgetting the manufacturer whose role in the implementation of the service is pivotal.

Conclusion

RM is an innovative paradigm that could supplant conventional episodic in-office device interrogation. Advantages include earlier detection of patient events (arrhythmia onset and device therapy), programming issues (therapies programmed off) and device integrity problems (notably lead fracture). Moreover, patient and physician satisfaction have been largely demonstrated. In this context, it would be too simplistic to think that RM has become a gold standard in the management of patients and in the daily activity of cardiologists. The reality is much less attractive and shows large disparities between countries. Countries where RM can be considered as a gold standard have quickly defined modalities of reimbursement as well as the liabilities of those involved (patients, health professionals, manufacturers, the health establishment). In France, there has been an important delay regarding these items, which has led to limited implementation of RM. Further discussions should be initiated promptly to catch up, especially in view of the ageing population, the announced reduction in the number of cardiologists and the emergence of indications, such as heart failure.

Disclosure of interest

Vincent Probst is a consultant for St. Jude Medical and a board member for Medtronic; he has received honoraria for presentations from Boston Scientific. All other authors: none.

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