Organizational model and reactions to alerts in remote monitoring of cardiac implantable electronic devices: a survey from the Home Monitoring Expert Alliance (HMEA) project

Gabriele Zanotto[1], MD, Antonio D'Onofrio[2], MD, Paolo Della Bella[3], MD, Francesco Solimene[4], MD, Ennio C. Pisanò[5], MD, Saverio Iacopino[6], MD, Cristina Dondina[7], MSc, Daniele Giacopelli[7], MSc, Alessio Gargaro[7], MSc, Renato P. Ricci[8], MD

[1] Ospedale Mater Salutis, Legnago
[2] Ospedale Monaldi, Napoli
[3] Ospedale San Raffaele, Milano
[4] Clinica Montevergine, Mercogliano (AV)
[5] Ospedale Vito Fazzi, Lecce
[6] Villa Maria Care&Research, Cotignola (RA)
[7] BIOTRONIK Italia, Vimodrone (MI)
[8] CardioArrhythmology Center, 91 Poerio st, Rome, Italy

Corresponding author:

Gabriele Zanotto, MD
Department of Cardiology
Ospedale Mater Salutis
Via Giannella 1, 37045 Legnago (VR), Italy
Phone: +39 0442622111; Fax: +39 044226372
e-mail: gabzanot@tin.it

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Structured abstract

Background: This survey aimed to describe the organizational workflow of cardiac implantable electronic devices (CIEDs) remote monitoring (RM) service in ordinary practice.

Methods: A questionnaire was designed for our purpose and completed by 49 sites participating to the Italian Home Monitoring Expert Alliance.

Results: A dedicated organizational model for RM was set up for 86% of centers. The median RM team consisted of 2 [Interquartile range (IQR):1-3] physicians and 1 [IQR:0-2] nurse. RM service was available in working hours and the median percentage of patients included was 100% [IQR:10%-100%] for implantable cardioverter-defibrillator (ICD) and cardiac resynchronization therapy (CRT) recipients and 5% [IQR:0%-30%] for pacemakers. In-office follow-up was performed every 12 and 6 months for pacemaker and ICD/CRT recipients, respectively. More than 90% of sites used to activate all technical alerts, with a prompt reaction in case of an out-of-range parameter. The threshold for atrial fibrillation (AF) daily burden notification in most cases ranged from 2.4 to 7.2 hours. All ventricular arrhythmias alerts were usually switched on: an inappropriate therapy or more than one appropriate episode triggered an urgent in-hospital visit. Concerning heart failure, low CRT percentage pacing alert was always used, while the other available notifications were less frequently switched on.

Conclusions: This survey showed that RM service was usually set up with a primary nursing model including on average 2 responsible physicians and 1 nurse and mainly offered to ICD/CRT patients. Technical, AF and ventricular arrhythmia alerts triggered prompt reactions, while heart failure related indexes were generally less applied.

Key words: Remote monitoring; telemonitoring; cardiac resynchronization therapy; implantable cardioverter defibrillator; pacemaker; atrial fibrillation.

Introduction

Remote monitoring (RM) of cardiac implantable electronic devices (CIEDs) is a class IA recommendation in the 2015 Heart Rhythm Society Expert Consensus Statement[1]. Several benefits for patients, including early detection of technical malfunctions and clinical arrhythmias, have been demonstrated by several randomized trials[2-4]. In addition, a debate on possible positive effect on hard clinical endpoints, such as mortality and hospitalization is now ongoing[5,6]. Despite this scientific data supporting RM, it is still unclear which is the best organization model of a RM team and the optimal workflow of reactions to remote data flow to be implemented in ordinary practice. Integration of a daily review of remotely collected data into clinical practice is challenging, but it may be the key factor to improve patients' outcome. This survey aimed to describe how RM service has been set up in a group of Italian sites with extensive experience in this field and which are the reactions usually implemented to technical and clinical remote alerts.

Methods

This survey is based on a questionnaire sent to all the sites participating to the Italian Home Monitoring Expert Alliance (HMEA) project in order to provide details on the current use of remote monitoring for CIEDs in Italy. The HMEA is an independent, nationwide repository of data generated during routine RM of CIED patients[7]. Responses were received from 49/57 (86%) centers, from a wide Italian area, with a minimum 5-year experience of RM service, listed in the Appendix. Overall, 26% of the sites follow with RM 800 or more patients, 24% between 500 and 799, 33% between 200 and 499, and 17% less than 200. The majority of the sites use four of the currently available RM systems: Biotronik Home Monitoring, Medtronic Carelink, Boston Latitude, Merlin Abbott (ex St. Jude Medical). Responding centers were public hospitals (64%), university hospital (26%), or private clinics (10%). The questionnaire consisted of two parts: the first was intended to investigate the organizational model of hospital RM team, while the second consisted of questions about type and timing of reactions to remote alerts in different fields (device functioning, atrial fibrillation for stroke prevention, atrial fibrillation for rhythm control, ventricular arrhythmias, and heart failure). Since the distinct RM systems for each device's manufacturer have different characteristics relative to alerts, the second part of the questionnaire was specifically referred to the Home Monitoring, which is the system used in the framework of the HMEA project. The questionnaire was designed for the purpose of this study on a self-devised base and included the topics we wanted to address.

Results

Organizational model of remote monitoring team

A structured organizational model for RM was set up in 86% of responding centers. The median RM team consisted of 2 [Interquartile range (IQR): 1-3] physicians and 1 [IQR: 0-2] nurse. A minority of sites (29%) reported to have an internal technician in the RM team. The most frequent model (72%) was based on a cooperative interaction between a nurse and a physician. Each nurse-physician pair in some cases was exclusively dedicated to an assigned subgroup of patients (32%), usually according to device's manufacturer, while in other cases followed all remotely controlled patients (40%). Twenty-eight percent of responding sites adopted a model in which the physician directly checked monitoring data, without prior transmissions reviewing by a nurse.

The median percentage of patients who were offered RM as part of the standard follow-up management strategy was 100% [IQR: 10%-100%] for implantable loop recorders (ILRs), 100% [IQR: 100%-100%] for implantable cardioverter-defibrillator (ICDs) and cardiac resynchronization therapy (CRT) devices and 5% [IQR: 0%-30%] for pacemakers. In patients with RM, the in-office follow-up was usually performed every 12 months for pacemaker and ILR recipients and every 6 months for ICD e CRT recipients.

In pacemaker/ILR patients, the RM had led to a reduction of in-office follow-ups in 54% of sites. In 11% the frequency of face-to-face check was reduced to less than one per year. For ICD/CRT devices, 43% of sites reported an effect of RM on in-hospital follow-up scheduling, 41% planned a yearly visit and only one center reported to reduce the frequency to less than one per year.

As shown in figure 1, most sites provided RM service every working day in office hours with direct access to the website as main method of data notification. E-mail, sms or fax massage were used for alert notification in 56%, 22%, and 17% of sites, respectively. RM transmitter was provided to the patient at device implantation (63%) or before discharge (22%), while in only 15% of sites patients received it at the first in-clinic follow-up visit. Responding sites stated that the transmitter could be delivered to the patient and its functioning explained by the manufacturer external technician (61%), the RM reference nurse (29%), the physician (29%) or the internal technician (29%).

Remote monitoring alerts

Device functioning

As shown in figure 2, more than 90% of sites used to activate all the available technical alerts: high pacing threshold, low sensing amplitude and impedance measurements out of range. The most frequent reaction to this class of alerts was an unscheduled in-hospital visit (63% of sites). Approaches based on remote monitoring until next planned visit or phone contact only were less frequently adopted (28% and 9% of sites, respectively). These actions were performed at the first alert notification of one parameter for 38% of responders, at the first combined alert of at least two or three parameters for 10% of responders, and after at least two consecutive days of alerts for 35% of responders. Of note, 6% of sites stated that the decision depended on the years of the implanted system affected by the notification.

Atrial fibrillation for stroke prevention

The atrial fibrillation (AF) daily burden threshold usually set for RM alert in patients without anticoagulant therapy to detect potential asymptomatic arrhythmias and to prevent thromboembolic event widely differed among sites. Seventy-two percent of responders identified a threshold ranging from 2.4 to 7.2 hours (AF burden from 10% to 30%), while

13% stated that few minutes of AF (burden>0%) were enough to justify a RM alert (figure 2). More than half of responders (54%) declared to react immediately at this alert, while the remaining (43%) had different approaches depending on patient clinical history. As shown in figure 3, the most frequent reaction (64%) was an unscheduled in-hospital visit, followed by phone contact only (36%). Interestingly, all sites used to perform one active action following AF alert in this group of patient.

Atrial fibrillation for rhythm control

In the subgroup of patients with known AF episodes and rhythm control strategy, sites used to set less sensitive AF alerts (figure 2). Nine percent of responders did not active any AF alert and another 9% set an AF burden threshold of 18 hours (burden>75%). However, the most frequent (34%) threshold was once again 7.2 hours (burden>30%), showing a similar approach for AF alerts among patients with different arrhythmic history. Fifty percent of sites declared to react immediately at this alert, 43% had different approaches depending on patient clinical history, while 7% used to wait for at least 2 days of alert persistence. As shown in figure 3, the most frequent reaction (51%) was an unscheduled in-hospital visit, followed by phone contact only (37%) and monitoring with no further action (12%). Other RM variables were considered of interest and monitored when dealing with AF in this group of patients: percentage of CRT pacing (81%), mean heart rate (72%) and percentage of right ventricular pacing (66%).

Ventricular arrhythmias

In the RM systems there are several alerts for ventricular arrhythmias and, as shown in figure 2, all of them were active for most of sites: episode in monitor zone (87%), ineffective shock (98%), episode with device therapy (96%), episode in ventricular tachycardia (VT) zone (96%), and episode in ventricular fibrillation (VF) zone (100%). The adopted reaction changed based on the severity of RM alert (figure 3). An inappropriate device therapy or more than one VT/VF episode in the same day usually led to an urgent in-

hospital visit (88% and 85% of sites, respectively). In case of a single VF, 45% of responders used to perform an in-clinic visit, while 41% to contact the patient only by phone. The latter was the most frequent action after a single VT episode (40%), however, in this case, many sites did not even perform any active intervention (34%).

Heart failure

Concerning heart failure alerts, low CRT percentage pacing RM alert was active in all sites. As shown in figure 2, half of sites used to set the other available alerts: high number of pre-ventricular contractions (PVCs), mean rest heart rate, and mean heart rate. Seventy-five percent of sites reported to evaluate and react to this alert within 2 days, 23% within 7 days and 7% within 2 weeks. The most frequent adopted reaction was patient phone contact (49%), followed by unscheduled in-hospital visit (31%) and remote monitoring only (20%). Of note, a direct collaboration with the ambulatory care services for patients with chronic heart failure was present in 51% of clinics. Table 1 reports the evaluation of reliability of all heart failure indexes provided by RM, also if not equipped with automatic out-of-range notification, as perceived by the centers. Heart rate and AF burden were considered as the most important variables, while patient activity and thoracic impedance were classified as little reliable for 49% and 44% of responders, respectively.

Discussion

Remote monitoring service in clinical practice

The implementation of RM requires changes in the organizational model of CIED follow-up service with different roles and responsibilities. We found that the most common organization is based on the HomeGuide model[8,9]. This workflow is essentially based on a cooperative interaction between a nurse/technician and a responsible physician. The main responsibilities of the nurse/technician are: patient's education, RM activation and daily reviewing of transmissions. In order to complete these tasks, team member must have the

same training, qualifications, and experience as required to perform in-clinic CIED follow-up. Thereafter, any alert requiring physician's competence is referred to the responsible physician for further evaluations. Of note, we found that in Italy this role is mainly covered by a nurse. We might expect that in future dedicated allied professionals with technical background and experience in CIED technology will be increasingly used for this important task in cooperation with nurses who play a key role in clinical management according to their clinical background.

In our survey, despite check of RM website was usually performed only in working days, almost a quarter of centers had a 24 hours service for red alerts. This prompt reaction may be meaningful in case of remote evidence of lead or device malfunctions, such as inappropriate shocks for lead failure or T-wave oversensing[10], to avoid adverse events. Anyway, due to technical limitations of remote monitoring services and telecommunication systems, currently RM cannot be considered a system for emergency management, as stated in the international guidelines[1].

In most cases (85%) sites used to provide transmitter to the patient before discharge. This approach has been specifically suggested in case of early discharge after CIED implantation, as RM can be useful in indicating lead-parameter stability during the immediate postoperative period[11].

Despite we considered sites with extensive experience in RM, we found a huge difference in the percentage of patients who were offered RM according to device category: 100% of ICD and CRT recipients and only 5% of PM recipients. This may be due to the common belief that RM provides more benefits for more complex devices. However, it should be considered that several aspects which are not uncommon in pacemaker patients can be appropriately managed remotely, such as new-onset atrial fibrillation episodes[12]. In addition, pacemaker recipients are older than other population and, therefore, may have important benefits in

reducing frequent in-hospital visits[13]. For these reasons, we may speculate that organizational benefits from RM may still be increased providing more pacemaker patients with RM. From this survey, frequency of in-hospital follow-ups seemed not significantly affected by the presence of RM. Interestingly, more than half of sites planned more than one office check per year for ICD/CRT recipients, despite guidelines on the monitoring of CIEDs recommend only a yearly in-person visit for all remotely followed patients[1]. Few sites reduced in-person visits to less than one per year and this is concordant with a survey undertaken by the European Heart Rhythm Association few years ago [14]. However, experiences of fully remote follow-up model has been reported in low-risk patients with satisfactory results[15,16]. These results should be carefully discussed considering also the results of the ATHENS trial, where only the 22% of in-hospital pacemaker follow-ups had a clinical or device-related action, whereas not even one change was made to medical treatment or device programming during 77.2% of the visits[17]. This is still more impressive considering that published data reported that 27 minutes were required on average for a single in-hospital visit, involving both a physician and a nurse in 53% of cases[18]. Therefore, the yearly reduction of around 17% of the ambulatory visits found in fully remote model implementation for pacemaker patients might have significant economic and organizational benefits for the healthcare system[16].

Of note, the initial patient education represents a crucial point that can alleviate, if not eliminated, potential patient's concerns on the RM. In addition, the increasing use of wireless and automatic RM technology is improving the transmission reliability and reducing the percentage of patients not adherent to RM[19,20].

Reactions to events detected by RM

Several non-randomized studies and large-scale database registries reported an improvement in clinical outcome using RM systems[21,22]. Although these results were

confirmed also by one randomized trial and by a recent meta-analysis with the Home Monitoring (BIOTRONIK SE&Co, Berlin, Germany) technology[6,23], some recent large randomized trials have been neutral[5,24,25]. Beyond the RM technologies that have differences in frequency and reliability of transmissions[26], these conflicting results may depend on the role of clinical reactions triggered by RM alerts. In none of the trials there was a standardized treatment after telemonitoring observations limiting the comprehension of the relative contributions of each single mechanism possibly affecting the clinical outcome. In some cases less than 30% of alerts were actually followed by a clinical action[24]. Although this survey does not address the link between reported alerts and patient outcomes, it may help to understand which are the reactions usually implemented to technical and clinical remote alerts in ordinary practice. We found that generally the majority of RM alerts were active, both technical and clinical. Crossing the threshold for AF burden, the majority of sites triggered an unscheduled visit for patients without history of atrial tachycardia. The prevalence of AF was found to be very high in CIED recipients[7] and a relative low amount of arrhythmic burden may be considered enough to start anticoagulant therapy. Despite the evidence of stroke reduction using RM is still awaited, the early detection and manage of AF was speculated as one of the main mechanisms of patient outcome improvement. Our data showed that atrial-related alerts were intensively used also for patients with AF history to early detect any progression of the arrhythmia.

All the ventricular arrhythmias related alerts were usually activated, one single episode led to a phone contact, while multiple episodes for the majority of responders were managed with an urgent in-person visit. Ventricular tachycardia or fibrillation and ICD therapy were found to correlate with mortality[27,28] and their early detection could likely be a mechanism behind RM positive effect.

In heart failure patients approaches based on combined multiparameter algorithms have been proposed to identify the risk of hospitalization[29,30]. However, it is this unclear which

are the most significant variables to allow pre-emptive therapy in case of heart failure deterioration. We found that the notification of low CRT percentage pacing was active in all sites, while high number PVCs, mean rest heart rate, and mean heart rate alerts were less frequently used. Beyond RM alerts, physicians considered heart rate and AF burden as the most reliable variables for patient status evaluation. On the other hand, patient activity and thoracic impedance were classified as little reliable by many responders. This behavior for the latter may be explained by the neutral effect seen in the Optilink study[25], while increased attention should be paid for daily activity, since its significant decrease was observed for impaired health condition[31].

We believe that all these device-sensors may be meaningful if provided also to heart failure ambulatory care services. This direct collaboration should definitely be encouraged in clinical practice, since in our survey it was present only in half of clinics.

Conclusions

This survey showed that RM service was usually set up with a primary nursing model including on average 2 responsible physicians and 1 nurse. RM was provided for all ICD/CRT patients, but for few pacemaker recipients with a service mainly available in working hours. Technical, AF and ventricular arrhythmias alerts triggered prompt reactions, while heart failure related indexes were generally considered less reliable.

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Conflicts of interest: C.D., D.G and A.G. are employees of BIOTRONIK Italia. All other authors have reported that they have no conflicts relevant to the contents of this paper to disclose.

Supplementary material.

List of HMEA centres.

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Figure legend

Figure 1. Organizational model of remote monitoring team.

*More than 1 possible answer.

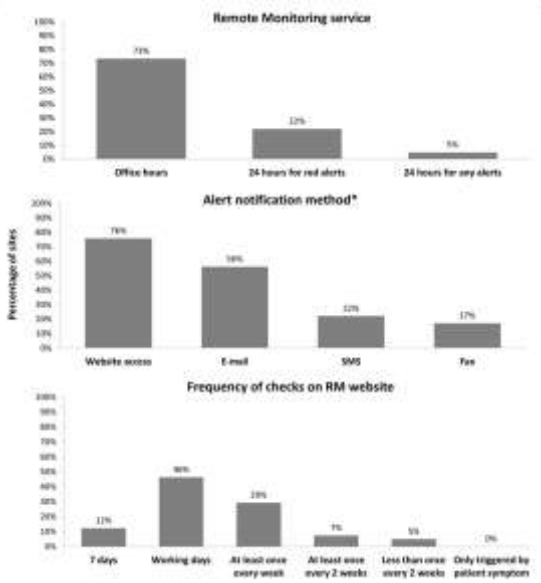


Figure 2. Remote monitoring alerts set by sites. Percentages are referred to total number of sites.

RM = remote monitoring; AF = atrial fibrillation; VT = ventricular tachycardia; VF = ventricular fibrillation; PVCs = pre-ventricular contractions; CRT = cardiac resynchronization therapy.

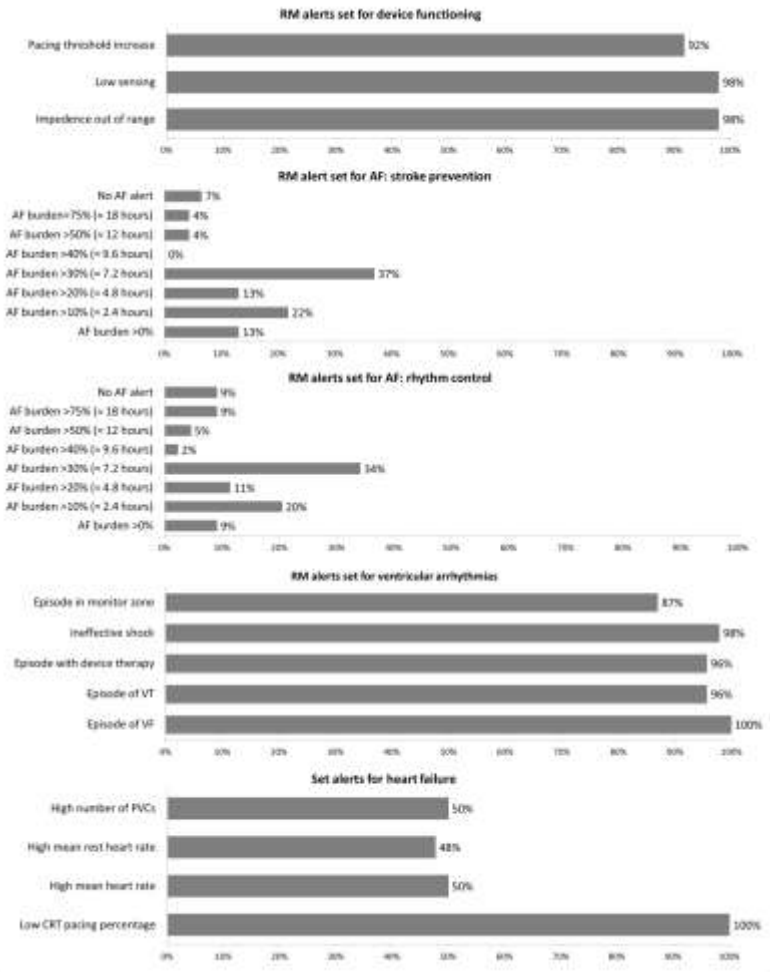
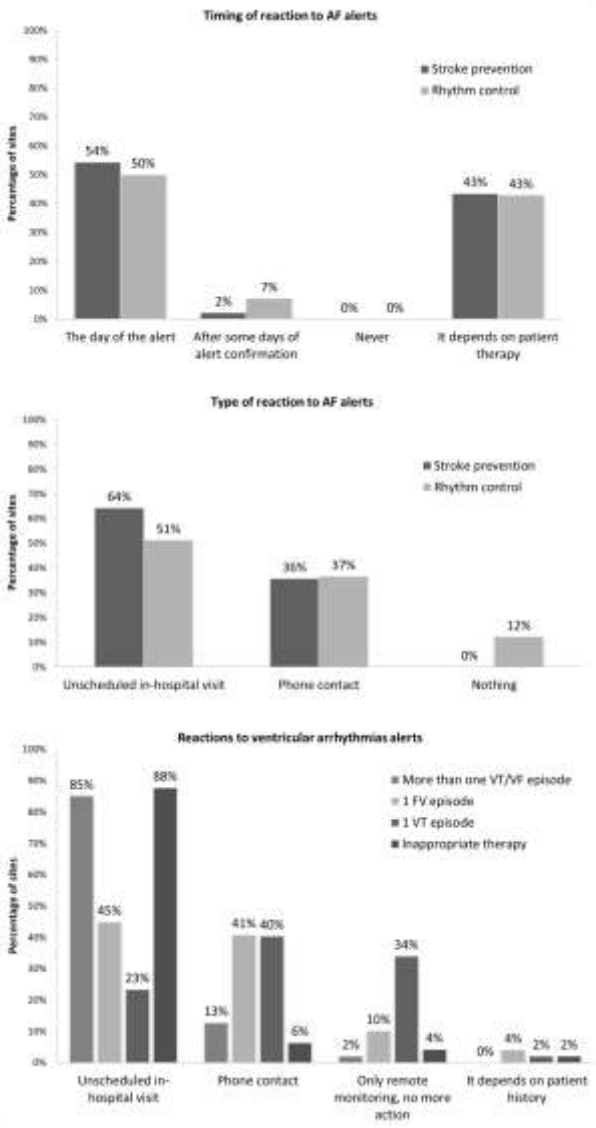


Figure 3. Reactions to atrial and ventricular arrhythmias alerts.

VT = ventricular tachycardia; VF = ventricular fibrillation.



Tables

Table 1. Reliability and clinical utility of heart failure indexes provided by RM* in center feeling (1 = very low; 4 = very high)

	1	2	3	4
Heart Rate	5%	21%	30%	42%
Heart rate variability	12%	35%	33%	19%
Patient activity	26%	23%	23%	23%
Atrial arrhythmic burden	2%	7%	40%	56%
PVCs	16%	26%	30%	26%
Thoracic impedance	23%	21%	28%	28%

*Percentages are referred to total number of sites.

PVCs = pre-ventricular contractions.