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Society Position Statement

Canadian Cardiovascular Society/Canadian Heart Rhythm Society Joint Position Statement on the Use of Remote Monitoring for Cardiovascular Implantable Electronic Device Follow-up

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ABSTRACT

Remote monitoring (RM) is a form of telemedicine technology that permits implanted pacemakers and implantable cardioverter-defibrillators to transmit diagnostic information for review by health care professionals without patients needing to visit the device follow-up clinic. A bedside transmitter in the patient's home conveys the device data using standard telecommunication protocol to a protected

RÉSUMÉ

La surveillance à distance (SD) est une forme de télémédecine qui permet l'implantation de stimulateurs cardiaques et de défibrillateurs pour transmettre des renseignements diagnostiques aux professionnels de la santé sans que les patients aient besoin de se rendre à la clinique de suivi des dispositifs. Un transmetteur de chevet au domicile du patient communique les données du dispositif en utilisant le protocole

Practice guidelines in Canada recommend that patients receiving cardiac pacemaker (PM), implantable cardioverter-defibrillator (ICD), and cardiac resynchronization therapy (CRT) devices, collectively referred to as cardiovascular implantable electronic devices (CIEDs), undergo routine device follow-up assessment of their CIED at regular intervals.[1,2] The purpose of these assessments is to evaluate the patient and the CIED including reprogramming of the device where clinically appropriate. Traditionally, these assessments have been conducted at a designated Device Follow-Up Clinic (DFC), which might be remote from the patient's location. Recently, CIEDs have been manufactured with remote monitoring (RM) capability, a technology that permits surveillance and device assessment virtually from any patient location accessible by a landline or mobile telephone. RM adds no new diagnostic or therapeutic capabilities to a CIED but is an important "enabling technology" that facilitates more efficient interaction between the CIED health care team and patient. Implantable hemodynamic monitors and implantable loop recorders are diagnostic devices that can also be followed by RM. They were included in the discussion of RM use by the European Heart Rhythm Association (EHRA).[3] However, hemodynamic monitors are not currently available in Canada and implanted loop recorder use is somewhat limited. Therefore, this document focuses solely on examining the clinical utility and potential role of RM for PM, ICD, and CRT patient follow-up. It also offers practical advice on RM integration into the routine practice of the modern DFC in the

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This statement was developed following a thorough consideration of medical literature and the best available evidence and clinical experience. It represents the consensus of a Canadian panel comprised of multidisciplinary experts on this topic with a mandate to formulate disease-specific recommendations. These recommendations are aimed to provide a reasonable and practical approach to care for specialists and allied health professionals obliged with the duty of bestowing optimal care to patients and families, and can be subject to change as scientific knowledge and technology advance and as practice patterns evolve. The statement is not intended to be a substitute for physicians using their individual judgement in managing clinical care in consultation with the patient, with appropriate regard to all the individual circumstances of the patient, diagnostic and treatment options available and available resources. Adherence to these recommendations will not necessarily produce successful outcomes in every case.

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internet-accessible RM data server, which authorized health care professionals can access at any time using standard web browser software. Evidence indicates it can accelerate identification of clinical events and potential device problems. RM raises important medico-legal issues concerning the protection of a patient's rights and the safeguarding of patient health information related to the collection, storage, and use of patient device information that must be addressed by follow-up centres. This position statement recommends that remote monitoring be available at all device follow-up clinics as an integral part of the standard of care of device patients and also provides helpful advice to centres for the proper design, implementation, and integration of a remote monitoring system into the clinic.

de télécommunication standard à un serveur de données de SD accessible par internet en mode protégé, auquel les professionnels de la santé peuvent avoir accès à tout moment en utilisant le logiciel de navigation standard. Les données scientifiques indiquent qu'il peut accélérer la détection d'événements cliniques et les problèmes de dispositif potentiels. La SD soulève des problèmes médicolégaux importants concernant la protection des droits du patient et la sauvegarde des renseignements sur la santé du patient liés à la cueillette, au stockage et à l'utilisation des informations du dispositif du patient qui doivent être traitées par les centres de suivi. Cet énoncé de position recommande que la SD soit disponible dans toutes les cliniques de suivi des dispositifs en tant que partie intégrante des normes de soins aux patients portant un dispositif et offre également des conseils utiles aux centres pour la conception, la mise en œuvre et l'intégration appropriées d'un système de SD à la clinique.

Canadian health care context but other readers might find some of the suggestions relevant to their situation.

CIEDs and Remote Monitoring

Most CIED manufacturers have developed RM systems specific to their own devices. There might be important differences in RM operation and features of which centres need to be cognizant, but the hardware components and principles of operation are similar. Patients receiving a CIED are given a small RM transmitter to take home and connect to their telephone line, preferably in the bedroom (units that communicate using mobile phone connections have also been introduced). The CIED sends information to the RM transmitter and it conveys the encrypted information by standard telecommunication protocol to a protected internet-accessible RM data server under the control of the CIED manufacturer. Presently, RM does not permit transmission of programmable setting changes from the DFC to the CIED; only the retrieval of data stored from the CIED. Any authorized health care team members may review the data from any location with internet access using standard internet web browser software. Thus, RM can be managed by DFC staff and represents an extended function of the DFC. Like any data obtained from in-clinic visits, RM data is useful in guiding patient management. Anonymized patient data might also be used by the manufacturer for retrospective analysis of trends, product reliability, and for the prediction of product advisories.

RM transmissions are of 3 types: (1) routine or pre-scheduled transmissions scheduled by the DFC staff to occur on a particular date, (2) CIED alert events, when CIED data are automatically transmitted when they fall outside a value range preprogrammed for the patient's CIED, and (3) patient-initiated transmissions. Routine and CIED alert transmissions are performed automatically by the RM system with minimal patient involvement. Patient-initiated transmissions are manually triggered when the patient suspects a CIED-related problem and require the patient perform several simple steps to start and complete the transmission. The RM system can be programmed to notify staff by sending a text, fax, e-mail, pager, or voicemail message if an alert event of predefined severity is received.

Scientific Evidence

A comprehensive literature search was performed on combined PubMed and Cochrane databases for the terms "remote monitoring" and "implantable defibrillator" or "pacemaker" or "cardiac implantable electronic device" published up to December 2011. The search identified 6 systematic reviews, 7 randomized controlled trials, and 19 reports for 16 cohort studies. Most recent available guideline statements on the management of implantable devices and, if available, on the use of remote device monitoring from the Canadian Cardiovascular Society, Heart Rhythm Society (HRS), and EHRA were also reviewed. Recommendations were developed using the **G**rading of **R**ecommendations **A**ssessment, **D**evelopment, and **E**valuation (GRADE) system after a critical evaluation of the literature and expert consensus.[4] The strength of each recommendation was categorized as "strong" or "weak (conditional)" and the quality of the evidence as "high," "moderate," "low," or "very low." The balance among desirable and undesirable consequences, values, and preferences were considered. These guidelines were externally reviewed by experts and modified, based on those reviews. All recommendations were unanimously approved.

Several early cohort studies, predominantly from single centres, examined the potential benefits of RM for CIEDs.[5-18] These studies reported that RM significantly reduced the time required for CIED interrogation with improved patient and clinician satisfaction. Three of these studies also suggested that RM might reduce the number of inappropriate shocks delivered to ICD patients through earlier identification of lead and/or CIED problems.[19-21] The largest cohort study found that RM allowed earlier detection of atrial fibrillation (AF) and ventricular arrhythmias.[8] Four cohort studies involving ICD patients with concomitant heart failure (HF) demonstrated the feasibility of RM to monitor CIED HF diagnostic characteristics (heart rate, heart rate variability, intrathoracic impedance), which informed therapeutic decision-making or predicted impending HF hospitalization.[22-25] All of these early studies were limited by insufficient follow-up duration and nonrandomized trial design.

In the PM population, there have been 2 published multicentre, randomized trials that compared RM vs traditional in-clinic follow-up.[26,27] Both showed an increase in adverse clinical event detection frequency and a reduction in response

time to those events with RM. Crossley et al. enrolled 875 patients; 382 had 1 or more clinical events. Most of these were nonsustained ventricular tachycardia or AF episodes longer than 48 hours. RM significantly increased detection of clinical events (two-thirds were detected by RM alone) with a reduction in time to detection (5.7 vs 7.7 months).[27] Halimi et al. found that RM significantly reduced the time of hospitalization after a PM implant.[26] That study followed patients an average of only 31 days yet demonstrated that RM significantly shortened medical reaction time for all adverse events by almost 5 days.

In the ICD population, there have been 5 published randomized trials comparing the efficacy of RM vs in-clinic assessment with regard to reduction of subsequent in-clinic visits and time to detection of clinical events.[28-32] In the largest multicentre trial, Crossley et al. followed 1997 ICD and/or CRT patients.[30] After an average follow-up of 15 months, RM significantly reduced time from clinical event to medical decision by more than 79% compared with in-clinic visits (4.6 vs 20 days; $P < 0.001$). The most common events were AF or fast ventricular rates (> 120 bpm). The number of clinic visits was reduced by 38% (3.9 vs 6.3). Total health care utilization was not significantly different between the 2 strategies but the hospitalization duration was shorter in the RM group (3.3 vs 4.0 days, $P = 0.002$). In another large study ($n = 1450$), Varma et al. demonstrated a 45% reduction in clinic visits by RM with significant reductions in the time from onset of atrial or ventricular arrhythmias to physician assessment over 15 months of follow-up.[32] Both of these studies showed no adverse safety events with RM, and both also failed to demonstrate a reduction in ICD therapy or morbidity/mortality using RM. Another smaller study showed no difference in clinic/hospital visits or patient quality of life with RM.[28]

Two additional randomized trials comparing RM monitoring with in-office follow-up have been performed and their preliminary data presented. The **Eva**luation of the "**Tel**e-follow-up" for the Follow-up of Implantable Defibrillators (EVATEL) study included 1501 patients from a variety of device manufacturers and found no difference in the primary end point (composite of death, hospitalization, inappropriate ICD therapy) but a significant reduction in inappropriate or ineffective ICD therapy (8.1% vs 5.5%, $P = 0.04$).[33] However, 7% of patients in that study crossed over from RM to in-clinic visits mainly because of telephone connection difficulties. The **E**ffectiveness and **C**ost **o**f ICD Follow-up **S**chedule With **T**elecardiology (ECOST) study involved 433 patients using a single manufacturer's device followed for up to 27 months. It, too, found that RM decreased inappropriate ICD shocks by 52% and hospitalizations by 72% and was noninferior to in-office follow-up in terms of major safety events including death.[34] Formal cost effectiveness analyses from these and other trials are pending.

RM offers other benefits that are difficult to study in a randomized trial but might be equally important from a patient and DFC perspective. Some centres that were early adopters of RM have reported improved device clinic efficiency by using RM. RM can be used during routine follow-up to identify the few patients with CIED issues that require in-clinic assessment while allowing most CIED patients without any CIED issues to be followed mainly by RM. Over the course of an average day, more assessments can be performed from RM transmissions than can occur from in-clinic visits because delays related to patient interaction are eliminated. This effectively increases the patient capacity of the DFC. RM transmission can be particularly useful when the response to a device advisory/recall mandates increased surveillance. The resulting increased volume of DFC visits can otherwise overwhelm an already overburdened clinic. RM also allows greater latitude in the decisions regarding explant and replacement of devices on advisory or those approaching end of service.

RM also has tangible benefits for patients. A number of countries, including Canada, have a population dispersed over a large area and DFCs tend to be concentrated in larger urban centres. This creates challenges for patients needing access to CIED-related care. RM can help decrease the inconvenience, patient expense, and risks associated with visiting the DFC and offers patients a sense of security, especially when a device advisory is involved. Some DFCs permit the patient to actively participate in his/her own care through patient-initiated unscheduled transmissions, and when allowed by the DFC, might contribute to psychological wellness.

In summary, available studies have consistently shown that RM reduces clinic visits and time to evaluation of clinical/arrhythmic events in PM and ICD populations without increasing adverse events. Recent trials have demonstrated a reduction in inappropriate ICD therapies and hospitalizations with RM. RM consistently reduces direct patient costs and transportation and waiting time that might partially account for increased patient satisfaction. Though these conclusions cannot be extrapolated to all patients subgroups, such as those with substantial physical or cognitive impairments, the evidence to date demonstrates that RM is efficacious and safe and offers substantive benefits to patients and DFC staff. This body of evidence served to inform the subsequent recommendations.

RECOMMENDATION

1. We recommend that DFCs integrate RM capability into their routine functions and include this service as part of the standard of care for CIED patients (Strong Recommendation, Moderate-Quality Evidence).

Values and preferences. The recommendation places great value on RMs ability to more quickly identify actionable CIED issues, reduce direct patient costs related to follow-up visits, and improve DFC workflow and efficiency. These benefits accrue without an increment in adverse events.

2. We recommend that RM should only be implemented in CIED patients who provide explicit consent after proper education about the nature of RM, its potential benefits and limitations, and how RM-transmitted information will be managed and used. The medico-legal implications of RM and the effect on patient privacy and confidentiality of personal health information should be included in such discussions (Strong Recommendation, Very Low-Quality Evidence).

Values and preferences. This recommendation places great value on the patient as an important stakeholder whose cooperation ensures the maximum benefit from RM.

Practical tip. RM transmission has important privacy and confidentiality implications for which the patients need to be informed.

RECOMMENDATION

3. We suggest that, in CIED patients in whom no device issues are identified, routine follow-up assessment during the maintenance phase should blend RM with in-clinic assessments beginning after the 3-month postimplant assessment, alternating assessments between in-clinic and RM transmissions in a 1:1 ratio (Conditional Recommendation, Low-Quality Evidence).

Values and preferences. This recommendation places great value on current CIED guideline recommendations concerning CIED follow-up assessment frequency and the need to integrate RM into, rather than superimpose RM on, the current assessment schedule. It also places value on patient convenience and DFC efficiency.

Practical tip. There is insufficient scientific evidence to support implementation of any single RM schedule across all centres. We encourages centres to take a flexible approach, tailor RM follow-up to the individual patient, and to recognize that the 1:1 ratio serves as a starting point.

RECOMMENDATION

4. We recommend that RM be used to supplement in-person monitoring of the patient and device in clinical circumstances that warrant more intensive surveillance of the CIED, and the evidence suggests that RM might be efficacious (Strong Recommendation, Low-Quality Evidence).

Values and preferences. This recommendation places value on the ability of RM to more frequently monitor CIED status and to quickly detect CIED system abnormalities with minimal negative effect on the patient.

5. We recommend that DFCs develop the infrastructure, resources, policies, and procedures to optimally support the RM program in a manner analogous to in-clinic assessment (Strong Recommendation, Very Low-Quality Evidence).

Values and preferences. The recommendation places value on the importance of careful planning and development of appropriate policies and procedures that reflect the values of the centre and the objectives of RM at the centre before initiating an RM program.

Practical tip. RM improves DFC efficiency but has associated costs that need to be recognized and supported by centres through the allocation of sufficient resources.

RECOMMENDATION

6. We recommend that health professionals responsible for interpretation of RM transmissions and subsequent patient management decisions have the same qualifications, training, and experience as those performing in-clinic assessments (Strong Recommendation, Low-Quality Evidence).

Values and preferences. This recommendation places great value on RM data being as important and clinically useful as CIED gathered during in-clinic visits and the knowledge and expertise required to deal with RM data.

7. We suggest that representatives of private industry involved in RM systems should provide support but should not have any direct involvement in RM-related patient care (Strong Recommendation, Very Low-Quality Evidence).

Values and preferences. Industry representatives are an important knowledge resource for DFC staff and have an important support role but this recommendation places great value on the autonomy of DFCs and the confidentiality of CIED data. Those responsible for CIED patient care must have the necessary training and experience, and be accountable for patient management decisions made.

Implementation Issues

Privacy and medicolegal issues

Traditionally, the medical information generated from CIED follow-up assessments at a DFC remain within the confines of the facility. RM changes the paradigm by gathering electronic data into a data repository that is remote from the health facility, yet readily accessed and shared with various health care providers involved in a patient's care or can be used for research or educational purposes. With accessibility, however, come challenges to maintaining the privacy of patient health information and potential issues related to liability and reimbursement for RM-related services. Like other patient health information, data collected by RM are regulated by federal and provincial legislation but the fact that RM servers might be located outside of this country adds a degree of complexity and privacy risk that need to be addressed by centres before proceeding with RM implementation. xCentres usually negotiate a formal RM service agreement with the RM vendor that addresses the responsibilities of all parties in maintaining patient confidentiality. Information contained in the RM service agreement should also be available to the patient.

Reimbursement

This review affirms that device follow-up care is a vital service that ensures patients derive maximum benefit from their CIED. RM extends the capacity of DFC to meet the needs of a growing burden of patients receiving CIED and has the capacity to achieve this more efficiently than in-clinic assessments. In light of the benefits of RM and because RM

improves access to specialized CIED-related care, RM needs to be supported through adequate reimbursement of RM-related medical services that are rendered while professional bodies establish guidelines for appropriate use.

Integrating remote monitoring into CIED follow-up assessments

The following discussion highlights important aspects of RM that DFC centres should address when developing an RM implementation strategy. The tables referred to in the following sections are intended as tools to aid in RM implementation and are available online at the Canadian Cardiovascular Society Web site (www.ccs.ca).

1. Patient selection, education, and consent. Many patients are potentially eligible to participate in, and benefit from, RM (Supplemental Table S1). Potential issues with language, familiarity with modern technology, or education level should not constitute a barrier to RM use. Even travel is not an impediment to RM but DFC policies must specifically address how transmissions during patient travel would be managed and these should be discussed with the patient. If RM is allowed during patient travel, patients must keep the DFC informed of their travel plans and how they can be contacted. RM modules necessitate either a landline connection or mobile telephone connection, so patients with access to neither would be unable to participate. Centres report that patients appear more satisfied with RM care if it is initiated early after CIED implant and those who have become accustomed to in-clinic visits are more resistant to the technology. Active patient participation in RM is only required for patient-initiated transmissions and would likely be difficult for patients who have major cognitive or physical impairment but they could still take part and benefit from routine scheduled or CIED-triggered RM. Finally, patients who are dependent on the DFC as their sole source of health care and physician contact require access to a local primary physician in their community before RM is implemented because RM is an adjunct and not a substitute for routine or emergency medical care.

RM requires patient cooperation and this is best elicited through proper patient education that culminates in explicit patient consent specifically for RM participation. Patient education needs to be a continuous process that does not end with patient consent. The educational components are numerous and complex. Centres should consider developing an educational package (paper brochures and other electronic media) that can be provided to the patient and family (Supplemental Table S2). Consistent and frequent repetition of information can reduce the potential for misunderstandings. Consenting patients are authorizing the transmission and storage of their medical information to CIED manufacturers, often outside the jurisdiction of Canada so it is vital to discuss the implications of this, along with a discussion of the rights and responsibilities of all parties involved. Another important goal of education is to establish patient expectations that are realistic about RM participation. Although RM makes CIED information immediately and easily accessible, patients should be informed about whether and when feedback about the results of their RM transmission might be expected. RM is not intended as an emergency service and does not replace all in-person medical assessments. Patients also need careful instruction and reminder tools for what actions to take should they develop serious symptoms or concerns about their CIED, regardless of whether they send an RM transmission. Patients also have responsibilities that include keeping the DFC informed of any changes in contact information, CIED status (for example, device removal at another centre), or responsible physician contact.

2. CIED follow-up assessment schedules. Canadian guidelines for CIED follow-up that were published in 2000 and 2002 reviewed the objectives, requirements, and components of device follow-up care.[1,2] The recommended follow-up CIED assessment visits were most frequent in the postimplant period and tapered to a maintenance routine follow-up interval for PM patients of once per year whereas, for ICD recipients, follow-up every 6 months was endorsed. However, these guidelines were developed prior to the introduction of RM, which is intended to supplement and not eliminate the need for all direct patient contact.

In the absence of new scientific evidence, no change in the pre-existing guidelines concerning follow-up frequency was made and the recommendations for RM transmission frequency were simply integrated into it (Supplemental Table S3). The panel recommended initiating RM transmissions after the 3-month postimplant visit, when the device has matured and device reprogramming is less likely, assuming there are no identified device issues. The first routinely scheduled RM transmission for PM would occur 12 months later (15 months postimplant) and subsequent assessments would alternate between RM transmissions and in-clinic assessments in a 1:1 ratio. For ICD patients, the first RM transmission would occur at 9 months postimplant and alternate with in-clinic visits every 6 months thereafter. CRT patients are more complex and might require more intensive in-clinic follow-up initially. Centres should implement RM only after the patient's clinical and CIED status have stabilized, after which, a follow-up schedule similar to that for ICD patients can be assumed.

It is recognized that some variability in CIED follow-up frequency exists among Canadian centres and that some DFC might wish to blend the RM to in-clinic visits in a ratio different from that suggested herein. The need for CIED reprogramming to optimize device function is another factor that will modulate RM and in-clinic visit scheduling. The recommendations contained in Supplemental Table S3 are intended as a guide, not a rigid prescription.

Every patient will likely require more intensive surveillance at some time during the life of the CIED (Supplemental Table S4). Typically, this occurs as the battery energy depletes and CIED recommended replacement time approaches. Device advisories, in which the manufacturer has identified a potential for premature CIED generator or lead failure represents another circumstance but the manufacturer must be able to identify a reliable indicator of CIED failure that can be followed by RM. The frequency and manner (RM vs in-clinic visits) of the accelerated assessments in these situations will necessarily depend on the particular circumstance and centre. In contrast, many CIED patients might have no identifiable device issues on repeated follow-up assessments and

might warrant a greater proportion of follow-up assessments be conducted by RM.

3. Development of an RM program. Development of an RM program should include consultation with a range of stakeholders that include the CIED manufacturer, DFC staff and associated physicians, and Risk Management and Information Technology experts at the centre. The perspectives of the patient and their circle of care teams (community physicians, nurse practitioners, specialists) must also be considered (Supplemental Table S5).

A centre first needs to understand the RM hardware and software requirements, features, and limitations of the RM system to be used. If a centre plans to implement RM for multiple manufacturers, it would be wise to start with 1 manufacturer and apply the lessons learned to subsequent implementations. A key step in developing an RM program involves mapping out the workflow involved in a hypothetical RM patient, beginning from the moment that the CIED patient candidate is identified to the final steps of processing of an RM transmission from that patient (Supplemental Table S6).

When the details of the RM system are known, the centre should identify the needs, challenges, and risks (such as staff education, privacy, security, workflow, staff roles and responsibilities) involved in RM and then develop policies and procedures that guide RM program management and support staff in the delivery of quality patient care using RM. Some important specific issues are highlighted below.

Roles and responsibilities of each staff member in an RM program. Personnel responsible for assessing the RM transmissions need to be identified. RM transmissions contain information identical to that obtained from an in-clinic visit. Therefore, the health care professionals reviewing RM transmissions must have the same training, qualifications, and experience as those who assess patients in the DFC. Other staff may be used to support the program but the actual interpretation and patient management must be left to health professionals qualified to manage CIED patients. For allied health professionals, policies must identify the nature of decisions that should and should not be made based on RM transmission information and such decisions should be included in the list of delegated responsibilities, where appropriate.

Management of RM transmissions. RM transmissions may be sent at any time but DFC might not have adequate resources to immediately review these transmissions. DFCs need to clearly define how RM will be managed during and outside of regular business hours (how frequently the RM server will be checked, whether and when patients may be notified of the results) and the circumstances, if any, under which RM transmission results will be communicated to the patient, their legal representative(s), or local physicians. If patient feedback is to occur, the DFC should define a minimum response time (time from transmission receipt to first attempted patient contact) and patients need to be informed. RM should not result in the patient losing contact with their DFC.

Access to RM data. RM facilitates ready access to data by a range of health care providers or teams virtually anywhere and at any time, provided an internet connection is available. In Ontario, centres involved in CIED care are identified as Type 1 (typically academic centres or those that implant and follow-up PM, ICD, and CRT devices), Type 2 (typically those implanting only PM), or Type 3 centres (CIED follow-up only centres). Type 2 and 3 centres are encouraged to establish linkages with a Type 1 centre to comanage challenging CIED issues. RM should facilitate strengthening of these linkages and make patient comanagement easier. Any linkages between centres that allow shared access to patient RM data must be clearly documented.

Local RM data repository. RM data resides on servers owned and managed by the manufacturer. There are disadvantages in relying solely on private industry to maintain patient health information. Centres need to consider the short-term and long-term goals of the DFC and should consider CIED data storage independent of the manufacturer. Database software for local storage of CIED data (both RM and in-clinic visits) is commercially available. If used, DFCs need to address data access, privacy, confidentiality, security, and information disclosure issues related to these local databases.

Medical documentation. Centres must be able to track all patient RM transmission activity. This ensures that scheduled patients who fail to RM transmit are identified and contacted. Similarly, nonscheduled RM transmissions need to be logged. Most RM software already provides this capability but it must be optimally utilized.

Quality assurance process. Centres must establish a quality assurance process to audit RM management performance on a regular basis. This exercise ensures that the DFC can identify what it does well and where it can improve performance. This is important also for maintaining patient confidence in RM.

Role of industry and industry representatives in the RM program. Manufacturers and their employee representatives are responsible for maintaining an RM system that is safe, accurate, and reliable. Some manufacturers also assume the role of delivering the RM transmitter directly to the patient but, whatever those responsibilities might be, they must be identified and agreed upon prospectively. Any limits to authorized access to their RM servers, limitations of the RM hardware, potential risks of the RM system, and steps to mitigate these risks should be described. To be clear, individuals employed by CIED manufacturers have an important role in staff education and technical support (especially troubleshooting) but they should refrain from direct involvement in patient decision-making or patient care.

Conclusion

Remote monitoring epitomizes the capabilities and benefits that technology brings to healthcare. It breaks down communications barriers and makes patient health information accessible virtually whenever and wherever it is needed. It is patient-centred in that the patient is able to stay within their community while maintaining access to specialized care offered by DFCs. This position statement affirms that RM is an integral part of the standard of medical care for CIED patients.

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Supplementary Material

To access the supplementary material accompanying this article, visit the online version of the *Canadian Journal of Cardiology* at www.onlinecjc.ca and at http://dx.doi.org/10.1016/j.cjca.2012.11.036.