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EXPERT REVIEWS

Remote monitoring of cardiovascular implanted electronic devices: a paradigm shift for the 21st century

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Traditional follow-up of cardiac implantable electronic devices involves the intermittent download of largely nonactionable data. Remote monitoring represents a paradigm shift from episodic office-based follow-up to continuous monitoring of device performance and patient and disease state. This lessens device clinical burden and may also lead to cost savings, although data on economic impact are only beginning to emerge. Remote monitoring technology has the potential to improve the outcomes through earlier detection of arrhythmias and compromised device integrity, and possibly predict heart failure hospitalizations through integration of heart failure diagnostics and hemodynamic monitors. Remote monitoring platforms are also huge databases of patients and devices, offering unprecedented opportunities to investigate real-world outcomes. Here, the current status of the field is described and future directions are predicted.

Keywords: cardiac resynchronization therapy • implantable cardioverter defibrillator • pacemaker • remote monitoring

When Michel Mirowski developed the first implantable cardioverter defibrillator (ICD) in 1980 [1], he would scarcely have imagined that 30 years later, millions of such devices implanted in patients all over the world would be transmitting data on device and patient status to physicians' offices via global networks. From technologically primitive transtelephonic monitoring (TTM) of pacemakers from the 1970s onwards, rapid evolution to automatic continuous remote monitoring sets the future standard of care [2].

Definition

Remote monitoring of cardiovascular implantable electronic devices (CIED) involves the transmission of data regarding the status of the device, patient variables gathered by the device and sometimes additional disease-related data collected by the patient or caregiver (blood pressure and weight), over a network from the patient's location via a central database to a hospital or physician's office. A distinction should be made between true remote monitoring involving the automated transmission of data at regular intervals, and remote interrogation, in which scheduled device interrogations are carried out by the patient in their home, and the data are transmitted. Remote programming of devices, while technically feasible with existing systems, has not yet been implemented.

A paradigm shift

Traditional follow-up of recipients of CIEDs involves an office visit during which the device is interrogated and reprogrammed if necessary. The frequency at which patients are followed-up is arbitrary, requiring adjustment according to individual need, but is typically every 6–12 months for pacemakers, and every 3–6 months for ICDs and cardiac resynchronization therapy (CRT) devices [3]. There are two problems with this episodic approach. First, with expanding indications for ICD and CRT therapy, this leads to an unsustainable burden on device clinics. Second, the majority of visits involve data collection without reprogramming or change in patient medications or investigations ('nonactionable'). More significantly, patient or device events (lead malfunction or tachyarrhythmia therapy) may remain undetected for a prolonged period between device interrogations.

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The safety and efficacy of remote monitoring to replace most routine office visits was demonstrated by the the TRUST trial [4]. In this multicenter study of the BIOTRONIK Home Monitoring® system (Biotronik AG, Berlin, Germany), 1339 recipients of single- or dual-chamber ICDs were randomized to Home Monitoring, with office visits at 3 and 15 months, or conventional care with office visits only. Overall, 85.8% of the 6-, 9- and 12-month follow-ups were performed remotely only. Given that following physicians were permitted to follow-Home Monitoring with in-person visits if desired, this may represent a minimum estimate of the potential for remote monitoring to reduce clinic burden. Reinforcing the concept that the vast majority of device follow-ups involve only data download without programming changes or other alterations to the patient's therapy, only 6.6% of the 3-monthly scheduled checks in TRUST were actionable [4]. These data from US practice were supported by a recent European study indicating that 78% of scheduled ICD follow-up clinic visits did not involve reprogramming, medication change or any other intervention – in other words, they purely involved purely data download from the ICD, and those data were non-actionable [5].

The potential for remote monitoring to allow near-real-time diagnosis and treatment of disease or device malfunction was also strikingly illustrated in TRUST. The time from event onset to physician evaluation for combined atrial fibrillation, ventricular tachycardia and ventricular fibrillation was 1 day in the Home Monitoring group versus 35.5 days in the conventional group [4]. The early detection of silent arrhythmic or device events can facilitate action and has the potential to positively affect patient outcomes. This early notification function of remote monitoring depends on reliable transmission pathways. Current systems use different proprietary technologies. In an early study (the PREFER trial), [6], remote follow-up using the wanded CareLink® platform (Medtronic Inc., Minneapolis, MN, USA) was compared with transtelephonic monitoring (TTM) of pacemakers. The median time to diagnosis of a clinically actionable arrhythmic event was 5.7 months in the remote arm versus 7.7 in the conventional (TTM with in-office follow-up) arm. A difference of this magnitude is not very useful for clinical purposes, and the comparator, TTM, is primarily useful for determining battery status. In a later trial (CONNECT) [7], utilizing a wireless CareLink system with automatic clinician alerts incorporated into ICDs, the time from event onset to a clinical decision being made improved substantially, but the median 4.6 days from event to decision in the remote monitoring group indicates residual inefficiencies in workflow, or perhaps reluctance on the physician's part to take action based on device-detected events. Of more concern, only 31% of alert messages were successfully triggered and transmitted [7]. This modest ability questions whether this system is sufficiently robust for follow-up, since the lack of face–face encounters mandates technology that can be relied on to provide reliable alert transmission when problems arise. This role may be filled by systems that are used in TRUST: Home Monitoring was associated with a transmission success rate of (i.e., the proportion of daily device transmission reaching the clinic) 91% [8].

Available platforms

Remote monitoring is currently available on five different platforms in Europe and four in the USA (Table 1). These vary in their technical specifications and other details, but share a common basic design. This involves transfer of data from the CIED to a transmitter unit, which then sends data over either a landline or global system for mobile communications (GSM) network to a central server. There, the data are formatted for display on a secure internet website, which can be accessed by the following physician or device specialist. The data available are comparable to those available in the office, and include comprehensive diagnostics, device performance and intracardiac electrograms. Clinicians can also be alerted via other means, such as e-mail, short message service or fax, for critical events.

Home Monitoring

BIOTRONIK pioneered automatic remote monitoring in the late 1990s and early 2000s with its Home Monitoring system. This is

Table 1. Technical aspects of currently available remote monitoring platforms.

	CareLink™ (Medtronic)	Home Monitoring™ (BIOTRONIK)	LATITUDE™ (Boston Scientific)	Merlin.net™ (St. Jude Medical)	SMARTVIEW™ (Sorin)
Compatible CIEDs	Pacemaker, ICD, CRT-D, CRT-P, ILR	Pacemaker, ICD, CRT-D and CRT-P	ICD, CRT-D	Pacemaker, ICD, CRT-D and CRT-P	ICD, CRT-D
Data transmission	Landline, GSM	Landline, GSM, GPRS	Landline	Landline, GSM, GPRS, 3G	Landline, GPRS
Frequency of follow-up	Daily monitoring, scheduled follow-up	Daily monitoring, daily follow-up	Daily monitoring, scheduled follow-up	Daily monitoring, scheduled follow-up	Daily monitoring, scheduled follow-up
Notification	Voice message, pager, SMS, e-mail, technician call, mobile device application	SMS, e-mail, fax	Fax, phone call, SMS, e-mail	SMS, e-mail, fax	SMS, e-mail, fax
Battery drain	Each transmission reduces service life by 0.7–1.8 days or 0.03–0.05%	Approximately 2% of battery power over device lifetime	Unknown	Approximately 3 months over a 9-year service life for pacemakers	Approximately 0.3–0.8 years over device lifetime

Availability of platforms, and some features, varies by country and device.
CIED: Cardiovascular implantable electronic devices; CRT-D: Cardiac resynchronization therapy-defibrillation; CRT-P: Cardiac resynchronization therapy-pacing; GPRS: General packet radio service; GSM: Global system for mobile communications; ICD: Implantable cardioverter defibrillator; ILR: Implantable loop recorder; SMS: Short messaging service.

available in all of its current pacemakers, ICDs and CRT devices. Wireless transmission from a miniature antenna in the device occurs daily to a receiver apparatus (CardioMessenger®), which is usually placed on the patient's bedside table, to enable transmission at night. The CardioMessenger can use either a landline or the GSM network to transmit these data to the central server, where they are processed and made available to the following physician or device specialist through a password-protected website. To date, Home Monitoring is the only system that allows daily device transmission independent of any patient or physician interaction with the system.

LATITUDE®

Boston Scientific's LATITUDE system incorporates wireless radiofrequency (RF) telemetry and is available on Boston Scientific's ICDs and cardiac resynchronization therapy-defibrillation (CRT-D) (but not cardiac resynchronization therapy-pacing [CRT-P]) devices, with pacemaker support planned in the future. The LATITUDE Communicator transmits via a landline only. Transmissions can be either automatic or manual (patient initiated). Additional blood pressure and weight scales can also transmit data to the Communicator, and hence to the physician's office, via this platform. The potential for early intervention in heart failure patients using this system is under investigation. The extensive data available from the LATITUDE platform are analyzed by a physician panel and have provided important insights into several clinical questions [9–11].

Merlin.net™

St. Jude Medical's platform also uses RF telemetry to communicate with the Merlin@home monitor, which transmits data over either a landline or GSM network. Automatic or manual transmissions are possible from current ICDs, CRT devices and newer pacemakers, and data from office visits can also be integrated into the system. The Merlin.net system includes a programmable feature that can call patients with prerecorded messages when transmissions have not been made, to encourage compliance and reduce the time spent by the device clinic following up missed transmissions. Alerts, including electrograms, are also available to read directly on several mobile devices.

CareLink®

Medtronic's CareLink system is the only platform to still utilize an inductive system where it is necessary for the patient at home to place a wand over the device, similar to a programmer in a face-to-face clinic visit, as well as wireless transmission for newer device series. Data are then transmitted from the CareLink monitor over a landline or GSM network to the central server. Medtronic pacemakers, antitachycardia devices and implantable loop recorders are compatible with this system. The disadvantage of an inductive system is that patient interaction, and therefore compliance, is necessary. It can, however, be used to download data from devices lacking wireless capability. Automatic RF transmissions for programmable alert conditions are available in newer ICDs and CRT-D devices, but were found to have suboptimal transmission success when tested in a clinical trial (CONNECT) [7]. Once triggered, an alert can only be reset during an in-office evaluation. In addition, frequent transmissions impose conspicuous battery drain [12].

Smartview™

Sorin is the latest entrant to the remote monitoring field. Their Smartview platform received the Conformité Europeene mark in May 2011, and is available in Europe but not currently in the USA. It is compatible with current-generation ICDs, and operates on either a landline or GSM network. Data are downloaded from the device automatically at night, and scheduled as well as on-demand interrogations are available. Following physicians can access portable document format reports online.

Emerging uses of remote monitoring: beyond device interrogation

While remote monitoring has the potential to replace much in-office device follow-up, other uses have the potential to offer improved, timely interventions to patients. Successful application to these purposes demand daily automatic transmission as tested in TRUST, rather than scheduled intermittent remote interrogation.

Device integrity

Analysis of the TRUST trial showed that ICD generator and lead malfunction, while rare, are underestimated by conventional in-office follow-up and are detected late. By contrast, these are detected rapidly in devices monitored remotely, enabling rapid clinical intervention [13]. Indicators of a device problem, such as lead impedance out of range, trigger alerts, which are transmitted to the following physician or device specialist, may avoid symptomatic presentation with, for instance, inappropriate therapy [14]. Detection of asymptomatic device failure is especially facilitated by platforms capable of automatic daily transmission.

Existing estimates of device failure rates in the population at large are based on conventional in-office follow-up and symptomatic presentation, and differing definitions of failure further cloud the picture [15]. Remote monitoring provides the opportunity for long-term surveillance of device performance in the population at large, which may lead to earlier identification of increased failure rates and more accurate definition of the magnitude of the problem.

Atrial fibrillation

Atrial fibrillation greatly increases the risk of stroke or systemic thromboembolism, which is common and often asymptomatic in CIED recipients, and can be detected by dual-chamber CIEDs. Early physician notification of this through remote monitoring permits appropriate anticoagulation, cardioversion and other management decisions [16,17]. Such action was taken a median of 148 days before the next scheduled in-office follow-up in a recent Italian study of 166 patients using the Home Monitoring system [17]. Computer modeling suggests that in patients monitored daily, with anticoagulation commenced on identification of atrial fibrillation, a reduction in stroke of 9–18% over 2 years is possible [18]. The ongoing IMPACT trial is a prospective, multicenter trial which will test the hypothesis that initiation and withdrawal of oral anticoagulant therapy guided by remote monitoring of atrial

intracardiac electrograms will improve clinical outcomes by reducing the combined rates of stroke, systemic embolism and major bleeding compared with conventional management in patients with a $CHADS_2$ score ≥1 [19].

Heart failure monitoring

Telemonitoring of heart failure patients, using a variety of devices, has recently been reviewed [20,21]. The term 'telemonitoring' is preferred when referring to devices that are designed purely to monitor patient status, as opposed to remote monitoring of CIEDs, which while developed primarily to assess device performance, may also incorporate patient status indicators.

Several physiological variables, which are measured easily by CIEDs, have been found to predict impending heart failure exacerbation. These include patient activity, mean heart rate, heart rate variability and arrhythmias [22,23]. Most manufacturers now include a suite of these measurements as part of the device interrogation, either in-office or remotely. With frequent remote monitoring, it should in theory be possible to detect impending decompensation and adjust therapy accordingly to avoid hospitalization. However, any single measurement or combination of measurements has not been specific enough to be useful. Medtronic ICDs and CRT devices measure the intrathoracic impedance, which should decrease if significant pulmonary congestion is present. This is reported as the OptiVol Fluid Index™, and can trigger an audible alert if it exceeds a prespecified threshold. However, intrathoracic impedance can be affected by other conditions, such as pericardial or pleural effusion, pneumonia and pocket hematoma, and it has low sensitivity and low positive-predictive value for predicting worsening heart failure [24]. In fact, in the recent DOT-HF trial, patients who had the audible alert turned on had a higher rate of heart failure hospitalization and office visits [25]. The use of the CareLink network to remotely follow a newer iteration of OptiVol to adjust therapy is being examined in the ongoing Phase IV OptiLink HF study [101]. Boston Scientific's LATITUDE platform includes optional blood pressure and weight sensors, data from which can be transmitted along with symptom status to the following heart failure specialist. The utility of this data was studied by the as-yet unpublished observational DECODE study [26]. These systems, while useful, have not been shown to impact patient outcomes, and may be more useful to trigger an unscheduled evaluation rather than to remotely guide therapy.

Remote monitoring may be an ideal technology to combine with implantable hemodynamic monitors, several of which are currently in development. The HeartPOD™ device (St. Jude Medical) is implanted through the interatrial septum and directly measures left atrial pressure. It is currently under evaluation in a Phase III trial [102]. It can be implanted as a stand-alone device, or integrated with a CRT or ICD device (Promote® left atrial pressure system). Several stand-alone hemodynamic monitors are also in development, which use various telemonitoring systems to communicate with the patient and physician.

Data fidelity & security

Of the currently available proprietary remote monitoring systems, published data on transmission characteristics are available for the Home Monitoring and CareLink networks [2,7,8]. These show variable rates of successful data transmission, as discussed earlier. A mobile communicator that transmits on the GSM network is a clear advantage when a patient travels. Currently, international GSM access varies greatly by manufacturer and location. Interference from sources of electromagnetic interference, such as mobile phones, has not been reported [27]. With inductive systems, most missing transmissions are as a result of the patient missing a transmission, or of the communicator not being plugged into the phone line or otherwise incorrectly set up [7].

Of more concern is data security. While we are not aware of any reports of actual data loss to theft or hacking, the potential for this exists, despite encrypted transmission and password-protected internet platforms. While one group effected programming changes in a Medtronic Maximo® DR ICD under laboratory conditions, this would be difficult to replicate in the real world without the patient's knowledge [28].

Workflow

Remote monitoring appears to be a solution to the ever-increasing burden of follow-up encountered by device clinics worldwide. However, the reality may be more complex, and may depend on the system used and the healthcare infrastructure within which it is applied. Even though remote monitoring reduces in-office follow-up, data transmitted do require review by the following physician or device specialist [4–7]. It is intuitive that this is accomplished more rapidly; however, conclusive data on the overall effect on workflow are lacking. With the development of automated pace capture threshold determination by many devices, remote transmissions deliver almost exactly the same data that are seen during an office interrogation. Remote programming is not currently implemented; therefore, direct comparison with office follow-up, which does permit programming changes, is not possible. Certainly, review of a nonactionable remote transmission is faster than a similar interrogation in-office. A European survey found that scheduled visits lasted 27 min [29], compared with a mean of 11.5 min for scheduled or unscheduled remote transmissions at our institution [30]. Our data also suggest that while review of remote monitoring transmissions can be rapidly performed, telephone contact with patients to schedule office follow-up, and especially to troubleshoot and encourage compliance among patients from whom transmissions have not been received, is time-consuming [30]. It is possible that mechanisms for feedback via the communicator to patients to encourage compliance would be useful to ameliorate this limitation.

It is crucial to have a clear and efficient system in position to triage and act upon the large amount of information transmitted from CIEDs. At the Cleveland Clinic (OH, USA), a trained device nurse is rostered to review all four remote monitoring platforms each day for scheduled and unscheduled transmissions. Issues requiring the physician's attention are directed to the patient's attending electrophysiologist. This removes any uncertainty regarding whether action has been taken on a particular issue, as the remote monitoring websites can only record whether a transmission has been reviewed, but not by whom or whether the issue has been resolved. Platforms

include the option to personalize alerts for each patient, and this should be used to tailor the data presented to the most useful for each individual patient.

An issue that frequently limits the utility of remote monitoring in our experience is patient compliance. For example, Movsowitz *et al.* cite data from Medtronic showing that out of 265,024 patients implanted with a wireless device, only 66% had been enrolled in the CareLink system, 25% of these had never made a transmission and only 5.2% had completed the scheduled quarterly transmissions [31].

Patient acceptance & satisfaction

One factor that might decrease patient compliance with remote monitoring is satisfaction. Although it has been assumed that patients would appreciate the convenience of remote follow-up, this has been questioned and might not be the case in all cultures, patient populations or at all times post-CIED implant [32]. In a pilot study of remote monitoring using the CareLink system versus standard in-office follow-up in patients implanted for a mean of 1.5 years at enrollment, health-related quality of life and patient satisfaction measures were worse at 6 months but the difference had disappeared by 12 months [33]. It is possible that personal contact is important to satisfaction shortly after CIED implant, and declines thereafter. However, the vast majority of the evidence available to date indicates a high level of patient satisfaction with remote monitoring. Overall, 98% of the patients in the remote monitoring arm in TRUST elected to continue this mode of follow-up after completion of the trial [34]. Other studies reporting patient satisfaction in diverse populations with CareLink [35–38], Home Monitoring [39] and Housecall II (the forerunner of Merlin.net) [40] are universally positive, though each has used different methodologies. Physician satisfaction has also been high, where assessed [35–38].

Economic impact & cost–effectiveness

Cost–effectiveness studies on remote monitoring are few. Unique healthcare system organization, costs, reimbursement rates and populations mean that generalization from one country to another may be inaccurate. Studies from France [41] and Finland [37] estimate savings of US$2149 over a projected 5-year lifetime of an ICD, and €524 over 9 months, respectively. However, a US pilot study using the CareLink system, which randomized 151 patients to remote monitoring or quarterly in-office interrogations, did not show any reduction in unscheduled hospital visits or costs [33]. Indeed, the remote monitoring strategy was slightly more expensive. The much larger CONNECT trial examined healthcare utilization as a secondary end point. While there were no differences in mortality, emergency room visits, hospitalizations or unscheduled clinic visits between the arms, length of stay was shorter in remotely followed patients who were hospitalized during the study. This led to an estimated US$1793 reduction in cost per hospitalization [7]. Remote monitoring involves an initial outlay for the transmitter and installation, and due to the earlier and more frequent detection of device problems and patient deterioration, it has the potential to increase in-person evaluations, medications and interventions in the short term [4,6,7,13,14,16]. While this should logically be offset by improved patient outcomes and reduced costs over the longer-term, this remains to be demonstrated in practice. The economic analyses of the recently completed EVATEL and ECOST trials from France should provide further information on cost–effectiveness [103,104]. Multinational data on healthcare economic aspects of remote monitoring will also be provided by the ongoing EuroEco trial (Table 2) [105]. Ultimately, analyses specific to each health system are needed to accurately gauge the cost–effectiveness of remote monitoring. The complex economic implications of remote monitoring have been reviewed in depth by Burri *et al.* [42], and the current state of reimbursement across Europe for both in-person and remote follow-up of CIEDs by Boriani *et al.* [43].

Reimbursement contributes to cost, but can also either drive or inhibit implementation of remote monitoring. While reimbursement is established in the USA, it is available in only a few countries in Europe, such as the UK, Germany and Portugal, where it is similar to that offered for standard follow-up visits. Proof of cost–effectiveness, as discussed above, may be required before reimbursement for remote monitoring is universally implemented.

Research

Remote monitoring platforms can be viewed as vast databases of device characteristics, programming, therapies, and patient data including physiologic and disease state. As such, they are a treasure trove for researchers seeking 'real-world' outcome data. In the USA, the ALTITUDE study group coordinates research into relevant clinical questions using the LATITUDE database. Survival is determined from the Social Security Death Index, and device electrograms are adjudicated by an expert panel, with good interobserver agreement [44]. The striking finding of the ALTITUDE survival study was that remote monitoring was associated with a 50% relative reduction in the risk of death (ICD hazard ratio: 0.56; CRT-D hazard ratio: 0.45; $p < 0.0001$) versus office follow-up only [9]. Whether this is due to improved surveillance of clinical status, improved compliance or subtle differences between remotely and conventionally monitored patients (confounding) remains to be elucidated. It is difficult to imagine a randomized clinical trial being large enough, or with long enough follow-up, to detect findings such as this. The ALTITUDE group has also provided insights into the effect of programming on appropriate and inappropriate shocks, the influence of percentage biventricular pacing on outcome and several other issues [10,11].

Remote monitoring also provides a more convenient and efficient method of following patients enrolled in clinical trials of CIEDs, as seen in the DAVID II trial [45]. Patients may be more likely to enroll in studies if some follow-up can be performed remotely, lessening the burden of office follow-up visits.

Guidelines

While specific professional society guidelines do not exist for remote monitoring, the topic is covered by the 2008 Heart Rhythm Society/European Heart Rhythm Association expert consensus on the monitoring of CIEDs [3]. These are necessarily consensus-rather than evidence-driven, and were written before the publication of TRUST or CONNECT. Remote interrogation

Table 2. Ongoing studies of remote monitoring registered on ClinicalTrials.gov† as of January 2012.

Study	NCT identifier	Sponsor	Design	Outcomes	Locations	Status
Evaluation of an Organizational Model for Remote Monitoring of Pacemaker and Implantable Cardioverter Defibrillator Recipients	NCT01459874	San Filippo Neri General Hospital	Observational	Utility of the organizational model	Italy	Ongoing
REMOTE-IPG	NCT00631709	Medtronic	Observational	Quality, satisfaction, costs	Canada	Completed February 2010
Investigation on Routine Follow-up in Congestive Heart Failure Patients with Remotely Monitored ICD SysTems (InContact)	NCT01200381	St. Jude Medical	Randomized – in clinic versus remote follow-ups	Heart failure clinical composite response	Germany	Recruiting
Clinical Evaluation of Remote Monitoring with Direct Alerts to Reduce Time from Event to Clinical Decision (REACT)	NCT01090349	St. Jude Medical	Randomized – alerts on versus alerts off	Time from detection of event to clinical decision	Germany and UK	Ongoing
Observational Study of Patient Comprehension, Perception, Fears and Appreciation Following Home-Monitoring Implementation (Educ@t)	NCT01006746	BIOTRONIK France	Observational	Qualitative measures	France	Ongoing
Treatment Satisfaction in Implantable Cardioverter Defibrillator Recipients (SAN REMO 2)	NCT01230073	Deutsches Herzzentrum Muenchen	Randomized, parallel assignment, open label – remote monitoring versus conventional follow-up	Patient satisfaction	Germany	Not yet recruiting
Benefits of Implantable Cardioverter Defibrillator Follow-up using Remote Monitoring (ECOST)	NCT00989417	BIOTRONIK SE & Co. KG	Randomized, parallel assignment, open label	Adverse events	France	Preliminary results presented at ESC 2011
Evaluate the Benefits of Pacemaker Follow-Up with Home Monitoring (COMPAS)	NCT00989326	BIOTRONIK France	Randomized, parallel assignment, open label	Adverse events	France	Preliminary results presented at Cardiostim 2010
Home Monitoring in ICD Patients (Monitor-ICD)	NCT00787683	Charité University, Berlin,	Randomized, parallel assignment, open label	Costs	Germany	Recruiting
TRIAGE-CRT Telemonitoring in Patients With CHF and Indication of CRT-D	NCT00395642	BIOTRONIK	Nonrandomized, single-arm, multicenter feasibility study	Patient compliance	USA	Completed January 2008
EuroEco	NCT00776087	BIOTRONIK	Randomized, parallel assignment, open label	Costs	Europe	Ongoing
Health Economic Evaluation of Remote Follow Follow-up for ICD Patients (TARIFF)	NCT01075516	St. Jude Medical	Observational	Costs	Italy	Recruiting
Strategy of Early Detection and Active Management of Supraventricular Arrhythmia with Telecardiology (SETAM)	NCT01108692	BIOTRONIK	Randomized, parallel assignment, single blind	Time to clinical decision (antithrombotic and/or antiarrhythmic drugs)	France	Recruiting

†All trials available at [106].
ECOST: Effectiveness and Cost of ICD Follow-up Schedule with Telecardiology; EuroEco: European Health Economic Trial on Home Monitoring in ICD Therapy; EVATEL: Evaluation Telecardiologies; ICD: Implanted cardioverter defibrillator; MORE-CARE: Monitoring Resynchronization Devices and Cardiac Patients; RAPID-RF: Remote Active Monitoring in Patients with Heart Failure; REMOTE-IPG: Remote monitoring transmission evaluation of implantable pulse generators; TRIAGE-CRT: Telemonitoring in Patients with CHF and Indication of CRT-D.

Table 2. Ongoing studies of remote monitoring registered on ClinicalTrials.gov† as of January 2012 (cont.).

Study	NCT identifier	Sponsor	Design	Outcomes	Locations	Status
MORE-CARE	NCT00885677	Medtronic	Randomized, parallel assignment, open label	Time to clinical decision, morbidity/ mortality, and healthcare utilization	Europe and Israel	Recruiting
RAPID-RF	NCT00334451	Boston Scientific	Observational registry	Alert notifications and resulting medical interventions	USA	Completed
Evolution of Management Strategies of Heart Failure Patients with Implantable Defibrillators (EVOLVO)	NCT00873899	Regione Lombardia	Observational	Cardiac or device-related clinic visits	Italy	Recruiting
Care Link Evaluation	NCT01023022	Medtronic	Observational	Patient and clinician satisfaction, costs	Poland	Recruiting
Evaluation of the 'Tele-follow-up' for the Follow-up of Implantable Defibrillators (EVATEL)	NCT00598026	Rennes University Hospital	Randomized, parallel assignment, open label	Noninferiority of remote monitoring with respect to safety	France	Preliminary results presented at the European Society of Cardiology 2011
Cardiac Rhythm Monitoring after Acute Decompensation for Heart Failure (CARRYING ON)	NCT01216670	Medtronic	Post-market, open-label, pilot trial of the Reveal XT™ implantable loop recorder	Clinical and arrhythmic events in patients with low ejection fraction	Italy	Recruiting
Comparison between Remote Patient Management and Standard Care in CRT-D and ICD-patients to Assess the Impact on Hospital Length of Stay because of Heart Failure (ConnectOptiVol)	NCT00730548	Medtronic	Randomized, parallel assignment, open label	Length of hospital stay – OptiVol® with remote monitoring versus standard care	Germany	Recruiting
Psychosomatic Effects of Implantable Cardioverter Defibrillator with Home Monitoring Function (QUANTUM)	NCT00325221	BIOTRONIK	Randomized, parallel assignment, open label	Hospital Anxiety and Depression Scale anxiety score	Germany, Austria and Switzerland	Ongoing
The IMPACT of BIOTRONIK Home Monitoring Guided Anticoagulation on Stroke Risk in Patients with Implanted ICD and CRT-D Devices	NCT00559988	BIOTRONIK	Randomized, parallel assignment	Stroke, systemic embolism and major bleeding	North America, Europe and Australia	Recruiting

†All trials available at [106].
ECOST: Effectiveness and Cost of ICD Follow-up Schedule with Telecardiology; EuroEco: European Health Economic Trial on Home Monitoring in ICD Therapy; EVATEL: Evaluation Telecardiologies; ICD: Implanted cardioverter defibrillator; MORE-CARE: Monitoring Resynchronization Devices and Cardiac Patients; RAPID-RF: Remote Active Monitoring in Patients with Heart Failure; REMOTE-IPG: Remote monitoring transmission evaluation of implantable pulse generators; TRIAGE-CRT: Telemonitoring in Patients with CHF and Indication of CRT-D.

rather than remote monitoring was the objective of discussion. These guidelines recommend that remote monitoring can replace office follow-up in patients whose condition is stable and device reprogramming is not required. In-office visits are still recommended for the immediate post-implant assessment and early surveillance period (4–12 weeks post-implant), and once yearly thereafter. As remote monitoring does not provide an opportunity to take a cardiovascular history or to examine the patient or the wound, these in-office visits are essential to monitor the patient, educate the patient about their device, and assess wound healing.

Expert commentary

Remote monitoring represents a paradigm shift in the follow-up of CIEDs. Intermittent data download, which may miss significant events and uncover others several months after they have occurred, can now be replaced with near-real-time monitoring of device function and patient status. This has significant potential for monitoring both atrial and ventricular arrhythmia occurrence, surveillance for generator and lead integrity, and heart failure status. Although remote monitoring has the potential to improve the device clinic workflow and efficiency, and is probably cost saving, these variables are healthcare system specific and it is difficult to extrapolate from an experience in one area to all others. Lack of reimbursement for remote device follow-up is currently inhibiting the expansion of this technology in several areas of the world. Further economic analyses will be necessary to clarify the economic impact of remote follow-up of CIEDs and provide the stimulus for reimbursement and widespread, worldwide adoption. Remote monitoring networks provide unparalleled opportunities for 'real-world' outcomes research regarding patients with CIEDs. Perhaps most intriguingly, remote monitoring of patients with ICDs and CRT-D devices was associated with a 50% reduction in mortality in a large unselected population [9].

Five-year view

Remote monitoring will become the usual method of follow-up for patients with CIEDs in most health systems. Manufacturers will move towards automatic transmission without the need for patient interaction with the system to simplify the interrogation, and improve information flow and compliance. Cellular transmission will also be favored over landline-based communicators given the declining use of landlines and to allow portability. Remote programming, probably in a simple form, will become available for clinical use. However, complex programming changes will still require in-person consultation, as will early post-implant and annual visits. Analysis of remote monitoring databases will continue to provide novel insights into outcomes of patients with CIEDs that would not be possible with conventional research methodology.

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Key issues

- Remote monitoring is the transmission of cardiac implantable electronic device performance and patient data over a network from the patient's home to their physician's office. Data transfer can be automated or manual.
- This represents a paradigm shift from episodic in-office device interrogation, which largely consists of analysis of nonactionable data and may miss important clinical or device issues.
- Advantages include earlier detection of patient events such as arrhythmia onset and device therapy, programming issues such as therapies programmed off, and device integrity problems such as lead fracture.
- Remote monitoring platforms are marketed by all the major cardiac electronic implantable device manufacturers, including Medtronic (CareLink®), St. Jude (Merlin.net™), Boston Scientific (LATITUDE®), BIOTRONIK (Home Monitoring®) and Sorin (SMARTVIEW™).
- The effect on workflow is complex but probably results in significant time and cost savings, depending on the healthcare system and platforms available.
- Remote monitoring is associated with patient and physician satisfaction. Data security appears to be robust. However, technical performance is not uniform across different proprietary technologies.
- Although limited available data suggest cost savings, large-scale economic analyses are needed to confirm this before widespread acceptance and reimbursement is implemented.
- Remote monitoring platforms provide an unparalleled dataset of real-world patients, which can be utilized to assess outcomes and improve practice.
- In a large unselected population with implantable cardioverter defibrillators and cardiac resynchronization therapy defibrillation devices, remote monitoring was associated with significantly improved survival.

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