

## Novel devices

# Telemedicine and cardiac implants: what is the benefit?

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Cardiac implantable electronic devices are increasing in prevalence. The post-implant follow-up is important for monitoring both device function and patient condition. However, practice is inconsistent. For example, ICD follow-up schedules vary from 3 monthly to yearly according to facility and physician preference and availability of resources. Recommended follow-up schedules impose significant burden. Importantly, no surveillance occurs between follow-up visits. In contrast, implantable devices with automatic remote monitoring capability provide a means for performing constant surveillance, with the ability to identify salient problems rapidly. Remote home monitoring reduces the volume of device clinic visits and provides early detection of patient and/or system problems.

### Keywords

Cardiac implantable electronic devices • ICD • Remote monitoring • Follow-up • Recall management • Early detection • Atrial fibrillation

## Introduction

The implantation of cardiac electronic devices has increased substantially over the last decade in response to widening indications (an estimated half a million units were implanted in Europe in 2009 alone).<sup>1</sup> Subsequent monitoring is an integral part of both device and patient care. This ongoing responsibility, stated by professional societies, has, until recently, been unguided by any prospectively derived data.<sup>2</sup> Traditional practice has followed an in-clinic follow-up protocol by physicians and/or device specialists to retrieve stored diagnostic data. For ICDs and cardiac resynchronization therapy (CRT) devices, this is performed at short intervals due to safety concerns, e.g. every 3–6 months. This schedule generated over 3 million device encounters occurred in the USA alone in 2007. These routine evaluations impose a significant clinical workload, which episodically increases further when devices approach ERI, or in response to product advisories and recalls.<sup>3,4</sup>

Additional challenges are ability for early problem detection, management of unscheduled encounters, and management of data downloaded from increasingly complex devices. Recently developed remote patient monitoring (RM) technologies may provide mechanism(s) for facilitating these tasks.<sup>1</sup> Remote patient

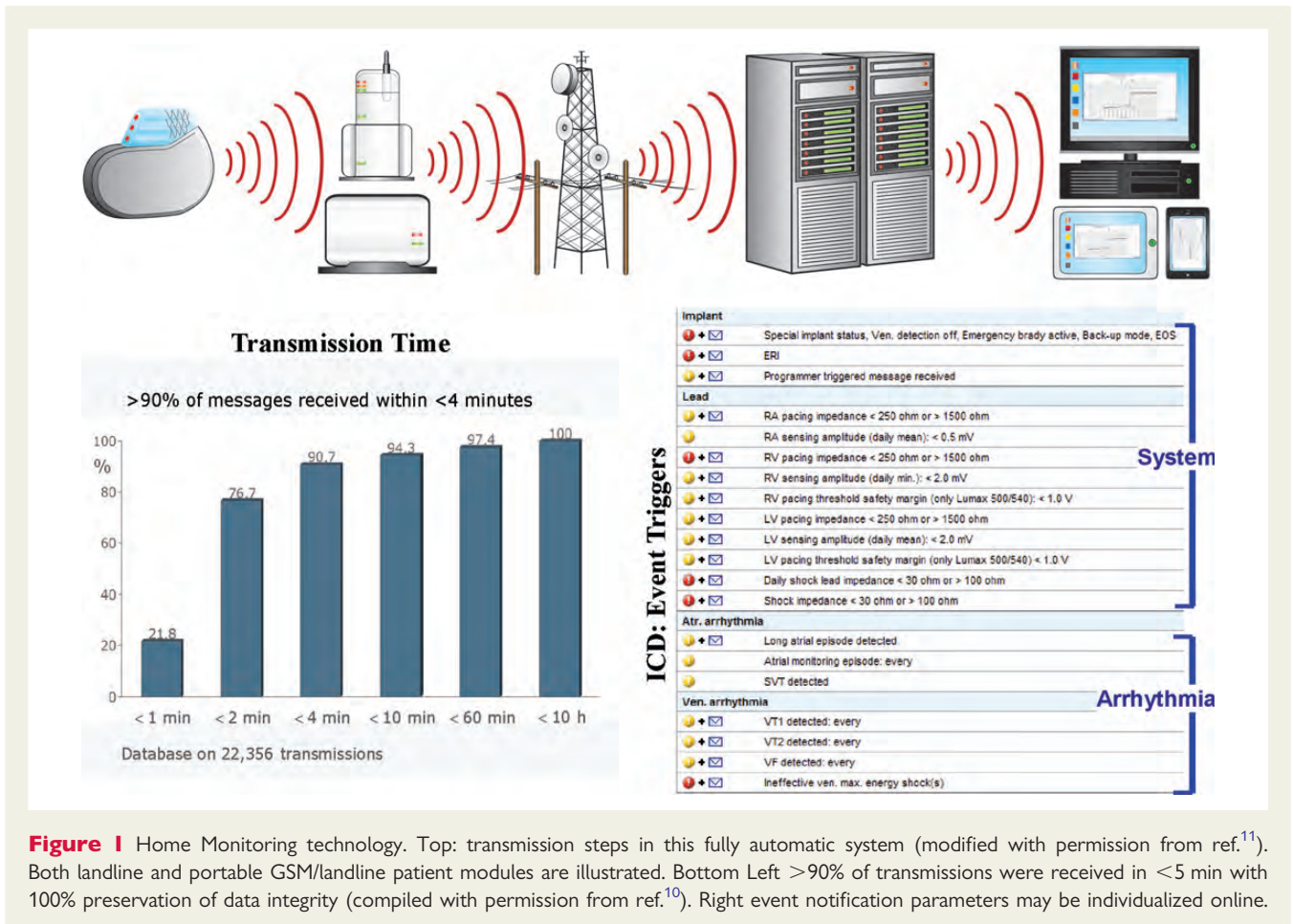
monitoring involves the transmission of data regarding the status of the device, patient variables gathered by the device, and sometimes disease-related data, over a network from the patient's location via a central database to a hospital or physician's office (Figure 1). A distinction is beginning to emerge between *remote interrogation* (i.e. scheduled device interrogations performed by the patient at home) and true *remote monitoring* involving the automated transmission of data at regular intervals with prompt alert notifications as needed.

Remote technologies available operate differently. Wand-based ('inductive') systems, which have existed for several decades, require patient-driven downloads relayed via telephone connections to following facilities.<sup>5,6</sup> This time-consuming process may be cumbersome to use, challenge compliance, and remains vulnerable to overlooking asymptomatic events. This form of calendar-based remote interrogation essentially substitutes for conventional in-person evaluation and is likely to yield similar data transfer and problem discovery rates. Thus, when used to follow-up a pacemaker population, clinically actionable events took several months for discovery and only 66% of events were detected during remote transmission.<sup>7</sup> These limitations were coupled with a failure to reduce cardiac-related resource utilization.<sup>8</sup>

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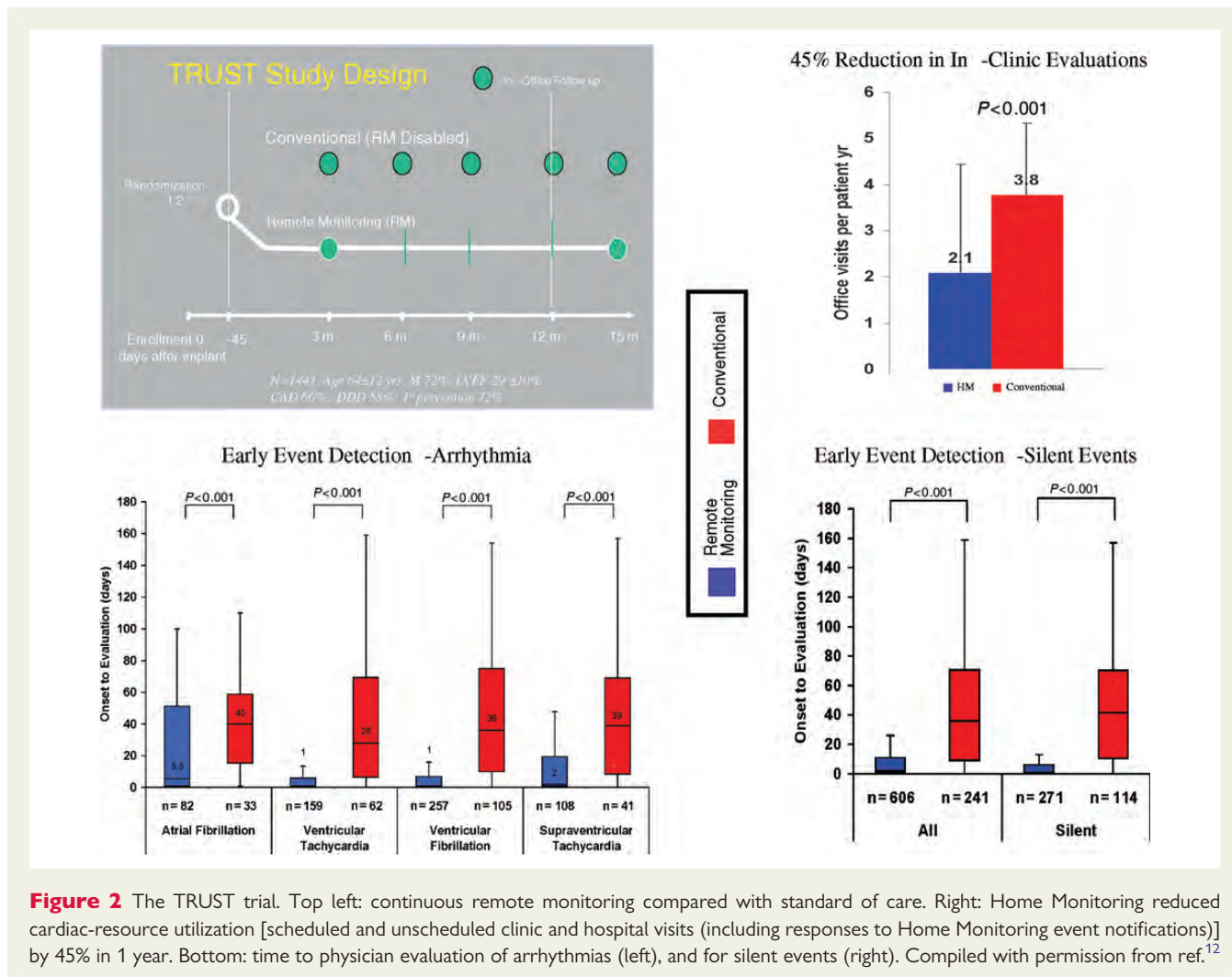


**Figure 1** Home Monitoring technology. Top: transmission steps in this fully automatic system (modified with permission from ref.<sup>11</sup>). Both landline and portable GSM/landline patient modules are illustrated. Bottom Left >90% of transmissions were received in <5 min with 100% preservation of data integrity (compiled with permission from ref.<sup>10</sup>). Right event notification parameters may be individualized online.

Considerable time is spent to patient coordination for scheduled appointments.<sup>9</sup> This form of RM is being rapidly superseded by automatic transmission mechanisms that are fully independent of patient or physician interaction. This form of technology was pioneered by Biotronik [Home Monitoring (HM): FDA approved 2002]. An implanted device initiates transmissions daily, with additional alerts for pre-specified out of range parameters, using cellular or landline communication. These data are available for website review. Reliability and early notification ability of this communication system were excellent<sup>10</sup> (Figure 1). Other manufacturers have followed but each system is proprietary and all at different stages of development.

The ability for automatic remote monitoring to supplant 'routine' in-clinic evaluations with remote checks and also to maintain continuous surveillance with early event detection was tested first in the TRUST prospective multicentre clinical study using HM.<sup>11,12</sup> Notably, the control arm of this trial provided the first data for 'standard of care', i.e. routine 3 monthly in-clinic follow-up (Figure 2). The results demonstrated that remote patient management reduced health care utilization by ~50% when inclusive of one compulsory in clinic check per year. This was measured by the sum of all quarterly scheduled as well as unscheduled (emergency room visits, patient- or physician-initiated) hospital evaluations that occurred. The reduction resulted predominantly from the reduction in scheduled encounters, the bulk of which involve collection of routine measurements only (e.g. battery status, lead

impedance, and sensing function) requiring no clinical intervention (e.g. reprogramming, alteration of antiarrhythmic medications) and could be performed by on-line data review. This may represent a minimum estimate of the potential for remote monitoring to reduce hospital-based evaluations given that following physicians were permitted to follow HM checks with in-person visits if desired. The follow-up CONNECT study using a different technology endorsed TRUST results.<sup>13</sup> These US data were supported by recent European studies indicating that 78% of scheduled ICD follow-up clinic visits were 'non-actionable', i.e. could be effectively performed remotely<sup>14</sup> to reduce routine hospital follow-up.<sup>15</sup> Furthermore, TRUST noted that the use of remote monitoring secured greater follow-up adherence to 3 monthly calendar-based checks. This is presumably because patient data may be monitored remotely anytime and from anywhere, as opposed to in the conventional arm, which relies on patients to present themselves physically in their physician's office. Thus, RM maintains better continuity of patient follow-up. Transmission reliability (>90% of daily transmissions successfully completed) permitted punctual completion of >99% of scheduled remote-only checks and also facilitated management of unscheduled encounters provoked by symptoms.<sup>16</sup> For example, an appropriate or phantom ICD shock could be managed simply with a reassuring telephone conversation. However, in-person evaluation was recommended if physician and/or patient expressed any reservation regarding

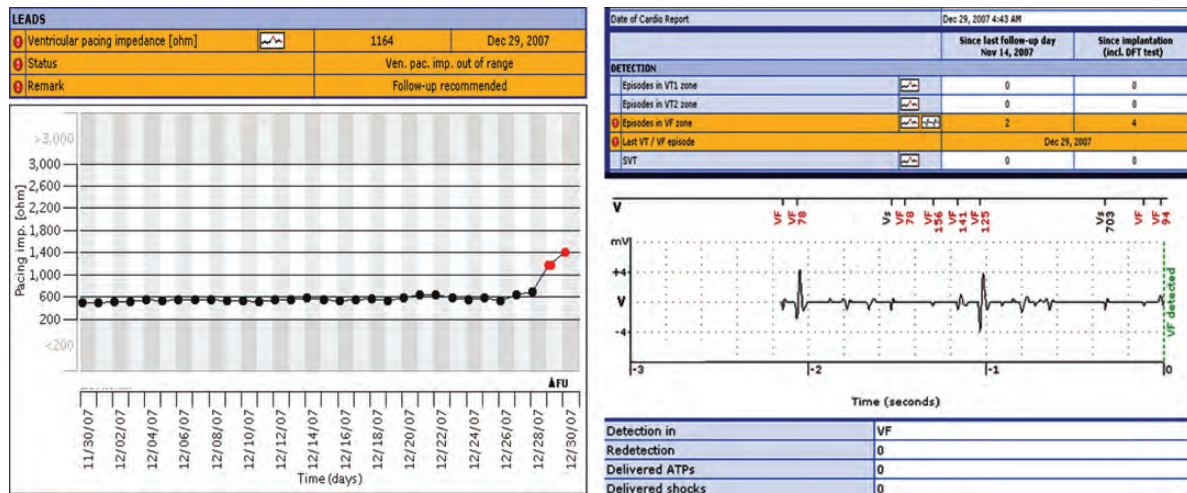


**Figure 2** The TRUST trial. Top left: continuous remote monitoring compared with standard of care. Right: Home Monitoring reduced cardiac-resource utilization [scheduled and unscheduled clinic and hospital visits (including responses to Home Monitoring event notifications)] by 45% in 1 year. Bottom: time to physician evaluation of arrhythmias (left), and for silent events (right). Compiled with permission from ref.<sup>12</sup>

reconciliation of stated symptoms with remotely acquired data. Importantly, the overall reduction in face to face visits in TRUST was accomplished safely, since there was no difference between the two study arms in death, incidence of strokes, and events requiring surgical interventions (e.g. device explants or lead revision). This safety profile was maintained in patients with NYHA Class III/IV, i.e. lack of scheduled in-clinic device evaluation during remote monitoring did not predispose to risk in sicker patients. The second critical finding was early detection capability. In conventional care, this occurred at in-office interrogation (scheduled or unscheduled). In contrast, evaluation in HM occurred on receipt of event notifications in response to detection of pre-programmed events or in-office interrogation (scheduled or unscheduled). Diagnostic ability may be aided by wirelessly transmitted electrograms (RIONI).<sup>17</sup> TRUST results demonstrated that HM enhanced problem discovery despite less frequent hospital evaluations. Median time from onset to physician evaluation of was 1 day, dramatically less than the value in conventional care of 35.5 days. Clinically silent events were detected equally effectively (Figure 2).

TRUST results indicated that aims of monitoring were fulfilled more effectively with HM than traditional calendar-based face to face encounters. The recent COMPAS trial using HM indicated

similar value for patients receiving pacemakers.<sup>18</sup> Certain caveats need to be considered. Remote care does not supplant the important in-person follow-up in 2–12 weeks post-implant<sup>19</sup> which permits assessment of wound healing, determination of chronic thresholds, and setting of final pacing parameters.<sup>20,21</sup> Lead problems requiring revision and symptomatic reactions to implantation (e.g. pacemaker syndrome, diaphragmatic pacing, and pocket infection) cluster in this early post-implant period.<sup>20–22</sup> The 3-month encounter also provides an opportunity for patient (and/or the patient’s family’s) education regarding continuation of post-implant follow-up and gaining familiarity with RM. During subsequent remote follow-up, patients may receive notification via the receiver (call-back function, third-party arrhythmia service, or live interaction) which may be reassuring. However, remote reprogramming of devices, although technically feasible, remains unavailable due to safety and security concerns. Hence, actionable events, even if straightforward and easily resolved with simple reprogramming, require in-person assessment. At the other end of service life, conventional monitoring demand increased scheduled visits, e.g. for generators approaching ERI. With RM, affected devices can self-declare an issue rapidly, avoiding non-actionable clinics encounters. Notably, lack of face to face encounters mandates



**Figure 3** Home Monitoring generator coupled to a Fidelis (MDT 6949) lead. Two separate event notifications that were transmitted immediately on occurrence of lead fracture, occurring silently during sleep at 4:43 am, 6 weeks after last clinic follow-up in November 14. Left: lead impedance suddenly increased; right: ventricular fibrillation detection due to irregular sensed events. Electrogram definition in current generation has improved resolution (1/128 s) and includes post-detection sequences (e.g. Figure 2). The patient was reviewed within hours (FU) of the notifications. Compiled with permission from ref.<sup>29</sup>

use of technology which can be relied on to provide reliable alert transmission when problems arise. The early detection capability demonstrated in TRUST gained FDA approval in May 2009.<sup>23</sup> This application may not be extrapolated readily to all RM technologies. For example, almost 70% of alert messages failed to be communicated with Carelink wireless technology, limiting its role and safety profile for early detection, especially critical for asymptomatic problems.<sup>13</sup> This emphasizes that clinicians need to be cognisant of the performance characteristics of different proprietary technologies. On the one hand, inductive systems are dependent on patient interaction and therefore compliance is a challenge, especially true for children and the elderly.<sup>24</sup> On the other side, wireless systems differ regarding transmission frequency, report generation, ancillary data, e.g. weight and blood pressure (available with Boston Scientific Latitude), and alert notification management. With wireless Carelink, alerts have to be directly set in the device and, once triggered, some alerts can only be reset during an in-office evaluation. Frequent transmissions with this system impose significant battery drain.<sup>25</sup> (Impact on longevity appears negligible with Biotronik HM but remains unreported with Boston Scientific Latitude and St Jude Merlin systems). In HM, programming of multi-parameter alerts may be performed via the website without the need for a patient attendance (Figure 1). Mobile transceivers with wireless 4 band GSM compatibility (and an increasing number of households are wireless) provide mobility for patients who travel, particularly internationally.

## Emerging applications

### Lead and device performance

Monitoring hardware performance is a physician responsibility expressed in recent HRS position statements and often demanded

by patients.<sup>3,4</sup> The task is daunting in view of increasing volume and device complexity, and added burdens imposed by advisory notices. Intensive monitoring by increasing office visits (e.g. monthly) is impractical, onerous, and inefficient (since problem incidence is very low) and is likely to fail to detect potentially catastrophic problems occurring between interrogations.<sup>26,27</sup> Remote monitoring systems relying on patient-driven communication may have similar limitations for detection of asymptomatic failure. In contrast, automatic remote technology providing near continuous remote surveillance of system integrity with automatic alerts of significant problems as and when they occur, even when the patient is unaware of them, offers advantages. Early reports illustrated these points, e.g. failure of an ICD to properly charge its capacitors and deliver appropriate therapy,<sup>28</sup> inappropriate ventricular tachycardia (VT) detection caused by supraventricular tachycardia and intermittent T-wave oversensing, change in lead impedance and simultaneous noise leading to a non-sustained VT alert with lead fracture occurring during sleep<sup>29</sup> (Figure 3). These were all diagnosed by remote alert transmissions IEGM and managed by urgent non-routine follow-ups. In another assessment of lead failure ( $n = 54$  patients), 80% of patients were asymptomatic at first episode of oversensing, and symptomatic problems were reduced with those managed with HM (27.3%) vs. without (53.4%,  $P = 0.04$ ). Events were notified 54 days after the last ICD interrogation and 56 days before next scheduled visit, i.e. reaction time was advanced by almost 2 months to avoid adverse events.<sup>30</sup>

The utility of RM illustrated by these earlier reports were confirmed in the TRUST trial.<sup>31</sup> System-related problems occurred infrequently (since implantable systems used were reliable) but usually asymptomatic. Conventional follow-up resulted in delayed detection and underreporting of important events. In contrast, HM enabled prompt detection (<24 h). Event triggers covered

an extensive range of potentially lethal (and asymptomatic) system problems, e.g. ERI, lead fracture, and high voltage circuitry failure. Remote management permitted prompt intervention either surgically, e.g. for lead failure, or conservatively, e.g. to prevent potential inappropriate therapies [e.g. electromagnetic interference, atrial fibrillation (AF)]. The non-sustained ventricular arrhythmia notification may be triggered by system issues such as lead electrical noise artefacts caused by fracture or non-physiological electrical signals. Their identification may direct intervention to pre-empt shock delivery and reduce patient morbidity and also premature battery depletion.<sup>32</sup> The ability to collect detailed device-specific data, with component function assessed daily and automatic archiving, sets a precedent for longitudinal evaluation of lead and generator performance. Hence, remote monitoring is a rigorous means of follow-up, superior to traditional methods, enhancing patients' safety and providing assurance for both patients and their physicians.

## Arrhythmia management

### Atrial fibrillation management/stroke risk

Atrial fibrillation is very common in patients with cardiac electronic implantable devices, even in those without any history before implant. During device lifetime, AF incidence may be as high as 50%, and is mostly asymptomatic.<sup>10,33</sup> Atrial fibrillation episodes, regardless of symptoms, are independent predictors for major clinical events, including stroke and mortality.<sup>34–36</sup> Potential benefits of remote monitoring include early detection and early reaction (e.g. drug therapy, device reprogramming, or electrical cardioversion) to prevent atrial remodelling and AF related severe adverse events. In particular, early anticoagulation may reduce stroke incidence. Early AF detection was tested in both pacemaker and ICD patients with different remote monitoring systems. Using an inductive RM system in 980 pacemaker patients, the number of events reported per patient was significantly higher with remote monitoring (wanded 3-monthly remote interrogation) than standard follow-up (in-office visit every 6 months and transtelephonic transmission every 2 months) (0.061 vs. 0.037 for new onset AF and 0.198 vs. 0.105 for AF lasting more than 48 h).<sup>7</sup> With wireless RM, a pilot Italian single-centre study involving 166 patients (73% pacemakers; Biotronik Home Monitoring) demonstrated that 20% of patients triggered AF alerts.<sup>37</sup> The median reaction time to AF was advanced 148 days compared with the scheduled follow-up. In the TRUST trial (ICDs; Biotronik Home Monitoring system), AF detection was 34.5 days earlier with RM vs. standard follow-up (5.5 vs. 40 days,  $P < 0.001$ ).<sup>12</sup> These results were supported by use of another proprietary RM system in a similar patient population.<sup>13</sup>

Clinical evidence for stroke risk reduction by remote monitoring is still awaited. The potential benefit was modelled by running repeated Monte Carlo simulations based on a real population of 166 patients prospectively followed daily. The results suggested that daily monitoring may reduce the 2-year stroke risk by 9–18% with an absolute reduction of 0.2–0.6%, compared with conventional inter-visit intervals of 6–12 months.<sup>38</sup> The COMPAS trial randomized 538 pacemaker patients and noted that the incidence

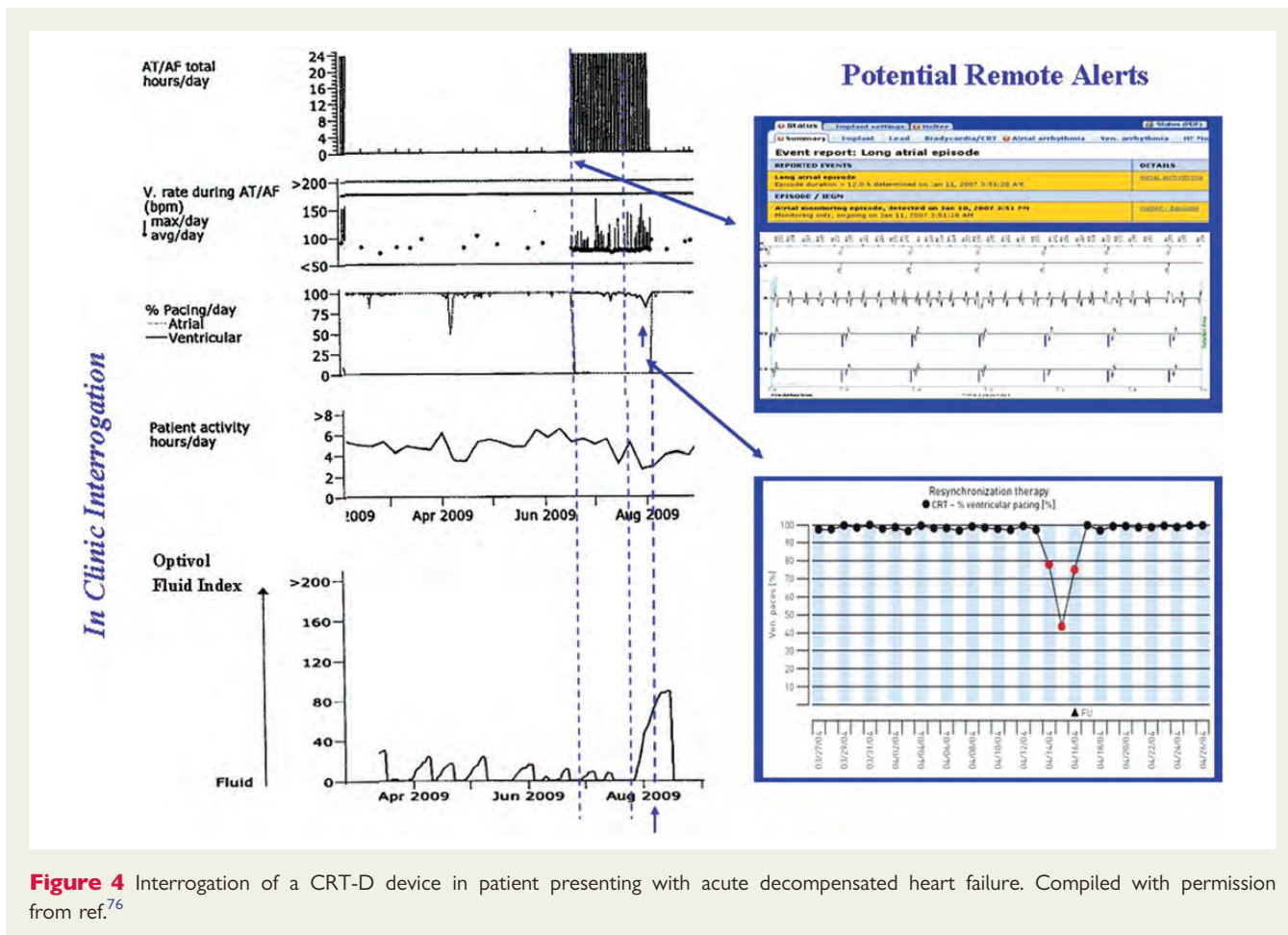
of hospitalizations for atrial arrhythmias and related stroke was 0.073 in the control group and 0.024 in the remote monitoring group ( $P = 0.02$ ), with a stroke rate of 0.033 and 0.008, respectively.<sup>18</sup> However, COMPAS was not powered to test this hypothesis.

Few studies have addressed the important interaction of AF and heart failure in patients implanted with CRT devices. Potential negative effects include heart failure worsening, more frequent hospitalizations, inappropriate ICD shocks, loss of CRT therapy, increased sympathetic tone, haemodynamic compromise, and thromboembolism. One large multicentre study (1193 CRT-D patients from 44 Italian centres) reported significantly higher freedom from the composite endpoint of death or heart transplantation or heart failure hospitalization in patients with sinus rhythm than in those with AF.<sup>39</sup> Pooled data analysis from two prospective international, observational studies in CRT-D patients (EverestT1 and HomeCARE2) demonstrated that patients with newly detected AF or a prior history of AF were more likely to develop thromboembolic events than those without.<sup>40</sup> The ongoing randomized IMPACT trial (projected 2718 patients, analysis in 2015) tests the clinical effects of an HM-guided anticoagulation strategy based on early AF detection on the composite endpoints of stroke, systemic embolism, and major bleeding.<sup>41</sup>

### Ventricular tachycardia/ventricular fibrillation management

Remote patient monitoring may be valuable for prompt evaluation of appropriateness of detection and efficacy of therapy delivered. Current generation wireless devices send a virtually immediate transmission for review. The physician can evaluate the episode detail on the website, including internal electrograms and marker chain. With inductive systems, patients may manually send a transmission to the service centre and inform the referring physician by phone in case of perceived shock and/or palpitations or syncope. (Obviously, asymptomatic problems may be missed with this form of RM.) If the shock is appropriate and if the clinical status is stable, the physician can reassure the patient without an in-hospital visit. In a pilot Italian multicentre study using the non-wireless CareLink Network system,<sup>42</sup> 81% of ventricular tachyarrhythmia episodes could be analysed remotely and in 85% of them no further action was needed. Sometimes, patients remain unaware of shocks, because of syncope before therapy delivery. Conversely, patients may report a shock although none was delivered (phantom shocks). In these situations, remote management may optimize patient care and avoid unnecessary emergency department visits and hospitalizations.

The TRUST study demonstrated that remote monitoring allows earlier detection of ventricular tachyarrhythmias if compared with the standard follow-up (1 day vs. 36 days for ventricular fibrillation (VF) and 1 day vs. 28 days for VT,  $P < 0.001$ ).<sup>12</sup> The 'ineffective shocks at the maximum energy' may be concerning but the study demonstrated that the majority of them were due to supra-ventricular tachycardias or T-wave over-sensing. Actionability of maximum energy ineffective shocks was 48%, including device reprogramming (64%), drug therapy changes (29%), and surgical interventions (14%).<sup>31</sup>



**Figure 4** Interrogation of a CRT-D device in patient presenting with acute decompensated heart failure. Compiled with permission from ref.<sup>76</sup>

Further potential benefits of remote monitoring are prevention of inappropriate shocks and also of appropriate but unnecessary shocks. Inappropriate detection due to supraventricular tachyarrhythmias (or, e.g. T-wave oversensing, EMI)<sup>31</sup> may prompt patient notification for in-hospital reprogramming or other clinical interventions. Appropriate delivery of ICD shock for stable and slow VTs may prompt device reprogramming with a wider use of painless antitachycardia therapies. Asymptomatic recurrent self-limited fast VT entering the VF window (which trigger alerts with some systems irrespective of therapy delivered) may be detected early and appropriate intervention scheduled to prevent electrical storms.<sup>32</sup> Clinical reactions include device reprogramming with further lengthening of detection time, drug therapy modification, and tachycardia radiofrequency ablation. Furthermore, timely treatment of such tachycardias may prevent early battery depletion induced by continuous device charge without shock delivery.<sup>32</sup> Recurrent episodes of sustained or unsustained VT may induce deterioration of heart failure, or vice versa, i.e. they may signal acute decompensation. The ECOST trial, which randomized 433 ICD patients, demonstrated that RM significantly reduced the number of actually delivered shocks (−72%), the number of charged shocks (−76%), the rate of inappropriate shocks (−52%),<sup>15</sup> and at the same time exerted a favourable impact on

battery longevity. Similarly in the randomized EVATEL trial (1501 patients), the rate of inappropriate shocks was 7.5% in the control group and 4.7% in the remote group ( $P < 0.05$ ).<sup>43</sup> These results demonstrate considerable superiority of RM using HM over standard follow-up.

## Monitoring disease progression

Implantable devices may play an important role in the management of heart failure.<sup>44</sup> This is a dynamic condition. The development of acute decompensation is complex, involving several processes (e.g. haemodynamic, neurohumoral, electrophysiological, and vascular abnormalities) that converge to manifest with fluid congestion. After hospitalization, management is directed to identification and correction of precipitating factors and comorbidities and management of fluid overload, arrhythmias, and any conduction system problems. Therapeutic strategies aimed at interrupting this train of events are potentially valuable. This may be possible since, in most cases, pathophysiological processes progress over days to weeks prior to clinical presentation with a fluid-overloaded state. This is supported by retrieved records from implanted devices which record multiple patient parameters. A typical example is illustrated in Figure 4. However, the initial inciting event(s), by definition

asymptomatic, are varied and follow different time courses. Tracking is therefore challenging. In this regard, the ability for early detection of silent parameter deviations by remote monitoring technology is potentially important. For example, both advent of AF and withdrawal of ventricular pacing in CRT-D may be immediately notified by remote monitoring.<sup>45</sup> Action taken on these notifications may prevent hospitalizations. This is being tested in current multi-centre studies.<sup>46,47</sup> This ability may be enhanced by incorporation of fluid or haemodynamic monitoring. Although results with thoracic impedance have been inconsistent,<sup>48,49</sup> in the future, incorporation of other sensors may provide sentinel notification of conditions leading to decompensation and prompt rapid pre-emptive therapy.<sup>50–53</sup> The ability to process several parameters and notify deviation in a pre-specified combination is likely to improve the specificity of heart failure detection.<sup>54</sup> Transferring this computing responsibility from implanted unit (necessarily limited) to external service centre is an important advantage of wirelessly transmitted data with high frequency. Access to Internet-based information systems provides a framework for multidisciplinary communication and collaboration (e.g. with heart failure specialists) and potentially may play a critical role in reducing heart failure burden.<sup>55</sup>

## Implementation

### Workflow

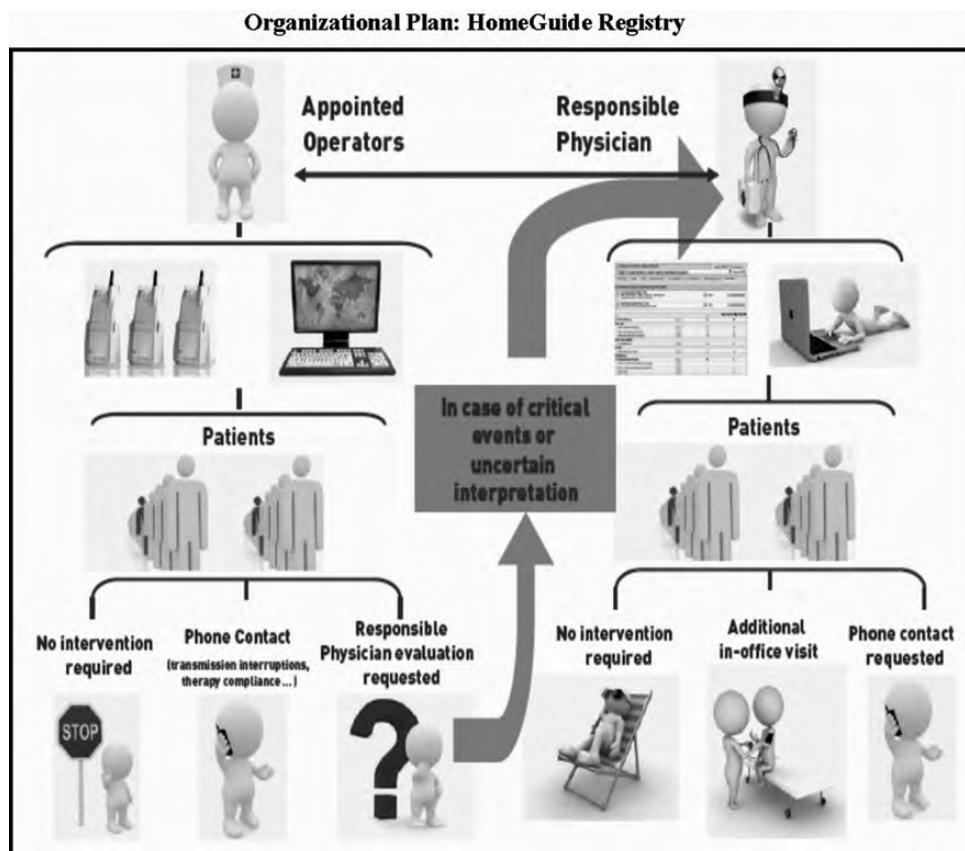
Implementing RM in standard clinical practice needs development of new organizational models, greatly involving allied professionals. Few data are available to guide this. In the first model tested,<sup>56</sup> each patient was assigned to a nurse responsible for continuity of care. More specifically, nurse duties included patient training and education, web site data entry, remote data review, data screening, critical case submission to physician, contacting patients, and following patient compliance and therapy benefits. Each nurse reported to a referring physician responsible for informed consent submission, overview, and check of the full process, and clinical management. Model strengths were maintenance of the human relationship with the patient (remote monitoring does not mean severance of the clinic–patient connection), continuous patient education, patient compliance, and symptom monitoring. In particular, patients need to be made aware that RM does not function as an emergency system but rather is a tool to improve overall clinical management. This model was adopted by the Italian Society of Arrhythmology and Pacing (AIAC) and introduced in the National guidelines.<sup>57</sup> The Home Guide Registry is an Italian multicenter registry, designed to evaluate this model for implementing remote monitoring in daily clinical practice. It aims to estimate remote monitoring performance in event detection and management and to analyse manpower. An extensive training programme was performed before starting to promote the Home Guide organization model and familiarize centres with it (Figure 5). The registry closed (December 2011) following enrolment of 1650 patients from 75 centres. Data analysis is ongoing but preliminary results demonstrate that the Home Guide workflow requires remarkably low manpower, namely 1.3 h × health-personnel-unit per month per every 100 patients.<sup>58</sup>

### Patient satisfaction and quality of life

Patient acceptance of RM has been evaluated in a few studies and shows divergent results. Some reported no difference in quality of life and patient satisfaction when compared with conventional follow-up strategy.<sup>8,18</sup> Others demonstrated high patient satisfaction rate, ease of use, and compliance with remote monitoring systems, even when manual data transmission with non-wireless devices was requested.<sup>59–61</sup> Marzegalli *et al.*<sup>59</sup> found that 78% of the patients preferred remote FU to in-clinic visits. The percentage of those preferring RM was even higher in a Danish study<sup>61</sup> (95%), although 84% of them wished for more detailed feedback, and 21% wished for a faster reply after routine transmissions. Patient acceptance and satisfaction have been demonstrated for different aspects including relationship with their health-care provider, ease of use of technology, psychological aspects, implications on general health, and overall satisfaction.<sup>60</sup> In spite of initial concerns, ease of use and acceptance of RM was high even for elderly people and for those patients with a low level of scholarship.<sup>62</sup> Only a minority (<5%) of patients found remote monitoring unacceptable. Underlying reasons include fear of technology, loss of privacy, and concerns regarding loss of human contact with nurses and physicians. It is critical to alleviate these by making patients clearly aware about benefits that accrue with remote management as well as the actual activity organization. Personal familiarity with the allied professional designated to call the patient in case of trouble tremendously improves patient assurance and compliance.<sup>63</sup> Automaticity and reliability of remote technology used is important. In the TRUST trial, >99% of 2275 completed 6-, 9-, and 12-month remote evaluations were accomplished successfully, since transmission failure occurred in only 22 (0.97%) of 2275 patients. No patient assigned to HM crossed over during the study and 98% elected to retain this follow-up mode on trial conclusion, indicating patient acceptance and confidence in follow-up with this technology.<sup>64</sup> In striking contrast, with conventional management, 145 of 1098 (13.2%) evaluations scheduled at those same time points were missed.<sup>65</sup> This follow-up attrition illustrates how onerous patients find scheduled clinic visits.

### Economics: healthcare resource utilization

Since the first small randomized trial (REFORM),<sup>66</sup> remote monitoring has consistently shown ability to reduce patient visits (almost 50%), time required for patient follow-up, physician time, costs of patient transport, and hospital incurred costs. Absolute cost saving may vary according to health care models in different countries. Thus, remote monitoring permitted a saving of €524 per patient per year (41% of standard follow-up cost) in Finland<sup>67</sup> but \$2149 per patient over 5 years in France.<sup>68</sup> Even after absorbing the extra cost (\$1200) for technology acquisition, the break-even point could be reached after 33.5 months. Thus source saving with RM may be obtained without compromising safety (definitively confirmed in the TRUST trial in a wide population).<sup>12</sup> Remote monitoring may further impact on resource consumption by preventing acute events and limiting hospitalizations. Thus, remotely managed heart failure patients had significantly



**Figure 5** Home guide registry.<sup>58</sup>

shorter length of stay leading to an estimated \$1659 saving per hospitalization<sup>13</sup> (the USA). In the COMPAS study,<sup>18</sup> hospitalizations for atrial arrhythmias and strokes were fewer in the active than in the control group. Final results are awaited from several multicentre randomized trials incorporating cost analysis as a primary or a secondary endpoint. These include ECOST, EUROECO, EVATEL, EVOLVO, MONITOR-ICD, and MORE CARE.<sup>15,43,69</sup>

Despite these advantages, reimbursement policies for remote monitoring by health care systems and insurances vary extensively among different countries. This impedes adoption. In USA, Medicare and Medicaid reimbursement codes for remote follow-up of pacemakers and defibrillators have existed since 2006, and were comprehensively updated in 2009. In Europe, some form of reimbursement exists in Germany, Portugal, UK, Netherlands, and Nordics, although actual fee delivery to hospitals and doctors may vary extensively, even within the same country. Recently, in France, reimbursement has been acknowledged to the companies for service for the device lifespan. Germany is the only country with specific reimbursement for the disease management program, including a fee related to alert review. Remote patient monitoring may be cost effective from the viewpoint of the third party payer or the patient, but not from the hospitals' perspective unless there is reimbursement. The ongoing Italian TARIFF study

(Health Economics Evaluation Registry For Remote Follow-up)<sup>70</sup> aims to develop a cost-minimization analysis from the hospital perspective and a cost-effectiveness analysis from the third payer viewpoint (National Health Care System), by direct assessment of the costs and quality of life associated with remote follow-ups compared with standard ambulatory follow-ups, in ICD and CRT-D recipients. It is expected that, by actually measuring overall costs and benefits, the appropriate level of reimbursement may be defined for RM of implanted devices. Homogeneous and appropriate reimbursement is critical not only to stimulate widespread adoption of RM, but perhaps also to prevent any future erosion of this valuable innovation.

## Remote monitoring databases

Remote monitoring platforms provide an unparalleled data set of real-world patients which can be utilized to assess outcomes and improve practice. 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 inter-observer agreement.<sup>71</sup> 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 (HR), 0.56; CRT-D HR, 0.45;  $P < 0.0001$ ] vs. office follow-up only.<sup>72</sup> Whether this is due to improved surveillance of clinical status, improved compliance, or subtle differences between remotely and conventionally monitored patients requires elucidation. The ALTITUDE group has also provided insights into several other issues, e.g. effects of programming on appropriate and inappropriate shocks and influence of percentage biventricular pacing on outcome.<sup>73,74</sup> Discoveries from these large remote monitoring data sets may guide design of prospective studies aiming to refine patient management.

## Future

Remote patient management has already become standard of care in some large volume centres.<sup>75</sup> However, overall adoption remains low. Reimbursement notwithstanding, physician reluctance has often centred around liability concerns regarding alerts received but not acted on, although remote monitoring is not an emergency system. However, the authors are unaware of any legal challenges occurring in over a decade of use of automatic remote monitoring. The counterargument is that as RM becomes standard of care—TRUST data in particular showing that this outperforms traditional methods—future questions may be directed to why the technology may not have been selected. Although prospective clinical outcome studies are required to endorse this position, in the authors' opinion, the current status offering near continuous monitoring already permits enhanced patient care, and promotes a paradigm shift in both the management and development of implantable electronic cardiac devices.

**Conflict of interest:** N.V. was Consultant to Biotronik for and Principal Investigator of the TRUST Trial and currently serves on the Boston Scientific Altitude Steering Committee. R.P.R. received minor consultancy fees from Medtronic and Biotronik.

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