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Remote monitoring costs, benefits, and reimbursement: a European perspective

Catherine E. Chronaki[1] and Panos Vardas[2]*

[1]FORTH, Institute of Computer Science, Heraklion, Crete, Greece; and [2]Cardiology Department, University Hospital of Crete, Heraklion 71000, Crete, Greece

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Aims To provide a European perspective on reimbursement issues surrounding remote monitoring of cardiac implantable electronic devices in view of the anticipated costs and benefits.

Methods and results Review of recent literature addressing clinical, economic, sociocultural, and technological factors associated with remote monitoring. When healthcare transformation is urgently needed, remote monitoring offers opportunities to innovate and cope with escalating costs and constrained resources, while improving patient safety, quality, and access to care as reflected in clinical studies. The introduction of remote monitoring into daily practice requires analysis of reimbursement policies to address funding scope, payment method, payer, price and allocation, and alignment with health system objectives and goals to ensure financial and operational sustainability of resources, infrastructure, and processes. Remote monitoring policies should gradually transition from activity-based, added-value services in a care-and-cure setting, to performance and outcome-oriented highlighting prevention, surveillance, and empowerment. By encouraging and rewarding innovation and interoperability, proprietary remote monitoring technologies can open up using standards and connect to support a growing evidence base that guides clinical decision support and planning of future policies.

Conclusion Careful planning, sharing of experiences, and gradual adoption of reimbursement models that focus on outcome, performance, and cost-effectiveness are key aspects of containing escalating costs and improving quality and access to healthcare. Despite differences in health systems and payment methods in Europe, policy-makers, professional societies, payers, providers, and the industry need to join forces to transform healthcare and make innovation happen.

Keywords Remote monitoring • Cardiac implantable electronic devices • Remote follow-up • Cost-effectiveness • Reimbursement

Introduction

Healthcare systems in Europe are challenged by an ageing population, rise in prevalence of chronic diseases, escalating healthcare costs, and a healthcare workforce under constant pressure to deliver more with less. There is an urgent need to innovate to transform healthcare. Remote monitoring provides such an instrument for innovation and illustrates a case, where a viable reimbursement model that balances the costs and benefits is urgently needed.

Europe is facing a grave demographic problem: by 2020, there will be 104.7 million Europeans over 65 (a 19.4% increase from 2010), and by 2060, seniors will be 29.6% of the population.[1] As of 2010, ischaemic heart disease and stroke remain the leading causes of death in Europe, cardiovascular and circulatory diseases account for 2.8% of all years lost to disability.[2] In 2009, cardiovascular disease (CVD) costs in the European Union were estimated at €196billion per year, comprising direct healthcare costs (54%), productivity losses (24%), and informal care (22%).[3] As shown in *Figure 1*, direct costs to the health system are over 106 billion of these 49% for inpatient care and 29% for medication. Productivity losses due to illness in those of working age are estimated at €19 billion annually. Indeed, the burden of chronic conditions that require ongoing management is a key challenge for the healthcare systems of Europe, since current prevention and disease management practices seem to be suboptimal. The condition may be remediable. For instance, the EURIKA study reported that with improved management of CVD up to 30% of CVD deaths can be averted, saving an estimated 135 000 lives per year.[4]

* Corresponding author. Tel: +30 2810 392422; fax: +30 2810 542055, Email: cardio@med.uoc.gr

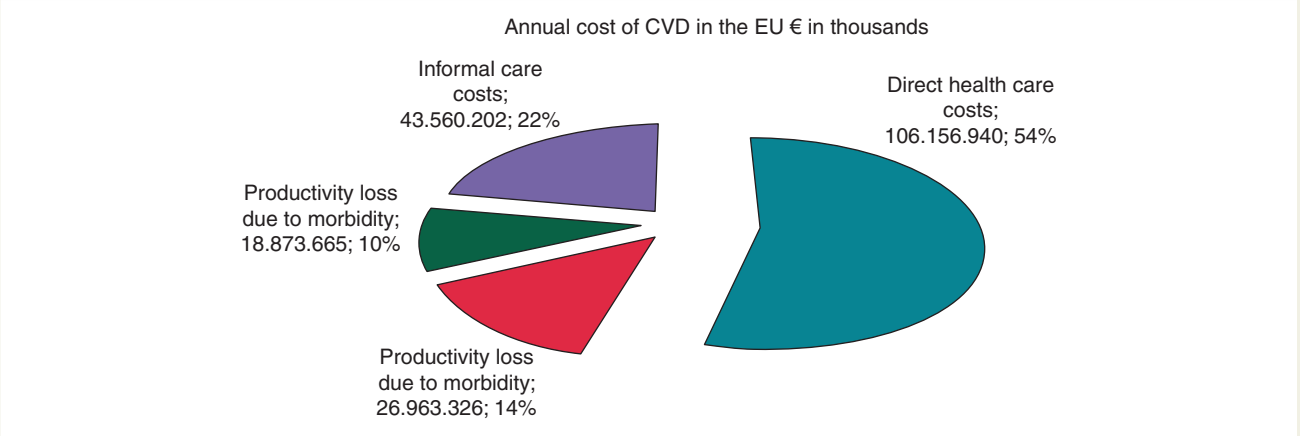

Figure 1 Annual cost of CVD in thousands in the EU in 2009.[3]

Remote monitoring

Since the first pacemaker implantation in 1958,[5] there have been rapid technological advances in cardiovascular implantable electronic devices (CIEDs). Their size has decreased dramatically, while their complexity and functionality have improved.[6] The number of patients that do benefit from these smaller, smarter devices is increasing; a trend reflected by the units of cardiac rhythm management products per million inhabitants reported by Eucomed.[7] In 2005–2011, the cumulative annual growth rate of CIED implantations has been steadily raising for defibrillators (10.37%) and the more complex therapeutic devices [cardiac resynchronization therapy pacemaker (CRT-P): 6.48%, cardiac resynchronization therapy defibrillator (CRT-D): 19.54%] and to a lesser extend for pacemakers (2.09%). This situation *increases the pressure on the healthcare workforce*, which is called to meet an ever increasing volume of surgical procedures, scheduled and emergency appointments.[8] Remote monitoring may offer cost-effective ways to better leverage the limited resources of the healthcare system and empower patients. Remote monitoring technologies have evolved since the original trans-telephonic monitoring of pacemakers for battery levels[9] to current era CIEDs with wireless telemetry capabilities, the first of which received Conformité Européenne (CE) mark in 2000. A decade later, most CIEDs support remote monitoring allowing scheduled remote interrogation and follow-up, alert management, as well as patient-initiated transmissions. However, any shift to remote patient management on a large scale needs *careful planning and re-organization of healthcare services addressing clinical, economic, sociocultural, and technological factors*.

Current evidence

Remote interrogation and follow-up meets the requirement for scheduled follow-ups to check on the patient and the device. With remote follow-up cardiologists, nurses, and allied health professionals use innovative technologies to 'do the same things differently'.[10] A scheduled appointment in the hospital that typically requires the physical presence of a nurse, a cardiologist, and optionally an allied health professional may be replaced with remote interrogation of the device. As a result of remote follow-up, laboratory exams may be scheduled and medication treatment may be revised. An in-clinic appointment may be scheduled if reprogramming is necessary. Currently, a large percentage of scheduled appointments do not require action. When directly measured, <10% of calendar-based follow-ups were actionable in the TRUST trial.[11] Lazarus[12] analysed a worldwide database (3 004 763 transmissions) of 11 624 CIED patients monitored for 1–49 months (mean = 10.5 ± 9.4 months). He reports that on the average 47.6% of patients had no events [pacemaker 54.8%, implantable cardioverter-defibrillator (ICD) 43.5%, and CRT-D 28.3%]. He also reports that an event occurred on average 26 days after the last follow-up, offering a potential 64–154 days window for earlier action. These data highlight the potential of remote follow-up to optimize the allocation of healthcare resources and enable early action after an event.

There is evidence that remote follow-up has the potential to reduce unnecessary visits and transportation costs: several studies report fewer in-patient visits in patients monitored (TRUST: −45%, COMPAS: −55%,[13] EVOLVO: −35%,[14] REFORM: −63%[15,16]). In some countries, the payer/insurance agency reimburses transportation costs for patients attending in-office services. Depending on the distance from the hospital, the 5-year costs have been estimated between 1377 and 4133 USD.[17] In a Finnish study, the costs savings in 9 months have been estimated at €524 per patient.[18] The REFORM[15,16] study identified reduction in hospital visits by 63%, and productivity gains in cardiologists' time of 40% (€712 or 50 min per patient per year).

Remote monitoring for alert management and user-initiated interrogation is about 'doing different things'.[10] It is about introducing novel hospital workflows and care pathways. In the outpatient visit, alert thresholds are set for the device. The technology in some current era devices permits same-day problem discovery.[19]

A series of large prospective clinical trials report favourable clinical outcomes for such early detection by remote monitoring compared with traditional care:[20] remote monitoring facilitates the timely detection of major adverse events, the risk reduction of critical cardiac events, an improved monitoring of medication compliance, and the reduction of unnecessary shock treatments. For instance, in the COMPAS trial,[13] patients assigned to remote care had fewer

hospitalizations for arrhythmia and stroke and reduction in emergency visits (56%). After the first 6 months, 50.8% did not need to visit the hospital. For defibrillators, TRUST[11,19] and CONNECT[21] confirmed that in clinical practice remote monitoring greatly advanced the time to action after an event (2–4 days) compared with traditional care (over a month), yet almost halved hospital visits over 12 months. EVATEL[22] reported a lower number of adverse events for remote monitoring (4.7 vs. 7.5%, $P = 0.03$). ECOST[23] showed that patients undergoing daily remote monitoring registered 52% fewer inappropriate shocks, fewer hospital admissions for inappropriate shocks (3 vs. 11, $P = 0.02$), and 76% fewer capacitor charges leading to longer battery life. The EVOLVO study[14] showed 35% reduction in emergency visits, and a 21% reduction in healthcare visits for heart failure, arrhythmias, or ICD-related events. Clinical status measured by the Clinical Composite Score was similar in the two groups, whereas quality of life (as measured with the Minnesota Living with Heart Failure Questionnaire) improved with remote monitoring. The ALTITUDE survival study[24] analysed a database of about 200 000 ICD patients. Patients remotely monitored had 50% higher survival rates, possibly attributable to a higher engagement of patients and physicians.

Remote monitoring also contributes to safety later in the lifespan of a device when malfunctions are common.[25–27] Remote monitoring sets the basis for cultivating better relations of the patient with the care team leading to improved quality of life, higher engagement, and medication compliance.[28–30] Recent studies suggest that educated patients are content with remote monitoring and wish for faster feedback and more information.[31]

Although the protocols of the relevant studies differ, certain consistent results emerge, which support the introduction of remote monitoring and follow-up as an integral part of the daily medical practice. The studies presented above and many others show that remote monitoring and follow-up have the potential to improve patient safety, quality, and access to care by providing timely information on device status and critical events, improving management of resources and cost-effectiveness.

Current practices in remote monitoring

Beyond the consensus statements of professional societies,[8,20,32] only a handful of national societies like the Netherlands,[33] Italy,[34] Switzerland,[35] and the UK[36] have issued guidelines for remote monitoring and follow-up. The European Heart Rhythm Association (EHRA) research network conducted two studies in 2010 and 2011 to investigate levels of adoption and current practices in remote monitoring and follow-up. In 2010, 51 out of 61 centres in 15 countries reported engaging in remote monitoring sometimes (45.9%) or frequently (39.3%).[37] Remote monitoring and alert surveillance was offered in 41.5% of the centres, 33% of the centres alternated remote follow-up with hospital visits, and 25.5% offered it as an added-value service. Remote monitoring was supported by allied professionals (58.8%), call centres (27.5%), and electrophysiologists (13.7%). The majority projected that in the future remote monitoring will contribute to continuity of care (76.8%), improve the patient's quality of life (78.6%), decrease the time for device check (55.4%), lower the cost of follow-up (66.1%), and reduce the number of in-person visits (85.7%).

In 2011, the EHRA study on follow-up practices reached 40 centres in 16 countries reporting that electrophysiologists (40%), cardiologists (12.5%), allied health professionals (25%), and nurses (22.5%) are responsible for CIED follow-up.[38] Official professional certification is required only in 27.5% of the centres. Regarding frequency of follow-up, in 66.6% of the centres, CRTs and ICDs are followed every 6 months, and in 22.5–35% every 3 months. Half the centres offer remote ICD monitoring, but only 17.5% pacemaker monitoring, typically through a call centre operated by doctors and allied health professionals.

Remote monitoring infrastructure

Cardiovascular implantable electronic device manufacturers have invested in remote monitoring also by creating central databases, where alerts and device reports are transmitted through data transmitters located at the patient side. Besides their primary objective of making the transmitted data accessible to the treating physician, over time these databases may serve as data registries that benefit medical research in the context of retrospective studies.[12,24] For example, Boston Scientific manages a database of >150.000 patients and 7 million transfers with their Latitude system, while Medtronic through the Discovery Link database provides study data from >100.000 patients associated with 3000 organizations.[39]

When remote monitoring data are regularly transmitted to the hospital in a standard format and incorporated into hospital-based electronic health records along with the patient's activity and wellness status (possibly transmitted automatically from a personal health record), they can assist clinical decision support and influence adoption of clinical guidelines.[40] Additionally, systematic analysis can inform the care protocols, workflows, and resource allocation in the healthcare facility. There are important security and privacy aspects that need to addressed,[33,41] and hospitals that decide to adopt remote monitoring need to analyse the organizational and operational aspects of the service and set up appropriate vendor agreements and infrastructure so that remote follow-up reports and triggered alerts are safely stored in the electronic health records of their patients. Providers should also invest on education and training, key elements of change management. Tutorials and educational seminars empower patients and their families in understanding their disease and the operation of the implanted device, raising their awareness about the potential and limitations of remote monitoring. Last but not least, a suitable reimbursement solution should be adopted to incentivize and engage all stakeholders to drive the intended transformation of healthcare delivery.

Reimbursement models

The introduction of remote monitoring in daily practice requires careful analysis of reimbursement policies to ensure sustainable availability of resources, infrastructure, and processes.[10,42–44] Developing a thorough understanding of policy alternatives and their implications can support health systems in coping with the challenge of escalating costs and constrained resources.

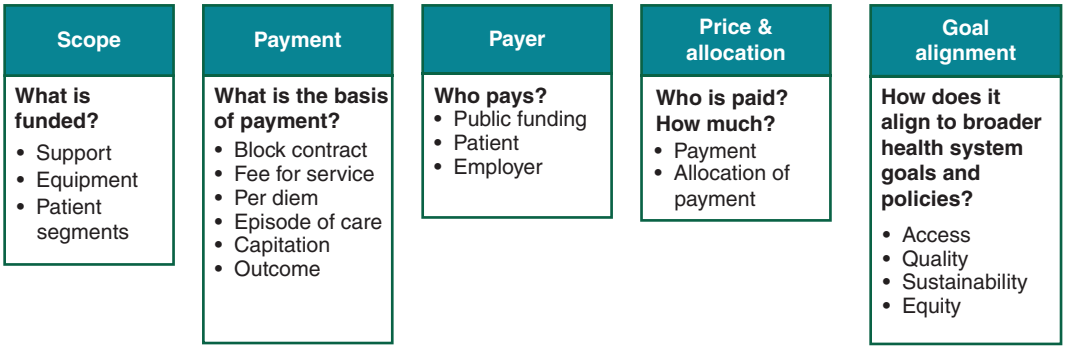

Figure 2 Key issues/questions when formulating a reimbursement model.[10]

A recent Eucomed White paper analyses the reimbursement situation in Germany, England, Spain, Italy, and the Netherlands, making important observations and suggesting general principles for effective and inclusive reimbursement models.[10] Health systems in Europe bare significant differences, which impact their approach to reimbursement of remote monitoring and follow-up. In Germany, a country supported by statutory health insurance for 90% of the population, remote follow-up is reimbursed at the same rate as face to face and remote monitoring can be reimbursed in the context of integrated care contracts. In the Netherlands, a country supported by statutory health insurance through private insurance companies, an activity code for remote follow-up has been established, but reimbursement needs still to be negotiated between providers and health insurance. In Italy and Spain, regional pilots and grass root initiatives attempt to establish a case for remote monitoring and follow-up, in an adverse economic climate. In the UK, an approach towards disease management or service bundling is emerging driven by efforts such as the Whole System Demonstrator trial and the 3millionlives programme (3millionlives.co.uk).

Figure 2 illustrates five key issues/questions to be addressed by reimbursement models: funding scope (*what will be funded?*), payment method (*on what basis payment will be made?*), payer (*who will pay?*), price and allocation (*who receives payment and how much?*), and goals (*how does it align to the broader health system objectives and policies?*).

The funding scope should account for all costs treating remote monitoring and follow-up on a basis comparable with face-to-face activities. The funding scope should also consider risk-stratifying patients (by diagnosis, location, preferences, etc.), noting the best alternative to remote monitoring and follow-up. Frequently physician fees are highlighted, but infrastructure and support services should also be considered for the service to be financially sustainable.

The payment method provides the structure of a possible payment (e.g. block contract, fee for service, fee per diem, fee per episode of care, capitation, and outcome). The payment method should accommodate incentives, gradually moving from the flat fee-for-service model, towards innovative fee structures that reward quality, outcome, and performance improvement. In terms of payment for remote follow-up, a wide range of practices were identified:[10]

- national face-to-face follow-up tariffs used for remote follow-up (Germany);
- local/national hybrid payments (UK/England);
- reimbursement fees limited to pilots (Spain, Italy, etc.);
- national activity code negotiated with health insurance (The Netherlands).

In the EHRA survey of 2010, 51 centres reported that reimbursement of remote follow-up was established per episode in 8.9%, as fixed fee per patient per year in 5.4%, charged as a service by private companies in 8.9%, but in 82.1% there was no reimbursement structure.[37] The fee-for-service payment approach at reimbursement rates lower or equal to those of the in-clinic follow-up has been considered many European countries.[41–44] For remote monitoring, a flat fee per patient per month or per year can been adopted as part of integrated care or disease management contracts. Germany has promoted integrated care with more than 6000 integrated care contracts treating in excess of 4 million patients.[45] Similarly in the UK, chronic disease management programmes can cover remote monitoring.[10]

Regarding the question 'Who pays?', different sources of funding are possible, e.g. government (national, regional, local), hospital (budget, capitation), patient (out of pocket or private insurance), employer (private insurance). Although the main payers are insurers and national health systems, in some countries like Spain, Italy, and Austria remote monitoring and follow-up are expected to be supported by the regional or hospital budget. The Eucomed White paper suggests that the costs should be borne by the party receiving value, i.e. better service, cost savings, higher productivity, etc. Where payments are made today, they often focus on the physician's services rather than the wider value-generating system, e.g. by including the remote monitoring system technology (hardware, data management system, etc.). Likewise on price and allocation, stakeholders should be rewarded according to the value they produce. While the costs of remote monitoring and follow-up should not exceed the costs of traditional care, with remote monitoring technology it is possible to increase productivity, improve quality, and contain costs. Those benefits need to be considered in a viable reimbursement solution.

Goal alignment for remote monitoring should focus on encouraging and rewarding innovation, fostering adoption by clinicians and patients, and highlighting how these new health services align with the broader objectives of the health system towards access, quality, sustainability, and equality. If remote monitoring and follow-up are aligned with the national health policy goals, then this needs to be

acknowledged so that implementation be better supported, e.g. by helping hospitals to overcome investment hurdles for remote monitoring equipment. Existing funding schemes for hospital services such as Diagnosis Related Group (DRG) payments have proven unsuitable to drive uptake of remote monitoring. Lastly, when rolling out remote monitoring, the reimbursement model should leverage a short-term and a longer-term approach building on existing and transitioning towards performance-oriented and accountable reimbursement mechanisms.

As a practical example of these principles, productivity gains at provider level can be harnessed appropriately and fair, and used to reimburse the payer, the provider, and the industry.[10] For example, assuming a fee-for-service model for in-office and remote follow-up, a possible inclusive reimbursement model would use a lower fee for a remote follow-up, but incentivize the physicians and the industry by distributing the gains from increased productivity. Thus, the payers would save money, the efficiency of the health system would improve, and incentives would make change easier for providers. Meanwhile, patients would receive quality care, enjoy comfort and productivity, save time, and travel costs.

Outlook

Healthcare is changing and remote monitoring can serve as paradigm illustrating that the effective use of innovative technology can improve care and contain costs. It is also an example for an innovation that is widely accepted and appreciated, but for various reasons has been deprived of reimbursement. As suggested in the Eucomed White paper,[10] reimbursement policies should enable the gradual transition from models emphasizing activity to models emphasizing outcomes, from remote monitoring and follow-up considered as added-value services to telemedicine as part of an integrated solution, from a 'care and cure' orientation to one that embodies health prevention and surveillance as core principles. Moreover, by encouraging and rewarding innovation, proprietary health information technologies will open up using standards and connect to support a growing evidence base that guides clinical decision support and planning of future policies.

Looking forward to the next steps, stakeholders in remote monitoring need to work together to transform healthcare through innovation. European health systems are heterogeneous and there are significant income disparities which impact the ability to enforce guidelines and advance adoption of remote monitoring and follow-up. Payers should foster flexible policies, informed guidelines, and innovative reimbursement mechanisms for remote monitoring to deliver its promise.

Advocates and early adopters should step forward and champion reimbursement of remote monitoring and follow-up within their governments and the European Union (EU), presenting the evidence that reimbursement of remote monitoring and follow-up can actually make smarter use of the healthcare workforce, and provide higher quality care at the same or lower cost.

The industry must work to lower the investment hurdle for the infrastructure offering services such as a bundled annual fee that helps financing the remote monitoring hardware over a given period. The industry supporting common standards should enable interoperability with electronic health records in the hospital, for the physicians to make informed decisions, and the patients to be empowered. Finally, the industry should work with other stakeholders to consolidate evidence on the value of remote monitoring for patients with specific characteristics.

Policy-makers across Europe and worldwide should work to establish a harmonized innovation-friendly legal and regulatory framework and ensure that the unprecedented volume of data created by remote monitoring benefits medical research without compromising the security and privacy of patients.

Providers should foster remote monitoring and follow-up through education and training of health professionals and patients. Providers should also assure that the organizational structures, roles, and people serving them are in place along with protocols and guidelines. This would be part of a wider programme of change management to support healthcare transformation and adoption of new working practices that embody continuous evaluation and assessment in refining patient selection criteria for remote monitoring, and personalizing care pathways.

Professional organizations such as EHRA and the European Society of Cardiology (ESC) in collaboration with national societies can play an important role in catalysing reimbursement and adoption. So far they have not addressed cost and reimbursement issues in depth largely due to heterogeneity and income disparities. However, with the advent of social media and mobile health there are innovative ways for the professional societies to reach out above and beyond these disparities. The ESC is already social media and mobile apps to deliver news and up-to-date guidelines. Indeed, the EHRA and ESC offer a fertile environment for interaction, exchange of best practices, and education, but they can do more. They can change the culture to embrace innovation and transform the work of cardiologists making it collaborative, stimulating, rewarding, and exciting. Professional societies can review and potentially endorse mobile apps that offer valuable decision support and empower the physician's relationship to the patient.[46] They can foster ties to other stakeholders and support the healthcare systems in their transition, promoting innovation, and excellence, so that constrained budgets balance costs and benefits, rather than lowering care standards. It is a significant challenge, but significant is also the reward.

Remote monitoring and follow-up offer exciting opportunities, in an era of healthcare transformation. Careful planning, sharing of experiences, and adoption of reimbursement models that encourage innovation and focus on outcome, performance, and cost-effectiveness form key elements of a bright future, where technology lightens the burden of cardiologists in their relentless battle against heart disease.

Conflict of interest: none declared.

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