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Moving towards good practice in the reimbursement of CIED telemonitoring

A study conducted in five European countries: Germany, Italy, Spain, the Netherlands and the UK.

Sponsored by:

Eucomed Medical Technology

Supported by:

EUROPEAN Heart Rhythm ASSOCIATION
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Foreword

Remote monitoring of cardiac implants is an exciting technology innovation that has the potential to make cardiac implant follow-ups more efficient and more effective, ultimately benefiting the patient, the provider and the healthcare payer. It is one of various promising applications of E-Health that will help European healthcare systems to meet the increasing needs of its ageing population against the background of budget constraints and capacity shortages. Having said that, telemonitoring is still confronted with many obstacles that prevent full adoption of this innovation – and one of these is the fact that, compared to the traditional in-hospital device follow-ups, there is hardly any reimbursement for this E-Health alternative, putting users and manufacturers of this innovation at a disadvantage. This paper has the objective to provide concrete recommendations for country-level reimbursement of Cardiac implantable electronic devices (CIED) remote monitoring based on a newly developed generic framework

The development of concrete recommendations for country-level reimbursement is the logical next step in the collaboration between Eucomed, the European Medical Technology Industry Association, and the European Heart Rhythm Association (EHRA). The collaboration between the two associations started in 2008 after EHRA, together with the Heart Rhythm Society (HRS), issued the consensus document on CIED monitoring. We would like to thank Prof. Angelo Auricchio (President of EHRA), Prof. Giuseppe Boriani (Chair of the Health Economics Committee, EHRA) and Prof. Panos Vardas (President of the European Society of Cardiology (ESC)) for their continuous engagement in our joint activities and for their support in the completion of this White Paper.

This White Paper "Moving towards good practice in the reimbursement of CIED telemonitoring" is sponsored by Eucomed, supported by EHRA and PWC was commissioned to do the fieldwork, research and draft the paper. The fieldwork, which forms the basis of the White Paper, was executed between January and May 2012. In total, the PwC Team conducted approximately 54 interviews with various stakeholders including physicians, payers, patient organisations and industry in five countries: Germany, Italy, Spain, The Netherlands and the UK. The learnings from the interviews helped shape the generic framework and the recommendations of this paper.

The most important prerequisites for the research were that the recommendations needed to:

1. Be realistic and actionable at national level while taking into account that there is no "one size fits all" solution in reimbursement;
2. Tie well into ongoing debates and activities at national level and, as recommendations, inspire the national debate and policy making.

We hope that many will find this White Paper inspiring and that it will ultimately contribute to securing patient and healthcare professional access to state of the art medical technology.

Markus Siebert
Chair, Eucomed CRM Telemonitoring Working Group

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List of abbreviations

CIED	Cardiac implantable electronic device
CRM	Cardiac rhythm management
CRT	Cardiac resynchronization therapy
CRT-D	Cardiac resynchronization therapy with defibrillator
CRT-P	Cardiac resynchronization therapy with pacemaker
DBC	Diagnosis Treatment Combination (old Dutch DRG)
DOT	DBCs On their way to Transparency (new Dutch DRG)
DRG	Diagnosis-related group
DTC	Diagnose Treatment Code
EBM	Einheitlicher Bemessungsmaßstab (uniform valuation scale)
ECG	Electrocardiogram/electrocardiograph
F2F	Face-to-face
FU	Follow-up
G-DRG	Diagnosis-related group
HRG	Health Resource Group (British DRG)
i.c.w.	in conjunction with
ICD	Implantable cardioverter-defibrillator
KBV	Kassenärztliche Bundesvereinigung (German National Association of Statutory Health Insurance Physicians)
PM	Pacemaker
RFU	Remote follow-up
RMS	Remote monitoring system
SHI	Statutory health insurance
TM	Telemonitoring
WHO	World Health Organisation

A Executive summary

Context

The current European healthcare market is characterised by constrained funding and rapidly increasing demand, driven by an ageing population and growth in long-term conditions. Faced by this challenge, healthcare leaders are seeking innovative forms of care to ensure the goals of access, improved clinical outcomes, efficiency and equality are met. Telemonitoring for patients with cardiac implantable electronic devices (CIEDs, including pacemakers and implantable defibrillators) is one such area of innovation. However, whilst the evidence base for this form of care is building[1], reimbursement for it remains inconsistent and a constraint to growth.

Objective of this study

A robust reimbursement model in healthcare should support the wider goals of the healthcare system, reward fairly and incentivise appropriate further investment. Based on these principles, this study considers current reimbursement for CIED telemonitoring in five countries – Germany, Italy, Spain, the Netherlands and the UK (focused on England) – and makes recommendations for change going forward. Its goal is to encourage pragmatic action in the field of CIED telemonitoring reimbursement.

Defining reimbursement

A well-defined healthcare reimbursement model should make clear choices in response to five key questions:

1. Scope: What services, material and patients will be funded?
2. Payment method: On what basis will payment be made?
3. Payer: Who pays?
4. Price and allocation: Who receives payment, and how much?
5. Goals: Does it align with the broader health system objectives and policies?

These questions, and the choices they imply, are outlined in Figure 1:

Fig. 1 Key reimbursement questions

1 Scope	2 Payment Method	3 Payer	4 Price and allocation	5 Goals
What will be funded? • Support services • Equipment, drugs and infrastructure • Patient segments	**On what basis will payment be made?** • Block contract • Fee for service • Per diem • Episode of care • Capitation • Outcome	**Who pays?** • Public Funding – National – Local • Patient – Private medical insurance • Employer – Private medical insurance	**Who receives payment and how much (price)?** • Payment level (price) • Allocation of payment to multiple providers	**Does it align to broader health system objectives and policies?** • Access • Quality • Sustainability • Equality

[1] See, for example, Dubner et al., ISHNE/EHRA expert consensus on remote monitoring of cardiovascular implantable electronic devices (CIEDs), Europace 14 (2), 2012, and the Whole System Demonstrator (WSD) programme in England.

CIED background and use cases

For CIEDs, regular follow-ups are required to check the device and its key functions. Additionally, patients need to be monitored, either during scheduled meetings with the physician or additional reactions after any events the patient has noticed. Both can be supported or even replaced using devices and corresponding technology that enables remote follow-ups and the remote monitoring of patients.

Besides a TM-enabled device, telemonitoring of CIEDs requires a certain infrastructure, mainly a data transmitter at the patients' side, a central server and a (data) communication infrastructure. In the following, this infrastructure is referred to as TM technology and support services. Additionally, providers may need to integrate the information from CIED TM in their IT-systems and train their medical staff.

In order to answer the key questions on reimbursement with sufficient depth and specificity, we have focused on the two most common applications (use cases) for CIED telemonitoring[2]. Throughout this study, we will employ these two use cases as the basis for our thoughts and models.

Tab. 1 Use cases for CIED telemonitoring

Use Case	Description	Key facts
Case 1: Remote follow-up *"Doing things differently"*	A straight replacement of existing face-to-face device check follow-ups with remote follow-ups using telemonitoring. This aims to make the existing care pathway more efficient.	• Benefits mainly in the areas of efficiency and convenience for follow-ups • Reimbursement comparator is face-to-face follow-up • Clinical outcomes the same under telemonitoring and face-to-face
Case 2: Remote monitoring *"Doing different things"*	This involves capturing and monitoring data on an ongoing basis, and using it to inform clinical choices and interventions. It involves new pathways and new methods of working, harnessing the benefits of the additional data and information the approach provides to improve clinical outcomes.	• Additional economic benefits of improved clinical outcomes • Reimbursement comparator is traditional treatment methods and pathway

[2] Throughout the study, when we refer to "telemonitoring" we are referring to these two use cases specifically.

Current state of CIED reimbursement

The key findings of our interviews and analysis of the current state of CIED telemonitoring reimbursement in the five focus countries are as follows:

Tab. 2 Observations on current reimbursement for CIED telemonitoring

Theme	Observations
Scope	• There is typically no national framework or tariff in place to reimburse the physician services and hardware costs (eg, transmitters) associated with remote monitoring (Case 2).
Payment method	• There is no consistent approach to reimbursing remote follow-ups (Case 1), with the current range of practices including – the use of existing face-to-face national follow-up tariffs (eg, Germany), – the development of inconsistent local/national hybrid payments (eg, UK) or – no formal reimbursement at all (eg, Spain, Italy – with the exception of some pilots). • The Netherlands, with its introduction of an "activity code" for telemonitoring in 2012, appears to be moving towards a more consistent national reimbursement approach.
Payer	• Typically, payment responsibility lies with insurers and national health systems. However, in some cases – where payment for such services must come from the devolved regional or hospital budgets (eg, Italy and Spain) – the commitment and motivation to pay may be unclear.
Price and allocation	• Where payments are made for CIED telemonitoring, they are typically focused on the physician's services rather than the wider, value-generating system (eg, hardware and associated triage services).
Goal alignment	• The reimbursement of CIED telemonitoring does not reflect an increasing emphasis across Europe on clinical outcomes and efficiency.

Proposed solutions

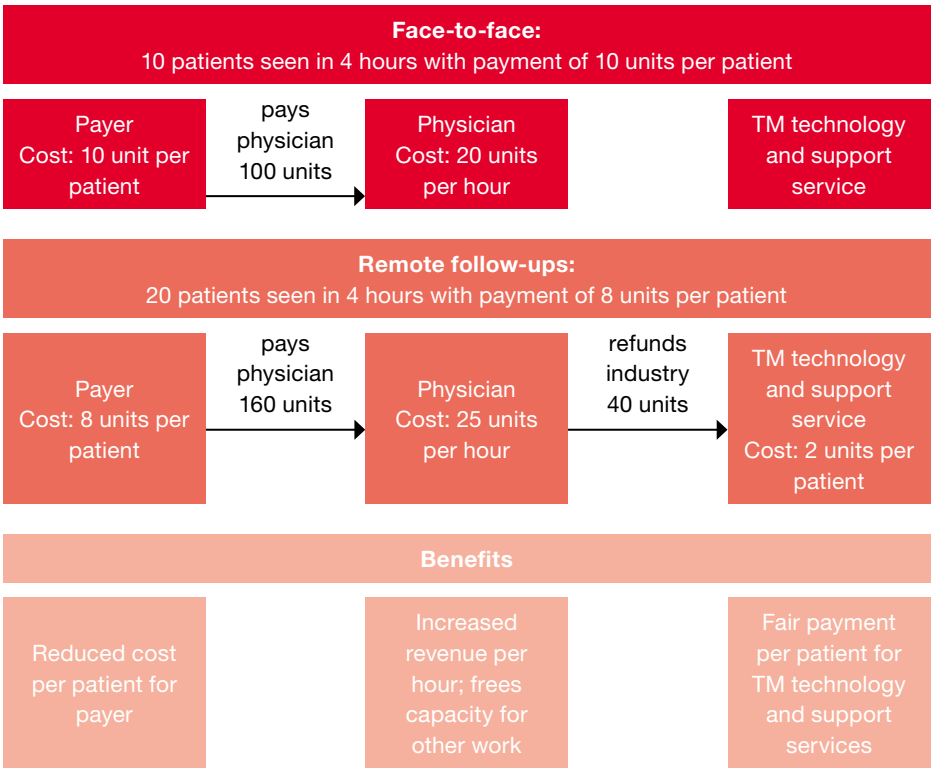
Our proposed solutions are designed to be pragmatic, fair and enduring, to encourage innovation and to support better outcomes for patients. To underpin these objectives, we have devised 12 principles that we believe should shape any future reimbursement model for CIED telemonitoring:

Tab. 3 Principles for CIED telemonitoring reimbursement

Decision	Principles
Scope of funded activity	1. Account for all costs (physician services, infrastructure and monitoring services) 2. Treat remote activities on a basis comparable to face-to-face activities, provided they deliver at least an equivalent result 3. Risk-stratify patients (by diagnosis, by region, etc.) and target/reimburse accordingly
Payment method	4. Increase emphasis on the reward of outcomes
Payer	5. Costs should be borne by the party receiving the value
Price and allocation	6. Reward stakeholders in proportion to the value they create 7. The total cost per patient of telemonitoring should, as a minimum, not exceed that of the next best alternative; where telemonitoring leads to improved outcomes, this should be rewarded cost-effectively
Goal alignment	8. Encourage innovation 9. Encourage adoption by clinicians and patients 10. Support the long-term objectives of the healthcare system (access, quality, sustainability, equality)
Roll-out	11. Create a practical short-term solution that is both compatible with and leads to a longer term one 12. In the short term, build on existing or planned reimbursement mechanisms

These principles support the wider core goals of any healthcare system: access, quality, sustainability and equality. Given the pressure under which healthcare funds are currently operating, principle 7 offers a conservative minimum starting point, stating that the total cost per patient should not exceed the next best alternative. In reality, and taking remote follow-ups as an example, a number of the clinicians we interviewed cited productivity gains of between 100% and 300% when managing follow-ups remotely. If these gains can be harnessed appropriately and fairly, then payer, service provider (hospital/clinician) and industry should all benefit, whilst giving patients greater freedom to live their lives without interruptions. This is illustrated in Figure 2:

Fig. 2 Illustration of rewards for remote follow-ups



In the case of face-to-face care, the lower efficiency of the service might result in a payment of ten units per patient seen by a clinician. Under remote follow-ups, where a clinician in this example reviews twice as many patients in an hour, the provider might earn more per hour (which would be partly used to cover additional support costs) whilst costing the payer less per patient. This also frees the physician's time to do other things, whilst ensuring that industry still gets reimbursed for its contribution to the service. Furthermore, the patient benefits by not having to interrupt his day to attend a face-to-face meeting, and does not incur any travel costs. In a similar fashion, we would expect any benefits generated by remote monitoring (eg, reduced emergency hospital admissions) to be shared across the participants appropriately (adhering to principle 6: rewarding stakeholders in proportion to the value they create).

Applying the twelve principles above to the two use cases outlined in Table 1, we have developed the following "generic" solutions, which have then been adapted to each country's specific health system (see the following Tables 4–7).

"Generic" solution for remote follow-ups (Case 1):

Tab. 4 Generic solution for Case 1

Theme	Description
Scope	• Reimbursement covers all costs associated with the service, namely physician, hardware and support service costs • Applicable to all patient groups
Payment method	• Fee for service for the remote follow-up activity, eg, with an annual fee for the required hardware, infrastructure and services (eg, transmitter)
Payer	• Existing payer of face-to-face service, with some potential for patient co-payment • Provider (hospital/clinician) covers the cost of infrastructure and support
Price and allocation	• Both providers (hospitals/physicians) and industry are rewarded in line with the value they generate, incentivising uptake • Total reimbursement value for remote follow-ups (ie, paid to all participants) should not exceed the amount which the payer would have paid for their face-to-face counterparts
Goal alignment	• The level of reimbursement (ie, less than current face-to-face value) should incentivise the providers to be more efficient and prevent recurring visits (eg, by not rewarding them if the patient must return unexpectedly within a certain period)

Solutions for remote follow-ups (Case 1):
For all countries, the scope incorporates all physician services, TM technology and support services required to deliver the remote follow-up service. The solutions apply to all patients.

Tab. 5 Reimbursement solutions for remote follow-ups

	Physician service	Infrastructure
Germany		
Payment method	Fee for service, as currently defined in the EBM	Annual fee for both TM technology and services or providers buy this infrastructure
Payer	Statutory health insurance/private health insurance	Providers (plus potential patient co-payment)
Price and allocation	Same level as face-to-face follow-ups (part of lump sum paid to providers)	Physician fee reflects efficiency gain Patient co-payment should not exceed the average travel cost that the patient saves
Italy		
Payment method	Fee for service (same as existing face-to-face)	Annual fee for both TM technology and support services or hospitals buy this infrastructure
Payer	Government/regions: directly or through local healthcare units	Hospital, with part of the fee potentially coming from regional funding and patient co-payment
Price and allocation	Total budget per follow-up includes components for physician services and infrastructure Allocation defined a) via contract between hospitals and industry or b) by the regions	
Spain		
Payment method	Same budget for remote follow-ups as for current face-to-face follow-ups	Annual fee for both TM technology and support services
Payer	Government/regions	Government/regions
Price and allocation	Total budget for follow-up includes components for physician services and infrastructure Allocation defined a) via contract between hospitals and industry or b) by the regions Hospital efficiency savings translate into increased capacity and reduced waiting lists	
The Netherlands		
Payment method	Fee for service for the RFU (on same basis as current face-to-face follow-ups)	Annual fee for both TM technology and support services or hospitals buy this infrastructure
Payer	Insurance companies	Hospital, with potential patient co-payment
Price and allocation	Total follow-up budget includes components for physician services and infrastructure Allocation defined via contract between hospitals and industry	Patient co-payment should not exceed the travel cost that the patient saves
UK		
Payment method	Fee for service: revised national HRG outpatient remote monitoring follow-up tariff	"Top-slice" of HRG
Payer	Local commissioner (through national tariff)	Local commissioner (through national tariff)
Price and allocation	New tariff for remote follow-up, reflecting the increased throughout efficiency	Infrastructure and support service providers reimbursed through "top-slice" of HRG, with proportion determined within national tariff

"Generic" solution for remote monitoring (Case 2):

Tab. 6 Generic solution for Case 2

Theme	Observations
Scope	• Reimbursement covers all costs associated with the service, namely physician, hardware and support service costs • Solution only applied to those patient groups for whom the clinical and economic benefits of remote monitoring exceed the associated costs (primarily for TM technology)
Payment method	• Physician services reimbursed through existing tariff/budget systems by introduction of telemonitoring or pathway tariff • Annual fee for the required hardware, infrastructure and services (eg, transmitter)
Payer	• Existing payer of cardiac services for the patient (eg, NHS, insurer) • Provider (hospital/clinician) covers the cost of infrastructure and support
Price and allocation	• Payment allocated to the various contributors on the basis of the value they generate • Price of serving the patient should be no more than the cost of the next best alternative (eg, emergency admission to hospitals twice a year)
Goal alignment	• Governance must focus on outcomes for the patient, to validate improved quality and reduced total cost of care

Solutions for remote monitoring (Case 2):
For all countries, the scope incorporates all physician services, support services and hardware required to deliver the remote monitoring service. It also most likely requires a risk stratification of patients and assessment of the clinical and financial benefit of offering remote monitoring, which should then be rewarded in relation to the value it brings.

Tab. 7 Reimbursement solutions for remote monitoring

	Physician service	Infrastructure
Germany		
Payment method	Follow-up treatments paid via EBM (fee for service), as with remote follow-ups	Annual fee for both TM technology and support services, as part of contract agreement
	Potentially use TM tariff as part of an integrated care contract	TM tariff also includes infrastructure investments required by providers
Payer	Statutory health insurance/private health insurance	Statutory health insurance/private health insurance
		Government might fund part of fee to foster telemonitoring
Price and allocation	Same level as face-to-face follow-ups (part of lump sum paid to providers)	
	Total fee for the year should not exceed savings through fewer hospital stays	
Italy		
Payment method	TM tariff for hospitals: fee for service for one year (one month) of TM service, including the follow-ups	Annual fee for both TM technology and support services or hospitals buy this infrastructure
		Hospital investments should be covered by the TM tariff; additionally, the hospitals can make use of efficiency gains
Payer	Government/regions: directly or through local healthcare units	Regions/local healthcare units
		Hospital participation according to efficiency gains from remote follow-ups
Price and allocation	Introduction of TM will increase cost at implementation (eg, investing in infrastructure), whilst the general budgets for hospitals will stay unchanged	
	Objective after implementation: reduction in emergency room admissions frees up additional capacity in hospitals, thus minimising overall capacity investment in the mid- to long-term	
Spain		
Payment method	TM budget for hospitals, including physician monitoring services and follow-ups	Annual fee for both TM technology and support services
		Hospital investments should also be covered by the budget for TM
Payer	Government/regions	Government/regions
Price and allocation	Introduction of TM will increase cost at implementation (eg, investing in infrastructure)	
	Objective after implementation: reduction in emergency room admissions frees up additional capacity in hospitals, thus minimising overall capacity investment in the mid- to long-term	

	Physician service	Infrastructure
The Netherlands		
Payment method	TM tariff for hospitals: fee for service for one year (one month) of TM service, including the follow-ups Follow-ups paid via respective activity codes (fee for service), same as remote follow-up	Annual fee for both TM technology and support services or hospitals buy this infrastructure Hospital investments should be covered by the TM tariff
Payer	Insurance companies	Insurance companies Hospital contribution according to efficiency gains from remote follow-up
Price and allocation	Generally same level as face-to-face follow-up/agreed price for the respective activity code Total fee for the year should not exceed savings through fewer hospital stays	
UK		
Payment method	Local commissioner reimburses a "lead provider" offering an integrated, end-to-end service for specific cardiac care pathways (eg, acute trust) Risk-adjusted year-of-care payment for that pathway (tariff), which covers all services For this to work, there must be interoperability with the wider NHS systems	
Payer	Local commissioner pays via national tariff for specific pathway, which adjusts for risk profile of patient Lead provider reimburses organisations supplying services and equipment to it	
Price and allocation	Total value reimbursed for follow-up and ongoing community care should be less than equivalent care provided through existing face-to-face mode Allocation of payment to the different participants arranged through contracts with the lead provider	

Getting practical: key actions and next steps

To realise these changes requires actions – both small and large; immediate and long-term. A number of these apply across all countries; they include the following:

1. Payers must foster the right environment in which remote follow-ups and monitoring can flourish. This requires policies, guidelines and reimbursement mechanisms that position these services appropriately and enable them to support the wider system goals of access to care, efficiency and high-quality clinical outcomes and patient experience.
2. In the case of remote follow-ups:
   – Industry must work to reduce the investment hurdle for infrastructure, for example by offering hardware and services for a bundled annual fee, and continue to demonstrate that efficiency gains are achievable.
   – Providers (hospitals and clinicians) must ensure their staff is trained appropriately, and support patients to ensure the uptake of the service does indeed take place.
3. In the case of remote monitoring:
   – Industry must work with the other stakeholders to consolidate evidence on the value of CIED telemonitoring in a format and scope acceptable to them.
   – Providers must ensure that the required capacity to provide remote monitoring – both personnel and technology – is in place. This extends beyond training to a wider programme of change management to support the transition to new working practices. They must also develop an approach for the assessment and targeting of patients most suitable for remote monitoring.

In addition, we have identified a number of country-specific actions to address:

Tab. 8 Country-specific actions recommended to enable successful implementation of changes in CIED telemonitoring

	Payers	Providers	Industry
Germany	• Commit to reimbursing telemonitoring on the same basis as face-to-face care • Lay out criteria and conditions for patient target groups who will benefit from telemonitoring	• Review and confirm the efficiency gains enabled by telemonitoring • Evaluate the business case for telemonitoring	• The committee defining which outpatient treatments will be reimbursed (Bewertungs-ausschuss) is currently reviewing the business case for telemedicine services – use this opportunity to clearly position the value that telemonitoring can bring and support the development of business cases
Italy	• Define the fee for service for remote follow-ups • Develop a telemonitoring tariff	• Work with regions/local healthcare units and industry on target groups and the required setup for a positive case	
Spain	• Develop a financing model which takes into account additional hospital capacity • Consider the set-up of regional tenders for telemonitoring infrastructure	• Work with regions and industry on target groups and the required setup for a positive case	• Forge new structures, alliances and consortia to enable the integrated delivery of cardiac care pathways
The Netherlands	• Create new activity code or enhance existing one • Define fee for service for remote follow-ups and telemonitoring with hospitals • Engage patient organisation (STIN)	• Review and confirm the efficiency gains enabled by telemonitoring • Evaluate the business case for telemonitoring	• Engage with patient organisations to foster remote follow-ups • Support health insurers in developing remote monitoring business case
UK	• Analyse the Whole System Demonstrator (WSD) results to understand the benefits for cardiac patients • Department of Health to develop tariffs for specific cardiac care pathways and for outpatient remote monitoring follow-up • Adapt payment platform to enable direct reimbursement to industry for infrastructure and monitoring services	• Provide a programme of training for clinical and managerial staff on the use of telemonitoring • Only implant devices with remote monitoring capability	• Forge new structures, alliances and consortia to enable the integrated delivery of cardiac care pathways

B Objectives and background information

1 Objectives

The challenges faced by European healthcare systems in 2012 are well documented; they include an ageing population, unhealthy lifestyles, an associated rise in chronic disease, rising medical costs, funding pressure exacerbated by economic uncertainty and increasing patient expectations. As a result, healthcare spending continues to rise faster than economic growth in most OECD countries [3].

In responding to these challenges, governments and healthcare leaders consistently return to the theme of innovation, although they may differ in how they conceive and implement it[4]. As John Dalli, European Commissioner for Health and Consumer Policy, stated in 2011:

Europe needs innovation in health to provide better healthcare, to more people, in an efficient manner, in the long term. We need to use innovation to make health systems deliver more; and in a more sustainable manner [5].

Initiatives such as the European Innovation Partnership on Active and Healthy Ageing and England's Whole System Demonstrator Programme – the largest ever randomised control trial of telehealth and telecare – are clear indicators of political commitment to the development of new and innovative solutions.

In the case of telemonitoring, industry seeks to match this political commitment with technological and service innovation. However, such advances require fundamental changes to how care is provided, organised and reimbursed. A sustainable reimbursement model should encourage efficiency and quality, reward fairly and incentivise appropriate further investment.

This study focuses on reimbursement for telemonitoring cardiac implantable electronic devices (CIEDs). Through a review of current practices in five European countries (Germany, Italy, Spain, the Netherlands and the UK) and informed by more than 50 interviews with payers, providers, health leaders, politicians and clinicians – the study

- outlines current reimbursement practices for CIED telemonitoring,
- identifies good practice and opportunities for improvement,
- proposes principles that should govern any future reimbursement of CIED telemonitoring and
- applies these principles to the five countries to develop proposals for reimbursement changes and practical next steps to deliver them.

[3] Cf. OECD, OECD Health Data 2011, 2011.
[4] Cf. Economist Intelligence Unit, Future-proofing Western Europe's healthcare: A study of five countries, 2011.
[5] John Dalli speaking at the Innovation in Healthcare conference in Brussels, Belgium, March 30th 2011.

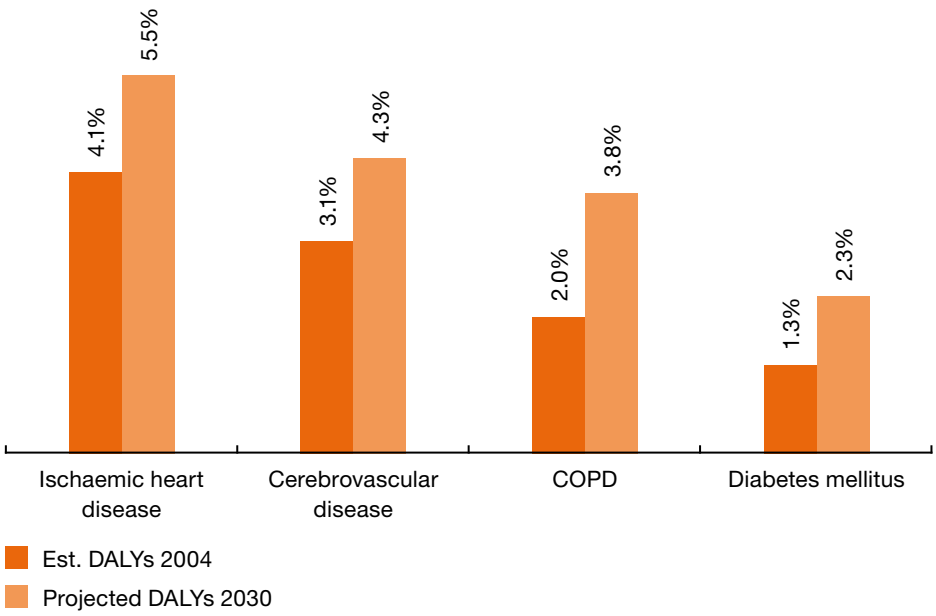
This study is not solely about a long-term vision, although this gives necessary direction to what can be achieved. Rather, we are offering pragmatic solutions to a complex problem. We fully acknowledge the challenging environment in which Europe is currently operating, and seek workable, short- to medium-term solutions that take important but graduated steps towards improved care for patients, and more efficient solutions for healthcare leaders.

2 Chronic conditions: the key challenge for European healthcare

Long-term, or chronic, conditions – which require ongoing management over a period of years or decades – are the greatest challenge for health economies in Europe. Comprising mainly cardiovascular diseases, cancers, stroke, chronic respiratory disease and diabetes, they accounted for nearly two thirds (36 million) of the 57 million deaths that occurred globally in 2008 [6].

Furthermore, analysis[7] by the World Health Organisation (WHO) indicates their burden is expected to increase significantly in the future. Figure 1 illustrates this increasing burden in terms of disability adjusted life years (DALYs) – broadly defined as one lost year of "healthy" life, measured as the average gap between current health status and an ideal situation where everyone lives to old age in full health[8].

Fig. 3 Global average of DALY for selected chronic conditions in 2004 and outlook for 2030

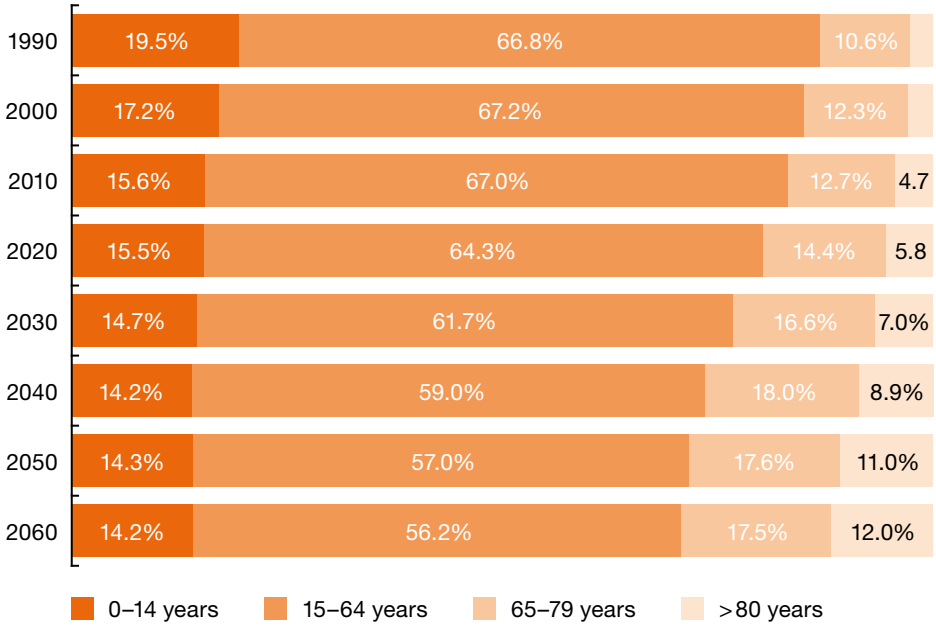


Source: World Health Organisation, Global health risks: Mortality and burden of disease attributable to selected major risks, 2009.

[6] Cf. World Health Organisation, Global status report on non-communicable diseases 2010, 2010.
[7] Disability-adjusted life year (DALY) is a measure of overall disease burden, expressed as a number of years lost due to ill-health, disability or early death.
[8] Cf. World Health Organisation, Global health risks: Mortality and burden of disease attributable to selected major risks, 2009.

What is driving this growth? The WHO cites three "common modifiable risk factors" – unhealthy diet, physical inactivity and tobacco use – as the main causes of the vast majority of chronic diseases for all ages, in men and women [9]. These are underpinned by wider social, economic and cultural trends including globalisation, urbanisation and rapid population ageing (the impact of risk factors increases over the course of an individual's life). The facts are stark: the proportion of older people (aged 65 years and older) in Europe is forecast to rise from 15.6% in 2000 to 23.6% by 2030, while the proportion of those aged 80 years and over is expected to more than double from 3.3% in 2000 to 7.0% in 2030 (see Figure 4)[10].

Fig. 4 Population age structure for the EU-27, 1990–2060



Source: Eurostat; excludes French overseas departments in 1990; 2010, provisional; 2020–2060 data are projections (EUROPOP2010 convergence scenario).

[9] Cf. World Health Organisation, Preventing chronic diseases: a vital investment, 2005.
[10] Cf. Eurostat (online data codes: demo_pjanind and proj_10c2150p); 2020–2060 data are projections (EUROPOP2010 convergence scenario).

However, global and European trends hide regional variation; cardiovascular disease (CVD) mortality is falling in most Northern, Southern and Western European countries, whilst it is not falling, or not nearly as fast, in Central and Eastern European countries. This notwithstanding, for chronic conditions the management of CVD offers the greatest opportunity for improved health in Europe. CVD is the number one cause of death; each year, 17 million people die from CVD, of which over 2 million are in the European Union[11]. They account for 29% of all deaths globally and nearly half of all deaths due to chronic disease[12]. Of those 17 million deaths per year, the largest share of around 7.2 million falls under the category of coronary heart diseases (CHD)[13]. It is estimated that Europe could save 135,000 lives a year through better cardiovascular care[14]. CVD is also expensive, costing the European Union just under €192 billion in 2006[15].

The challenge facing European healthcare systems is therefore twofold:

1. To reduce the prevalence of chronic conditions by influencing the common modifiable risk factors. To do so, governments are increasingly looking to prevention and a holistic approach to public health management (eg, an integrated approach to health and social care, and indeed welfare).
2. To manage more effectively and efficiently patients with chronic conditions. This has driven a focus on pathway redesign and a shift away from hospitals to increased care in the community.

In both cases, as growth in demand outpaces that of funding, there is an underlying need to innovate – to find new ways of managing old problems while satisfying the key goals of any healthcare system: access, quality, sustainability and equality. In Europe, this has been gaining increasing prominence through both national initiatives (eg, the quality, innovation, productivity and prevention programme in UK health care) and centrally coordinated campaigns, including the European Innovation Partnership on Active and Healthy Ageing. These initiatives are often integrated propositions that combine a range of services and products from multiple providers and involve new models of care. They may be supported by technology, but best practice ensures they are clinically led. It is in this space that CIED telemonitoring has developed, and is now set to mature.

Nolte and McKee summarise the situation neatly:

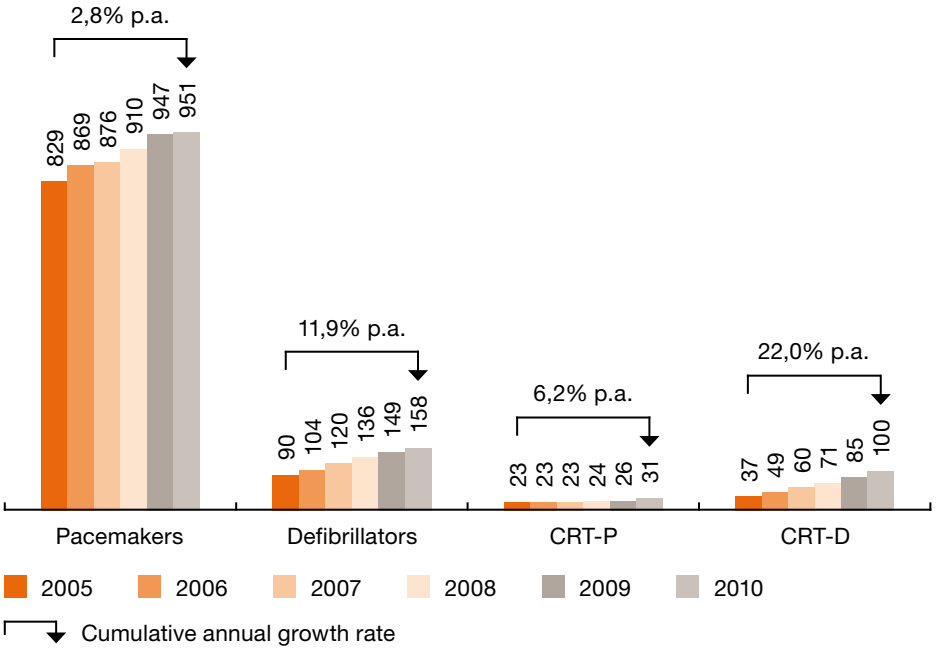
The common theme is that these [chronic] conditions require a complex response over an extended time period that involves coordinated inputs from a wide range of health professionals and access to essential medicines and monitoring systems, all of which need to be optimally embedded within a system that promotes patient empowerment [16].

[11] Cf. www.escardio.org/about/press/Factsheets/Pages/Cardiovascular-Disease-in-Europe.aspx.
[12] Cf. World Health Organisation, Noncommunicable diseases – Fact sheet, September 2011.
[13] Cf. de.globometer.com/krankheiten-herzinfarkt.php.
[14] Cf. the European Study on Cardiovascular Risk Prevention and Management in Daily Practice (EURIKA).
[15] Cf. European Heart Network, European cardiovascular disease statistics 2008, 2008.
[16] Nolte, E.; McKee, M., Caring for people with chronic conditions. A health system perspective, Open University Press, McGraw Hill, 2008.

3 Cardiac implantable electronic device (CIED) telemonitoring

Since their introduction in 1958, CIEDs have become a common feature of the healthcare landscape and their usage continues to grow as demand increases and technology advances (see Figure 3). Each of these devices requires regular technical checks and adjustments, with the physician managing both patient and device. In addition, the increasingly sophisticated capabilities of these devices offer the opportunity to capture a continuous flow of physiological data (biosignals), and thereby potentially gain new insight and enable more effective and timely intervention.

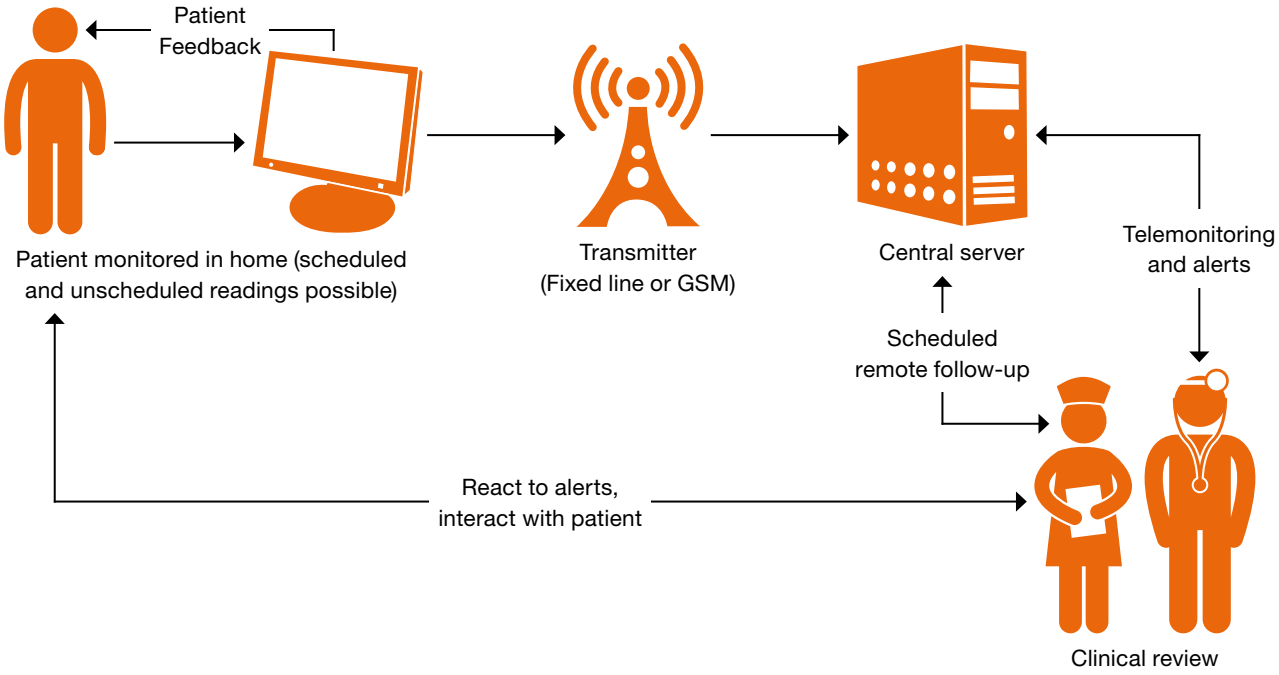
Fig. 5 CIED implants per million inhabitants, 2005–2010



Source: www.eucomed.org/uploads/_medical_technology/facts_figures/110518_statistics_for_cardiac_rhythm_management_products_20052010.pdf.

What may surprise some is that telemonitoring of CIEDs also has a long history: the remote monitoring of pacemakers trans-telephonically was introduced in 1971 and, today, cardiac patients represent the largest patient segment monitored by wireless telemetry[17]. Obviously, the sophistication of the technology – and the manner in which this technology has been adopted, adapted and integrated into new models of care – has significantly advanced in recent years. A typical set-up for CIED telemonitoring is outlined in Figure 6:

Fig. 6 Typical CIED telemonitoring set-up



Such a set-up brings with it a need to change CIED follow-up paradigms and protocols[18], and the opportunity to transform cardiac care. Indeed, in January 2012, a group of leading cardiologists published a consensus paper summarising current findings on CIED telemonitoring[19]. Whilst acknowledging the need for further research, the authors outlined a number of potential benefits of the service:

Today's evidence demonstrates that a replacement of calendar-based follow-ups with RM [remote monitoring] can increase patient safety by early detection of technical events, reduce the number of in-office follow-ups, detect medical events early, may reduce length of stay and hospitalization rates, may reduce the risk of stroke and atrial arrhythmias, and may cut down mortality risk by about 50%[20].

On this basis, they shift the debate from one of finding evidence to one of implementation and, critically, reimbursement: "With this supportive evidence in place the responsibility for establishing reimbursement policies is now shifting back to the policy makers[20]."

[17] Cf. Dubner, S. et al., ISHNE/EHRA expert consensus on remote monitoring of cardiovascular implantable electronic devices (CIEDs), Europace 14 (2), 2012, pp. 278–293.
[18] Cf. Wilkoff, B. et al., HRS/EHRA Expert Consensus on the Monitoring of Cardiovascular Implantable Electronic Devices (CIEDs), Europace 10 (6), 2008, pp. 707–725.
[19] Cf. Dubner, S. et al, ISHNE/EHRA expert consensus on remote monitoring of cardiovascular implantable electronic devices (CIEDs), Europace (2012) 14 (2), pp. 278–293.
[20] Consus-Paper: Dubner et al (2012) ISHNE/EHRA expert consensus on remote monitoring of cardiovascular implantable electronic devices (CIEDs), Eurospace (2012) 14 (2): 278–293

From a patient's perspective, our interviews indicate that remote follow-ups provide real benefits for those who are still active and do not want to be absent from work for a medical check-up.

This is an important change in emphasis. To date, adoption of CIED telemonitoring in the EU has been slower than many anticipated, and our research and interviews indicate a number of reasons for this, summarised in Table 9:

Tab. 9 Issues and challenges with CIED telemonitoring

Stakeholder	Issues/challenges
Payer	• Budget constraints have limited some payers' ability to invest in telemonitoring • Some have found it difficult to define the business case for telemonitoring in the absence of sufficient evidence and data
Patient	• There is a low-level of awareness of telemonitoring and its benefits amidst patients, resulting in a lack of "patient pull" • The large-scale uptake of telemonitoring requires a change in patient behaviour (eg, replacing face-to-face visits with telemonitoring)
Physician	• Some clinicians have expressed concerns about governance and accountability risks associated with telemonitoring • Clinical buy-in and championing of telemonitoring has been variable • Education of clinicians in telemonitoring has been limited and inconsistent
Hospital	• In some cases, there are financial disincentives to hospitals adopting telemonitoring (ie, loss of revenue from current in-office follow-ups) • Managing the transition from acute to community care is challenging and requires the alignment of a number of different parties in in- and outpatient care
Device manufacturers	• There are no common reimbursement schemes in place for TM technology and support services, resulting in a financial disadvantage for the industry • Interoperability and integration with wider healthcare technologies and IT systems currently is still challenging

As part of a wider set of changes, developing a robust reimbursement model can help reduce some of these barriers and support the transition to new models of care for patients suffering from chronic heart conditions. The remainder of this study considers the limitations of current reimbursement schemes for CIED telemonitoring, and offers practical solutions to address them.

C CIED reimbursement in Europe: an overview

Establishing an effective and fair healthcare reimbursement scheme is not a simple undertaking. Basic questions such as "Who pays?" and "What should be covered by the payment?" often have complex answers and generate much debate.
This section begins with an outline of the key components of a reimbursement model in health care. In doing so, it provides the framework for all that follows – a prism through which to observe both current practices (this section and the next), and recommended changes for the future (in the remaining sections).

1 What is a "reimbursement model"?

Although complex in its nature, a healthcare reimbursement model can be defined by responding to five related questions, as outlined in Table 10:

Tab. 10 Key questions for a reimbursement model

Theme	Key question	Considerations
1 Scope	What will be funded?	The system must determine which services, devices, drugs, supplies and infrastructure will be covered by the payment. This concerns the full pathway of patient care from prevention, through to initial hospital intervention, recovery, rehabilitation, reablement and ongoing monitoring and community care as appropriate. How the service is envisaged and commissioned fundamentally affects the scope of reimbursement; for example, an integrated frail elderly service must reimburse all components from assistive technologies through to monitoring.
2 Payment Method	On what basis will payment be made?	The basis on which payments are made has potentially significant implications, particularly in areas such as risk, outcomes, incentives and, ultimately, sustainability of the service. Furthermore, different choices may be made for different elements of a service, as is seen for example in imaging, where capital and revenue payments may be handled separately or, as is increasingly the case, together.
3 Payer	Who pays?	Potential payers include public payers, health insurers, patients and employers, and more than one may contribute. The decision about who pays also goes to the heart of the social, ethical and political values that underpin the health system, and can be a contentious area.
4 Price and allocation	Who receives payment and how much (price)?	There are a number of different stakeholders and entities involved, each of which must be fairly rewarded for the value they contribute. However, this must ultimately pass through the filter of affordability and sustainability for the overall service.
5 Goal alignment	Does it align to broader health system objectives and policies?	Reimbursement must be aligned with the broader goals of the healthcare system, including access, quality, sustainability and equality. The relative weighting placed on these criteria will influence reimbursement choices, as will the pragmatic push to avoid unnecessary complexity.

Each of these five questions entails design choices made within the context of the wider health system. In addition, a sixth and final set of choices must be made as to how the new system will be implemented. These implementation decisions are far from incidental, with fundamental questions about governance, long-term goals and the nature of existing reimbursement solutions all requiring consideration. Figure 7 summarises these choices:

Fig. 7 Key reimbursement choices

Design					Impl.
1 Scope of funded activity	**2 Payment method**	**3 Payer**	**4 Price and allocation**	**5 Goals alignment**	**6 Roll-out**
• Support services • Equipment, drugs and infrastructure • Patient segments	• Block contract • Fee for service • Per diem • Episode of care • Capitation • Outcome	• Public funding – National – Local • Patient – Private medical insurance • Employer – Private medical insurance	• Payment level (price) • Allocation of payment to multiple providers	• Access • Quality • Sustainability • Equality	• Short, medium and long term • Adapt existing vs create new • Management and governance
Example considerations					
• Services comprise physician and monitoring services • Capital vs revenue costs	• Single or multi-provider • Disease-specific or patient-based • Definition of outcomes • Incentives	• Single or multiple payers • Acceptability • Feasibility	• Affordability/ sustainability • “Fair” allocation of payment	• Relative weighting of criteria • Economic benefits	• Existing reimbursement models • Complexity

Given the complexity of – and interdependencies within – healthcare systems, the move to a new reimbursement model cannot happen overnight. Consequently, the proposed reimbursement solutions outlined in this paper should be considered the first practical steps in support of a longer-term vision for CIED telemonitoring. The differences between the short and long-term outlook are illustrated in Table 11:

Tab. 11 Short-term vs long-term outlook for CIED telemonitoring

Short- to medium-term outlook		Longer-term outlook
Cost neutral vs tradition care models (a better solution)	→	Reduced cost per patient (a better and cheaper solution)
Reimbursement emphasises activity	→	Reimbursement emphasises outcomes
Telemonitoring seen as an additional service	→	Telemonitoring part of an integrated solution
Relatively small number of patients per available cardiologist	→	Relatively large number of patients per available cardiologist
Proprietary telemonitoring technologies	→	Emphasis on interoperability

2 Current reimbursement schemes for CIED telemonitoring in the five focus countries

Currently, none of the five countries in our study has a complete, end-to-end solution for the reimbursement of CIED telemonitoring. Differences in approach reflect in part the different structures of each healthcare system, which are described below[21].

2.1 Germany

The Federal Republic of Germany currently has circa 82 million inhabitants and is organised in 16 federal states. The German healthcare system is an insurance based system, with about 90% of the population insured through statutory health insurance (SHI) and the rest through private health insurance companies. The purchasing of health insurance is a legal obligation.

A distinctive characteristic of the German healthcare system is the separation of inpatient and outpatient care. This separation is reflected in the reimbursement mechanism overall, and in reimbursement for CIED telemonitoring specifically. Typically, hospitals are responsible for operations, with inpatient services, including cardiac implants, reimbursed via diagnosis related groups (DRGs). However, certain procedures may also be performed in an outpatient setting, and then reimbursed as part of the catalogue for outpatient services (Einheitlicher Bewertungsmaßstab, or EBM). Regular follow-up device checks are performed in the outpatient sector through outpatient cardiologists or outpatient care centres within hospitals. The SHI generally reimburses physicians for outpatient services, which are part of the EBM, via lump sum payments to the Associations of Statutory Health Insurance Physicians (Kassenärztliche Vereinigungen). This lump sum includes follow-ups but not outpatient procedures, which are reimbursed as an additional service.

[21] Cf. Commonwealth Fund, International Profiles of Health Care Systems, 2011.

Germany may be seen as the most advanced of the five countries in this study when considering the reimbursement of CIED remote follow-ups. An EBM code for the physician outpatient services relating to remote follow-ups already exists on the same basis as that for face-to-face follow-ups. However, the accompanying TM infrastructure with support services is not covered through this mechanism. To reimburse the infrastructure, payers conclude individual contracts with providers and industry partners. Such contracts need to be economical and payers must ensure that they are at least cost-neutral when compared to traditional care models. Currently, very few contracts have been concluded by large SHIs.

As part of a new law to improve healthcare provision (GKV-Versorgungsstrukturgesetz), the broader use of telemedicine in the outpatient sector shall be further evaluated. The committee defining which outpatient treatments will be reimbursed (Bewertungsausschuss) will investigate how and where telemedicine could be used for outpatient care, and will report back in October 2012. Approved activities will then be included in the EBM in the first quarter of 2013.

2.2 Italy

Italy has a population of circa 59 million citizens, residing in twenty regions and two autonomous provinces (Trento and Bolzano). The National Health System (Servizio Sanitario Nazionale) provides universal healthcare coverage to the population, funded through a combination of public (regional general taxation) and private sources (payroll taxes).

Legally placed under the central responsibility of the Ministry of Health, the system is largely decentralised and comprises three levels: national, regional and local. The content of the benefits package (Livelli Essenziali di Assistenza, or LEA) is defined by the Ministry of Health, with inpatient and primary care included in the basic benefits package and therefore not subject to co-payments. For specialist visits, co-payments are usually required. Italians must register with a general practitioner (GP) who refers patients to medical specialists.

GPs are paid through a capitation system. Hospitals are generally reimbursed according to global budgets and/ or DRGs with rates set by the regions within limits defined by the central government. Regions co-operate either directly with hospitals or via local healthcare units. The latter are public companies acting for regions providing a range of healthcare services, from outpatient to inpatient care. Private health insurance is available in Italy, but is not widespread (only about 15% of the population purchases cover).

CIEDs, like all implantable medical devices, are not explicitly mentioned in the LEA but are included in the inpatient procedures performed at a hospital level and are reimbursed through the DRG. However, DRG levels vary considerably by region. Differences between regions and different types of hospitals can be observed in terms of the volumes assigned.

Currently, there is no reimbursement scheme for remote follow-up or remote monitoring activities. Pilot projects are an exception: for example, the Veneto region is participating in the Renewing Health project where a value is assigned to the different services provided across the care pathway, including remote monitoring. With the pilot tariff, an overall value per patient treated is assigned to hospitals to cover a package of services related to all domiciliary activities (eg, calls, monitoring, visits at the beginning and at the end of the pilot). The pilot project EVOLVO may be seen as a first step towards successful reimbursement of telemonitoring: chronic patients are treated as outpatients while physician services are reimbursed via tariffs – both measures are meant to contain costs. EVOLVO aims to evaluate benefits resulting from the use of CIED telemonitoring in terms of the reduction of visits and hospitalisation.

2.3 Spain

Spain has a population of circa 46 million inhabitants and its health affairs are delegated to the 17 autonomous communities. The Spanish healthcare system is highly decentralised and is funded independently by each of the regions. The central government allocates block grants to each region according to its population and demographics, resulting in wide variations of healthcare spending and quality across the regions.

The Spanish hospital funding system operates mainly through a mechanism of general budgets, so that one cannot speak of reimbursement in a narrower sense. However, in the following we nevertheless refer to the financing of the healthcare services as reimbursement.

The new general government initiated the widespread introduction of free choice in hospitals, primary care centres and GPs, although in some autonomous communities the free choice regulation was already in place (eg, Madrid and Andalucía).

Waiting lists have led to an increased demand for supplementary private health insurance. This has resulted in a two-tiered system where about 23% of the population[22] receives higher quality care by purchasing private insurance. Most physicians are quasi-civil servants and are paid through a salary system based on seniority and credentials. As a consequence of lower salaries, Spain has fewer doctors and nurses per capita than most OECD countries.

No standards or reimbursement schemes are in place yet for the remote follow-up and remote monitoring of CIEDs in Spain. Although severely constrained by budgets, physicians' demonstrate a high willingness to implement CIED telemonitoring, supporting the training of their teams and explaining the effectiveness of telemonitoring tools to patients. Furthermore, a shortage of physicians and long waiting lists are fostering the demand for telemonitoring solutions and the development of reimbursement models which could ultimately lead to reduced hospital stays and improved treatment methods.

[22] Cf. ICEA 2011.

2.4 The Netherlands

The Netherlands have a population of circa 16 million citizens. All income tax paying inhabitants of the Netherlands are obliged to join the statutory health insurance scheme through any one of the many private insurance companies, each offering nationwide health plans. The individual pays a health insurance contribution (Zvw) and a contribution for exceptional medical expenses (AWBZ), which comprises basic care and support in the event of long-term illness, disability or old age as laid down by the Health Insurance Act 2006.

Consumers may also purchase supplementary care through private insurance, which includes care not reimbursed under the mandatory health insurance scheme. Typically, individuals purchase the supplementary insurance at the same insurer as the mandatory insurance package. Insurance companies providing mandatory basic health cover under the Health Care Insurance Board (CVZ) are obliged to accept every individual whereas they may apply risk selection tools for the supplementary insurance. Individuals pay community-rated flat-rate premiums directly to the insurer and income-related premiums to the health insurance fund, which collects contributions and redistributes them to insurers according to their policy-holders' risk profiles (explicit cross-subsidies). The aim is to reduce the complexity of the insurance system and to strengthen solidarity.

Individuals have the right to choose their preferred insurer and policy type on a yearly basis. The government defines the benefit package of the mandatory insurance scheme based on the advice of the CVZ and insurers are encouraged to negotiate favourable contracts with providers for certain health plans (selective contracting). The legislation allows insurers to sign contracts with only a limited number of preferred providers, including specific agreements on prices and waiting periods.

The insurance market is dominated by five large insurance companies, which account for over 80% of all insured individuals. The healthcare purchasing market is characterised by regulated competition which constitutes the main principle of the system. Hospital budgets are determined through negotiations on volume and price between insurer and hospital, meaning that each hospital negotiates with each insurer for the diagnosis treatment combination (DBC) rates.

Two-third of hospital-based physicians are self-employed and organised in partnerships, and the rest are salaried. Salaried physicians are either employed at the hospital or at integrated care centres (ZBCs) at the hospital site.

2012 saw the Dutch healthcare system undergo a significant change in its DRG system, moving from the DTC to the DOT (DTCs on their way to transparency) system. This has resulted in a reduction from 30,000 to only 4,400 active codes, which will have an impact on telemonitoring as well.

Generally, CIED telemonitoring is not included in the standardised reimbursement system. Telemonitoring can only become part of the DTC catalogue if it is approved as a new treatment method by the Health Authority. However, an "activity code" for telemonitoring has been established. This can be seen as a sound basis for future reimbursement approaches and a possible inclusion into the DOT catalogue. According to selective contracting mechanisms, insurers agree upon the price for remote follow-up. In the Netherlands all implanted CIED devices are enabled to perform TM activities.

2.5 United Kingdom

The United Kingdom has a population of circa 62 million inhabitants. The National Health Service (NHS) is a universal and comprehensive healthcare service made available to the entire population free at the point of use. Overall budgets are set once every three years as part of the general public expenditure planning process (Comprehensive Spending Review). Although funded centrally from national taxation, NHS services in England, Northern Ireland, Scotland and Wales are managed separately.

Most primary care in England is provided by GPs in group practices, or through walk-in centres. NHS hospitals, the main provider of secondary care in England, are organised either as NHS trusts (directly responsible to the Department of Health) or as foundation trusts (which gives them greater freedom over how they spend their budget).

Private health insurance in England is typically used by patients as a top-up to NHS services, for specific elective procedures. Both for-profit and not-for-profit companies provide private health insurance, and insurance premiums are risk-related and vary between collective and individual contracts, with the majority being collective agreements purchased by employers. Premium levels are not regulated.

Reimbursement is very different between primary and secondary care, with GPs paid through a standardised national general medical services contract and hospitals reimbursed for care services via a tariff based on Healthcare Resource Groups (HRGs). Pacemakers and CRT-P devices are included in the HRG tariffs. By contrast, ICDs and ICDs with CRT remain “excluded devices”, and are therefore subject to local negotiation between trusts and the commissioner (a further source of variation). Once implanted, there is also currently considerable inconsistency in how trusts are paid for remote monitoring CRM clinics. Some receive the follow-up outpatient cardiology rate (£108 in 2011/12), others receive a non face-to-face outpatient attendance tariff (£23 in 2011/12, although the 2010/11 tariff explicitly excluded telemonitoring from this category) and some get nothing (depending on the local commissioner).

Tables 12 summarises some of the key differences between these different healthcare systems:

Tab. 12 Key countries healthcare systems

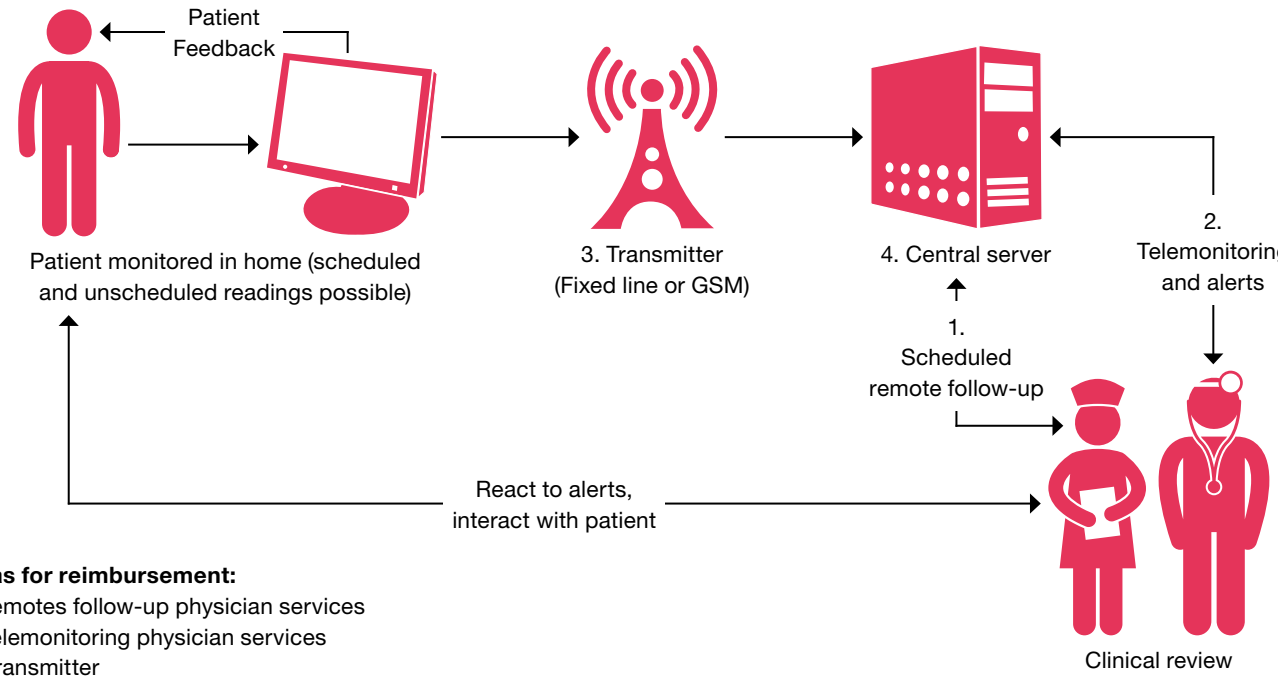
Focus countries	Government role	Public system financing	Private insurance role
Germany	Sets the rules for healthcare provision and health insurance coverage	Employer/employee payroll tax; general tax contribution to the SHI	Full cost coverage (for about 10% of the population, defined groups, eg, civil servants), supplementary insurance coverage
Italy	National health service	Business and value-added tax; regional tax revenue	About 15% buy coverage for access to private facilities and services
Spain	National health service	Public financing, mainly through general taxation	About 23% buy coverage for access to private facilities and services
The Netherlands	SHI system, with universally mandated private insurance (national exchange)	Payroll tax; community-rated insurance premiums; general tax revenue	Private plans provide universal core benefits; 80% buy extra benefits
UK	National health service	General tax revenue	About 10% buy for private facilities

The typical CIED telemonitoring set-up – as described in Section B, Figure 6 – comprises four key elements requiring reimbursement:

1. Physician services related to remote follow-up device checks (remote follow-ups)
2. Physician services related to ongoing telemonitoring
3. The physical transmitter used by the patient
4. The additional infrastructure and services required to support telemonitoring

These are illustrated in Figure 8:

Fig. 8 Areas for reimbursement in a CIED telemonitoring service



Areas for reimbursement:

1. remotes follow-up physician services
2. telemonitoring physician services
3. Transmitter
4. Infrastructure and support services

Table 13 summarises how the different healthcare systems in our study reimburse implantation and the four key elements of CIED telemonitoring:

Tab. 13 Overview of current CIED telemonitoring reimbursement regimes in the five focus countries

Focus country	Implantation (surgery and device – PM or ICD)	Remote FU (physician services)	Remote monitoring (physician services)	Transmitter	Service/ infrastructure
Germany	• Inpatient: Reimbursement by standard DRG, which includes the device (no premium for TM-enabled devices) • Outpatient: Surgery covered by EBM, device reimbursed separately	• Reimbursed on the same basis as F2F FU (defined in the EBM catalogue)	• Not reimbursed • Reimbursement can be agreed on in "integrated care contracts" with public health insurers	• Generally not reimbursed • Reimbursement can be agreed on in "integrated care contracts" with public health insurers	• Not reimbursed
Italy	• Surgery and device covered by DRG, which vary among regions and type of hospital	• Regional tariffs	• Not financed by public health system	• Not financed by public health system	• Not financed by public health system
Spain	• Public hospital • Private hospital via private health insurers • If not insured, out of pocket	• Public health system: physicians are paid by hospital as civil servants (no payment by activity)	• Not financed by public health system	• Not financed by public health system	• Not financed by public health system
The Netherlands	• Device and surgery reimbursed via DBC	• Special activity code for follow-up • Reimbursement to be negotiated between hospitals and health insurers	• Special activity code for follow-up • Reimbursement to be negotiated between HCPs and health insurers	• Generally not reimbursed	• Hospital pays technical infrastructure, data storage, etc.
UK	• Surgery reimbursed via HRG • PM covered by HRG • ICD determined separately	• Varies – but can be reimbursed under standard outpatient FU tariff	• Not reimbursed	• Various agreements in place between industry and commissioner • No general reimbursement	• Varies – some examples of locally agreed license fees

3 Key issues and challenges with current CIED telemonitoring reimbursement solutions

Despite the differences outlined above, one key issue is common across all current CIED telemonitoring reimbursement solutions: the telemonitoring infrastructure, including the transmitter and support services, are either not reimbursed at all or are reimbursed only via selected "island" solutions. In addition, there is a requirement in some of the countries to have a face-to-face examination in order to qualify for reimbursement.

There are also a number of country-specific reimbursement challenges, which are outlined below.

3.1 Germany

The providers typically responsible for the implant – the hospitals – are reimbursed using DRGs. The amount a hospital receives for implanting a CIED does not change whether the device is telemonitoring-enabled or not. This means, that a hospital will lose margin if they implant a device which is more expensive than the cheapest device which meets the required medical standards – eg, if a telemonitoring-enabled implant is used.

The second country-specific challenge is the clear disjunction between the inpatient and outpatient sector. In Germany, follow-ups are undertaken in the outpatient sector, and therefore the entity responsible for the implant (the hospital) does not reap the benefit of using telemonitoring-enabled implants for remote follow-ups.

3.2 Italy

Due to the regionalisation of the health system, telemonitoring takes place at a regional rather than national level. For this reason, regional administrators and hospitals must co-operate to find suitable reimbursement solutions, especially for physician and nurse services which are currently unpaid. Presently medical examination and surgical activities are reimbursed differently depending on the region; a uniform reimbursement approach for telemonitoring services in Italy would be helpful to support regions and hospitals.

3.3 Spain

Similar to the situation in Italy, regions and hospitals must be convinced of the benefits of telemonitoring. Generally, the current healthcare funding system does not capitalise on efficiency gains.

3.4 The Netherlands

The reimbursement of services needs to be agreed on between payers and providers. There is an activity code for remote follow-up, and although this is the prerequisite for reimbursement, it is not sufficient on its own. Hospitals need to be convinced that there is a positive business case for CIED remote monitoring.

3.5 United Kingdom

The NHS system in England is currently undergoing significant change, as defined by the recently established Health and Social Care Act (2012). The core principles of the Act are to put clinicians at the heart of decision making in the NHS and to strengthen the role of the market to drive improvements for patients. In practice, this means the transition of commissioning (buying) responsibilities from primary care trusts (PCTs) to newly formed clinical commissioning groups (CCGs) in 2013, the establishment of a new sector regulator with secondary care pricing responsibility (enhancing monitor's previous role as the regulator of foundation trusts) and a range of reforms to the provider sector.

One challenge is therefore the education of an entirely new set of commissioners on the benefits of CIED telemonitoring – although this will be aided by the "3 million lives" campaign announced in December 2011. This campaign aims to move 3 million patients onto telehealth over the next 5 years following the culmination of the WSD programme, the largest ever randomised control trial of telehealth and telecare.

In addition to these broader changes, there are some specific challenges related to CIED telemonitoring reimbursement. These include the separate reimbursement mechanisms used for primary and secondary care payments, which make cross-discipline payments such as those for telemonitoring more complicated. There are also financial disincentives to hospitals rolling-out telemonitoring, as in some cases a hospital stands to earn more through face-to-face visits than it would receive through remote follow-ups enabled by telemonitoring.

D Good practice in Europe

This study aspires to share good practice initiatives, knowledge and experiences on the field as a means of accelerating the uptake of CIED telemonitoring solutions and improving both policy-making and research. In the search for telemonitoring best practices, we have been made aware of a number of interesting examples.

1 Germany

In Germany, despite there being no regular funding in place, some compulsory health insurers like DAK, have agreed on individual contracts with physicians and an industry partner on the reimbursement of telemonitoring infrastructure. Although the exact design of the contract is specific to the German healthcare system, this solution is a good example of how the benefits expected from remote monitoring can be reflected in a reimbursement solution. Any patient with the need for a CIED and a defined risk profile is eligible for CIED remote monitoring. The payer funds the required infrastructure, including the patient transmitter. Through the risk-stratification of the patient base, the payer can target those patients for whom CIED remote monitoring will result in a marked reduction in emergency hospital stays. The resulting savings are at least as high as the additional cost for the infrastructure.

Physician services for follow-ups and monitoring are reimbursed on the same basis as any outpatient follow-up care, ie, on the – admittedly rather complex – system for outpatient reimbursement in Germany.

2 France

Currently, transmitters are reimbursed in the form of a “bonus”, which is unique in Europe. It requires a dossier submitted by the manufacturer who requests reimbursement. Furthermore, the transmitter must be on the list of devices approved for reimbursement (Liste des produits et prestations remboursables), ie, the products need to go through a health technology assessment process. The medical device reimbursement tariff is negotiated between the economic committee on healthcare products (Comité Economique des Produits de Santé) and the manufacturer, with the bonus calculated according to activity. If the number of transmissions is lower, the manufacturer, according to the agreed contract, will have to pay the difference back. If more activity takes place, nothing changes. Finally, the SHI pays the manufacturer directly. However, the current transmitter reimbursement solution is temporary and the trial period will expire in early 2013. Consequently, the industry is working with the French authorities to charge a yearly service fee to reimburse for telemonitoring services.

3 England

Given the local nature of telemonitoring reimbursement arrangements in England, a number of different models are emerging. One commissioner to whom we spoke had introduced a risk-stratification approach for a chronic obstructive pulmonary disease (COPD) telemonitoring scheme, whereby the scheme applied formal risk assessment models to identify medium- to high-risk patients who would respond most successfully to telemonitoring, whilst maintaining standard face-to-face care for those at the highest end of the acuity scale. This is similar to the approach seen in Germany and illustrated above.

In another example of good practice, a number of commissioners are exploring the use of license fee arrangements to enable the initial capital costs of the service to be spread across the lifetime of the unit, thereby reducing the up-front payment in a capital constrained environment.

4 Finland

For the past year, 60 heart patients have been monitored remotely in the hospital district of Pohjois-Pohjanmaa (around the city of Oulu) on a reimbursed basis. This solution has made the physicians' work easier and increased patient safety. Economically, remote monitoring has saved time for the patient and money for the healthcare system as remote monitoring significantly decreases the frequency of required control visits, which reduces the need to travel long distances to the hospital[23].

[23] Cf. Raatikainen, M. J.; Uusimaa, P.; van Ginneken, M. M.; Janssen, J. P. and Linnaluoto, M., Remote monitoring of implantable cardioverter defibrillator patients: a safe, time-saving, and costeffective means for follow-up, Eurospace 10 (10), 2008, , pp. 1145–1151.

E Proposed principles for reimbursement of CIED monitoring

1 Basic principles for CIED telemonitoring reimbursement schemes

Through our research and interviews, we have identified 12 principles that we believe should determine the future reimbursement models for CIED telemonitoring. These principles, which aim to be pragmatic, fair and enduring, are listed in Table 14:

Tab. 14 Principles for CIED telemonitoring reimbursement

Decision	Principles
Scope of funded activity	1. Account for all costs (physician services, infrastructure and monitoring services) 2. Treat remote activities on a comparable basis to face-to-face activities, provided they deliver at least an equivalent result 3. Risk-stratify patients (by diagnosis, by region, etc.) and target/reimburse accordingly
Payment method	4. Increase emphasis on the reward of outcomes
Payer	5. Costs should be borne by the party receiving the value
Price and allocation	6. Reward stakeholders in proportion to the value they create 7. The total cost per patient of telemonitoring should, as a minimum, not exceed that of the next best alternative; where telemonitoring leads to improved outcomes, this should be rewarded cost-effectively
Goal alignment	8. Encourage innovation 9. Encourage adoption by clinicians and patients 10. Support the long-term objectives of the healthcare system (access, quality, sustainability, equality)
Roll-out	11. Create a practical short-term solution that is both compatible with and leads to a longer term one 12. In the short term, build on existing or planned reimbursement mechanisms

2 Potential CIED telemonitoring reimbursement models

In exploring potential reimbursement models, we have outlined two broad cases for telemonitoring solutions: the first offering an alternative approach to existing device check follow-up practices; the second offering a more transformational use of the technology to drive new pathways and models of care. These cases are summarised in Table 15, and are in line with the most common clinical scenarios as defined by a group of leading European clinicians[24].

[24] Dubner et al., ISHNE/EHRA expert consensus on remote monitoring of cardiovascular implantable electronic devices (CIEDs), Europace 14 (2) 2012, pp. 278–293.

Tab. 15 Use cases for CIED telemonitoring

Case	Description	Summary
Case 1: Remote follow-up *"Doing things differently"*	A straight replacement of existing face-to-face device check follow-ups with remote follow-ups using telemonitoring. It involves making the existing care pathway more efficient.	• Benefits mainly in the areas of efficiency and convenience for follow-ups • Reimbursement comparator is face-to-face follow-ups • Clinical outcomes the same under telemonitoring and face-to-face
Case 2: Remote monitoring *"Doing different things"*	This involves capturing and monitoring data on an ongoing basis, and using it to inform clinical choices and interventions. It involves new pathways and new methods of working, harnessing the benefits of the additional data and information the approach provides to improve clinical outcomes.	• Additional economic benefits of improved clinical outcomes • Reimbursement comparator is traditional treatment methods and pathway

In Case 1, all else being held equal, the benefits accrue primarily to the follow-up providers (in most countries hospitals), which benefits from improved efficiency, and to the patient, who experiences a reduction in travel time and cost and less disruption to their day. There appears to be an emerging consensus on the efficiency benefits of remote follow-ups for patients with CIEDs, when compared to traditional face-to-face visits. A number of clinicians we interviewed cited productivity gains of between 100% and 300% when managing follow-ups remotely. In cases where the payer is accountable for patient travel costs, there is also a monetary benefit to the payer although, within the countries considered for this study, this is rare (eg, in Germany, when a patient is unable to travel, the outpatient cardiologist sends the patient to a hospital for an inpatient follow-up).

Case 2 builds on Case 1, but is wider reaching and more transformative in its nature. All the benefits of Case 1 that are associated with remote follow-up remain. However, the additional benefits associated with improved data and monitoring mean that the reimbursement solution will differ considerably from Case 1.

Below, we have outlined proposed "generic" reimbursement solutions for Case 1 and Case 2. These solutions provide the raw materials from which the specific country solutions – outlined in Section F – are constructed.

Generic reimbursement solution for Case 1

As the payer does not receive any direct monetary benefit from Case 1 (but also no disadvantage), one basic rule for a reimbursement model for Case 1 is that the total reimbursement for remote follow-ups should not exceed the amount which the payer would have paid for their face-to-face follow-up.

For the hospital/physicians doing the follow-up (henceforth referred to as the "provider"), the perspective is different. The clear and generally accepted advantage of remote follow-ups is increased efficiency: a physician can serve more patients per hour through remote follow-ups than through face-to-face follow-ups. This higher efficiency can either translate into an increase in the number of CIED follow-up patients per physician per hour, or to a reduction in the time required to examine patients, freeing capacity for other kinds of treatment. All else being held constant, the effect would be higher revenue per hour for the provider. As the provider is the main financial beneficiary of remote follow-ups, it follows that the provider should also bear the costs for the required infrastructure. For this to be acceptable to the provider, the following condition must apply: total revenue per hour for remote follow-up patients, less the costs for infrastructure, needs to be at least on a par with revenue per hour from face-to-face follow-ups. This obviously limits the amount available to fund infrastructure.

The other stakeholder receiving high value from remote follow-up – both qualitative and quantitative – is the patient. Although implementing patient co-funding it typically challenging, within our Case 1 generic reimbursement solution it does make sense to include a patient payment as an option. Depending on where patients are living and how travel cost is reimbursed by payers (usually not at all), even with a co-payment a patient might benefit financially from using remote follow-ups.

Currently, industry bears by far the largest proportion of the technology and infrastructure costs; whereby, this depends on the current reimbursement schemes within the countries. Going forward, and in contrast to current reimbursement practices, industry should be reimbursed for providing the remote follow-up infrastructure and associated services, and this may be included within the reimbursement rates agreed on between providers and industry.

Table 16 illustrate the benefits for each of the stakeholder groups and the proposed generic reimbursement solution for Case 1:

Tab. 16 Case 1 benefits

Stakeholder group	Benefits from remote FU	Suggested reimbursement solution	
		Pays for:	Receives payment for:
Patient	• Convenience, reduced travel effort • "Peace of mind" • Reduction of possible inappropriate device treatments	Potentially: co-payments/fee for service	–
Payer	• Selectively: reduced travel cost to be reimbursed • Selectively: marketing, customer retention (only for some healthcare systems)	Follow-up – same level as F2F follow-up	–
Hospital/physician	• Higher efficiency: more patients can be treated per day (or alternative revenue enhancing use made of additional capacity) • Customer retention	Higher CIED cost Infrastructure and services cost	Follow-up payment Potentially: patient payments
Industry	• Leverage of the technology developed and subsequent investments taken • Post-market surveillance of devices	Infrastructure and services cost	Infrastructure and services cost

Generic reimbursement solution for Case 2

Case 2 (remote monitoring) provides potential direct benefits for the payer in terms of reduced hospital admissions and length of stay under certain conditions. The risk-stratification of patients may be required to realise these benefits – ie, applying remote monitoring only to the cohort for whom it will deliver a clear benefit. Reimbursement could take the form of a remote monitoring tariff paid to providers, which would cover both physician services and the infrastructure and services for remote monitoring, including the transmitter. Providers would then receive this remote monitoring tariff for each participating patient and would reimburse the industry for providing the infrastructure. Also, providers need to fund the infrastructure required for remote monitoring, eg, personnel being available to react to alerts. On the other hand, they can realise efficiency gains by managing the scheduled follow-ups, which are also part of the treatment, remotely. These efficiency gains can be reflected in the tariff.

The total reimbursement for remote monitoring might be higher than current reimbursement for face-to-face follow-ups yet, with the additional value generated, the payer may experience a lower overall total cost per patient.

Table 17 summarises the benefits and generic reimbursement solution for Case 2:

Tab. 17 Case 2 benefits

Stakeholder group	Benefits from remote FU	Suggested reimbursement solution	
		Pays for:	Receives payment for:
Patient	• Better treatment/clinical outcome • Convenience, reduced travel effort • "Peace of mind" • Reduction of possible inappropriate device treatments	–	–
Payer	• Fewer emergency hospital stays; better care for the patient • Selectively: marketing, customer retention (only for some healthcare systems)	Remote monitoring tariff, including higher device costs (>current FU reimbursement)	–
Hospital/physician	• More capacity, meeting future capacity demands or generating other revenue opportunities • Customer retention	Higher CIED cost Infrastructure (incl. medical personnel) and services cost	Remote monitoring tariff
Industry	• Leverage of the technology developed and subsequent investments taken • Post-market surveillance of devices	Infrastructure and services cost	Infrastructure and services cost

3 Reimbursement model evaluation

The generic models described above are designed to meet the key principles for reimbursement solutions defined in Section E.1:

- The solutions generally account for all types of cost (principle 1), without stating which amount needs to be covered by which party.
- Remote follow-ups are treated on a comparable basis as face-to-face follow-ups (principle 2), as this is explicitly defined within the solution for Case 1, while Case 2 does work only with remote technology.
- Although not prescribed by the generic model, a risk-stratification of patients (principle 3) will be considered as part of the reimbursement of Case 2.
- An increased emphasis on the reward of outcomes (principle 4) is implicitly included in the models – potential reimbursement by payers in Case 2 may be higher or lower depending on the outcomes.
- Cost sharing according to the value received (principle 5) is one of the driving principles for both solutions: in Case 1, hospitals/physicians and patients receive the value – therefore, these two groups need to fund the infrastructure, while payers pay the same total amount as for face-to-face treatments. In Case 2, the payer receives additional value from the technology as well – therefore, the payer also has to invest additional resources in the solution.
- Also, the solutions are designed to enable a reward for stakeholders according to the value they create (principle 6) – this principle will only actually be met when payment amounts are agreed on.
- Both solutions are also designed to adhere to the principle that total cost per patient shall not exceed that of the next best alternative (principle 7): in Case 1, the next best alternative is a face-to-face follow-up. Therefore, the payment by the payer does not exceed the cost for this treatment method. In Case 2, there is not real next best alternative as face-to-face follow-ups do not allow for the same value generated by CIED remote monitoring – therefore, reimbursement by payers can be higher.
- Solutions need to be practical to be feasible short-term, while still being compatible with long-term solutions (principle 11): this principle is important, though difficult to fulfil.

The following principles are not explicitly met, as their fulfilment can only be judged when final, country-specific solutions have been agreed on:

- Encourage innovation (principle 8) –this depends strongly on the level of reimbursement; no innovation encouragement if reimbursement is too low. Yet, any agreed on reimbursement will be an improvement over a status where no reimbursement solution is defined, even if absolute amounts reimbursed do not meet expectations at the start.
- Encourage patient adoption (principle 9) – this will depend strongly on whether there are co-payments or not. While co-payments make sense from the point of view of the other principles, certainly they will not foster patient adoption (see also below).
- Support the long-term objectives of the healthcare system (principle 10) – can only be judged depending on the specific solution per country and the actual long-term objectives for the respective healthcare system.
- Create a practical short-term solution that is both compatible with and leads to a longer term one (principle 11) – see above; can only be judged when the actual model is defined.
- In the short term, build on existing or planned reimbursement mechanisms (principle 12) – same as before; yet, both solutions are designed in a rather simple way allowing the use of existing mechanisms.

There are several options for translating the generic reimbursement models described above into country-specific solutions, whereby the following must be considered:

- Co-payments: These are only acceptable in certain countries, depending on historical precedent and government policy. Even in countries where it is feasible, one has to assume that co-payment will not foster usage of the technology – many patients may not be willing to pay extra money. Yet, if one defines the level of co-payments according to the travel cost a patient would have to cover privately, this co-payment may still be efficient for the patient. Another question is whether such patient payments to get the infrastructure for remote follow-ups need to be co-payments – one could also define it as a payment for an addition service level received (fewer face-to-face meetings, less travel effort). In any case, co-payments will only apply to solutions related to Case 1, remote follow-up.
- Investment hurdle: An important hurdle for reimbursing the technology required for remote follow-up and remote monitoring is the required initial investment to buy the infrastructure, namely the transmitter. A solution which enables an annual fee to be paid for using the infrastructure, for example, will reduce this hurdle.
- Industry reimbursement: There are two broad options – industry is either paid directly by the payer or else by the providers (in most markets the hospitals). Based on interview feedback, in most markets the latter appears to be the preferred solution for both payers and providers, although ongoing costs are an area for debate.
- Physician reimbursement: The actual physician reimbursement depends nearly exclusively on the general framework defined within the respective healthcare system of the countries. For the solutions developed here, which should be practical solutions that can be implemented near-term, physician reimbursement is not bundled with disease management programmes or the like, but defined separately for remote follow-up/monitoring. Yet, if reimbursement is to put a greater emphasis on the achieved outcomes, this structure needs to be adjusted.

F Principles to practice: Applying the model in the different health economies

1 General considerations

Having considered the two use cases and defined the general reimbursement models in the previous section, we now turn our attention to the application of the generic models to the five focus countries of our study: Germany, Italy, Spain, The Netherlands and the UK. While the general approach for each use case will be similar, the actual implementation needs to reflect country-specific requirements, including but not limited to

- the integration of the different healthcare sectors (eg, primary, secondary),
- the responsibility for CIED implant follow-ups,
- the national reimbursement scheme for hospitals and physicians and
- the general acceptance of patient co-payments.

In the following subsections, we have described specific reimbursement solutions for each of the five focus countries. These solutions all use the generic models as their basis, and are therefore comparable in principle. For all markets, it is assumed that the ultimate objective is to implement remote monitoring solutions for the appropriate patient groups, and not simply remote follow-up, as the latter does not use the full potential of the technology.

2 Germany

As discussed earlier, reimbursement solutions for remote follow-up and remote monitoring already exist in Germany: physician services are reimbursed, and there are individual contracts to address the reimbursement of the required TM technology and support services. The solutions outlined below are practical, short-term reimbursement solutions for the German market and focus on statutory health insurance, which covers about 90% of the market; some considerations on how the models can be applied to private health insurers are added.

Case 1: Remote follow-up

For remote follow-up, the basis for reimbursement has already been defined and physician services are currently reimbursed. The statutory health insurance generally reimburses physicians for outpatient services via lump sum payments to the Associations of Statutory Health Insurance Physicians. As payers do not reap monetary benefits from remote follow-ups (with few exceptions, eg, for patients who would be admitted to hospital for the follow-ups due to their general health condition), their role in a reimbursement model would be to keep payments for outpatient services unchanged. This means that the infrastructure costs associated with remote monitoring must be carried by the parties receiving the value: providers and patients. As described in the generic model, providers – here the outpatient cardiologist or the outpatient care centre of a hospital – should contribute to the infrastructure cost according to the value they achieve through the efficiency gains. Patient co-payments are not unusual in Germany: there are small co-payments for most drugs, and for dental prostheses anything of higher quality than basic standard has to be paid by the patients – who might have a private medical insurance to cover those costs. The same applies for glasses, which have to be paid fully by patients. In order to implement remote follow-ups, if used primarily to increase convenience for the patient, co-payments for the required infrastructure would be a logical instrument. The level of co-payment should not exceed typical costs for travel to follow-up examinations, so that in total the patients would not be at a financial disadvantage. Still co-payments are a controversial instrument, even if justified. Therefore, funding by the providers according to the efficiency gains they can realise seems the most promising solution. In order for this to succeed, there must be strong political support for telemonitoring, underpinned by an additional budget in order to achieve the required mid- to long-term capacity improvements in the healthcare system. CIED remote monitoring remains the more promising solution, providing greater value for the payers, and optimal leverage of the technology.

Scope

- Services: Physician services, TM technology and support services
- Patient segments: Generally all patients with a TM-enabled CIED, but specific focus on those living in areas with weak (medical) infrastructure – eg, some rural areas – and those who have difficulties travelling

Tab. 18 Specific reimbursement solution for remote follow-ups in Germany

	Physician service	Infrastructure
Payment method: On what basis will payment be made?	• Fee for services, defined in the EBM, as is currently already the case	• Annual fee for both TM technology and support services • Alternative: provider buys the required infrastructure
Payer: Who pays?	• Statutory health insurance (standard case)/ private health insurance (not specifically considered)	• Providers plus – potentially – patients via co-payments
Price and allocation	• Same level as face-to-face follow-up (part of the lump-sum to be paid by the payers)	• Physician fee should reflect efficiency gain • Potential patient co-payment should not exceed typical cost for travel to be paid by the patient

Case 2: Remote monitoring

If the generic reimbursement model described in Section E.2 is applied to Germany, the statutory health insurance would cover the cost of both the treatment and the required infrastructure through individual contracts. As mentioned in Section C.2, these may be either integrated care contracts according to section 140(a) of the social security statutes (Fünftes Buch Sozialgesetzbuch, or SGB V) or individual contracts for specific outpatient care (Selektivverträge) according to section 73(c) SGB V.

In the case of integrated care contracts, typical contractual parties would be the insurer, physician associations, potentially hospitals and an industry partner. Individual contracts according to section 73(c) SGB V may be concluded with physician associations (eg, with the association of outpatient cardiologists [Bundesverband niedergelassener Kardiologen]); they are relevant for the outpatient sector only. Such a contract would also define the relevant target group for the contract to ensure the desired benefits can be achieved.

It is important to note, that these contracts will only enable "island" solutions, not a general reimbursement solution for remote monitoring which should eventually be aimed for. Yet, these island solutions can lay the groundwork for a general solution, as they enable greater usage of remote monitoring and increase the amount of evidence about its value, which will subsequently form the basis for a common solution.

Telemedicine is on the agenda of healthcare policy makers in Germany and may also be supported by additional state funding, eg, for one-time investments in infrastructure. Physician services are generally reimbursed according to the reimbursement rules of outpatient services, the EBM; no additional reimbursement rules would have to be defined. Yet, monitoring services are not explicitly part of the EBM; if it were to be done as additional activity, this physician service would then also need to be part of the contract. Efficiency gains achieved for the scheduled follow-ups should be considered when defining the total reimbursement level. Another option for reimbursing the required infrastructure would be to charge it as special billable material (gesondert berechnungsfähige Materialien) in accordance with section 44(5) of the German framework agreement for doctors (Bundesmantelverträge – Ärzte) i.c.w. subsections 7(3) and 7(4) of the EBM. However, there are conflicting opinions on this option. While some see it as an easy and logical way of using the existing reimbursement regime, the statutory health insurance does not support this view. This is connected with the question whether telemonitoring is already part of the catalogue of services to be covered by the statutory health insurance. Legal clarity is therefore required on the appropriateness of this solution. From the systematic point of view, reimbursement as material would make sense for Case 2.

Scope

- Services: Physician services, TM technology and support services
- Patient segments: Patients with TM-enabled CIED to be risk-stratified according to a promising potential outcome improvement

Tab. 19 Specific reimbursement solution for remote monitoring in Germany

	Physician service	Infrastructure
Payment method: On what basis will payment be made?	• Follow-up treatments paid via EBM (fee for service), same as remote follow-up • Potentially, but not required: TM tariff as part of an integrated care contract: fee per patient monitored, excluding the follow-ups	• Annual fee for both TM technology and support services, as part of the contract agreement • TM tariff also includes infrastructure investments required by the physicians
Payer: Who pays?	• Statutory health insurance (standard case)/ private health insurance (not specifically considered)	• Statutory/private health insurance • Potentially, part of the fee: government funding to foster telemedicine
Price and allocation	• Follow-up: same level as face-to-face follow-up (part of the lump sum paid to outpatient physicians)	
	• Objective after implementation: total for TM tariff for one year plus infrastructure (TM technology, support services) cost, minus a potential government participation, should not exceed savings through fewer hospital stays	

For private health insurers, reimbursement solutions are generally comparable. Only the contractual terms and the reimbursement scheme for physician services would differ:

- For Case 1, as with the statutory health insurance, private insurers would reimburse remote follow-ups with the same amount as their face-to-face counterparts. According to the principles of the private health insurance, this relates to reimbursement of each single follow-up. The mechanism to fund the infrastructure would be the same as described above.
- For Case 2, the decision to reimburse CIED remote monitoring would need to be taken by each insurer individually. The general rule for all private health insurance policies is only to reimburse those services which are required from the medical point of view, and to decide on a case-by-case basis. Still, private health insurers may agree on contracts with providers and offer this service to their clients – in this respect, the reimbursement solution would be comparable with the one for the statutory health insurance.

3 Italy

Italy has a tax-funded healthcare system with the regions and local healthcare units as payers, instead of a system with health insurance companies as payers. Still the general reimbursement solution can be rather similar to those suggested for Germany and the Netherlands, as hospitals are reimbursed for services provided, according to DRGs for the most part. As a consequence, efficiency gains through remote follow-up or remote monitoring have an impact on the revenue of a hospital, which subsequently can be part of the reimbursement solution.

The general approach for both cases is close to the generic solutions described in Section E.2

Case 1: Remote follow-up

Remote follow-up should be funded by the regions or local healthcare units with the same amount as current face-to-face follow-ups are reimbursed; this means that remote follow-up will be cost-neutral for patients. A defined part of this fee for service needs to be earmarked to cover the infrastructure costs for remote follow-ups. As a consequence, the hospital will get less per patient for a remote follow-up, as the fee they receive – and which is equal to the one received for face-to-face follow-up – includes a part that needs to be passed on to the industry providing the infrastructure. There are two options which both seem feasible to implement the solution: either the hospitals agree with the industry on the reimbursement level for the TM technology and support services in a contract, or the level is defined by the regions. As described in the generic solution evaluation, there is an investment hurdle if hospitals have to purchase the infrastructure, namely the transmitters. Therefore, a solution allowing for an annual fee to be paid per patient could help to foster implementation. In addition to hospital funding for infrastructure, there may also be funding for the regions if they were to foster telemedicine. Also – though unusual and probably hard to implement – patient payments to receive remote monitoring (and to avoid travel) may be a component of the solution.

Scope

- Services: Physician services, TM technology and support services
- Patient segments: Generally all CIED patients, but specific focus on those living in areas with weak (medical) infrastructure – eg, some rural areas – and those who have difficulties travelling

Tab. 20 Specific reimbursement solution for remote follow-ups in Italy

	Physician service	Infrastructure
Payment method: On what basis will payment be made?	• Fee for service for the remote follow-up (same basis as current face-to-face follow-ups)	• Annual fee for both TM technology and support services • Alternative: hospitals buy this infrastructure
Payer: Who pays?	• Regions directly or through local healthcare units	• Hospital • Potentially, part of the fee: funding by regions • Potentially: patient payments
Price and allocation	• Total per follow-up includes a part for physician services and a part for infrastructure (TM technology and support services) • Allocation is defined a) via a contract between the hospitals and industry or b) by the regions, defining the level for infrastructure cost	• Total revenue per hour minus cost should not be lower using remote FU vs face-to-face follow-ups • Total level for co-payments should not exceed typical cost for travel to be paid by the patient

Case 2: Remote monitoring

For remote monitoring with a risk-stratified target group, the regions or local healthcare units need to fund both the physician services and the infrastructure. A part of the infrastructure cost might be covered by hospitals. As they benefit from the efficiency gains from the technology, this should be reflected in a future remote monitoring tariff.

The regions or local healthcare units on the other hand need to see a return on their investment through the benefits remote monitoring is expected to deliver. As in other countries, this might require the risk-stratification and targeting of specific patients for CIED remote monitoring. There is a long-term impact of the model which is important for the Italian environment: generally, though hospitals are reimburse by DRGs, the cost structure cannot be considered flexible – more capacity made available due to reduced hospitalisation rates and more efficient follow-ups do not translate directly into cost savings. Yet, in view of general trends (as described in Section B) the demand for medical capacity will increase – which means that the additional capacity that this technology offers reduces the need for investment to increase hospital capacity. Additionally, workload in hospitals may be reduced.

Scope

- Services: Physician services, TM technology and support services
- Patient segments: CIED patients to be risk-stratified according to a promising potential outcome-improvement

Tab. 21 Specific reimbursement solution for remote monitoring in Italy

	Physician service	Infrastructure
Payment method: On what basis will payment be made?	• TM tariff for hospitals: fee for service for one year (one month) of TM service, including the follow-ups (see below)	• Annual fee for both TM technology and support services • Alternative: hospitals buy infrastructure and related services and gets reimbursed • Hospital investments should be covered by the TM tariff; additionally, the hospital can make use of efficiency gains
Payer: Who pays?	• Regions directly or trough local healthcare • care units	• Regions/local healthcare units • Hospital participation according to efficiency gains from remote follow-up
Price and allocation	• Introduction of TM will increase cost at implementation, as investments in infrastructure (TM technology, support services) have to be funded, while the general budget of hospitals stays unchanged • Objective after implementation: reduction of emergency hospital admissions leads to additional capacity in hospitals, reducing overall healthcare cost/need for investment mid- to long-term	

4 Spain

The Spanish healthcare system has some specific challenges for developing a reimbursement system for telemonitoring. In addition to being decentralised, which requires individual regional approaches, a key challenge is that hospitals have defined budgets and physicians are mostly state employed. Consequently, efficiency gains achieved by a hospital do not translate into additional revenue potential for it. On the other hand, if the budget for hospitals were to be reduced, this would have a direct impact on the hospitals which would then need to cut costs accordingly. Furthermore, waiting lists for treatments could be reduced if hospitals could leverage the higher efficiency of remote follow-ups or even remote monitoring.

Therefore, the reimbursement solutions in Spain will require a slightly different approach to the other markets. For both use cases, the region as the "payer" will need to fund the service, but it will need to recoup its investment. Our proposed solutions are outlined below.

Case 1: Remote follow-up

For remote follow-up, the regions would cover the physician services on the same level as with current face-to-face follow-ups; in other words, the budget for the hospital stays unchanged. Additionally, the regions would fund the required infrastructure, namely the transmitter. To reduce the investment hurdle, it would be helpful for providers to pay for TM technology and support services through an annual fee rather than paying for them upfront. This annual fee needs to reflect the calculative efficiency gains which the hospitals can achieve, and obviously budgets have to be considered. The subsequent savings through better efficiency in the hospitals translate into higher capacities for hospitals, shortening waiting lists. For the regions, the calculation then needs to be as follows: while the budget for the hospital in total remains unchanged, per patient the budget does decrease. The cost for infrastructure should remain the same as the budget per patient decreases, making remote follow-up eventually cost neutral for payers. Price for infrastructure could be defined via tenders by the hospitals or regions; in the latter case, the regions would pay for the infrastructure directly. Otherwise, the hospitals would pay for the infrastructure, but would get a budget for this as defined above.

Scope

- Services: Physician services, TM technology and support services
- Patient segments: Generally all CIED patients, but specific focus on those living in areas with weak (medical) infrastructure – eg, some rural areas – and those who have difficulties travelling

Tab. 22 Specific reimbursement solution for remote follow-ups in Spain

	Physician service	Infrastructure
Payment method: On what basis will payment be made?	• Same budget for remote follow-up as for current face-to-face follow-ups	• Annual fee for both TM technology and support services
Payer: Who pays?	• Government/regions	• Government/regions
Price and allocation	• Total per follow-up includes a part for physician services and a part for infrastructure (TM technology/support services) • Price for infrastructure is defined via a) tenders by the hospitals or b) tenders by the regions • Savings through better efficiency in the hospitals translate into higher capacities for hospitals, shortening waiting lists	

Case 2: Remote monitoring

Assuming the potential benefits outlined by Dubner et al.[25] with regard to remote monitoring, the key difference in Case 2, in comparison to Case 1, is that regions would fund the additional budget to reimburse infrastructure costs associated with remote monitoring, resulting in a potential increase in the total budget for cardiac care. The scope for such a model will be those patients where remote monitoring is expected to deliver its full value potential – eg, a defined group of ICD patients. Remote monitoring may reduce the length of stay and hospitalisation rates, which then leads to increased capacity in hospitals. This not only reduces waiting lists, but also the need for investment in additional capacity if the number of cases keeps increasing mid- to long-term. The solution is summarised in the Table 23:

Scope

- Services: Physician services, TM technology and support services
- Patient segments: CIED patients to be risk-stratified according to a promising potential outcome-improvement

Tab. 23 Specific reimbursement solution for remote monitoring in Spain

	Physician service	Infrastructure
Payment method: On what basis will payment be made?	• Budget for TM for hospitals, including physician monitoring services and follow-ups (see below)	• Annual fee for both TM technology and support services • Hospital investments should also be covered by the budget for TM
Payer: Who pays?	• Government/regions	• Government/regions
Price and allocation	• Introduction of remote monitoring will increase cost at implementation • Yet, objective within the first years: reduction of emergency hospital admissions leads to a higher available capacity in hospitals, reducing overall healthcare cost/need for investments mid- to long-term	

5 The Netherlands

In the Netherlands, the situation in 2012 can be considered a "window of opportunity" as the framework for a reimbursement of telemonitoring will be defined for the first time. As described in Section C.2, a new activity code within the reimbursement scheme has been defined for remote follow-up. It is not yet defined for all CIEDs, and an activity code is just the precondition for reimbursement as payers and providers still have to agree on the actual reimbursement. Nevertheless, the new activity code drives the development of a reimbursement solution. The proposed solutions for the Netherlands are outlined below.

[25] Dubner, S. et al, ISHNE/EHRA expert consensus on remote monitoring of cardiovascular implantable electronic devices (CIEDs), Europace 14 (2), 2012, pp. 278–293.

Case 1: Remote follow-up

As in the other markets, the hospitals are the key stakeholders, as they must decide whether to use remote or face-to-face follow-ups. The starting point is that remote follow-ups be reimbursed by the insurance companies at the same value as their face-to-face counterparts; this has to be agreed on based on the new activity code. The hospital would then have to agree with the industry on the conditions under which the required infrastructure will be provided. An annual fee solution would lower the investment hurdle, but the hospital could also purchase the infrastructure outright (ie, the transmitters). The key determinant with regards to price and allocation is that the price for the infrastructure reflects the efficiency gains which the hospitals can achieve.

Scope

- Services: Physician services, TM technology and support services
- Patient segments: Generally all CIED patients, but specific focus on those living in areas with weak (medical) infrastructure – eg, some rural areas – and those who have difficulties travelling

Tab. 24 Specific reimbursement solution for remote follow-ups in the Netherlands

	Physician service	Infrastructure
Payment method: On what basis will payment be made?	• Fee for service for the RFU (same basis as current face-to-face follow-ups); may be the agreed rate for the new activity code for RFU	• Annual fee for both TM technology and support services • Alternative: hospitals buys the required infrastructure
Payer: Who pays?	• Insurance companies	• Hospital • Potentially: patient co-payments
Price and allocation	• Total per follow-up includes a part for physician services and a part for infrastructure (TM technology/support services) • Allocation is defined via a contract between the hospitals and industry	• Total revenue per hour minus cost should not be lower using RFU vs face-to-face FU • Total level for co-payments should not exceed typical cost for travel to be paid by the patient

Case 2: Remote monitoring

For remote monitoring, the reimbursement for the infrastructure does not have to be limited by the amount of efficiency gained by the hospitals. Here, the key beneficiary are the insurance companies, which can expect quantitative benefits for the target group of CIED patients (probably: ICD patients) selected for telemonitoring. Reimbursement for physician services can be divided into two parts: scheduled follow-ups fall under the activity code described above. The monitoring service for the physician, together with the infrastructure and services provided by the industry, would be part of a remote monitoring tariff to be agreed on between insurance companies and hospitals. The hospitals may then decide with the industry on the reimbursement scheme for the infrastructure – again, an annual fee may be advantageous.

Scope
- Services: Physician services, TM technology and support services
- Patient segments: CIED patients to be risk-stratified according to a promising potential outcome improvement

Tab. 25 Specific reimbursement solution for remote monitoring in the Netherlands

	Physician service	Infrastructure
Payment method: On what basis will payment be made?	• Remote monitoring tariff to be agreed on with hospitals: fee for service for one year (one month) of remote monitoring, excluding the follow-ups (see below) • Follow-up treatments paid via respective activity code (fee for service), same as remote follow-up	• Annual fee for both TM technology and support services • Alternative: hospitals buys the required infrastructure and gets reimbursed • TM tariff for the hospital includes hospital infrastructure
Payer: Who pays?	• Insurance companies	• Insurance companies • Hospital participation according to efficiency gains from remote follow-up
Price and allocation	• Follow-up: generally, same level as face-to-face follow-ups/agreed price for the respective activity code	
	• Objective after implementation: sum of remote monitoring tariff for one year plus infrastructure (TM technology, support services) cost, minus a potential government participation, should not exceed savings through fewer hospital stays	

6 United Kingdom

The English NHS is currently undergoing significant reform, and central teams are running a range of new initiatives including the development of a long-term condition tariff. As part of this study, we have liaised with the relevant teams involved in this development and have outlined below our proposals for Case 1 and 2.

Case 1: Remote follow-up

Currently, neither the outpatient (face-to-face) tariff nor the remote follow-up tariff is wholly appropriate. We propose the introduction of a dedicated remote follow-up tariff; the costs associated with the associated infrastructure and services would be reimbursed by "top-slicing" this payment and passing it to industry, reflecting the capital cost over the duration of the patient's use of the system. In essence, the benefit of the reduced cost per patient for follow-ups would be shared between the different stakeholders, assuming that any additional capacity made available through the increased throughput of patients could be either put to alternative use or used to treat more patients.

Scope
- Services: Physician services, TM technology and support services
- Patient segments: Targeting all CIED patients

Tab. 26 Specific reimbursement solution for remote follow-ups in the United Kingdom

	Physician service	Infrastructure
Payment method: On what basis will payment be made?	• Revised national HRG outpatient remote monitoring follow-up tariff (fee for service)	• "Top-slice" of HRG
Payer: Who pays?	• Local commissioner through national tariff	• Local commissioner through national tariff
Price and allocation	• New tariff for remote follow-up, on the basis of the on its face-to-face counterpart (£105 in 2012-13) but above existing non face-to-face outpatient attendance tariff (£23 in 2012-13) to reflect increased throughput efficiency	• Total value reimbursed for follow-up should not exceed equivalent care provided through face-to-face model • Infrastructure and support service providers reimbursed through "top-slice" of HRG, with proportion determined within national tariff

Case 2: Remote monitoring

In the case of remote monitoring, we propose the establishment of a year-of-care payment for the specific patient pathway. This marks a move away from reimbursement of the narrowly defined remote monitoring activity, and towards rewarding it in the context of the wider care pathway which it serves. Such a change would require not only a change in how the service is reimbursed, but also in how it is commissioned, with the idea of a lead provider managing the entire pathway. In addition, infrastructure and service costs would be met through contractual agreement between the lead provider and the industry participant(s). This is summarised in Table 27:

Scope
- Services: Physician services, TM technology and support services
- Patient segments: CIED patients risk-stratified according to potential outcome-improvement and cost-benefit analysis (likely to focus on medium to high-risk patients for services outside standard follow-up)

Tab. 27 Specific reimbursement solution for remote monitoring in the United Kingdom

	Physician service	Infrastructure
Payment method: On what basis will payment be made?	• Local commissioner reimburses a "lead provider" offering an integrated, end-to-end service for specific cardiac care pathways (eg, acute trust)	
	• Risk-adjusted year-of-care payment for that pathway (tariff), which covers all services	• Costs covered through centralised national or regional contract • For this to work, there must be interoperability between different TM platforms
Payer: Who pays?	• Local commissioner pays via national tariff for specific pathway, which adjusts for risk profile of patient	• National Commissioning Board/Department of Health pays through scale contracts (eg, call-off framework contracts)
Price and allocation	• Total value reimbursed for follow-up and ongoing community care should be less than equivalent care provided through existing face-to-face mode • Allocation of payment to the different participants in the care provision arranged through contracts between those participants and the lead provider • Sum of TM tariff for one year plus infrastructure and services cost, minus a potential government participation, should not exceed savings through fewer hospital stays	

G Recommendations and next steps

1 General considerations

In each of the focus countries there are specific tasks required to foster a stronger use of CIED remote follow-ups and monitoring. Yet, while some of the required actions are very specific for a certain country, others are relevant for all countries.

For both remote follow-ups and monitoring, payers must foster the right environment in which remote follow-ups and monitoring can flourish. This requires policies, guidelines and reimbursement mechanisms that position these services appropriately and enable them to support the wider system goals of access to care, efficiency, and high-quality clinical outcomes and patient experience.

For Case 1 (remote follow-ups), the following additional responsibilities and tasks to drive success apply:

- Industry will need to deliver solutions that reduce the investment hurdle for infrastructure. Providing infrastructure and services for an annual fee would mean predictable costs for payers and would reduce the initial investment required. However, in doing so it would need to ensure that any additional administration is kept to an essential minimum. Industry will also have an important role in illustrating the efficiency gains to the providers doing the follow-ups (these will be the hospitals in most countries) and supporting the integration with electronic patient health records.
- The providers (hospitals and clinicians) are central to fostering the uptake of remote follow-ups. They ultimately determine its use, and need to be convinced of the clinical and business benefits of deploying it. From a commercial perspective, this is a function of the cost to serve and the efficiency gains a provider expects to realise. These providers then have to promote remote follow-ups and their clinical and experience benefits to convince patients to use them. This includes supporting the required changes in patient behaviours, as in some cases face-to-face meetings are preferred, even if they are not clinically required. Additionally, providers have an important role in training nursing personnel and technical staff in how to screen and identify patients that need to be supervised by the physician.
- Remote follow-ups are only possible if patients accept them; the value that remote follow-ups bring need to be demonstrated to the patients, who must be willing to replace face-to-face with remote follow-ups.

For Case 2 (remote monitoring), the above items all apply, to which the following can be added:

- Industry must work with the other stakeholders to consolidate evidence on the value of CIED telemonitoring in a format and scope acceptable to them.
- The providers must ensure that the required capacity to provide remote monitoring – both personnel and technology – is in place. This extends beyond training to a wider programme of change management to support the transition to new working practices.

Our interviews suggest studies proving the benefit of CIED remote monitoring are considered very important and an area where further activities would be valuable. However, paradoxically, broader usage of this technology would greatly improve the available evidence. A solution could be joint studies funded by payers, industry and providers – according to the reimbursement models outlined above – over a longer period and with an accepted academic partner. This would lead to results and evidence accepted by all stakeholders.

2 Germany

As stated in Section C.2, the broader use of telemedicine in the outpatient sector and potential changes to the reimbursement rules will be further evaluated during the implementation of a new package of laws to improve healthcare provision (GKV-Versorgungsstrukturgesetz). Even though this will not lead directly to CIED telemonitoring, it still provides some momentum to develop the topic.

The following country-specific actions are necessary to implement remote follow-ups:

- The industry should use the current window of opportunity to clearly position the value that telemedicine in general and CIED telemonitoring specifically can bring. In particular, this relates to the illustration of the monetary value of CIED telemonitoring, as the Bewertungsausschuss is currently reviewing the business case for telemedicine services and will make a recommendation by October 2012.
- Payers need to be aware of the benefits remote follow-ups can bring. Though they generally will not have to act as remote follow-ups are already in the reimbursement catalogue (EBM), their commitment to reimburse remote follow-ups on the same basis as face-to-face follow-ups will provide a basis for the technology. This commitment will be cost-neutral for payers.
- Hospitals are the key stakeholder in determining whether to implant CIEDs – although there are outpatient operations as well. They should review the efficiency gains achievable for those patients where they perform the follow-up through an associated outpatient care centre. Yet, as outpatient follow-ups are often performed by outpatient physicians – and as efficiency gains for hospitals therefore are limited – hospitals will not be drivers.
- Outpatient cardiologists are the stakeholder group who would clearly benefit from the increased efficiency of remote follow-ups – though this also comes at a cost for the infrastructure. Those physicians who have a sufficient number of follow-up patients so that they can leverage the greater efficiency should review their case for remote follow-up in consideration of all factors.

For implementation of CIED remote monitoring, the key tasks sit with the payers and the industry. In addition to the general tasks, required actions include the following:

- Industry needs to work together with payers and providers on the business case for CIED remote monitoring. This case will be different depending on the target group selected by the payer, the connection with a disease management programme, the technology selected, etc. Industry can provide not only studies and sample calculations, but also recommendations on the target group where the technology provides the optimal value. Payers have to prove the validity of this positive case to their supervisory bodies if they are to agree on contracts.
- Payers will have to evaluate target groups and respective contract conditions for remote monitoring. While the reimbursement of physician services generally can be done via the existing regulations, the contract needs to define reimbursement for the infrastructure. If the contract is made with a specific supplier – as is the case in the current contracts – the amount reimbursed per device (including services) will be agreed on directly with the supplier. Additionally, if the payer wants to drive the implantation of CIED-enabled devices, more complex contracts are required for a respective incentive scheme.
- As for remote follow-up, hospitals need to evaluate the entire business case including monitoring if they are to conduct outpatient activities in their own centres.
- For outpatient cardiologists, the suggested model provides no disadvantages, as the payers would reimburse the required infrastructure and physician services are reimbursed according to current regulations. They can work together with the payers to define appropriate target groups for remote monitoring, which will help to establish the treatment method.

3 Italy

In addition to the general actions described above, the following country-specific actions are required, which focus on Italy's specific payer structure:

- For Case 1, the regions and local healthcare units have to define a fee for service for remote follow-up, which should be at the same level as face-to-face follow-up reimbursement. The reimbursement level for the infrastructure may also have to be defined by the regions; the other option is that the hospitals agree on this level directly with the industry.
- For Case 2, tasks for the regions and local healthcare units include developing a process to implement remote monitoring and a tariff for remote monitoring jointly with the hospitals.

4 Spain

As in Italy, the country-specific actions required to implement reimbursement solutions are related to the structure of the healthcare system.

For remote follow-up, this includes the following:
- The industry will have the important task of illustrating the quantitative benefits through efficiency gains and the qualitative benefits to the regions; ideally, they will be supported by hospitals. This will also require a business case for the regions to show the final impact on total healthcare costs of the proposed model of remote follow-ups.
- The regions have to evaluate potential savings through increased efficiency in the hospitals to have a clear view of the impact on available capacity. This needs to flow into a target model for remote follow-up financing, where the use of the additional available hospital capacity is also taken into account. Based on the pathway used to agree on infrastructure prices, the regions may also have to run a public tender on providing the remote follow-up infrastructure.

For remote monitoring, the required preparation is similar, with some differences:
- The industry will have to support the regions in developing a business case for the defined target groups for remote monitoring. Additionally, they may need to prepare and perform a study to prove the value of CIED TM in a format and scope acceptable to the government and the regions to make TM part of essential healthcare services that will be covered.
- Tasks for the regions remain comparable with remote follow-up – yet, the business case would have to focus on remote monitoring and the selected target group.

5 The Netherlands

Most of the required tasks are already mentioned in the general actions relevant for all countries.

Additional country-specific actions to implement remote follow-up reimbursement include the following:
- The industry may work closely together with patient organisations in order to foster remote follow-ups.
- The Health Authority would need to introduce an activity code clearly stating which activities the code might be used for, or alternatively it will have to enhance the current activity code and change the restrictions on face-to-face visits.
- The health insurers have to define a fee for service for remote follow-up with the hospitals, which should have the same level as face-to-face follow-up reimbursement.
- The patient organisation STIN is an important stakeholder, which might take a leading role in convincing patients of the value of remote follow-ups.

For remote monitoring, the required preparation is similar, with some differences:
- The industry will have to support health insurers in developing a business case for the defined target groups for remote monitoring. Together with hospitals, the industry also should support further efforts to improve the evidence available on benefits of CIED remote monitoring.
- Tasks for the health insurers include developing a tariff for remote monitoring together with the hospitals.

6 United Kingdom

For Case 1 (remote follow-ups), we have identified a number of important next steps, defined by stakeholder:

- We recommend that the Department of Health
  - define a national tariff for "remote follow-up", which is not limited to consultant-led services, and reflects the best demonstrated practice disaggregated cost of physician service, infrastructure cost and monitoring services – this tariff should cover both scheduled follow-ups and those triggered by alerts and requiring investigation;
  - adapt its payment platform to enable the direct reimbursement to industry for infrastructure and monitoring services via the HRG system;
  - develops a programme of clinician training and engagement to foster a greater understanding of the benefits of remote follow-ups for CIED patients.
- We recommend that hospitals
  - train clinicians.

For Case 2 (remote monitoring), we propose the following recommendations in addition to the above:

- We recommend that the Department of Health
  - define cardiac pathway national tariffs, including best demonstrated practice disaggregated costing of physician service, infrastructure cost and monitoring services;
  - adapt its payment platform to enable direct reimbursement of a wider group of stakeholders (eg, community service providers);
  - develop a programme of clinician training and engagement to foster buy-in to remote monitoring.
- We recommend that industry
  - forge new organisational structures, alliances or consortia to enable the integrated delivery of cardiac care pathways.

In both cases, we also recommend that the different stakeholders work together to develop local programmes which promote remote follow-up to patients and create "patient pull", working side-by-side with key patient groups such as the Arrhythmia Alliance.

7 Closing remarks

This paper has described some of the key changes that we consider necessary for the CIED telemonitoring reimbursement systems of five European countries. As healthcare systems in Europe prepare for the significant future demands that will be placed on them, it will be critical to harness the benefits of telemonitoring technology, and reimburse the relevant parties in a way that is fair, transparent and sustainable, and which encourages future innovation and improved outcomes.

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