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Device therapy and hospital reimbursement practices across European countries: a heterogeneous scenario

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As in other settings, in the field of clinical use of cardiac implantable electrical devices (CIEDs), the implementation, in various ways, of diagnosis-related groups (DRGs) has created new scenarios in most European healthcare systems. A DRG system is primarily a financial tool with the aim of promoting efficiency and improving utilization of resources. However, there are a variety of ways in which this system is used for funding the activity of centres implanting CIEDs. It is possible that the specific type and method of reimbursement may influence the implementation of CIEDs in the 'real world' through a variable spectrum of practices. These may range from the situation where reimbursement may, together with other factors, constitute a true barrier to the implementation of guidelines, to scenarios where reimbursement is adequate, and/or to situations where reimbursement may be adequate for standard devices but not for prompt implementation of effective technological innovations. The variety in reimbursement also affects how in-office checks of CIEDs are covered and, above all, the possibility to pay for remote follow-up of CIEDs. In the field of medical devices, refinement of DRG systems and adoption of new strategies and policies are needed to sustain and enhance those effective technological innovations that may be beneficial for specific patient populations. It is also important that physicians are deeply involved in the development and deployment of DRGs, and that each country DRGs agency has a transparent approach to engagement with stakeholders, along with robust and transparent mechanisms for updating these systems.

Keywords Cardiac resynchronization therapy • Diagnosis-related groups • Implantable cardioverter defibrillator • Pacemaker • Reimbursement

Introduction

On the basis of evidence derived from randomized clinical trials, specific recommendations regarding treatment with a cardiac implantable electrical device (CIED) are available in international consensus guidelines.[1,2] However, the implementation of device therapy in clinical practice is largely incomplete and growing interest is dedicated to analysis of all the multiple factors that may modulate the access to therapy in appropriately selected patients.[3–5]

The various factors that may affect the implant rate of CIEDs include lack or inadequate implementation of specific guidelines, lack of screening programmes and imperfect referral pathways, limited number of cardiac catheterization laboratories or implanting physicians, as well as the specific type of device analysed. In addition, the population demographic structure, socio-economic status, ethnic status, patient's cultural status, and patient's culture may have an influence on actual CIEDs implantation rates.[3,6] In this complex scenario, it is likely that also the variability in reimbursement practices for CIED and for specific types of CIEDs may have an impact in conditioning or modulating the use of device therapy or other invasive procedures in different organizational or socio-political contexts.[3,7–10] Moreover, the above factors may also impact on the availability of invasive or non-invasive diagnostic procedures used to establish a diagnosis that is associated with the indication for a CIED implant.

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The aim of the present study is to provide a general overview of the diverse patterns of reimbursement practices in a sample of European countries, with specific focus on reimbursement for CIEDs.

Funding in healthcare

European healthcare systems present a variety of financial and institutional arrangements, often reflecting domestic pathways. Hospital financing is no exception as different methods have been used with global budgets, activity-based financing (diagnosis-related group, DRG-like systems) being the most popular nowadays. In addition, the methods for remuneration of physicians are also variable, including both wages and remuneration with fee for service, sometimes combined.[8] It is beyond the scope of this article to enter the complex field of healthcare financing, but the variability existing in healthcare financing across Europe should be taken into account when reimbursement practices for specific hospital activities involving use of electrical devices are analysed.

Diagnosis-related groups

The evolution of medicine and the increase in complexity of procedures performed in hospitals in the last decades have prompted the creation of patient classification systems which, as a common basis, relate the characteristics of in-hospital-treated patients to the resources used. The methods used to classify patients across Europe were often derived from the Health Care Financing Administration system introduced in 1983 for the Medicare system in the USA. Initially developed as an information tool to monitor quality and use of services, patient classification systems later became prospective payment systems, named DRGs.[9,11] In recent years, new versions have been implemented which adjust for the severity of diagnosis and/or other co-morbidities: the Ms-DRG (Medicare-Severity DRGs) and Apr-DRG (All Patient Refined DRGs) systems. Today, the objective of DRG systems is to classify hospital cases into one of ~500–1000 groups, thus creating a patient classification system that relates the type of patients treated to the resources that they consume. These data are not only used as information for analysis—as a matter of fact, in most European countries a DRG system or similar grouping systems have been introduced as instruments for hospital reimbursement.[9]

The methods for paying hospitals for inpatient care have thus evolved over time from per diem or line-item budgets to global budgets and then again to case-based payment (mainly through variants of DRGs).[8] A wide variety of reasons may explain the introduction of DRGs in European countries: to control costs for care, to provide a clear payment system for both public and private hospitals, to stimulate competition among hospitals, and to reduce waiting times.[12] Hungary was one of the first European countries to introduce DRGs, beginning in 1987, with full implementation in 1993.[8,9]

Since the adoption of DRG systems, the link between financial and clinical aspects has become well established. From the clinical point of view, appropriate attention has to be paid to the application of a DRGs paradigm. Diagnosis-related groups, by definition, are 'groups or classes of patient episodes designated by codes or terms which describe to a greater or lesser degree of specificity a diagnosis or a procedure'.[11] Assessment of the impact of DRGs in the countries of the European Union suggests that implementation of DRGs is associated with increased levels of hospital activity in the short term,[13–15] but may also result in cost shifting,[16] growth in readmission rates and 'up-coding' ('DRG creep'),[11,14,17] or cream-skimming.[8] These are the reasons for a series of periodic revisions to DRG systems in several countries. They also imply a need to monitor the quality of in-hospital care in tandem with the implementation of DRG-based reimbursement of hospitals.

In *Table 1*, we summarize the role of DRG systems for funding in-hospital care for 19 European countries. Specifically, we report in detail for each specific country whether the DRG system and its tariffs play a predominant role in funding (if the system covers at least 50% of total funding for inpatient providers), or whether, conversely, a DRG-related system exists but is used primarily for information purposes with limited or no role in financing. We also report if the original US DRG system is used, or if a different system has been developed. Since it is difficult to obtain up-to-date and accurate information on this topic, and in particular

Table 1 Funding for in-hospital care in 19 European countries and role of diagnosis related group systems for funding hospital care, with regard to public and private hospitals, respectively

Country	DRG system for public hospitals	DRG system for private hospitals	DRG system
Austria	No	No	LDF
Belgium	No	No	APR-DRG
Czech Republic	Yes	Yes	ALFA-DRG
Denmark[a]	No	No	Dk-DRG
Finland[a]	No	No	NORD-DRG
France	Yes	Yes	GHS
Germany	Yes	Yes	G-DRG
Greece	No	No	USA DRG
Hungary	Yes	Yes	HBCS
Ireland	No	No	Australian AR-DRG
Italy[a]	Yes, with budget caps	Yes, with budget caps	USA DRG
Netherlands	Yes	Yes	DBC
Norway[a]	No	No	NORD-DRG
Poland	Yes	Yes	Procedure list
Portugal	Yes	Yes	USA DRG
Switzerland	Yes	No (Yes as from 2012)	AP-DRG; Swiss DRG (2012)
Spain	No	Yes/No	USA AP-DRG v23.0
Sweden[a]	No	No	NORD-DRG
UK	Yes	Yes	HRG

[a]Countries with a predominantly mixed system (diagnosis related groups and global budget).

on the one-dimensional use of DRGs for funding allocation versus multi-factorial funding allocation, the picture we present has to be considered in general terms.

Reimbursement for implantable electrical devices across Europe

Indications for therapy with implantable devices for brady or tachyarrhythmias, sudden death prevention, cardiac resynchronization in heart failure, or for the purpose of arrhythmia monitoring are today well described and graded in terms of recommendation levels and scientific evidence, summarized in international consensus guidelines.[1,2] Furthermore, in most countries, national physician societies or health agencies have issued national guidelines, transferring evidence from the literature and international guidelines into the specific context of healthcare organization in their country. While international guideline recommendations typically focus on published scientific evidence and clinical expert judgement but pay less attention to cost-effectiveness aspects, more and more national guideline documents incorporate information on the cost effectiveness of treatments in the grading of recommendations for their clinical application (e.g. guidelines from the National Institute for Health and Clinical Excellence, UK, and Swedish Board of Health and Welfare).

However, while international and national European guidelines for device therapies come to similar conclusions, the rates of device implantation vary considerably from country to country[4,18–22] as well as from region to region,[6,22] for all the various types of CIEDs. While heterogeneity in implant rates has been a subject of evaluation and investigation,[6,18,19] limited attention has been dedicated to heterogeneity in reimbursement mechanisms across the various European countries. In *Table 2*, we report a summary of the predominant reimbursement methods in specific European countries for CIEDs, with regard to both implantable pulse generators (IPGs) and implantable cardioverter defibrillators (ICDs). The complexity of European healthcare systems is enhanced in most countries by variations in reimbursement practices between public and private hospitals, or between payers, as well as by variations according to geographic regions (e.g. in Italy) or hospital type.[23]

Table 3 shows specific data on the actual state of reimbursement in various European countries, including indications on the specificity of the DRG tariff for the type of CIED (single-chamber, dual-chamber, or biventricular device) and on inclusion of the cost for device purchase in the DRG tariff. As shown, the scenario of reimbursement for electrical devices confirms a substantial variability, with some countries not differentiating the tariff for reimbursement according to the type of implanted device.

Reimbursement for in-clinic device check and for remote monitoring of implantable electrical devices

All CIEDs require periodic checks, as indicated by the recent Heart Rhythm Society/European Heart Rhythm Association (EHRA) Expert consensus document.[24] The in-office device check is included in the list of reimbursed outpatient services in almost all European countries; usually it is coded and reimbursed using specific tariffs that include control and reprogramming. A substantial variability between the countries is present in this case too, since some countries have specific codes for single or dual chamber and others use a single code for all types of CIEDs, as reported in *Table 4*.

Current technologies now allow for remote follow-up of CIEDs. This may represent a more efficient way of organizing CIEDs follow-up, by reducing the workload of routine follow-up visits. As shown in *Table 5*, there is a substantial variability across Europe with regard to reimbursement of remote CIEDs follow-up, with definition of specific tariffs only in a few countries. Healthcare payers may be reluctant to reimburse remote device management due to lack of robust economic analysis and evidence of improved patient outcome, despite acknowledging the strategy to be safe.[25] In the USA, Medicare and Medicaid have expanded reimbursement for remote device monitoring for all states since 2006. Reimbursement rates may vary from state to state, and are in some instances the same as an in-office visit without device programming.

In patients with heart failure, some devices provide dedicated diagnostic features for the monitoring of fluid retention and disease state, aiming to improve the maintenance of stable compensation. These features open the perspective of remote disease management by CIEDs.[26] The possibility to establish a specific reimbursement for disease management of heart failure patients by remote monitoring should be the subject of

Table 2 Models existing across Europe for reimbursement to healthcare providers of implantable pulse generators and implantable cardioverter defibrillators

Case payment (DRGs) predominant	Mixed model (DRGs a component in some)	Reimbursement list (DRGs may co-exist)
Germany	Austria	Belgium
Hungary	Czech Republic	Czech Republic (reimbursement list for highly innovative product in centres of excellence)
Italy (on a regional basis)	Denmark	France
Netherlands	Finland	
Poland	Greece	
Portugal	Hungary	
Switzerland	Ireland	
UK	Italy (on a regional basis)	
	Norway	
	Sweden	
	Spain	

Table 3 Methods for reimbursement of implantable pulse generators and implantable cardioverter defibrillators to healthcare providers across Europe

Country	Reimbursement system	IPGs		ICDs	
		Specificity for device type	Inclusion of the device in the DRG tariff	Specificity for device type	Inclusion of the device in the DRG tariff
Austria	LKF (AU ver. of DRG)	SC, DC, CRT-P	Yes	All ICD, CRT-D	Yes
Belgium	List price (only device)	SC, DC, CRT-P[a,b]	No	SC, DC, CRT-D[b]	No
Czech Republic	Specific tariff available for each procedure	SC, DC, CRT-P	No	SC, DC, CRT-D	No
Denmark	Global budget + NORD-DRG	No	Yes	No	Yes
Finland	Global budget + NORD-DRG	No	Yes	All ICD, CRT-D	Yes
France	List price (only device)	SC, DC, CRT-P[b]	No	SC, DC, CRT-D[b]	No
Germany	DRG	SC, DC	Yes	SC, DC, CRT-D	Yes
Greece	Global budget	n/a	n/a	n/a	n/a
Hungary	DRG	No	No	No	No
Ireland	Global budget + DRG	No	n/a	No	n/a
Italy	Global budget + DRG	No	Yes	No	Yes
Netherlands	Global budget + DRG	No	No	No	Yes
Norway	Global budget + NORD-DRG	No	Yes	All ICD, CRT-D	Yes
Poland	DRG (procedure list)	SC, DC	Yes	No	Yes
Portugal	DRG	No	Yes	No	Yes
Switzerland	AP-DRG; Swiss-DRG from 2012	SC, DC, CRT-P	Yes	SC, DC, CRT-D	Yes
Spain	Global budget	No	No	No	No
Sweden	Global budget + NORD-DRG	No	Yes	All ICD, CRT-D	Yes
UK	DRG	SC, DC, CRT-P	Yes	No	No

SC, single-chamber; DC, dual-chamber; n/a, not available.
[a]Third lead not reimbursed.
[b]Leads reimbursed on top of the device.

investigations considering that this activity may have an impact on chronic outpatient care.

Reimbursement practices and funding of innovation

Since patients are usually not able to directly cover the expenses for their healthcare, coverage, and reimbursement practices are crucial in conditioning the way that new medical technologies are used in daily practice.[27] In many countries, it is not well defined how and how often updating of DRG tariffs will occur. This is relevant with regard to implementation of innovative devices or device features. When an innovative device/procedure becomes available, generally at an increased price for purchasing, the application of current DRG codes and tariffs to new more expensive devices may be problematic or may fail, despite formal approval of the new device, for purely financial reasons.[28] As a consequence, different reimbursement mechanisms can result either in acceleration or in slowing of the adoption and implementation of innovative and more expensive technologies. In such a situation, the decisions on how to identify new technologies, devices, or procedures that are subject to coverage and reimbursement strongly influence clinical practice and profoundly influence the scenario that supports medical innovation, creating either incentives or disincentives for manufacturers to propose innovations. In fields with rapid technological evolution, it is important to adapt reimbursement practices to innovative, more sophisticated technological advancements, thus allowing implementation of these innovations in clinical practice as soon as evidence of benefit is available.[10,27] At the same, it is essential that any innovation is adequately evaluated in terms of net clinic benefits and cost effectiveness. In the absence of any facilitation or adaptation of the system, the implementation of innovative medical technologies with a higher price in comparison with the currently used technology remains a challenge. If the extra costs are not reimbursed, hospitals will not find any incentive to adopt a new technology, except for marketing reasons or for research purposes, and the unadapted DRG systems might result in slowing down technological innovation.

Alternative options to support innovation may include separate or additional budgets for funding innovation. Some countries with DRG funding have channels to support the introduction of innovative, more expensive technologies. These solutions include the activity supported by Neue Untersuchungs- und Behandlungsmethoden in Germany, Integrated Care contracts in Germany, special funds dedicated to financing innovative and expensive technologies in France, regional initiatives in Italy, etc. However, these processes may not be well understood by stakeholders and implementation of technology may have some limitations. We feel that lack of a systematic approach in this field opens up space for discussion in the European Commission on the most effective ways for promotion of novel technologies, including specific incentive programmes.

Table 4 Reimbursement for in-office follow-up of implanted electrical devices

Country	IPG		ICD		CRT
	Single	Dual	Single	Dual	
Belgium	×	×	×		n/a
Czech Republic	×	×		×	
Denmark			×		
Finland	×	×	×		n/a
France		×	×		n/a
Germany			×		
Italy			×		
Netherlands		×	×		n/a
Norway			×		
Portugal		×	×		×
Spain			×		
Sweden		×	×		×
Switzerland	×	×	×	×	n/a
UK			×		

The presence of specific reimbursement according to the characteristics of the implanted device or the lack of specific reimbursement are indicated.
×, availability of reimbursement.

For CIEDs, accumulation of clinical evidence requires a relatively long time period. Therefore, one option for coverage of promising technological innovations, including devices, that would not otherwise meet full standards of available evidence is 'coverage with evidence development' — a policy proposed in the USA by Medicare in 2005.[29] This policy is targeted at diminishing the logjam between innovation and evidence-based medical policy, allowing a formal option for coverage of promising technologies that includes collection of longitudinal data for a better understanding of the risks, benefits, and costs of the new treatment options.[29,30]

Conclusions

As in other settings, also in the field of clinical use of CIEDs, the implementation, in various ways, of DRGs has created a new scenario in most healthcare systems in Europe. Diagnosis-related group systems are primarily financial tools that also have the aim of promoting efficiency and improving the use of resources. However, there are a variety of ways in which DRG systems are used for funding the activity of centres implanting CIEDs, particularly with regard to how specific types of devices are reimbursed.

Table 5 Reimbursement of in-clinic device check and current availability of tariffs for reimbursement to hospitals of remote device check across Europe

	Availability of a tariff for reimbursement of in-clinic device check	Availability of a tariff for reimbursement of remote device check	Availability of a tariff for procurement of hardware and service for remote device check
Belgium	×	No	No
Czech Republic	×	No	No
Denmark	×	No	No
Finland	×	No	No
France	×	No	Price premium on selected systems
Germany	×	×	No
Italy	×	No	No
Netherlands	×	No	No
Norway	×	No	No
Portugal	×	×	No
Spain	n/a	n/a	No
Sweden	×	×	No
Switzerland	×	No	No
UK	×	No	No

×, availability of reimbursement.

The variability of reimbursement across Europe has to be taken into account when trying to interpret the effective implementation in specific regional or national contexts of consensus guidelines on indications to implant specific types of CIEDs. It is likely that the specific type and method of reimbursement may influence the implementation of device therapy in daily 'real-world practice' through a variable spectrum of effects, often poorly understood and sometimes undesirable. These influences may range from the situation where reimbursement may, in combination with other factors, constitute a true barrier to widespread implementation of consensus guidelines, to situations where reimbursement appears to be adequate and, finally, to situations where reimbursement may be adequate for most standard devices but is not fully adequate to allow prompt implementation of effective technological innovations.

The heterogeneity in reimbursement systems between European countries also affects how in-office check of CIEDs is covered and, above all, the possibility to pay for remote follow-up of CIEDs. Despite the potential for improving the efficiency of device clinics, remote device checks are currently reimbursed only in a minority of countries.

In the field of medical devices, refinement of DRG systems and adoption of new strategies and policies are needed to sustain and enhance those effective technological innovations that may be beneficial for specific patient populations, allowing an improvement in patients' outcome and quality of life, with an affordable absorption of economic resources. It is important that physicians are deeply involved in the development and deployment of DRGs, and that each country DRG agency has a transparent approach to planning, communication, and engagement with stakeholders, along with robust and transparent prioritization mechanisms for updating codes and tariffs. Data quality assessment is also essential for DRG systems. For this reason, it is imperative to ensure a high degree of accuracy and compliance in clinical coding (diagnosis, co-morbidity, and procedure) and also in cost measurement and allocation. Necessarily, this requires strong efforts including investments in education and in database systems.

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