



Special ESC report

Patient access to medical technology across Europe

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Access to medical technology differs across Europe. Differences in funding and reimbursement systems create barriers for the adoption of new and innovative medical technology. It is obvious that a joint effort between representatives from the industry and the profession has great potential to emphasise inequitable discrepancies and thereby improve the availability of accepted innovations in cardiovascular medicine. It is equally obvious that future efforts to overcome such restrictions to availability must be directed at the individual country level. The involvement of the profession, perhaps best accomplished by activation of National Cardiac Societies, will be mandatory for success. Collaboration with the industry is then a likely key factor for success. Presently there seems to be a great lack of knowledge and interest for this important aspect of a well functioning health care system and the responsibility to improve it remains with the professional societies. They need to allocate time and resources for this purpose, educate their members and lobby within their countries with the ambition to create better, more uniform and transparent procedures, and to become natural partners in the funding and reimbursement processes.

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Introduction

The European Society of Cardiology (ESC) has investigated the practice of cardiovascular medicine in Europe via the Euro Heart Survey programme in 40 member countries. Experience gained verified that practice differs much from country to country despite commonly accepted management guidelines. Discrepancies were for example found in the prevalence of coronary artery disease, the frequency of coronary angiographies and resulting numbers of coronary interventions. Moreover implantable cardioverter defibrillators (ICDs) are con-

siderably more often utilized in Germany than in other countries such as Sweden, France and the UK. This variability was not only identified by the medical profession but had also been experienced by the medical technology and pharmaceutical industries. Possible explanations to these and other discrepancies may be differences in funding and reimbursement mechanisms for new technology intended for cardiovascular health care.

A forum comprising leadership from the ESC and the medical technology and pharmaceutical industries, the Cardiovascular Round Table, was recently inaugurated by the Society. The shared interest around the issue of patient access to medical technology across Europe formed the background to Task Force 2 of this Round Table with the objective to try understanding factors

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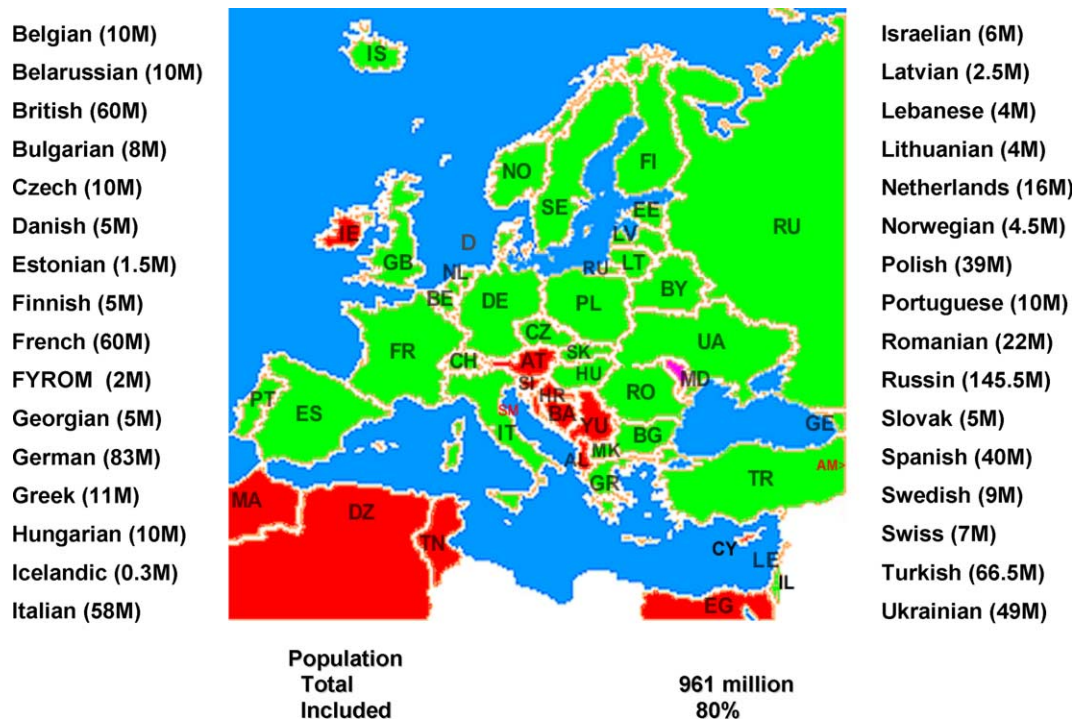


Fig. 1 Response to the questionnaire on patient access to medical technologies across Europe. Green = responding ($n = 32$) and Red = not responding ($n = 15$) National Societies. The figure also outlines the number of inhabitants in various countries and the proportion of the population covered (80%).

limiting access, and thereby the quality and equity of cardiovascular health care in general terms including diagnostics, pharmaceuticals and devices for treatment and monitoring. By distributing such knowledge it was hoped that a debate regarding patient access to proven and innovative medical technology should be facilitated triggering efforts to improve current conditions (see Appendix A).

To meet this goal, information was gathered on a number of potentially important topics including the role of medical professionals and their organisations, governmental agencies and policy makers. Attempts were also made to look at the transparency of the process of introducing new technology including possible barriers to equitable access. Linking regulatory approval with health economics may serve as a tool to restrict the application of professionally accepted medical knowledge. It was therefore considered important to study funding and reimbursement in various European countries. Information derived from various sources was subsequently cross-linked in order to find possible patterns of interest for understanding the complex nature of patient access to medical technology.

Search for information

The task force mainly used two sources of information. One was a review of existing European and National systems for health care funding and reimbursement¹ and the other, a questionnaire distributed to the 47 National Cardiology Societies within the ESC. The questionnaire

contained a general section and two further sections on pharmaceuticals and medical devices/monitoring equipment, respectively. It also comprised some questions on the availability of "life saving" versus "life style" drugs and some on specific devices as well as diagnostic and monitoring equipment. A total of 32 Societies, covering about 80% of the European population, responded (Fig. 1). The replies were used to highlight existing differences and similarities between countries as perceived by the National Societies. The information derived by the general section was correlated to responses to individual questions on drugs and devices. Data on utilisation and funding were correlated. No formal statistical analysis was applied considering the difficulties to truly validate the collected information. Moreover the main intention was to get a general impression on relevant issues and to find fields of interest for future more detailed investigations.

Economic aspects of health care

Health care systems in Europe are subject to conflicting pressures. Among them are rising costs due to demographic factors, increased public involvement and awareness and the continued introduction of new and innovative technologies. Against these pressures governments need to remain within budgetary and spending limits. The pressure to increase spending on health care is driving governments to look for greater efficiencies usually by introducing health care reforms. Despite their very different structures and funding

mechanisms, all health care systems in Europe are experiencing such challenges. Across Europe the amounts spent on health care (Fig. 2) varies as a percentage of the Gross Domestic Product (GDP). The European Union (EU) weighted average is 8.75% GDP ranging from 5.6% to 10.6%.² Enlargement of the EU is under way. The amount spent on health care in the accession countries is significantly less than in the present EU. For example, the mainland candidate countries spend on average 7.0% of GDP (range: 5.9–9.0%). In monetary terms, this equates to \$ 2165/caput in the EU and \$ 678/caput for the accession countries. Health care expenditure as a percentage of GDP stabilized during the latter part of the 1990's and even declined in some EU countries.²

When it comes to the provision of funding for health care, European countries tend to rely primarily on public sources, either from taxation and/or social health insurance. A third significant element is out-of-pocket expenditure. This includes user charges paid in the public system and direct payments for services provided in the private sector. Private health insurance represents the smallest proportion in virtually all countries with the exception of the Netherlands, although governmental influence is strong in this country as well. As outlined in Fig. 3 EU countries may be grouped into three clusters according to their sources of funding.³ One group receives funding predominantly from taxation; another from social health insurance and a third uses a combination of tax and social health insurance. This compared well with the opinions as expressed by the National Cardiology Societies responding to the questionnaire. It is evident that the sources and amounts of funding for health care vary significantly across Europe. Total healthcare expenditure in OECD countries is lower on average in systems predominantly funded through taxation (Ref OECD Health Data 2003). Whilst it may not be immediately apparent just how patient access to medical technology is influenced by the sources of health care funding, characteristics associated with the different

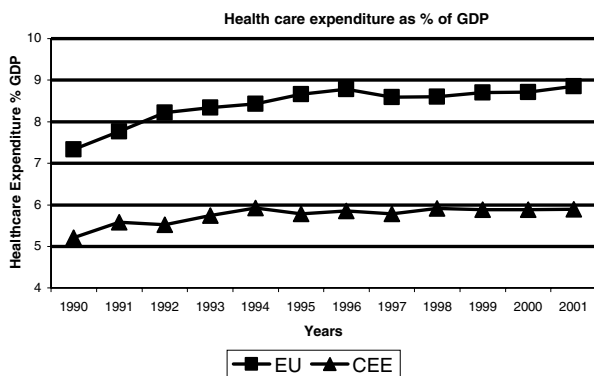


Fig. 2 Total expenditure on healthcare as a percentage of the Gross National Product (GDP) in some European countries. EU = European Union; CEE = Central and Eastern Europe. Source: European Health for All Database (HFA-DB Ver.2), World Health Organization.

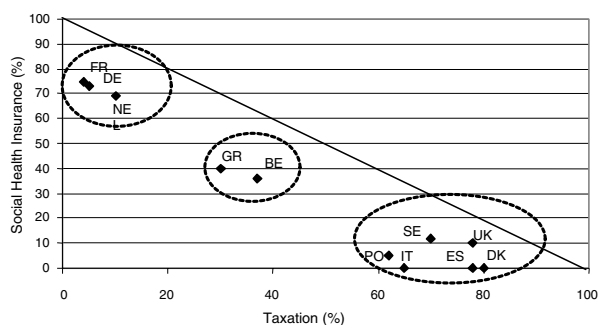


Fig. 3 Sources of health care funding in EU. One group of countries receives funding predominantly from taxation, local (Denmark and Sweden) or central (Italy, Portugal, Spain and the UK). Social health insurance represents the main source of funding in France, Germany and the Netherlands. In Belgium and Greece funding is almost equally provided from tax and social health insurance. The gap between the line and the dots for various countries represent private payments. (Modified from Figure 1.5 Percentage of total health expenditure financed by taxation and by social health insurance in selected western European countries in 1998 or latest available year in Elias Mossialos, Anna Dixon, Josep Figueras, Joe Kutzin (eds). Funding health care: options for Europe. Buckingham, Open University Press 2002 (European Observatory on Health Care Systems Series).)

funding mechanisms may provide opportunities for the National Societies to pursue. If one assumes that insurees are more likely to raise their demands to maximise the returns on their contributions by increasing patient awareness (by the Societies) of innovative medical

Table 1 Example of decision systems and authorities responsible for decision making on reimbursement of medical technology in seven European countries with altogether >700 autonomous decision makers with their own systems

- Germany
 - 16 counties – 450 public & 50 private sick funds
 - High decision making power at the hospital level
- Italy
 - 21 local health authorities with full decision power
 - High decision power at the hospital level
- France
 - Public, decentralized structure
 - Private, centralized decision making
- Spain
 - 17 autonomous regions
 - High decision making power at the hospital level
- UK
 - 308 primary care trusts
 - 28 strategic health authorities
- Sweden
 - 27 autonomous county councils
 - High decision making at the hospital level
- Belgium
 - 1 centralized system

Ref. Jacoti bvba, European Medical Devices Conference, Rome 2003.

technologies in countries funded predominantly from social insurance could be beneficial.

When it comes to patient and physician accessibility to medical technology the reimbursement system or mechanisms by which medical technology is paid for, should also be considered. The complexity of the reimbursement and procurement systems operating within Europe is illustrated in Table 1 summarizing the present situation in seven European countries.

Relation between funding and utilization of medical technology

As illustrated in Figs. 4 and 5, the reimbursement system and the magnitude of health care resources provided have a considerable influence on the accessibility of medical technology. The relative usage of coronary stents has been greater in countries with a social health insurance-based funding system. Likewise there is generally a greater usage of implantable cardioverter defibrillators in countries where funding is primarily from social health insurance sources (Fig. 5). Information from the questionnaire underlines the relation between funding and access to medical technology both for established and new products. Twenty-one of the National Societies declared that such factors limited the availability of established medical technology while 11 considered these factors of minor importance. For new technology the corresponding numbers were 23 and 9, respectively (Fig. 6). With few exceptions there were no differences between pharmaceuticals, medical devices or diagnostics in this respect. The reasons for limited availability of new technology were declared to be cost-constraints ($n = 10$), high patient co-payment ($n = 2$) or a combination of these two factors ($n = 8$).

Less than half of the National Cardiac Societies, representing professional interests, claimed to be involved in funding and reimbursement issues. When involved, it is generally in an advisory capacity rather than in lobbying and there was very little collaboration with the industry in these respects.

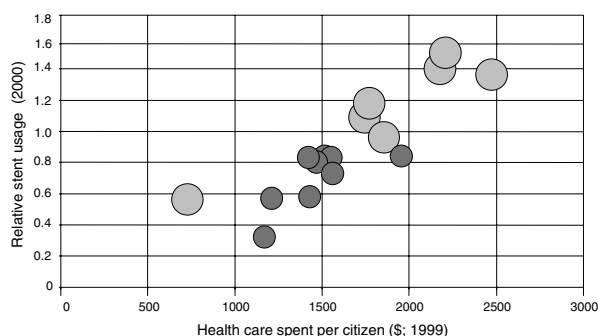


Fig. 4 The relative use of coronary stents during the year 2000 in relation to 1999 health care spending in \$/caput. Black dots = tax based systems; Grey dots = insurance based systems.

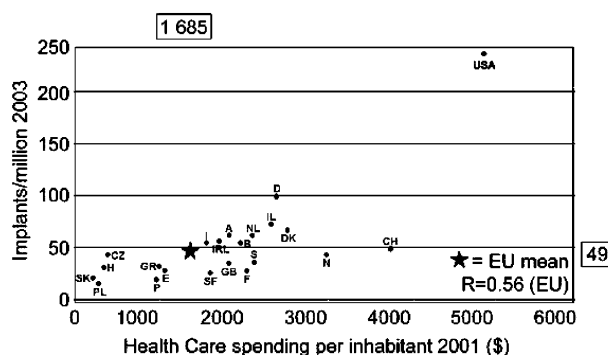


Fig. 5 The rate of implanted cardioverter-defibrillators across Europe in the year 2003. ★ = European mean, 49/million at \$1 685 health care spending in the year 2001. The corresponding relation for the US is shown for comparative purposes.

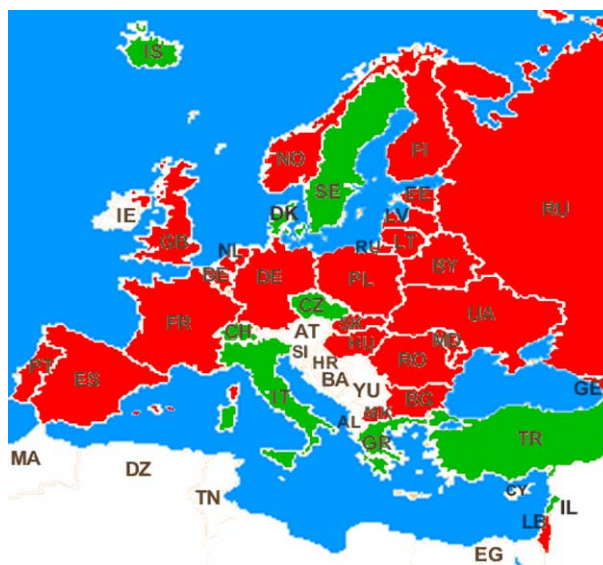


Fig. 6 Reply to the question: Does the current funding system in your country limit the possibility for patients to have access to new, innovative cardiovascular medical technology? Green countries = no; Red countries = yes.

Specific information

The specific sections of the questionnaire covering pharmaceuticals, medical devices, diagnostics and monitoring equipment were confirmatory. Some examples may, however, be given to further underline concerns and involvement of the profession. Even such well documented and life saving compounds such as statins and GPIIb/IIIa inhibitors was subjected to restrictions. The reasons varied considerably comprising a mixture of defined prescription limitations to financial constraints. Moreover restrictions were different from country to country illustrating that measures to accomplish equal access to pharmaceutical therapy must be carried forward with a country specific agenda. Once more National Society involvement was reported limited. A clear majority of the National Cardiology Societies not involved

were not involved at all and those involved mostly provided general advice rather than claiming the rights of patients with serious cardiovascular disorders.

Coronary stents and implantable cardioverter defibrillator (ICD) technology are examples of rapidly evolving medical technologies already referred to in this report. Patient access to these technologies varies across Europe and appears related to the type of healthcare funding system in place. Even though there is a growing evidence base supporting the clinical use of ICDs it is clear that national societies feel that funding and reimbursement barriers do have an impact on limiting patient access to this life saving therapy. The situation with coronary stents appears to be somewhat different with 50% of National Societies claiming that funding and reimbursement barriers do not limit the use of this technology. As with pharmaceuticals, more than 50% of National Societies claim not to be involved in any funding and reimbursement activities and involvement is, when existing, limited to clinical advice.

Available documents on funding and reimbursement

There are many sources of information regarding health care systems at the country level and their respective approaches to funding and reimbursement. Some are listed in Table 2. It is apparent that the differences in funding and reimbursement systems have an impact on the accessibility of innovative medical technologies throughout Europe. Observations from the questionnaires indicate that the knowledge on these systems within the professional societies is variable and surprisingly limited. One example may be that about half of National Societies responded that there are no funding or reimbursement barriers limiting the use of various medical technologies, which unfortunately does not appear to be the situation in most European countries when actual utilisation rates are examined. Another reply is that a medical device becomes available once it has re-

ceived a CE-mark. Whilst this statement is essentially true the CE marking system does not take into account financial and economic constraints. The replies clearly indicate there cannot be any trans-European solutions to the problems with funding and reimbursement. Such issues need to be addressed locally according to a strategy that is determined by local conditions and constraints. An ideal goal would be to lobby for more consistency and definitely transparency as regards patient access across Europe, based on clinical evidence, existing practise guidelines and patient needs.

Comments

There are many factors influencing patient access to medical technology across Europe. Differences in funding and reimbursement systems can and do create barriers for the adoption of new and innovative medical technology. Collaboration and joint problem definition between the medical profession identifying and recommending patient need for technology, the industry providing the technology and the national health system finally allowing patient access has great potential to emphasise inequitable discrepancies and thereby improve the availability of accepted innovations in cardiovascular medicine. It is suggested that future efforts to overcome such restrictions to availability must be directed at the individual country level.

Unlike funding and reimbursement the regulatory system is much more transparent and harmonised at the European level. For example, the Medical Devices Directives (93/42/EEC) were enacted to provide such a harmonized regulatory environment for all medical devices sold within the European Economic Area. Products that fall within the scope of the Directives must meet all applicable essential safety and performance requirements and must be CE marked to show they comply. This provides benefits for patients, clinicians and other health care workers, as they can be sure that the products have been designed and manufactured to high standards. The CE mark ensures that the product has been appropriately evaluated to meet strict safety and performance criteria. The Medical Devices Directives are currently being reviewed. Early indications appear to support the view that the current regulatory framework is considered to be satisfactory with only some fine-tuning required. Clearly, regulatory considerations form an important barrier to prevent technologies being used that are not safe and do not perform appropriately. It may appear that the regulatory environment does not directly impact funding and reimbursement considerations. However, if barriers to entry created by the regulatory environment are allowed to significantly increase, whilst at the same time cost containment measures limit healthcare systems ability to adopt new technologies, patient and physician access to medical technology could ultimately be impacted.

The involvement of the profession, perhaps best accomplished by activation of National Cardiac Societies, will be mandatory for success. Presently there seems to

Table 2 Examples of available sources of information on health care systems and different approaches to funding and reimbursement

<p>OECD Publications The Changing Health System in France The Changing Health System in the UK</p> <p>World Health Organisation www.observatory.com HIT Country Profiles : 39 reports available Commercial Publications www.jacoti.com : Germany, France, Italy, UK & Belgium Clinica Reports</p>
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be a lack of knowledge and implication for this important requirement of a well functioning health care system whilst the responsibility to improve it remains with the professional societies. They need to allocate time and resources for this purpose, educate their members and communicate within their countries with the ambition to create better, more uniform and transparent procedures, and to become natural partners to ensure actual patient access through equitable funding and reimbursement processes.

With regards to funding and reimbursement of medical technologies there is no single European model. Each healthcare system has developed its own approach within the context of the cultural, political, economic and historical environments from which it evolved. The various types of healthcare system in Europe tend to be either based on a 'Bismarckian-model' (e.g. Germany, France, Belgium and the Netherlands) which is typically an insurance based system, with the aim of providing universally accessible healthcare based on solidarity between the insured, or the taxed based 'Beveridgian-model' (e.g. UK and Italy). Nevertheless each government clearly wants to maximize the health of its citizens and provide equitable access whilst at the same time controlling expenditure. It is this balance that needs to be considered and made fair and transparent. The concern that the economical system, in a non-transparent way, may be used to ration medical technologies that are useful and approved must be addressed.

What does it take to get medical technology or a device to the patient and how do funding and reimbursement factors influence this process? In order to answer this question, one must consider the typical decision making process for medical technology. In the past the clinician has been the primary decision maker with hospital management and the regulatory environment being key influencers. The role of the patient and indeed that of the payers (e.g. insurance companies) and other government agencies appeared to be less directly involved. This situation is changing for many of the reasons previously outlined. Given the different mechanisms and levels of funding for health care across the countries together with complexity associated with reimburse-

ment, it seems reasonable to assume that these factors influence patient access beyond medical demands and needs. The complexity and dynamic nature of these systems, brought about to satisfy political considerations, can and should not be under-estimated.

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Appendix A

Members of Task Force 2 of the ESC Cardiovascular Round table

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John Dillon	GSK	Alexander Battler	ESC
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Antoinette Wenk-Lang	Boston Scientific		
Jan Vermeulen	Philips		
Lieve Verplancke	Bristol Myers Squibb		

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