Financing Medical Devices in Europe
- Executive Summary -

Medical technology assumes a central role in all sectors of major European health systems – including prevention, diagnosis, treatment, and rehabilitation. From modern incontinence products to hearing aids and cardiac pacemakers, medical devices are indispensable in the provision of modern, high-quality health care. In particular, in an era of aging populations and growing health expenditures, medical innovations can improve the quality of people's lives, lower the societal costs of poor health, unemployment and disabilities, and increase the efficiency of health care systems and economic growth.

While medical technology has brought such benefits, national policy-makers and other key stakeholders are continuously challenged with achieving multiple health system goals concurrently – investing in services that offer the best value for money, within the constraints of limited resources, while also stimulating and supporting medical innovation. Indeed, identifying the optimal allocation of available resources in order to maximize health gains of the population has been and continues to be a key challenge for health care systems. This is especially true in the case of medical technologies, as continued advances in research are expected to produce an ever-increasing number of alternatives for the detection, prevention, and treatment of a range of diseases. Consequently, policy-makers will continue to seek and adopt measures to regulate and manage the medical technology market, with regards to access, quality, and public funding.

While some of the measures stem from existing EU Directives and apply to the majority, if not, all Member States, as in the case of demonstrating product safety prior to market entry, other policy tools or mechanisms are developed and employed on a national, regional, and local level. One key area in this regard is the financing of medical technologies. Financing structures and mechanisms have a profound impact on patient access and utilization, innovation, and product diffusion and acceptability. However, to date, there is little systematic evidence on how they differ across key markets in Europe, and the benefits and hurdles presented by different systems. Moreover, historically much of the discourse and analysis around these issues has related specifically to pharmaceuticals, with minimal attention to medical devices. Arriving at a better understanding of medical devices and associated issues surrounding their financing is an important aim, especially as policy-makers and other decision-makers across Europe are increasingly implementing strategies, such as health technology assessment (HTA), to ensure value for money in reimbursement and other relevant decisions. While pharmaceuticals and medical devices do indeed share some similar challenges and opportunities in health care policy-making, there are distinct differences between the two sectors (Table 1) that need to be considered in the context of financing systems.

Table 1: *Key differences between pharmaceuticals and medical devices*

Structure & Organization	• Device sector is much more fragmented, characterized by more small and medium-sized companies, with significant innovations stemming from many small entrepreneurial entities. • Device sector is marked by generally less-defined markets, thereby creating greater risk and uncertainty in terms of financing and clinical development programmes.
Incentives for & Processes in Innovation	• For pharmaceuticals, specific drugs are patentable, whereas with medical devices, innovation lies in the underlying principle being used in a particular application. As such, as order of magnitude, patients assume greater importance with regards to pharmaceuticals. • In contrast with pharmaceuticals, which usually have a long (~12 years) R&D process, the innovation process for medical devices is incremental; iterative improvements in performance and safety of existing products are typical. • Medical devices often require "lead users" to facilitate its effectiveness. As such, the relationship between products, suppliers, and health service delivery organizations assumes a more integral role. • Post-market, a given pharmaceutical captures a long product life, remaining in their completed form. Medical devices, however, are constantly being modified to improve performance and adjust product features throughout the life cycle. This often renders a product outdated, often within 2 years or less. Overall, medical device manufacturers must bring products to market more rapidly than pharmaceuticals, in order to compete in the market and react to necessary product modifications.
Regulation	• Generally, medical devices are somewhat more difficult to assess and regulate, as they are usually based on a wide variety of technologies. • A number of medical devices are subject to less restrictive regulations than pharmaceuticals, as most do not have the potential for profound systemic effects and generating potentially damaging effects on the human body. For high-risk devices, however, the strictest regulations for market access and post market surveillance apply.
Reimbursement & Pricing	• Generally, more difficult for medical devices, as third-party payers may not directly reimburse a new technology until it has demonstrated value in the marketplace, which can often take several years to prove. This is especially evident regarding diagnostic procedures. • New and different challenges are posed by medical devices, in terms of economic evaluation to ascertain 'value for money' in support of reimbursement or pricing decisions. Characteristics unique to devices, such as multiple applications and iterative development, make evaluation more difficult and complex. RCT data is not often available with devices, which is often required by pharmacoeconomic guidelines. • Price of devices are much more likely to change over time, as new products continuously enter the market, rendering previous iterations (quickly) obsolete. On the contrary, once a drug is priced, it typically remains at the initial price point until the patent expires.

As continuous advancements are made in the medical device sector, accompanied by policy measures to manage and facilitate their use, it is evermore important to understand and highlight the unique contributions made by medical devices. New approaches need to be employed, as opposed to simply transposing those applied to pharmaceuticals or other health services, in order to maximize the potential of medical devices to deliver high-quality, cost-effective, and innovative care to patients. An expanded and more robust evidence base on the key issues and challenges associated with the financing of medical devices will help support policy-makers and other decision-makers to meet these important objectives.

Description of Research Approach

In the first year of research activity, the EHTI focused on the financing of medical technology in select European countries. As previously discussed, financing approaches and mechanisms are considered important factors impacting the availability of and access to medical devices. Indeed, the actual adoption of medical devices in individual Member States depends mainly on whether they are covered by public benefit baskets and how corresponding financial arrangements incentivize (or not) their use.

Accordingly, the research focused on key issues relating to a) coverage, b) procurement, and c) reimbursement of a number of specific medical technologies in various EU countries, including Germany, Italy, Spain, UK, and France. The sample of countries represents both large and small countries in the North and South, with a mix of tax-financed, insurance-based, decentralized, and centralized systems. The particular technologies examined include *urinary incontinence pads*, *knee endoprotheses*, *implantable cardioverter defibrillators (ICDs)*, *coronary stents*, *laparoscopic colorectal surgery,* and *negative pressure therapy*.

The technologies were selected to represent three main categories of medical devices:

- *Medical aids* are mainly given to and used by patients directly (e.g., incontinence pads) – represents technologies that potentially constitute health care benefits in their own right.
- *Implantable devices* which need to be implanted (e.g., coronary stents, ICDs, and endoprostheses) – represent technologies that entail only one component of health care benefits, with services by the hospital or ambulatory care provider forming the other.
- *Aids for health professionals* are used to provide services by physicians or other health care providers (e.g., laparoscopic procedures) – represents technologies where the service, not the device, represents health care benefits.

A comprehensive research framework was developed and used by all three academic partners to collect data on key actors, policies, practices, and processes associated with coverage, procurement, and reimbursement across the six technologies and six countries, as described in further detail below. Use of the framework allowed for the systematic collection of data and ensured the comparability of results across the six countries studied.

Qualitative research methods were employed to collect and analyze data. More specifically, data were collected from multiple sources, including 1) published and unpublished (grey) literature (e.g., Health Basket reports, WHO country profiles, conference papers); 2) institutional sources (e.g., official national/regional legislative/policy documents, government websites, relevant professional society or organization websites); and, select semi-structured interviews with industry representatives and health care professionals. Where available, quantitative analysis supplemented the qualitative evidence, especially in terms of product diffusion.

In terms of **coverage**, several issues were investigated: 1) whether the technology is explicitly included in the national/regional benefit basket or statutory insurance schemes; 2) main decision criteria for the inclusion/exclusion of the technology; and, 3) if and how frequently the inclusion has been updated following progress in the technology.

Financing mechanisms were analyzed along two distinct dimensions: procurement and reimbursement. **Procurement** is concerned with the price of technologies established between the producers and providers of health care services. The main areas of investigated included: 1) level of price setting and negotiation (centralized vs. decentralized procurement); 2) existence of "reference" prices to be used in tender negotiations; and, criteria used in price negotiations. Finally, analysis of **reimbursement** systems across countries examined: 1) different funding systems (tariff-based vs. global budgets) and 2) the decision-making actors and level(s) at which funding is established (national vs. regional level).

The herein report provides comprehensive and comparative evidence on medical technology financing policies and processes across six key countries and technologies, and their impact on diffusion, patient access, health system efficiency, and innovation.

Key Research Findings

<u>National health baskets and decision bodies</u>

- In Spain, Italy, and the UK, national bodies primarily maintain the role of guarantor of national citizen rights, but regional entities have assumed autonomy (to a greater or less extent) in funding and managing health services. In both the UK and Germany, self-governmental/regulatory bodies play a key role in defining (explicitly or implicitly) the health basket, as part of carrying out the duties bestowed upon them by central government. For example, NICE in the UK provides guidance to inform decisions on the funding of health technologies and interventions, direct clinical practice, and establish national standards. Other key actors include joint committees of payers and providers (Germany) and other professional bodies and associations.

- In most countries, the Ministry of Health assumes a direct role in national health policy.
- In countries undergoing decentralization, the shift of political power from the national to regional level remains a key influence in the decision-making process.
- The overall set of services guaranteed to citizens, as set out in national health baskets, have changed throughout the years in form, contents, and objectives. Nevertheless, most countries uphold the basic principles of access and equity in the provision of health care services.
- National health baskets serve to clarify national health rights, keep regional/local and self-governmental bodies accountable and, in part, to guide and monitor some performance aspects of the health system (e.g., provision of care).
- Differences emerge between countries regarding how the benefit package is defined, operationalized, and monitored. This includes differences in whether benefits are outlined in an explicit or implicit manner; the frequency with which they are updated; and, the incorporation of accountability and monitoring mechanisms for adherence to national standards and/or targets.

<u>General financing arrangements and processes for medical devices</u>

- Key actors in defining and determining entitlements and benefits for medical devices include payers, providers, sickness/health funds, hospital federations or associations, joint committees (e.g., Federal Joint Committee and IQWIG in Germany), departments of health, and relevant ministries.
- Depending on the country, devices are either positively or negatively listed in an explicit or implicit manner. In Germany, for example, in principle all (inpatient) health care services that are not explicitly excluded can be provided at the expense of the SHI. However, as inpatient services are reimbursed by DRG-based payment, medical devices are only mostly included indirectly and are linked to patient indications. In other countries (e.g. France, UK), what services are or are not included in the basket are more explicitly defined.
- HTA or other valuation bodies are increasingly playing a role in reimbursement and pricing determinations. This is especially true for Germany and the UK, as evidenced by the influence of IQWIG and NICE, respectively, on the adoption of various health technologies. These bodies

review the relative clinical- and cost-effectiveness of various health technologies to ascertain whether they provide good value for money. A variety of criteria are used to make recommendations for reimbursement and/or pricing, including the clinical benefit; cost-effectiveness; safety and quality of the product; appropriateness for GP and, if relevant, nurse prescribing; degree of innovation; budget impact; and, disease severity/public health need.

- As with most health technologies, reimbursement is often tied to certain conditions, such as prescription by qualified provider, setting of service provision (e.g., inpatient vs. community), severity of condition, etc.
- Many countries have introduced a DRG-based system to finance health technologies and services. Given that some of these systems are still unfolding (e.g., France, UK), it is considered important to sufficiently incorporate allowances for (the support of) innovation and timely patient access in their development.
- Increasingly, countries (especially those with DRG-based financing systems) are introducing supplementary or additional fees or tariffs for complex, innovative, or cost-intensive services. In Germany, a surcharge for innovative diagnostic and treatment methods (NUB) can be negotiated between contracting parties and hospitals.

<u>Insights on select technologies – *coverage, procurement, and reimbursement*</u>

- Whether a technology is specifically listed in the catalogue depends on the particular technology and appropriate setting of provision (inpatient vs. outpatient). In Spain, knee prosthesis and ICDs are explicitly listed, with detailed references to different models of the technology, whereas coronary stents are more generally included in the category 'Coronary Endovascular implants'.
- For devices provided in an outpatient setting, namely incontinence pads, many countries (Italy, Spain, UK) place specific limitations on coverage and patient access. For example, in the UK, patients with light incontinence are not typically eligible to receive pads on the NHS. Moreover, in some countries (e.g., Spain), specific categories of patients are subject to co-payment mechanisms.
- One issue highlighted by the Spain and Italy case studies was the lack of regular and timely updating of the list of reimbursement tariffs. This has several implications, including the obsolescence of the models included on the lists and the risk of inappropriate prescribing and use of the technology.

- In most countries, public procurement mechanisms are compulsory, both in outpatient and inpatient settings.
- Depending on the countries, procurement has increasingly become more centralized or decentralized. For example, in Italy, the process has been nationally promoted, with the 2007 National Financial Law introducing reference pricing for a wide category of medical devices. In the UK, however, procurement has been decentralized toward NHS Trusts; although, there has been an increased effort to better integrate national and regional purchasing actors and processes via 'collaborative hubs'. Moreover, some countries are supporting the creation of purchasing groups, frequently at the hospital level.
- Key criteria employed in procurement negotiations were identified and similar across countries. Firstly, price is one of the principal criteria (which is gained in relative importance, given increased cost concerns), especially with regards to more 'standardizable' products, such as incontinence pads. Secondly, the level of quality associated with the product is highly important, especially for high-specialty areas or more complex interventions. In this case, weight is given to the quality of the service as a whole, such as the existence of technical assistance in the theatre room. Other key criteria include volume, 'best value' (e.g., reliability, safety, device lifecycle), current related legislation, maintenance, production capacity, and total cost of purchase.
- Significant differences between countries lie in the reimbursement of medical devices, and whether providers have enough resources to actually deliver appropriate care, as funding systems may not adequately guarantee or provide funding for new medical technologies, especially those that are expensive. Despite the health care system and its financial arrangement (i.e., global budget vs. DRG), it was generally believed by thought-leaders that governments inadequately put forth appropriate financing or policy levers to promote technological innovation, especially in the hospital sector.
- While a comprehensive analysis of technology diffusion in all of the six countries will be conducted in the future (see 'Next Steps'), some preliminary data on coronary stents and ICDs in Italy and Spain indicates that variation in uptake is present in both countries and, more importantly, within countries. For example, the available data on the number of implants per million inhabitants across Italian regions and Spanish ACs showed high variability across and within national boundaries. Such variations may be explained by the different reimbursement schemes in the two countries (DRGs in Italy, global budgets in Spain), acceptability and knowledge of medical professionals, and differences in beliefs regarding the usefulness of the therapy in first-line treatment.

- Physicians and professional societies likely assume a significant role in the adoption and use of many devices or procedures, such as laparoscopic surgery.
- In particular to medical aids, financing trends are less clear, with only some countries explicitly including incontinence pads on positive lists. Moreover, there are divergent purchasing channels between countries, differences in patient co-payment requirements, and eligibility stipulations. However, it does appear that in many countries, such as Italy and the UK, utilizing a single source provider (usually, in connection with the lowest cost) is common. While this may result in some efficiency gains, it limits patient choice and may hamper innovation. With regards to VAC therapy, while some countries have introduced coverage of this new and highly-innovative treatment, more evidence is required to fully understand relevant financing structures and processes.
- Finally, with regards to implants, the price of the device and implantation fee is normally covered in the relevant DRGs (this may relate to a particular DRG code(s) or in the context of a more complex treatment or broader definition of the treatment/procedure). As these are typically expensive technologies with potential health and economic implications, HTA bodies in several countries (UK and Germany) have issued guidance on use. Additionally, as previously mentioned, in some countries, such as Germany, UK, and France, some implants are subject to receipt of supplementary or 'additional' fees to support access to innovative technologies (in addition to the respective DRG).

Next Steps

The first phase of research provided an important foundation to understand the financing systems for medical devices in a number of key European markets. To build upon the research findings from this phase, it is important to further explore and compare the actual availability and adoption of medical devices across markets. Thus, a follow-on analysis will be conducted by the three academic partners to analyze and quantify the impact of different national financing (reimbursement and procurement) systems on medical device diffusion and uptake.

Following this intermediate phase, the second phase of research carried out by EHTI will focus on ascertaining the social and economic value of medical technology through systematic qualitative and quantitative analysis. While technological innovation is perceived to be at the root of the recent cost escalation in health care, existing evidence suggest that, on average, increases in medical spending since 1960 and developments in technology have provided value, leading to significant differences in patient quality of life, disability levels, and mortality rates. However, the benefits produced by medical devices expand beyond gains in health to broader social and economic improvements. Although it is clear that innovation in general contributes to economic development and welfare improvements, the process whereby technological innovation in medical technology leads to growth and welfare gains is not well understood and would benefit from further empirical research. In conjunction with the research detailed in this report, this subsequent phase will address this evidence gap by lending a greater understanding of the unique contributions made by medical devices towards improved health outcomes, high-value health care, sustainable medical innovation, and more macro-economic gains, such as enhanced productivity.