Economics and Management
ISSN: 2683-1325
Volume: XVII, Issue: 2, Year: 2020, pp. 163-170

REIMBURCEMENT POLICIES AND HEALTH TECHNOLOGY ASSESMENT OF MEDICAL DEVICES IN EUROPEAN COUNTRIES

Iliyana Atanasova Belichenova[1]

Received: 24.09.2020 Accepted: 30.10.2020

Abstract

The aim of the paper is to provide an overview of the key criteria for accepting a certain medical device for reimbursement in United Kingdom. The reason for focus on UK is based on the long-term experience of the author. The activities performed by National Institute for Health and Clinical Excellence in England-technology appraisals are essential for health technology evaluation. The use of new and existing medical devices and procedures should meet the highest standards. The research goals are to present facts and data valuable for health technology assessment of medical devices in Bulgaria. The expected results are to provide such a quality research to help further improvement of reimbursement policy of medical devices in Bulgaria. Health technology assessment (HTA) has been defined as 'a multidisciplinary field of policy analysis studying the medical, economic, social and ethical implications of the development, diffusion and use of health technologies.

Keywords: *Health Technology Assessment, Medical devices, reimbursement policies, quality of life, UK, QALY, HRQoL*
JEL Codes: *H51, I 18*

1. HTA has a long history in the UK, with prominent early studies being those on major programmes funded by the Department of Health such as the heart transplant and the major shift is research that is oriented towards efficacy and safety.

NICE is by far the most influential institute which produces four types of guidance: technology appraisals, clinical guidelines, public health guidance and reports on interventional procedures. In producing its guidance, NICE considers both clinical and cost-effectiveness.

2. Reimbursement policies of medical devices and Health technology assessment in United Kingdom - QALI.

NICE has issued methods guidelines for technology appraisals which form the template for manufacturer submissions and the review by the independent assessment

[1] Faculty of Public administration, UNWE, PhD, e-mail: iliatanasova@abv.bg

groups. The guidelines embody the concept of the 'reference case', whereby preferred methods are outlined but manufacturers can also submit alternative analyses, if they think these are superior. The objective is to achieve some degree of standardization of submissions. NICE has been quite clear that the measure of health benefit to use in technology appraisals is the quality-adjusted life-year-QALI.

(Drummond, 2009, The NHS and HTA).

The quality-adjusted life-year (QALY) is a measure of the value of health outcomes. Since health is a function of length of life and quality of life, the QALY was developed as an attempt to combine the value of these attributes into a single index number. A quality-adjusted life year is a measure of quantity and quality of life lived used to assess the value for money of a medical intervention. It is based on the number of years that would be added to a patient's life by a particular medical intervention.

To determine QALYs, one multiplies the utility value associated with a given state of health by the years lived in that state. A year of life lived in perfect health is worth 1 QALY (1 year of life × 1 Utility value).

The QALY is primarily used in cost-effectiveness analyses to guide decisions regarding the distribution of limited health care resources among competing health programs or interventions for a population of interest, but has also been used to aid decisions regarding clinical management, medical devices and individual patient care. The QALY establishes and defines the cost of a new treatment or a health care intervention. By this means the QALY can be applied to provide a value for these treatments and interventions that can be used for comparison between new and established treatments.

As medical devices and public health advances have led to cures and better treatments of existing diseases and delayed mortality, it was logical that those who measure health outcomes would begin to assess the population's health not only on the basis of saving lives, but also in terms of improving the quality of lives. The concept of health-related quality of life (HRQOL) and its determinants have evolved since the 1980s to encompass those aspects of overall quality of life that can be clearly shown to affect health—either physical or mental.

Focusing on HRQOL as an outcome can bridge boundaries between disciplines and between social, mental, and medical services. Several recent federal policy changes underscore the need for measuring HRQOL to supplement public health's traditional measures of morbidity and mortality. Healthy People 2000, 2010, and 2020 identified quality of life improvement as a central public health goal.

Health-related quality of life is "An individual's or group's perceived physical and mental health over time" and as such should be monitored from public institututions.

Economic evaluations of health interventions pose a particular challenge for reporting. There is also a need to consolidate and update existing guidelines and promote their use in a user friendly manner. The Consolidated Health Economic Evaluation Reporting Standards (CHEERS) statement is an attempt to consolidate and update previous health economic evaluation guidelines efforts into one current, useful reporting guidance. The primary audiences for the CHEERS statement are researchers reporting economic evaluations and the editors and peer reviewers assessing them for publication.

Health economic evaluations are conducted to inform resource allocation decisions. Economic evaluation has been defined as ‘‘the comparative analysis of alternative courses of action in terms of both their costs and their consequences.’’ [1] All economic evaluations assess costs, but approaches to measuring and valuing the consequences of health interventions may differ.

Specific forms of analysis reflect different approaches to evaluating the consequences of health interventions. Health consequences may be estimated from a single analytical (experimental or non-experimental) study, a synthesis of studies, mathematical modelling, or a combination of modelling and study information.

Cost consequences analysis examines costs and consequences without attempting to isolate a single consequence or aggregate consequences into a single measure

Cost minimisation analysis (CMA)—The consequences of compared interventions are required to be equivalent, and only relative costs are compared Cost effectiveness analysis (CEA) measures consequences in natural units, such as life years gained, disability days avoided, or cases detected. In a variant of CEA, often called cost utility analysis, consequences are measured in terms of preference-based measures of health, such as quality adjusted life years or disability adjusted life years.

Cost benefit analysis—Consequences are valued in monetary units. Readers should be aware that an economic evaluation might be referred to as a ‘‘cost effectiveness analysis’’ or ‘‘cost benefit analysis’’ even if it does not strictly adhere to the definitions above. Multiple forms may also exist within a single evaluation. Different forms of analysis provide unique advantages or disadvantages for decision making. The Consolidated Health Economic Evaluation Reporting Standards (CHEERS) statement can be used with any form of economic evaluation.

The aim of the Consolidated Health Economic Evaluation Reporting Standards (CHEERS) statement is to provide recommendations, in the form of a checklist, to optimise reporting of health economic evaluations.

An ICER – another strong and important tool is used for medical devices HTA - calculated by dividing the difference in total costs (incremental cost) by the difference in the chosen measure of health outcome or effect (incremental effect) to provide a ratio of 'extra cost per extra unit of health effect' – for the more expensive therapy vs the alternative.

A cost-effectiveness ratio is the net cost divided by changes in health outcomes. Examples include cost per case of disease prevented or cost per death averted. However, if the net costs are negative (which means a more effective intervention is less costly), the results are reported as net cost savings.

IMPORTANT

What is the ICER threshold?

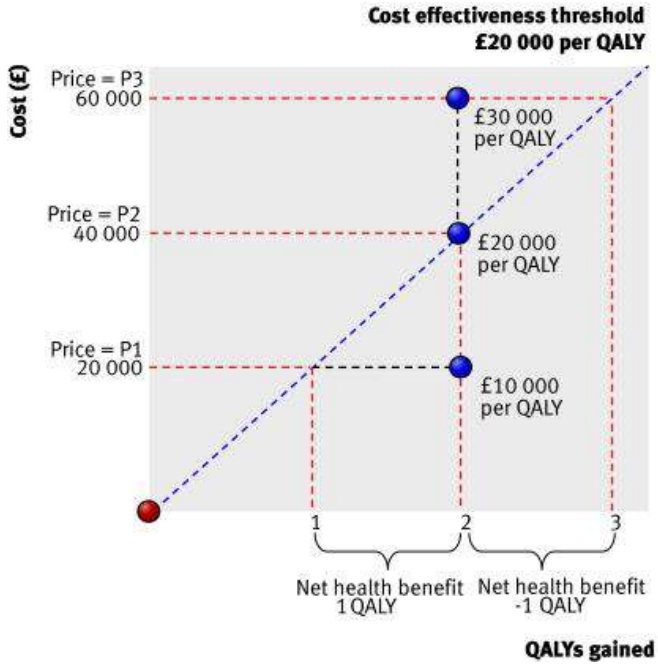
conditions and treatments. • ICER will use a broader range of cost-effectiveness thresholds between $50,000 and $150,000 per QALY to guide considerations of long-term value for money.

Table no. 1

Medical device	Price in lv.	Price in lv.	ICER
Heart	100 000	200 000	50 000

Source (author calculation)

$$\text{ICER} = \frac{\text{C b} - \text{C a}}{\text{E b} - \text{E a}} = \frac{200\,000 - 100\,000}{12 - 10} = \frac{100\,000}{2} = 50\,000 \text{ QALI}$$



3. HTA of medical devices in European countries

Health Technology Assessment (HTA) as a decision support tool and the suitability of this methodology for medical devices (MDs) in light of the discussion of the introduction of new regulatory provisions for their market authorization. Europe is one of the biggest markets for MDs, which encompass a broad and heterogeneous range of technologies. According to the European Union, a medical device is defined as "any instrument, apparatus, appliance, software, material or other article, whether used alone or in combination, including the software intended by its manufacturer to be used specifically for diagnostic and/or therapeutic purposes and necessary for its proper application, intended

by the manufacturer to be used for human beings for the purpose of diagnosis, prevention, monitoring, treatment or alleviation of disease". So incorporating the HTA perspective is crucial.

All institutions state a clear preference for direct evidence based on randomized controlled trials (RCTs), but also accept or suggest other designs under certain circumstances. In this respect, NICEstates that " the highest value has traditionally been placed on evidence from meta-analysis of RCTs or one or more well-designed and executed RCTs.

In Europe there is a growing recognition of the importance of methodological guidelines for HTA production, reflected also in collaborative initiatives toward methodological standardization (e.g., EUnetHTA).

However, the development and implementation of specific methodological tools for the assessment of MDs is still limited to the national level. Although some HTA institutions already consider different approaches for therapeutic and diagnostic technologies, other elements related to the use of MDs, such as device-operator interaction and the level of device activity require further methodological discussion. In conjunction with the efficient use of resources, the results raise the question if fully separate methodological guides are needed for the evaluation of MDs or if it is sufficient to include supplementary specifications in the general manuals of each institution. When researching specific methodological issues related to reimbursement policies and HTA, an overview of established practices is a prerequisite for facilitating knowledge transfer, analyzing best practice and formulating new methods. Variation in HTA practices may reflect historical development of processes, purpose of assessment, regulatory requirements or health system characteristics.

The study and analysis of the reimbursement policies of medical devices in other European countries make it possible to identify the possible development paths of the health insurance system in Bulgaria, as well as the optimal development path and the recipe for changing and solving the identified problems. An important component is the use of economic theory to make decisions about change and further development, using the methods of econometric analysis: regression and forecasts.

For this purpose materials from the health systems of Great Britain, Germany, France and others were studied, the existing Reimbursement lists were monitored with the prices of groups of medical devices from the same manufacturer and compared with the values of medical devices for this purpose in Bulgaria. Parallels are being made with activities in these European countries and prospects for improvement. The research deals with the management of health insurance funds in terms of proper allocation of resources between

different activities against the background of unworthy medical services and the increasing consumption of medical devices and diagnostic activities.

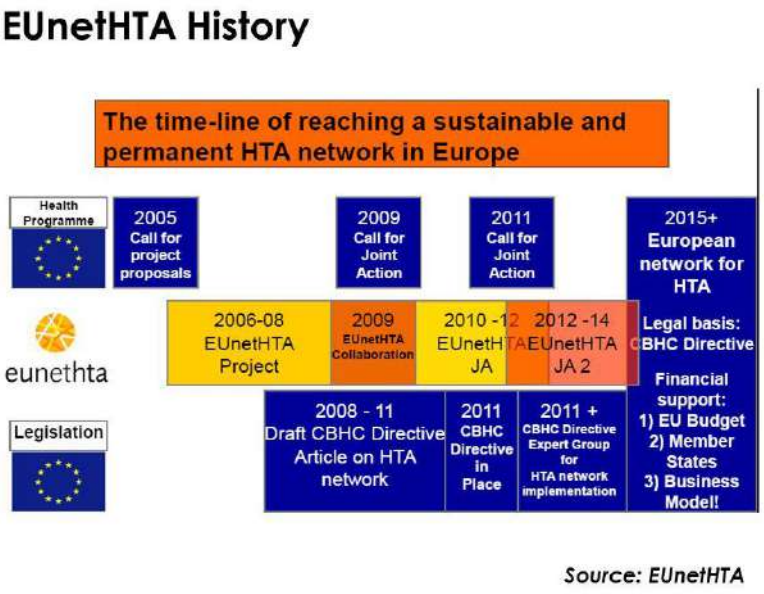
Taking into account the public fund resource over BGN 3 billion, the share of medical devices as a part of the general budget is low due to the partial reimbursement of important medical devices and due to the high single reimbursement value set for certain products, which requires an additional payment for some groups in 50:50 NHIF ratio: patient.

Figure 1

N	Country	Data	Kind of information and resource
1	FRANCE	List of medical devices - criteria, indications, prices	LISTE DES PRODUITS ET PRESTATIONS REMBOURSABLE
	POLAND	List of medical devices - Limits in medical devices financed by public funds, co-payment	Dziennik Ustaw
3	SPAIN	Legal framework, forms, instructions	www.aemps.gob.es/
4	GERMANY	DRG-Tariff	http://www.g-drg.de/
5	SLOVAKIA	List of medical devices	http://www.health.gov.sk/Clanok?zkszm-201710
			http://www.health.gov.sk/Clanok?zkzp-201710
6	SLOVENIA	List of medical devices	SEZNAM S ŠIFRANTOM, MEDICINSKIMI KRITERIJI, POOBLASTILI, POSTOPKI IN CENOVNIMI STANDARDI
7	LUXEMBOURG	List of medical devices	http://cns.public.lu/en/professionnels-sante/medicaments/dispositifs-medicaux.html
8	AUSTRIA	There is no centralized reimbursement	http://www.medizinprodukteregister.at/de/english-version#11a
9	CROATIA	List of medical devices	http://www.hzzo.hr/zdravstveni-sustav-rh/medicinski-proizvodi/
10	ESTONIA	List of medical devices	https://www.riigiteataja.ee/akt/129122016070
11	ROMANIA	List of medical devices	

The new approach contain a series of extremely important improvements to modernize the current system. Among them are stricter control for public spending towards high-risk devices via better monitoring pre-market mechanism with the involvement of a pool of experts at EU level. Very important is the reinforcement of public administration to the criteria for designation and processes for oversight of notified bodies and improved transparency through a comprehensive EU database on medical devices and a device traceability system based on unique device identification, introduction of an 'implant

card' for patients containing information about implanted medical devices, reinforcement of the rules on clinical evidence, including an EU-wide coordinated procedure for authorizing multi-centre clinical investigations. Another big step is strengthening of post-market surveillance requirements for manufacturers and improved coordination mechanisms between EU countries in the fields of vigilance and market surveillance to allow exchange of data.



Source: EUnetHTA

4. Conclusion

The work carried out aimed to identify and compare current methods, processes, and institutional practices for the evaluation of MDs in European countries to advance the debate on whether existing assessment tools have to be modified or adapted or if a wholly new approach is needed.

Despite growing consensus on the importance of the assessment of especially high-risk devices, existing initiatives for differentiated assessment practices, and relevant international activities, specific methodological tools for the assessment of MDs are rarely developed and implemented at the European level. Separate additional signposts incorporated in existing general methods guides may be sufficient for the evaluation of MDs.

The new approach contain a series of extremely important improvements to modernize the current system. Among them are stricter control for public spending towards high-risk devices via better monitoring pre-market mechanism with the involvement of a pool of experts at EU level. Very important is the reinforcement of public administration to the criteria for designation and processes for oversight of notified bodies and improved

transparency through a comprehensive EU database on medical devices and a device traceability system based on unique device identification, introduction of an 'implant card' for patients containing information about implanted medical devices, reinforcement of the rules on clinical evidence, including an EU-wide coordinated procedure for authorizing multi-centre clinical investigations. Another big step is strengthening of post-market surveillance requirements for manufacturers and improved coordination mechanisms between EU countries in the fields of vigilance and market surveillance to allow exchange of data.

REFERENCES

Drummond MF, Wilson DA, Kanavos P, Ubel P, Rovira J. Assessing the economic challenges posed by orphan drugs. Int J Technol Assess Health Care 2007; 23: 36–42.

House of Commons Health Committee. National Institute for Health and Clinical Excellence. First Report of Session 2007–08. Volume 1. www.publications.parliament.uk/pa/cm200708/cmselect /cmhealth/27/27.pdf (last accessed 15 December 2008)

International Network of Agencies for Health Technology Assessment. HTA Resources. www.inahta.org/HTA/ (last accessed 4 December 2008)

National Institute for Health and Clinical Excellence. Appraising life-extending, end of life treatments. www.nice.org.uk/media/88A/F2/SupplementaryAdviceTA CEoL.pdf (last accessed 23 January 2009) 11. Audit Commission. Managing the financial implications of NICE guidance. www.audit-commission.gov.uk/reports/NATIONALREPORT.asp?CategoryID=&ProdID=CC53DDFE-42C8- 49c7-BB53-9F6485262718 (last accessed 15 December 2008)

National Institute for Health and Clinical Excellence. Department of Health Selection Criteria. www.nice.org.uk/364841 (last accessed 5 December 2008)

National Institute for Health and Clinical Excellence. Guide to the single technology appraisal (STA) process. www.nice.org.uk/media/8DE/74/STA_Process_Guide.pdf (last accessed 15 December 2008)

National Institute for Health Clinical Excellence. Updated guide to the methods of technology appraisal. www.nice.org.uk/media/B52/A7/TAMethodsGuideUpdat edJune2008.pdf (last accessed 15 December 2008)

National Institute for Health Clinical Excellence. Updated guide to the multiple technology appraisal process. www.nice.org.uk/media/DDC/CF/MTAProcessGuidePubli cConsultation.pdf (last accessed 15 December 2008)

Phillips C. What is a QALY? London: Hayward Medical Communications, 2009.

Rawlins MD, Culyer AJ. National Institute for Clinical Excellence and its value judgments. BMJ 2004; 329: 224–227.