MedtecHTA | Methods for Health Technology Assessment of Medical Devices: a European Perspective

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ECONOMIC EVALUATION AND HEALTH TECHNOLOGY ASSESSMENT IN EUROPE AND USA

A Comparative Analysis

Executive Summary

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About MedtecHTA

The MedtecHTA project (Methods for Health Technology Assessment of Medical Devices: a European Perspective) aims at improving the existing methodological framework within the paradigm of Health Technology Assessment (HTA) for the assessment of medical devices, and to develop this framework into a tool that provides structured, evidence-based input into health policies. The research activities are conducted by a consortium of six European Universities and one Scientific Association. The project is funded under the European Union's 7th Framework Programme as Small or Medium-Scale Focused Research Project (2013-2015).

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EXECUTIVE SUMMARY

The use of health economic evaluation in Europe is characterized by its diversity. Health economic evaluation (EE), within the context of Health Technology Assessment (HTA), is widely applied in many countries in Northern Europe as part of the process for pricing, reimbursement or determining the appropriate use of health technologies. Conversely, its use in Southern Europe is much more variable, although most EU member states have some infrastructure for undertaking HTA.

Also, the ways in which EE is conducted varies across Europe. Some countries (e.g., Ireland, The Netherlands, Sweden and the United Kingdom) estimate a measure of health benefit, the most common being the quality-adjusted life-year (QALY) and compare the gains in QALYs from adopting the new technologies with their additional costs, usually expressed in the form of an incremental cost-effectiveness ratio (ICER). Other countries (e.g., France and Germany) prefer only to consider the direct clinical benefits of technologies, or make a judgment of their added clinical value, and use this in the discussions about whether to reimburse the technology and at what price.

In order to consider how the use of EE will develop in Europe in the future, it is important to understand why this diversity exists and whether it will be maintained. Specifically it is important to address questions such as (i) on what basis have particular countries determined their approach to HTA and EE? (ii) is there a particular approach that is best suited to a given type of health care system? (ii) can countries learn from each other's experiences or are most of the judgments concerning the local approach to HTA and EE context-specific?

The analysis focuses on the EU5 countries (France, Germany, Italy, Spain and the United Kingdom), with examples from other EU member states in cases where they exhibit similarities to one of the EU5 countries. In addition, the United States is considered, partly because its health care system exhibits a number of different characteristics from those in the EU5 and partly because increasing private funding, including patient copayments, is sometimes proposed as a policy option for addressing the financial problems of European health care systems.

The report is organized as follows. First, the potential influence of culture, social values and institutional context on the organization of health care systems and HTA is discussed. Following, the health system structural parameters, e.g. the way in which the governance, financing and organization of health care in a given country might determine the approach to HTA is explored across the countries. Following this, the key features of the approaches to HTA are discussed, focusing on the role and methods used for EE in addition to general HTA organization and use in policy decision making in the 6 selected countries.

The analysis of culture, social values and institutional context demonstrates that different types of health care systems are based on different underlying values. For example, the 'Beveridge' publicly funded health care systems prevalent in Northern Europe are based on a strong notion of social equity. In contrast, private insurance systems, such as that in the US, are based in a strong notion of patient sovereignty. The 'Bismarck' social health insurance systems, prevalent in France and Germany, are somewhat in-between.

In addition, country-specific institutional contexts determine the tradition of public administration. In countries in Southern Europe following the Napoleonic tradition, the principal role of the public

administrator is to consider him or her as charged with administering public law. This contrasts with the view of the public administrator as the manager, a view common in other administrative traditions, such as the Anglo-American one. This view of the job of the civil servant does not deny the importance of following the law, but does imply that the first responsibility of the senior public servant is to get things done.

Also, as compared with other countries, social actors (e.g., special interest groups, stakeholder groups) have a more limited role in the policy process in countries following the Napoleonic tradition. Indeed, interest groups, although a necessity, are often considered almost as illegitimate interventions into the governing role and autonomy of the state. This is in sharp contrast with the role of these interest groups in northern Europe, where stakeholder engagement is often an important part of the policy process. As a result, processes are likely to be less explicit and transparent than similar processes operating in other countries.

Overall, in countries following the Napoleonic tradition, the emphasis on law, formality, and on uniformity distinguish this tradition and make the implementation of many new public management reforms now so central to administration in other systems difficult, if perhaps not possible in some instances. This can impact on the development of HTA and the use of EE in decision-making

The analysis of health system structural parameters discusses differences among the 6 countries in terms of the scope, breadth and depth of health care coverage, financing and system governance and the methods of paying health providers. Some of these differences are critical in understanding the role of HTA and EE. For example, in a country where there is an emphasis on patient choice, often accompanied by patient copayments, HTA and EE is less likely to be employed to determine the level of coverage of health care or which treatments are made available.

Finally, the analysis of approaches to HTA and EE in the 6 countries discusses differences in the organization and governance of HTA, the methods of economic evaluation and the use of EE in decision-making. In France and Germany, with SHI- based systems, there is only a soft budgetary constraint, since expanding health care provision can be funded out of increased contributions. Rather the emphasis is on diversity of services and consumer choice. Therefore, the use of HTA and economic evaluation rarely results in the restriction of treatment options. Rather, the HTA systems in these countries place the emphasis on the use of economic evaluation to negotiate lower prices, especially in the case of pharmaceuticals.
There is also some reluctance in these countries to be too prescriptive about how the benefits of health care are valued, or any suggestion of a ‘threshold’ of cost-effectiveness that is deemed acceptable. Rather, these assessments are left to health professionals on the expert committees that have been established to determine the level of benefit from new technologies. One consequence of this is a reduction in the level of transparency, which would be consistent with the Napoleonic administrative tradition in France. However, one possible desirable effect, from the perspective of maintaining solidarity, of the relative lack of transparency is that the implications for the care of other patients of a coverage decision on a given therapy are not clear.

By contrast, in the UK, there is a hard budget constraint and hence a concern about the opportunity cost, for existing services, of adopting a new therapy. Of all the approaches to economic evaluation discussed here, the use of cost-utility analysis with an explicit threshold is best suited for taking account of the opportunity cost in services that would be displaced, given a fixed budget, as a result of reimbursing the new therapy. Also, consistent with the equality principle, all QALYs are valued the same irrespective of whom receives them (with an exception for ‘end-of-life’ treatments) and the

values placed on QALYs come from a survey of the general population. The process is also transparent and involves the participation of a number of societal groups, consistent with the Anglo-American and Nordic administrative traditions. It is no surprise, therefore, that most of the Nordic countries, which also have national health services funded from general taxation, operate an approach HTA and use of economic evaluation similar to that existing in the UK.

Spain and Italy probably represent the complex case. These countries have national health services with a hard budget constraint, but do not have the same approach to HTA and use of economic evaluation as countries in Northern Europe like the UK. This is partly explained by the existence of the Napoleonic administrative tradition, which has probably slowed down the development of the procedures for HTA, owing to the need to establish a legal basis and the lower propensity of public officials to act without the appropriate legal basis. In addition, regionalization may have had an influence, by softening the impact of national budget constraints and spreading the available resources for HTA across several agencies, rather than concentrating them nationally. Also, consistent with the Napoleonic administrative tradition, there is a relative lack of transparency concerning the procedures being followed.

The US serves as an interesting counterpoint to the 5 European countries. Here the emphasis is on consumer sovereignty and patients pay a non-significant proportion of the cost of their care, though the purchase of health insurance and copayments at the time of service use. In this context there is considerable resistance to any approach to the use of economic evaluation that results in restrictions on the use of services and very little recognition of budgetary constraints. Also, despite the existence of an Anglo-American administrative tradition, there is little transparency about the approaches to HTA and reimbursement decisions in the private health care sector, because of business confidentiality in a competitive market. However, some private health plans, which operate like independent health care systems, are beginning to use economic evaluation in a way which is consistent with maintaining consumer sovereignty.

Overall, our analysis demonstrates that the approach to HTA and the use of economic evaluation in a given country is likely to be dependent of the underlying culture and values of the country concerned, the specific institutional context and the organization, governance and financing of the country's health care system. Given the diversity in the use of HTA and economic evaluation, can we expect some convergence in the future? Because of fundamental difference in culture and values, we can expect that many of the individual differences between countries are likely to be preserved. However, increased financial pressures, caused by rising expectations, an ageing population and increases in the availability and cost of health technologies, may bring about some convergence owing to a growing recognition that there are limits on the amount of national resources that can realistically be devoted to health care. Therefore, more jurisdictions may operate as though there is a relatively fixed budget and the reimbursement of new technologies may have opportunity costs for existing services.

Finally, since participation in international networks of agencies (which most of the organization discussed in this work engage in - e.g. EunetHTA), further promotes agencies' independence from government and increased harmonization (or at least coordination) in the methods used to asses new technologies, we can expect that the role of independent regulators in health-care priority setting is likely to increase in the future.