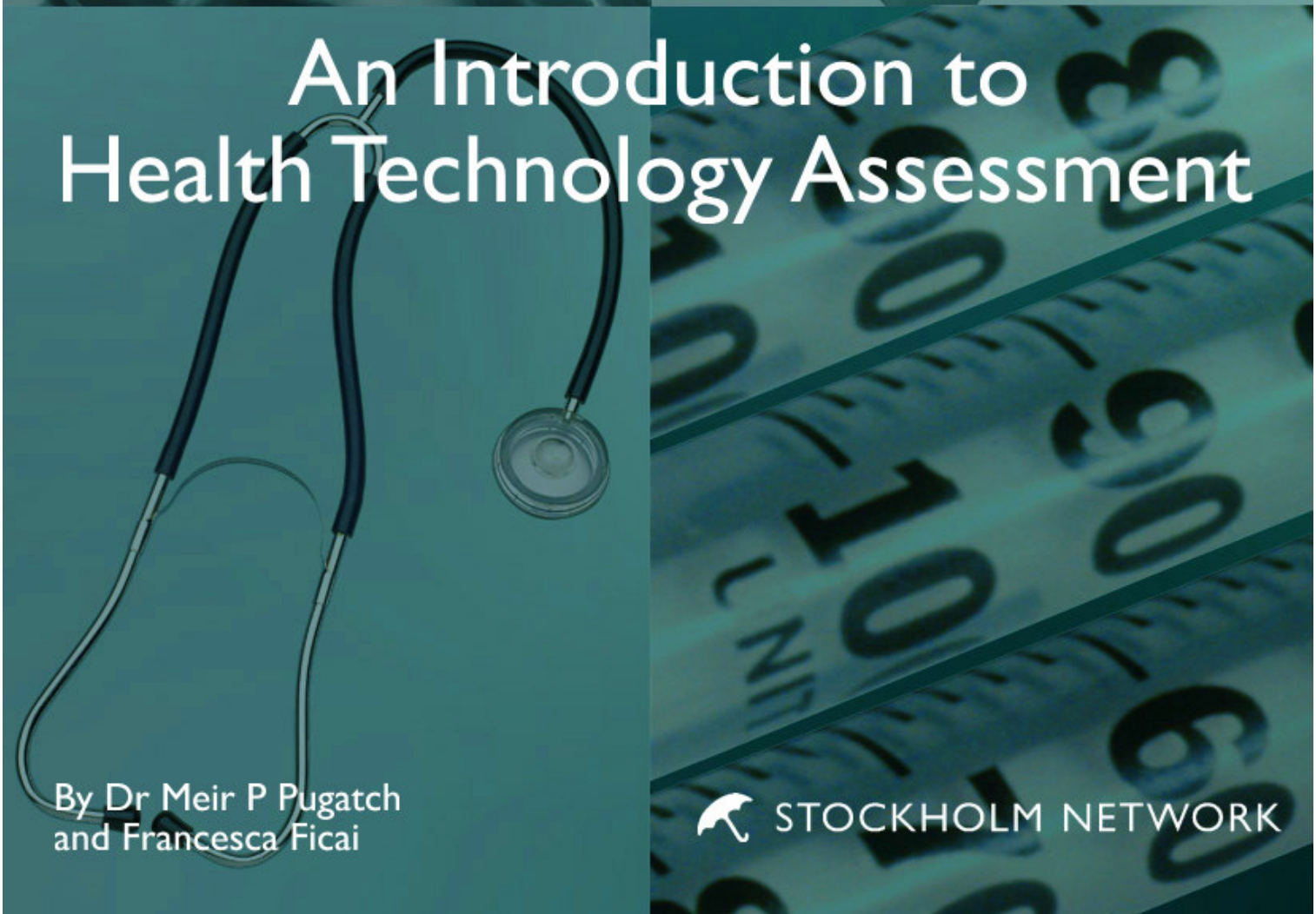
A HEALTHY MARKET?

An Introduction to Health Technology Assessment



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STOCKHOLM NETWORK

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An Introduction to Health Technology Assessment:

In this second series of *A Healthy Market?* publications, the Stockholm Network will provide a political and economic overview of the current state of play of health technology assessment (HTA). As a whole, the series will focus both on the political motivations and economic rationale of HTA. Among other things, it will highlight the gap between the theory and practice of HTA, as well as the extent to which the HTA process is exercised by the different national bodies. The paper below is an introductory definition of HTA.

From a state-centric point of view, the aim of HTA is to provide decision-makers with more accurate, evidence-based tools for prioritising healthcare treatments in terms of their utility, efficiency and cost-effectiveness. The moral rationale underpinning this perception is based on the fact that in most developed countries medicines and treatments are funded to a greater or lesser degree by public money (both directly, and indirectly, such as by tax credits). Thus, the aim of HTA is to help governments to balance the need to provide the most innovative and cutting-edge healthcare technologies on the one hand, with the need to control the costs associated with such technologies on the other hand.

In practice, however, it is not at all clear to what extent the so called national HTA bodies - such as the National Institute for Health and Clinical Excellence (NICE) in the UK or the Institute for Quality and Efficiency in Health Care (IQWiG) in Germany - focus on 'real' HTA or rather on the mechanistic allocation (some would argue, rationing) of fixed resources to existing healthcare technologies.

The political economy of HTA bodies suggests that the structures, processes and political constructs of different national bodies may have a significant effect on the manner in which these bodies apply HTA in practice.

Moreover, as will be discussed in future papers, the state-centric approach towards HTA (aimed at prioritising new medical technologies within cost restraints of governmental budgets) is subject to both ethical as well as practical controversies. Ethical concerns arise, among other things, due to governments' desire to control healthcare costs (and consequently the rationing of medicines or treatments), possibly at the expense of their citizens' health. Practical controversies concern the efficacy and utility of the HTA process itself.

Evolution of HTAs

Over the past fifty years, healthcare has undergone an incommensurable technology improvement, not only in terms of knowledge, but also in terms of monetary investments in equipment, medical devices, and medicines.

Thanks to these new technologies, significant improvements in terms of health gains have been achieved. Treatments are becoming more effective and safer, quality of life is improved, life expectancy, and undesirable side effects are reduced.

Coinciding with the pace of technological advancement (and, in part, deriving from it), society has also undergone significant changes – ageing populations, increasing public demands and expectations for better and more comprehensive health treatments, better educated health consumers and changes in disease patterns.

Yet the rapid pace of the development of new and innovative healthcare technologies has also led to some negative consequences.

Most notably, the increase in consumer demand for new and innovative healthcare treatments has been met by the growing constraints and concerns of governments (and other players such as private insurers) with regard to national expenditure on health. Indeed, governments find themselves dealing with growing demands for the financing of innovative health-related technologies without the necessary budgetary resources.

Added to this, the rapid growth of medical technology and the increasing volume of new knowledge have made it much harder for physicians and national healthcare providers in general to remain comprehensively updated about the benefits and risks of newly available treatments.

As a result, inappropriate practices and disparities have emerged in the manner in which different countries choose to allocate financial resources for the use of different healthcare technologies. This disparity may also have led to the distortion of resources within a given country, with the most effective technologies not always being used.

To this end, countries have started implementing the HTA process in order to improve their decision-making and priority-setting processes, in respect of both the use and government reimbursement of healthcare technologies.

HTA appeared in the late 1960s and early 1970s as a result of the development of technology assessment (TA) and of health technologies (HT). Technology assessment developed in order to study the role of technology in modern society and any risk of its misuse, while at the same time the study of health technology's impact on safety, cost and effectiveness emerged.

According to the International Network of Agencies for Health Technology Assessments (INAHTA[1]), today many countries have bodies that tackle HTA. However these entities have to date developed mostly in industrialised countries. Some countries have several

[1] www.inahta.org

bodies that assess HTA (for example, Spain which has strongly devolved regions and six different HTA bodies.)[2]

Despite the evolution of HTA as an acknowledged field of research, its institutional application at the national decision-making level is far from being homogeneous.

For example:

- Some HTA bodies and agencies can have an advisory role: that is to say they make reimbursement or pricing recommendations to a national or regional governing body. (e.g. Denmark, the Netherlands).

- Some HTA bodies and agencies can be regulatory: they are accountable to health ministers and are responsible for listing and pricing drugs, medical devices and other related services (e.g. Finland, France, Sweden and UK).

-Some bodies simply coordinate HTA assessments and produce reports. This can be the case for regional advisory bodies such as CRD in York (UK). [3]

The economic basis of HTAs

Generally speaking, one of the most important functions of HTA today is to provide decision-makers with a tool for prioritising (and, if needs be, rationing) healthcare technologies in terms of reimbursement and pricing. Properly used, HTA may help decision-makers to manage contradictory demands for resources.

HTA can help to determine the extent to which a given healthcare technology is cost-effective and for whom. From a national expenditure perspective, HTA can both prioritise different treatments for different conditions as well as prioritise different treatments for a given therapeutic class or category. The classification of the treatments would come as the result of the study of both economic factors and quality of life factors. Although these can be difficult to determine, they are, to date, the only available tools to reach the sought conclusions within the existing health systems.

HTA might also be used to determine the amount that a government should be allocating to a given healthcare technology, including in setting the price per unit of that technology.

According to a recent report on financing sustainable care in Europe,[4] broadly speaking, HTA derives from the field of TA and is based on cost-based analysis (CBA) - seeking to establish the monetary value of both the costs and benefits associated with the adoption of a new healthcare technology.

[2] AETS has a nationwide remit. Regional HTA bodies include AETSA in Andalucia. Avalia-T in Galicia, Gencat in Catalonia, Osceba in the Basque Country, and UETS in Madrid.
[3] "The Centre for Reviews and Dissemination (CRD) was established in January 1994, and aims to provide research-based information about the effects of interventions used in health and social care."
[4] Financing sustainable healthcare in Europe: new approaches for new outcomes, conclusion from a collaborative investigation into contentious areas of healthcare: intro by Pat Cox

Since it is much harder to quantify the benefits and costs of a certain healthcare technology in monetary terms, an alternative evaluation method was developed: one that seeks to conduct what is called a cost-effectiveness analysis (CEA) of a certain healthcare technology by using some kind of a "natural" unit[5] (say, years of life). However, since the benefits from the use of a given healthcare technology are diverse (and may be able to include a reduction in mortality rates, lower productivity losses and improvement in the patient's quality of life), HTA seeks to compare and prioritise new technologies based on different units that aggregate these benefits.

In HTA, the dominant aggregate natural unit is called quality-adjusted life years (QALYs). Generally, QALYs factor in both the quantity and the quality of life generated by new healthcare interventions. It is the arithmetic calculation of life expectancy and a measure of the quality of the remaining life years.

To date QALYs are the preferred indicator of HTAs calculations, although one may find additional tools in use by HTA bodies such as HRQol ('health related quality of life', which considers physical function, social function, cognitive function, distress, pain: in brief, anything to do with quality of life), DALYs ('disability life adjusted years' - of life lost due to premature mortality in the population and the years lost due to disability for incidents of the studied health condition), and Healthy-Year Equivalents (HYEs)

From a policy-making perspective, an HTA analysis should allow one to prioritise a technology that is both more effective and less costly. Conversely, an HTA analysis should help to de-prioritise a technology that is less effective and more costly.

However, for a significant number of innovative healthcare technologies, decision-makers will find themselves facing the dilemma of having to decide whether to prioritise (or not to prioritise) a technology that is both effective and costly. It is in these cases that decisions are becoming the most complex, not least when they involve life and death situations.

Problems with HTA

Despite its seemingly scientific basis, the field of HTA is fraught with controversies.

To mention a few:

- First, the HTA process itself is subject to some significant debates, not least over the uses and limitations of the economic analysis underpinning HTA models. Suffice it to say at this stage that there is a growing criticism on the ability of QALYs to accurately capture the various "units" of healthcare benefits, not least the gap between the theoretical assumptions guiding QALYs and the behaviour patterns observed in a real population.[6]

[5] Taken from the fields of exact sciences a cost-effectiveness analysis measures incremental effects in natural units such as lives saved, years of life gained, blood pressure measured in mm of Hg, etc.

[6] Duru G, Auray JP, Beresniak A, Lamure M, Paine A, Nicoloyannis N. Limitations of the methods used for calculating quality-adjusted life-year values. Pharmacoeconomics. 2002;20:463–73; Prieto, . Sacristán, José. (2003) "Problems and solutions in calculating quality-adjusted life years (QALYs)", in Health and Quality of Life Outcomes 1:80

- Second, the relationships between the economic and scientific considerations in the HTA model are subject to constant tensions. By definition, the prioritisation of economic or cost-based considerations may come at the expense of scientific considerations, and vice versa. Thus, a decision to prioritise a less therapeutically effective medicine because of cost-based considerations over an effective, but more expensive, medicine could lead to some serious political, social and moral dilemmas.

- Last, the manner in which the HTA process is taking place at the national level is also subject to some significant political pressures (both by the national authorities and by the different stakeholders), particularly in countries where HTA bodies are much less independent.

Conclusion

Assuming a state-centric approach and within publicly financed health systems, HTA is a logical policy tool, used to reconcile the growing public interest in the use of innovative healthcare technologies with governments' interests in controlling their spending on such technologies.

In theory, HTA may provide an objective, evidence-based process for prioritising the national need for different healthcare technologies, not least with regard to the reimbursement of these technologies.

In practice, in most countries, the HTA process is far from securing its ultimate goal.

No matter how sophisticated the economic analysis may be, it remains difficult for HTA to render an effective analysis of the benefits and costs of healthcare technologies in keeping with society's wishes.

Moreover, the HTA itself encompasses some serious conflicts between economics and ethics – not least when such decisions involve life-saving technologies, for example, new treatments for cancer.

HTA bodies are politically-driven bodies and are affected by different interests, many of which are rival interests: namely economic, scientific and social.

Nevertheless, within the current budget constraints of publicly-funded systems, HTA provides an arms-length method of assessment which at least attempts to bring a more independent and scientific approach to decision-making about healthcare.

While HTA has its flaws, without dramatic health system funding reform, it is unlikely to go away any time soon. That said, all stakeholders involved in health-care delivery - whether health-care providers (including physicians and pharmaceutical companies), economists or politicians - need to understand it better, not only so that patients can benefit but also that over time the HTA process can be serve its intended purpose.

Some HTAs work better than others and in future papers we will look at how countries can learn from one another's approaches to deliver maximum benefit for the public.

Bibliography:

- Abel-Smith, B and Mossialos, E (1994) *Occasional Paper in Health Policy No. 2 Cost Containment and Health Care Reform A Study of the European Union* (London School of Economics)

- Collaborative Investigation (2007) *Financing Sustainable Healthcare in Europe: New Approaches for New Outcomes*, (Luxemburg's Ministry of Health, Sitra, Pfizer).

-Docteur, E and Howard Oxley, H (2003) *Health-Care Systems: Lessons from the Reform Experience* - An OECD Report (Paris)

Duru G, Auray JP, Beresniak A, Lamure M, Paine A, Nicoloyannis N. (2002) "Limitations of the Methods Used for Calculating Quality-Adjusted Life-Year Values. *Pharmacoeconomics*. 2002;20:463–73;

- Goodman, Clifford S. C.S. Ph.D (2004), *Introduction to Health Technology Assessment*, The Lewin Group

- Lichtenberg, F. (2001) "Are the Benefits of Newer Drugs Worth Their Cost? – Evidence from the 1996 MEPS", *Health Affairs*, 20: 241-251.

- OECD Health Project (2005), *Health Technology and Decision-Making*, (OECD)

- Prieto, L. Sacristán, José. (2003) "Problems and solutions in calculating quality-adjusted life years (QALYs)", *in Health and Quality of Life Outcomes* 1:80

- Rossi, F. (2000) *Analysis of the Scientific and Technical Evaluation of Health-care Interventions in the European Union*. Report to European Commission (London School of Economics)

-U.K. National Institute for Clinical Excellence (NICE) Project Report (2000) - *Review of International Health Technology Assessment* (IHTA), NICE

Websites:

Canadian Coordinating Office for Health Technology Assessment (CCOHTA)

http://www.cadth.ca/index.php/en/home

www.inahta.org

http://www.nice.org.uk/