



Theory versus Practice

Discussing the Governance of
Health Technology Assessment Systems

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 STOCKHOLM NETWORK

Theory versus Practice: Discussing the Governance of Health Technology Assessment Systems

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Glossary of Acronyms

ACP	Advisory Committee on Pharmaceuticals (UK)
AETMIS	Agence d'Évaluation des Technologies et des Modes d'Intervention en Santé
AHMAC	Australian Health Ministers' Advisory Council
AHTA	Adelaide Health Technology Assessment
ANZHSN	Australia and New Zealand Horizon Scanning Network
ARTG	Australian Register of Therapeutic Goods
AWMSG	All Wales Medicines Strategy Group
BMG	German Federal Health Ministry
CADTH	Canadian Agency for Drugs and Technologies in Health
CDR	Common Drug Review
DAHTA	German Agency for Health Technology Assessment
DIMDI	German Institute of Medical Documentation and Information
DoHA	Australian Department of Health and Ageing
DH	United Kingdom Department of Health
DSAC	Devices and Systems Advisory Committee
G-BA	Federal Joint Committee
IHE	Institute of Health Economics
IQWiG	Institute for Quality and Efficiency in Healthcare
MAS	Medical Advisory Secretariat
MBS	Medicare Benefits Schedule
MSAC	Medical Services Advisory Committee
MOHLTC	Ministry of Health and Long-Term Care in Ontario
NHSC	National Horizon Scanning Centre
NICE	National Institute for Health and Clinical Excellence
OHTAC	Ontario Health Technology Advisory Committee
PBAC	Pharmaceutical Benefits Advisory Committee
PBS	Pharmaceutical Benefits Scheme
PDC	Prostheses and Devices Committee
RAMQ	Regie de l'Assurance Maladie du Québec
SHI	Statutory Health Insurance
SIGN	Scottish Intercollegiate Guidelines Network
TAB	Office of Technology Assessment
TGA	Therapeutic Goods Administration

Executive Summary

This paper examines the issue of governance of Health Technology Assessment (HTA) systems. It finds that, while there seems to be a convergence among different countries towards the HTA appraisal and review process, there are still considerable differences in the manner in which national HTA systems operate as a whole. Such differences, it is argued, ultimately lead to different outcomes and outputs of national HTA systems, not least in the context of patients' ability to access new and innovative healthcare technologies.

Focusing on four key countries – Australia, Canada, Germany and the United Kingdom – this paper analyses some of the key elements embedded in HTA systems, which by and large affect the issue of governance of such systems. Accordingly, the paper does the following:

- Describes and analyses the different HTA agencies in the above countries;
- Outlines and determines their relationship with healthcare decision makers;
- Assesses the competence of HTA bodies to provide recommendations and decisions about the endorsement or rejection of healthcare technologies;
- Considers the degree of openness and level of inclusion of inputs from different stakeholders;
- Gauges outputs and performance in terms of the number of reviews and decisions provided by the relevant HTA bodies; and,
- Discusses the overall public perception of these bodies.

The following table provides some of the key findings with regard to the four national HTA systems:

	Australia	Canada	Germany	United Kingdom
Policymaking	Centralised	De-centralised	Centralised	Centralised, with devolution
Competence	Non-binding recommendations	Non-binding recommendations	Non-binding recommendations	Binding recommendations
Accessibility	Open	Open	Closed	Newly open
Functionality	Medium funding, high output	Medium funding, high output	Medium funding, high output	High funding, medium output
Perception	Low public perception	Low public perception	Low public perception	High public perception

While identifying the differences between national HTA systems, which are at times considerable, this study also identifies certain “virtues” that national HTA systems could and should work towards.

First, HTA bodies need flexibility and the ability to appreciate local needs and individual concerns. The notion of a negative list, which many systems use, provides an indication of how inflexible these systems can be. Rather than a HTA agency declaring that “this treatment is not cost-effective”, it would be better if it said “this treatment would be cost effective if...” and outlined circumstances where a technology could be allocated.

Secondly, we argue that HTA systems should also focus on becoming more inclusive and transparent, allowing their decisions and decision-making processes to be open for all to see. Transparency does not just provide the reassurance that a decision has been reached fairly and sensibly, it also allows for a more comprehensive and effective recommendation.

Thirdly, and perhaps most importantly, the paper notes that HTA systems are but one part of the national health system in which they operate. As such one cannot look at the decisions made within the HTA system as being isolated from the provision of healthcare in a given country. Accordingly, the policy actions and budgetary decisions that take place in the wider context of the national health system are likely to have a significant effect on the manner in which HTA decisions affect the ability of patients to gain access to new healthcare technologies.

Finally the paper concludes that decisions-makers and politicians cannot just hide under the "scientific veil" of HTA bodies. Rather both politicians and the public need to examine the HTA system with a more critical eye – to endorse its main points of strength but also to identify its limitations and weaknesses and to address them accordingly.

Introduction

Context

The rise of health technology assessment or HTA reflects the tension between national health systems built on the use of public funding (in the majority of developed countries) and the rapid global growth of science and innovation in healthcare. This process is transforming our vision of the way future patients will be treated, yet also placing enormous pressure on publicly-funded healthcare budgets.

In a “perfect market” for healthcare, were such a concept possible, informed consumers would make rational choices from a range of medicines, doctors and hospitals. In practice, however, the creation of a welfare system in Europe and elsewhere - which evolved to make sure health treatment would never be denied as a result of a patient’s lack of money - means that the “informed consumer” in many cases becomes national governments who pay for treatment on our behalf.

Supporters of markets would not necessarily choose to have health decisions taken out of their hands but, based on the kind of health systems we now have in most of Europe, as well as in Canada and Australia, HTA has become an attempt to inject a less politicised, more “evidence based” process into the decision about which medicines and treatments should be funded by taxpayers’ money.

HTA is certainly not perfect and we are a long way from evolving a “patient centric” model of HTA. However, a comparative study of the different forms of assessment being used in different developed countries at least gives us the opportunity to exert pressure on HTA bodies to live up to some basic quality standards that patients can expect. These include transparency, fairness, involvement of all the relevant health stakeholders, and perhaps most importantly, a consideration of the external funding environment in which HTA operates.

Why study and compare HTA?

Wherever they may be used, HTA systems around the world are charged with a standard undertaking: to produce research that can be used to enlighten healthcare decision making. Above all, these decisions will be based around the use, or not, of new and existing health technologies, which can be anything from pharmaceuticals and medical devices, to medical and surgical procedures¹. Nevertheless, national HTA systems are far from being identical to one another. Indeed, the structure and outcomes of a given HTA system are generally influenced by and subject to national arrangements and local constraints.

In particular, the analysis that HTA generates will offer recommendations that are not simply based on scientific investigation about the safety and efficacy of a new healthcare technology. Rather the findings of HTA also take into consideration the economic and social implications of new technologies. This multidisciplinary approach is the main reason that healthcare policymakers are now increasingly looking to make use of HTA evaluations as the basis for the allocation of resources within their health systems.

One main reason that countries have turned to HTA is to a large extent due to modern rises in healthcare spending, most of which remains financed by the state. From 1960 to 2007, only five individual years did not see an increase in the OECD average total expenditure on health as a percentage of gross domestic product (GDP). Specifically, in 1960 the average stood at 3.8%, by 2007 it had risen to 9%². In real terms, this relates to an increase from \$78 per capita in 1960 to \$2915 per capita in 2007³. With these rises in mind, many healthcare decision makers now place an importance on the evaluation of health technologies to assess their cost-effectiveness, in order to ensure the use of public resources in the most efficient way possible and, in some cases, to contain budgets⁴. Furthermore, with healthcare

¹ The International Network of Agencies for Health Technology Assessment - HTA Resources. See <http://www.inahta.org/HTA/> (Accessed on 26 Jan. 09)

² OECD Health Data 2008. See http://www.oecd.org/document/16/0,3343,en_2649_34631_2085200_1_1_1_00.html (Accessed on 19 Jan. 09)

³ OECD – Using Purchasing Power Parities (PPPs) that eliminate the differences in price levels between countries in the process of conversion.

⁴ Roehrig, Céline and Kargus, Kimberley, *Health Technology Assessment in Canada and the G-7 Countries: A Comparative Analysis of the Role of HTA Agencies in the Decision Making Process*. (Healthcare System Division, Health Canada, 2003).

managed within the government-funded framework currently employed in most developed countries, like it or not, the HTA model is likely to be here to stay.

This rise of HTA has been recognised by the Stockholm Network in a series of papers which aim to highlight the gap between the theory and practice of HTA, as well comparing the extent to which the HTA process is applied by separate national agencies. In the first paper, Pugatch and Ficai (2007) presented an account of HTA and offered an analysis into its established growth. The second paper by Pugatch and Davison (2007), assessed cross-country differences in the importance and capacity of HTA, whilst attempting to relate these to the characteristics of the respective health systems. Building upon this, Niemietz and Pugatch (2007) sought to compare the main actors of HTA in two indicative countries, a leader in HTA (United Kingdom) and a follower (Germany). This paper went to great lengths to highlight how decisions within the HTA framework can be politically abused, both as a method of simple cost-cutting and also to avoid more challenging and profound healthcare reforms. The last paper in the series, published in 2008, took a more detailed look at a fundamental HTA issue by analysing the threshold discussion and the concept of placing a price upon a year of life in healthcare decision making. This most recent study emphasised the need for greater transparency in the establishment of any HTA threshold in order for all interested parties to better understand decisions, so that they can either support or challenge them⁵.

Building upon this background, this paper intends to describe and analyse the conduct of HTA in a number of key countries – Australia, Canada, Germany and the United Kingdom. Accordingly, the paper will consider the following: it will establish the key commonality that exists between the countries by describing the key stages associated with the HTA process, highlighting the three central steps to a “conventional” approach to HTA. This explanation will pave the way for a study into the key differences between each country that exist within their HTA systems. This study will describe the main HTA agencies and outline their differing relationships with healthcare decision makers and their connection to the actual allocation of resources within the healthcare system. Finally, the paper will offer a conclusion and

⁵ For more information on the Stockholm Network's HTA paper series, see <http://www.stockholm-network.org/Conferences-and-Programmes/Health-and-Welfare/HTA>

will put forward a number of policy recommendations that are designed at offering practical suggestions for improving HTA.

HTA Process

The paper has already highlighted a key consensus among countries with relation to HTA – the need to contain rising healthcare spending, and the relevance that those countries feel the multidisciplinary research performed by HTA agencies can offer. But it is also clear that, when it comes to the conduct of the HTA process itself, countries follow a common course.

Generally speaking, three central stages to a “conventional” HTA process can be identified. These are stages and procedures that are regular in the conduct of HTA in all the systems studied. Each of these stages will now be outlined in order to provide an understanding of the structure used by most HTA systems.

Identification and prioritisation of technologies

At the outset of any HTA process emerging health technologies must be identified or new requests relating to existing technologies must be proposed for assessment. Typically, this identification of technologies is carried out by a mixture of health policymakers, healthcare managers, third-party payers, patients’ advocates, and the HTA agency itself.

Yet all too often this identification is performed through an informal process that is led by power and influence⁶. A report by the European Observatory on Health Systems and Policies (2005) established that the variety in scope and level of detail of many HTA systems is dependent upon who commissioned a study and why⁷. Therefore, whilst we can establish that the countries in this study all share a similar process of identification we must appreciate the importance of the particular individuals charged with identification and then analyse what impact their role has on the HTA system.

⁶ Sassi, Franco, *Analysis of the Scientific and Technical Evaluations of Health Intervention*. (LSE Health and Social Care, London School of Economics and Political Science, 2003).

⁷ European Observatory on Health Systems and Policies (2005) - *Policy brief - Health technology assessment: An introduction to objectives, role of evidence, and structure in Europe*. See http://www.inahta.org/upload/HTA_resources/AboutHTA_Policy_brief_on_HTA_Introduction_to_Objectives_Role_of_Evidence_Structure_in_Europe.pdf (Accessed on 16 Dec. 08).

Once technologies are identified, a process of prioritisation will then filter or “streamline” each application in order to decide which technologies should be put through for assessment by the HTA agency. The reason for this prioritisation is simply because the numbers of new and existing health technologies that require evaluation often outweigh the available resources of an agency⁸. Therefore, the technologies which have been identified need to be filtered to ensure that the most important are put through for further review.

A number of factors will typically be taken into consideration at this stage, but the main preference should be for those technologies that will ultimately have a greater chance of being recommended for use in the public health system, as this will utilise the work of the HTA agency more effectively.

Though national actors often dominate the identification and prioritisation stage, there are an increasing number of international institutions that have “horizon scanners”, or “early warning systems”, such as EuroScan⁹, which identify new and emerging health technologies and encourage the sharing of technology across national borders.

Technology assessment and review

Once the health technologies have been identified and prioritised, it then becomes possible to begin the actual assessment. Although the HTA process is supposed to bridge the divide between evidence and policy, the way it is practised is most likely to reflect the history, culture and values of the country where it is being conducted¹⁰. Within this we can already steal a glimpse into how common HTA processes can nonetheless lead to different HTA systems, based on national arrangements and local constraints.

⁸ Noorani et al - *Development of a new prioritization method for health technology assessment* (2005). See <http://www.cochrane.org/colloquia/abstracts/melbourne/P-089.htm> (Accessed on 16 Dec. 08)

⁹ The International Information Network on New and Emerging Health Technologies (EuroScan) is a collaborative network of member agencies for the exchange of information on important emerging new drugs, devices, procedures, programmes, and settings in healthcare. See <http://www.euroscan.bham.ac.uk/> (Accessed on 16 Dec. 08).

¹⁰ Banta, D, “The Development of Health Technology Assessment” in *Health Policy*, February 2003.

The first priority of research focuses on the safety, efficacy and therapeutic features of a technology being assessed. This research considers the performance of the technology, as well as its compliance with certain design, manufacturing and reliability specifications. Within this examination, the safety of the technology is assessed, taking into account accepted risks associated with its use in a particular situation. Building upon this research, assessments will also study the effectiveness of the technology, considering how well it works to improve patients' health. When evaluating this, the assessment must take into consideration the technology's performance under general conditions, as opposed to the carefully controlled environment in which clinical trials are conducted.

Both of these types of scientific and technical research are most familiar to the academic community¹¹. However the HTA process also takes other factors into account.

First among these are the economic consequences relating to the health technology. In this instance, the HTA process essentially considers the extent to which the medical benefits of a particular healthcare technology outweigh the additional costs associated with that technology, using a range of analytical models, including cost effectiveness, cost utility and cost benefit.

On top of the economic considerations, a variety of healthcare technologies may also raise social and ethical dilemmas, or may alternatively have an additional social and ethical importance which goes beyond their medical benefits *per se*, for example in the development of orphan drugs. As a result, assessments will often spend time evaluating whether a technology is appropriate or necessary in respect to particular legal or societal norms.

Dissemination and implementation of recommendations

Once a full assessment of a specific healthcare technology is completed, HTA agencies will distribute its results to the appropriate bodies, policymakers, providers,

¹¹ Battista, Renaldo and Hodge, Matthew, "The evolving paradigm of health technology assessment: reflections for the millennium" in *The Canadian Medical Association Journal*, May 18, 1999; 160.

professionals and the public in general, in order to maximise the usefulness of their findings within the policymaking process. However, this can often be considered as an administrative “after thought” and, consequently, HTA findings can sometimes go unnoticed. This could be because the agency has failed to identify or understand the target audience or because the report is badly timed or poorly packaged.

The Organisation for Economic Co-operation and Development (OECD) Health Project (2005)¹² established that the most common forms of dissemination used by HTA agencies were reports or newsletters, in addition to publishing on the internet and at conferences or meetings. The National Information Center on Health Services Research and Healthcare Technology¹³ identified the importance of identifying target groups, i.e. the intended audiences of the report, when considering disseminating assessments findings. Typical target groups identified included clinicians, patients, providers, third-party payers, quality assurers, policymakers, biomedical researchers, healthcare product companies, news professionals and educational institutions.

When the results of an assessment have been suitably shared with the relevant stakeholders, it is at this point that the policy side of HTA takes over. Assessment findings are used to inform a wide range of decisions, whether planning a health system’s resource capacity, developing clinical practice guidance, informing organisational investment decisions, or advising on the reimbursement of a new technology.

In some countries there are also formal appeal processes, which allow objections to HTA decisions to be heard. This re-evaluation can take place at a pre-arranged time or can happen only when new characteristics or data materialises. These requests are important to the HTA process, but they should not create inefficiency, a burden of resources, or delayed access to treatment.

¹² The OECD Health Project (2005). *Health Technology and Decision Making*. See http://www.oecd.org/document/55/0,3343,en_2649_34537_35589431_1_1_1_1,00.html (Accessed on 09 Feb. 09)

¹³ National Information Center on Health Services Research and Healthcare Technology - *HTA 101: Disseminating Findings and Recommendations*. See <http://www.nlm.nih.gov/nichsr/hta101/ta101010.html> (Accessed on 11 Feb. 09)

Already it has been recognised that there is a key commonality between the four countries in this study, which is the overall process they use to perform HTA. The recommendations offered by agencies in all four countries are reached after health technologies have been processed through the procedures highlighted above. This is important as it shows that not only do the countries agree on the need for HTA to contain public healthcare costs, but they are also in agreement on the process with which to conduct it. The extent to which the countries' HTA processes correspond will now become obvious as the paper moves on to outline each HTA system country by country. The paper will show that whilst the HTA arrangements follow the same process, the systems themselves are markedly different and it is this diversity that the paper will now examine.

HTA Systems

An effective way for this paper to highlight the commonality that exists between the rationale and process for HTA, whilst also outlining the difference between the HTA systems, is to provide a description of each system, explaining how assessments are performed and analysing how each system differs.

The paper has already outlined the stages of a common HTA process and the description of each HTA system will show how these stages are followed in each country. However, in order to highlight the differences between each system the paper establishes five key themes that will need to be considered to understand where and how such variation exists: policymaking; competence; accessibility; functionality; and perception.

Policymaking

Since HTA agencies provide the basis for most decisions made on the allocation of health technologies within publicly-funded healthcare systems, it is important to appreciate the variety of relationships that exist between agencies and decision makers. In doing so, the study is able to ascertain the correlation between how HTA recommendations are made and how health decision making is performed, in particular focusing on whether the HTA system is centralised or decentralised, and indeed on whether that reflects the health decision making process.

In particular the paper will argue that when a country has a centralised healthcare system, then it is likely that the HTA system will reflect this, allowing for a more central and influential single agency. Whereas when healthcare is decentralised there is greater regionalisation of the HTA system. In such systems, it is usual for each individual region to have its own health ministry that independently decides on the reimbursements of particular health technologies, drawing upon local appraisals to provide a more efficient perspective.

Competence

The study will further analyse the relationship between HTA agencies and healthcare decision making by assessing the degree of influence that HTA recommendations have over the decisions made, thus demonstrating the competence of the HTA system. In particular, the study will focus on the interference that HTA recommendations experience on their way to the actual allocation of health technologies.

This study will attempt to show that if a recommendation from an agency is binding it will certainly enhance the competence of the HTA agency, whilst HTA agencies that require proposals to be approved will naturally have less independent power, as the uptake of their advice will depend on an additional actor, usually the national government.

Accessibility

If the recommendations offered by HTA agencies are to have an effective impact on the allocation of technologies in the public healthcare system, then it is vitally important that the system that makes those decisions is as open as possible. In particular, attention should be paid to the method in which technologies are identified and the degree to which relevant stakeholders are able to monitor and contribute to the assessment.

The more accessible HTA systems allow for public identification of health technologies, particularly allowing stakeholders to suggest technologies that should be considered. They will also have assessments that involve external stakeholders and relevant experts, allowing for interaction with a variety of appropriate parties leading to a more comprehensive appraisal. In a closed system it is often only specific individuals, such as health decision makers, who are able to put forward applications for assessment, and assessments will be performed without an appreciation of the expertise offered by stakeholders.

Functionality

Much of the variation that exists between different HTA systems is likely to come from a difference in the activity and resources of the publicly-funded HTA agencies. Whilst this paper focuses on HTA agencies that receive large amounts of public funds, since these are generally the most well-established agencies, it has tried to analyse the differences between the funding of the main HTA agencies. Of course the level of funding an agency receives will also have a direct effect on how many permanent members of staff they employ.

In addition to analysing these two “input” factors, it is also important to consider the “output” factors to try to understand how functional the HTA agencies are, and thus how functional the HTA system is as a whole. In particular, the number of assessments performed per year will provide an insightful look into how active an agency is, whilst the average length of assessments at the HTA agency will give an indication into how efficient it is.

Perception

The role of HTA agencies can often be perceived by the public in a number of different ways. In general, if they are even aware of it, the general public will tend to see a Health Technology Assessment agency as a technical organisation, providing scientific research on behalf of the government. However, if an agency is perceived as directly related to decisions about the reimbursement of health technologies, which they naturally are, it is inevitable that their role within society becomes viewed differently. Mostly public attention will be drawn to decisions that deny treatment to patients on the basis of cost-effectiveness, for example, by the media. As a result, the more alert the public are to decisions made by HTA agencies, the greater level of scrutiny their recommendations will come under.

The next section will introduce the HTA systems of Australia, Canada, Germany and the United Kingdom, as well as describing the healthcare structures within which they operate. In most cases, there are numerous active HTA bodies, however, this paper restricts its scope to examining those agencies with sufficient influence, or

which receive a significant amount of public funding to be deemed part of the national HTA system.

Australia

Overview

In general, HTA in Australia is undertaken by a number of different bodies and committees, at the national level, at state level, in individual hospitals, and in the private sector¹⁴, though a parallel national HTA process was created in 1998. The intention of this dual system is to produce guidance for the management of both the Medicare Benefits Schedule (MBS) and the Pharmaceutical Benefits Scheme (PBS), which is administered through Medicare Australia, the publicly-funded universal healthcare system.

The national HTA system is for the most part centralised, replicating the management of healthcare in Australia more generally. Recommendations are made by the central HTA agencies, based on completed assessments, which are then used as advice to the Minister at the Department of Health and Ageing (DoHA), who determines the allocation of public resources¹⁵. The recommendations put forward are non-binding and they rely on the Minister's approval, though it is rare for the advice to be rejected. In December 2008, the DoHA launched a review into the practice of HTA in order to improve its efficiency and reduce the regulatory burden in Australia¹⁶.

Australia covers a population of 21.7 million, the smallest in this study, and its publicly-funded HTA system appears in most cases to be focused on a collection of small committees. It is also important to highlight that the Australian model separates pharmaceutical assessments from the appraisals of other health technologies. However, it should be noted that the recent review into HTA practices proposes to address a duplication that appears to have been created as a result of this parallel system. Overall, the government funds 67.7% of all healthcare

¹⁴ European Observatory on Health Systems and Policies (2006) - *Health Systems in Transition Vol. 8 No. 5 2006*. See <http://www.euro.who.int/Document/E89731.pdf> (Accessed on 27 Jan. 09)

¹⁵ Jackson T. J., "Health technology assessment in Australia: challenges ahead" in *Electronic Medical Journal of Australia*, Issue 187, 2007. See http://www.mja.com.au/public/issues/187_05_030907/jak10484_fm.html (Accessed on 19 Jan. 09)

¹⁶ Department of Health and Ageing - Health Technology Assessment Review. See <http://www.health.gov.au/internet/main/publishing.nsf/Content/hta-review> (Accessed on 11 Feb. 09)

expenditure in Australia and governmental healthcare spending stands at 8.7% of GDP (a 128% increase from 1960)¹⁷.

HTA Agencies

Medical Services Advisory Committee

The Medical Services Advisory Committee (MSAC), formerly the Australian Health Technology Assessment Committee (AHTAC), is an expert panel that provides recommendations to the Minister of the DoHA that relate to the health technologies listed on the MBS. MSAC has only 14 members who are appointed by the Minister and are usually either practising clinicians or representatives from areas such as health economics, clinical trials, hospital administration, or planning. Secretariat and project support is provided by the Health Technology Section of the DoHA.

Pharmaceutical Benefits Advisory Committee

The Pharmaceutical Benefits Advisory Committee (PBAC) is an independent statutory body established in 1954 that makes recommendations to the Minister of DoHA on which drugs that should be made available through the PBS, or the National Immunisation Program. There are around seventeen members of PBAC from across Australia, including health professionals, consumer representatives, and experts from a range of HTA-related disciplines. Members are appointed by the Minister in accordance with the *National Health Act 1953* and the membership is published in the *Government Gazette*. PBAC can establish sub-committees, which would consist of appropriate experts who can offer assistance for the purposes of assessments. Currently, two such sub-committees exist: the Drug Utilization Sub-Committee, monitoring patterns and trends of drug use, and the Economics Sub-Committee, advising on cost-effectiveness.

¹⁷ OECD *Health Data 2008*, op. cit

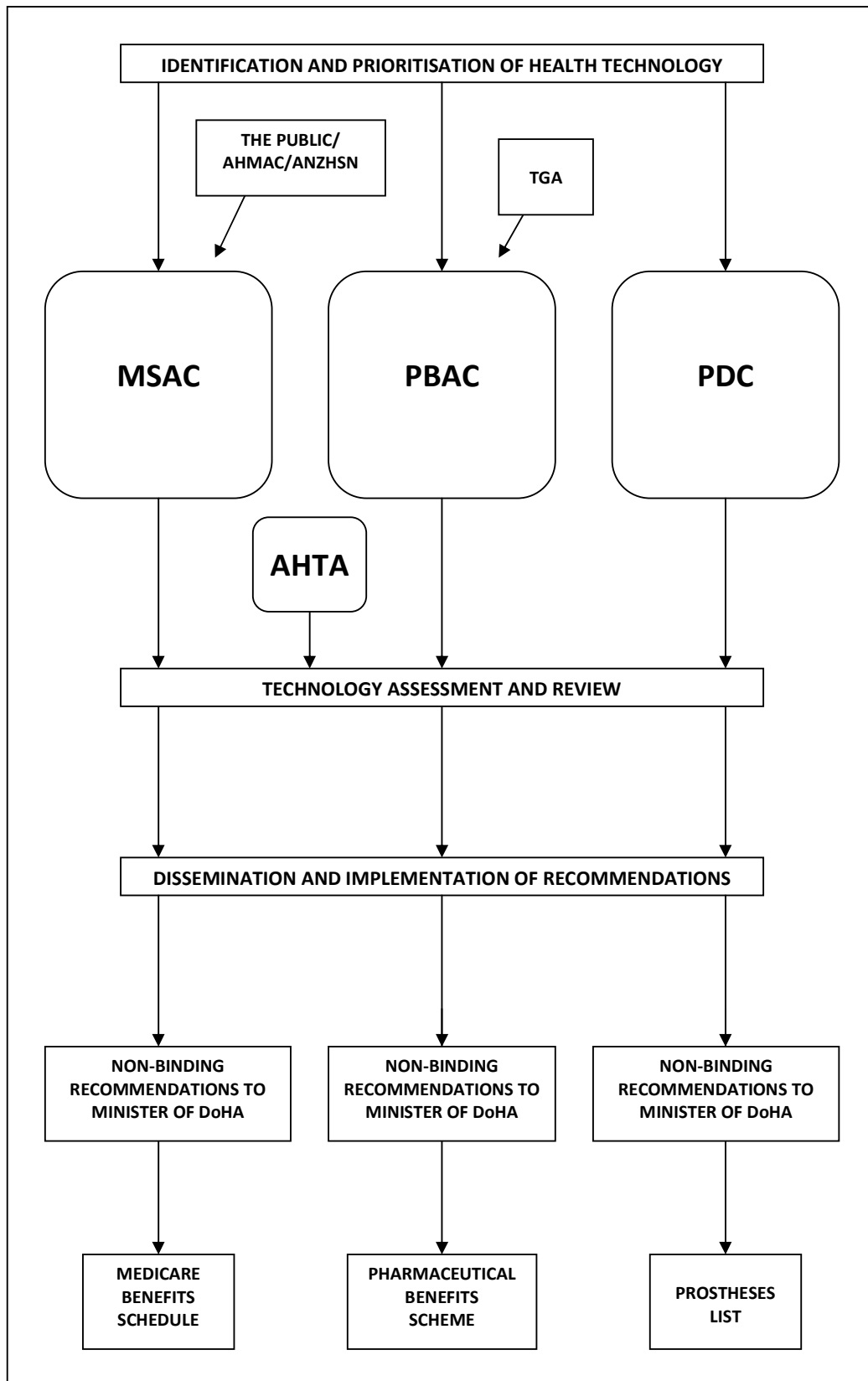
Prostheses and Devices Committee

The Prostheses and Devices Committee (PDC) is another agency, established in 1994 to advise the Minister of DoHA on assessing the benefits payable in respect of surgically implanted prostheses and human tissue items recorded on the Prostheses List. PDC has 13 members who represent major stakeholders, including health insurers, private hospitals, clinicians, prostheses and medical device suppliers, consumer organisations and the Department of Veterans' Affairs.

Adelaide Health Technology Assessment

Adelaide Health Technology Assessment (AHTA) is located within the Discipline of Public Health, University of Adelaide. It was established in 2001 and conducts HTA assessments commissioned to it on behalf of MSAC and PBAC. AHTA also conducts horizon-scanning, through the National Horizon Scanning Unit, on new and emerging health technologies and writes brief appraisals of these on behalf of HealthPACT.

Australian HTA system



HTA Process

Identification and prioritisation of technologies

New and existing technologies are occasionally referred to MSAC by the Australian Health Ministers' Advisory Council (AHMAC), which is a body made up of the heads of the health authorities in the Australian state and territorial governments, as well as the head of the New Zealand health authority and the head of the Australian Department of Veterans' Affairs. A further source of identification is performed by the Australia and New Zealand Horizon Scanning Network (ANZHSN), which provides advance notice of significant new and emerging technologies. In addition, applications are also made through an open process by anyone with an interest in seeking Australian government funding for a technology.

The total number of applications submitted to MSAC is relatively low and between 1998 and 2004 an average of only around fourteen were made per year¹⁸. The technologies that will be prioritised for an assessment are those that meet conditions for funding under the MBS arrangements. To meet this criterion, the proposed technology must represent a clinically relevant professional service within the meaning of the *Health Insurance Act 1973*. The technology must also have the approval of the Therapeutic Goods Administration (TGA), Australia's regulatory agency for medical drugs and devices, and thus have received inclusion on the Australian Register of Therapeutic Goods (ARTG).

Submissions of pharmaceutical products to PBAC are commonly made by industry sponsors of drug products, in particular for new products, due to the necessary data held by the sponsor. However, submissions are also made by medical bodies, health professionals, private individuals and their representatives. PBAC considers submissions, if registered by the TGA, and decides which products should be assessed, with direction provided by the Minister. However in 2008, it was reported that anti-depressants, such as Zoloft and Prozac, were being prescribed to children and subsidised through the PBS despite the fact that they have never received TGA

¹⁸O'Malley, Sue, "The Australian experiment: the use of evidence based medicine for the reimbursement of surgical and diagnostic procedures" in *Aust New Zealand Health Policy*, Volume 3, 2006. See <http://www.pubmedcentral.nih.gov/articlerender.fcgi?artid=1524967> (Accessed on 26 Jan. 09).

market approval for anyone under the age of 24¹⁹. Instead, PBAC had decided to advise that doctors should be allowed to prescribe without the drugs needing market approval, leaving the doctors to judge based upon circumstances.

Technology assessment and review

MSAC applications are assessed if they are eligible and if they are deemed to constitute an efficient and effective use of Commonwealth resources. An initial review is made of any information supplied in the identification of the technology, as well as any additional relevant data that might have been provided at the outset. A systematic review of relevant literature is then commissioned by MSAC and an advisory panel is usually appointed that will assist in the assessment of applications, and is chaired by a member of MSAC.

Assessments made by PBAC will predominantly be based on the evidence provided to it by the applicant and will not involve a full literature scan like those performed by the MSAC²⁰. Assessments consider the effectiveness and cost-effectiveness of the product in comparison with other PBS-listed products for the same, or similar, conditions. Where no similar PBS-listed product exists, PBAC considers its effectiveness and cost-effectiveness compared with standard medical care, or the benefits to patients that the new product will provide compared to the cost of achieving those benefits.

PDC commissions its own HTA process through Clinical Advisory Groups, and its assessments consider the comparative safety and relative clinical effectiveness of prostheses. It also conducts the negotiation of benefits through the Prostheses and Devices Negotiating Group²¹.

Dissemination and implementation of recommendations

¹⁹ *The Australian* - PBS foots bill for kids' Prozac (23/07/08). See <http://www.theaustralian.news.com.au/story/0,25197,24063150-23289,00.html> (Accessed on 06 May 09)

²⁰ Australian Department of Health and Ageing - *Health Technology Assessment Review* (2009). See [http://www.health.gov.au/internet/main/publishing.nsf/Content/208F913CD40AD7F9CA2575850080CACD/\\$File/htadiscussionpaper.pdf](http://www.health.gov.au/internet/main/publishing.nsf/Content/208F913CD40AD7F9CA2575850080CACD/$File/htadiscussionpaper.pdf) (Accessed on 30 Apr. 09)

²¹ Australian Department of Health and Ageing - Prostheses List. See <http://www.health.gov.au/internet/main/publishing.nsf/Content/health-privatehealth-prostheseslist.htm> (Accessed on 06 May 09)

MSAC prepares its advice to the Minister of the DoHA based on the strength of the evidence in relation to the safety and cost effectiveness of the technology, with recommendations on the circumstances under which public funding should be supported. The recommendations provided by MSAC generally fall into one of three categories: a recommendation that supports listing on the MBS based on strong evidence; a recommendation that does not support listing on the MBS; or a recommendation for interim funding to enable further evaluation of the technology.

The Minister of the DoHA will then consider the MSAC submission and, if the recommendations are endorsed, arrangements will be made for the funding of the new medical service through the MBS. The uptake of MSAC recommendations is high. For example, between 2006 and 2008, some 26 recommendations were made by MSAC with every one endorsed by the Minister and included on the MBS²². However, despite this, there have been a small number of examples where the Minister has not automatically approved a technology for Medicare coverage, despite MSAC recommendation²³. At the conclusion of the MSAC process the assessment report and recommendations, with the Minister's notation, are published and distributed to any interested parties, as well as being published on the MSAC website.

PBAC recommends to the Minister of the DoHA on maximum quantities and repeats, and may also recommend restrictions as to the indications where PBS subsidy is available.

For the recommendations of the PDC, the *Private Health Insurance Act 2007* outlined that private health insurers were required to reimburse prostheses included on the Prostheses List, when the prosthesis is provided as part of an episode of hospital treatment and a Medicare benefit is payable for the professional service associated with the provision of the prosthesis.

²² Medical Services Advisory Committee - Performance Report 2006- 2008. See [http://www.msac.gov.au/internet/msac/publishing.nsf/Content/CF6DDCF72B4D63CACA2574FF0004074A/\\$File/Final%20MSAC%20Performance%20Report%202006-2008.pdf](http://www.msac.gov.au/internet/msac/publishing.nsf/Content/CF6DDCF72B4D63CACA2574FF0004074A/$File/Final%20MSAC%20Performance%20Report%202006-2008.pdf) (Accessed on 11 Feb. 09)

²³ *Sydney Morning Herald*, "Nine seconds that could save your life". See http://www.smh.com.au/news/national/nine-seconds-that-could-save-your-life/2008/05/03/1209235222637.html?s_cid=rss_national (Accessed on 05 May 09)

Analysing the HTA system

Policymaking

Australia has a largely centralised system of healthcare and we can see from the study that this is also reflected in its HTA system. As a result, the relationship between the HTA agencies and the health decision makers is performed primarily at the national level with centrally-made decisions having an effect across the country.

Competence

The Australian HTA system does not allow for the recommendations made by the HTA agencies to be binding to health providers, instead the Minister of DoHA decides the allocation of health resources within the publicly funded system, though they will make their decision based on the recommendations put forward by the HTA agencies.

Accessibility

The process for identifying health technologies is open for submission at all HTA agencies and allows for direct access by relevant stakeholders. In particular, PBAC relies only on the information supplied to it by the sponsors of the technology and bases its assessments on it.

Functionality

The funding of Australian HTA agencies is favourable in comparison to other HTA systems, with the MSAC for example allocated \$22.83m²⁴ per year. As the MSAC is a committee, and because assessments are commissioned, there is only 15 permanent staff at the MSAC²⁵, and thus a smaller number of assessments are performed: 14 assessments per year. On average, MSAC assessments take around 16-17 Months²⁶.

Perception

²⁴ Medical Services Advisory Committee - Annual Report 2001-02. See [http://www.msac.gov.au/internet/msac/publishing.nsf/Content/38049A38B7D24871CA257267007F636B/\\$File/MSACar01-02.pdf](http://www.msac.gov.au/internet/msac/publishing.nsf/Content/38049A38B7D24871CA257267007F636B/$File/MSACar01-02.pdf) (Accessed on 11 Feb. 09)

²⁵ International Network of Agencies for Health Technology Assessment – List of members. See <http://www.inahta.org/Members/MSAC/> (accessed on 11 Feb. 09)

²⁶ Medical Services Advisory Committee – Annual Report 2001, *op. cit* (Accessed on 11 Feb. 09)

In general, the HTA system in Australia is seen as a scientific advisory service to health decision makers. In the media there have been some examples of criticism over HTA decisions. For example, a decision by MSAC to limit the rolling out of positron emission tomography (PET scans) to a select group and the MSAC decision not to reimburse ThinPrep for identifying cervical cancer. The PBAC seems to be more well-known than MSAC and there was a controversy in 2006 when the agency refused to reimburse Gardasil, a cervical cancer vaccine, for females aged 12 to 26. In face of this controversy, Prime Minister John Howard intervened to force the Gardasil price to be lowered and thus be approved by PBAC and put onto the PBS.

Canada

Overview

The Canadian healthcare system is characterised by universality and single-payer funding from general revenues, yet the system is not centralised²⁷. Healthcare in Canada is managed, organised and delivered by the provincial and territorial governments, of which there are ten and three, respectively. In 1984, the Canada Health Act established the publicly-funded universal healthcare system, which is mostly provided by a mix of public and private organisations.

There are a variety of established Canadian HTA agencies that exist from the national level, down to the provincial and territorial levels. The federal government licences pharmaceuticals, devices and equipment, yet leaves decisions about which ones should be purchased to the provincial and territorial governments. These provincial and territorial ministries of health are responsible for delivering health services by planning and financing hospital care, physicians, and some aspects of prescriptive care and public health. Decisions are made about which health technologies to include in the healthcare delivery system, as well as which services should be publicly funded under their respective health insurance plans and to what extent.

The provincial HTA authorities, who are publicly-funded, guide provincial decision making on health technology, as well as sharing their findings with other interested parties. The purpose of provincial HTA agencies can vary but in the main they are tasked with reporting to their respective ministries of health, who use the advice given to inform their healthcare decisions.

Canada has the most regionalised healthcare system of those studied and, as a result, its HTA processes are the most localised. Influence over the reimbursement of health technologies is shared among regional HTA agencies, inevitably reducing the

²⁷ Roehrig, Céline and Kargus, Kimberley, *Health Technology Assessment in Canada and the G-7 Countries: A Comparative Analysis of the Role of HTA Agencies in the Decision Making Process*.(Healthcare System Division, Health Canada, 2003).

significance of the central HTA agency in comparison to similar bodies elsewhere. Instead, the central HTA agency focuses on its co-ordinating role ensuring consistency in healthcare provisions across the country. Overall, the government funds 70.4% of all healthcare expenditure in Canada and governmental healthcare spending stands at 10% of GDP (an 85.2% increase from 1960)²⁸.

HTA Agencies

The Canadian Agency for Drugs and Technologies in Health

The national HTA authority is the Canadian Agency for Drugs and Technologies in Health (CADTH), formerly the Canadian Coordinating Office for Health Technology Assessment (CCOHTA). The body has been in existence in one form or another since 1989 making it one of the first national HTA organisations in the world. In 2004, a Health Technology Assessment Task Group published *Health Technology Strategy 1.0*²⁹, which focused on establishing a pan-Canadian strategy and resulted in CCOHTA becoming CADTH. In the implementation strategy, CADTH was tasked with moving beyond HTA to become a national health technology agency responsible for supplying assessments to healthcare policymakers, whether federal, provincial or territorial, though policymakers are not compelled to act upon its advice.

CADTH is responsible for the Common Drug Review (CDR), which provides a review into the cost effectiveness of drugs, with which the Canadian Expert Drug Advisory Committee, an independent CADTH advisory body, makes a formulary listing recommendation. This listing forms the basis for the publicly funded drug plans in Canada (except Québec), which are then decided by the provincial and territorial health ministries³⁰.

Agence d'Évaluation des Technologies et des Modes d'Intervention en Santé

²⁸ OECD *Health Data 2008*, *op. cit*

²⁹ Health Technology Assessment Task Group - *Health Technology Strategy 1.0*. See http://www.hc-sc.gc.ca/hcs-sss/alt_formats/pacrb-dgapcr/pdf/pubs/ehealth-esante/2004-tech-strateg/2004-tech-strateg-eng.pdf (Accessed on 06 Jan. 09).

³⁰ European Observatory on Health Systems and Policies (2005) - *Health Systems in Transition* Vol. 7 No. 3 2005. See <http://www.euro.who.int/Document/E87954.pdf> (Accessed on 27 Jan. 09)

Agence d'Évaluation des Technologies et des Modes d'Intervention en Santé (AETMIS), formerly the Conseil d'Évaluation des Technologies de la Santé (CETS), is based in Québec, where in 2003 it was placed within the portfolio of the newly formed Québec Ministry for Health and Social Services.

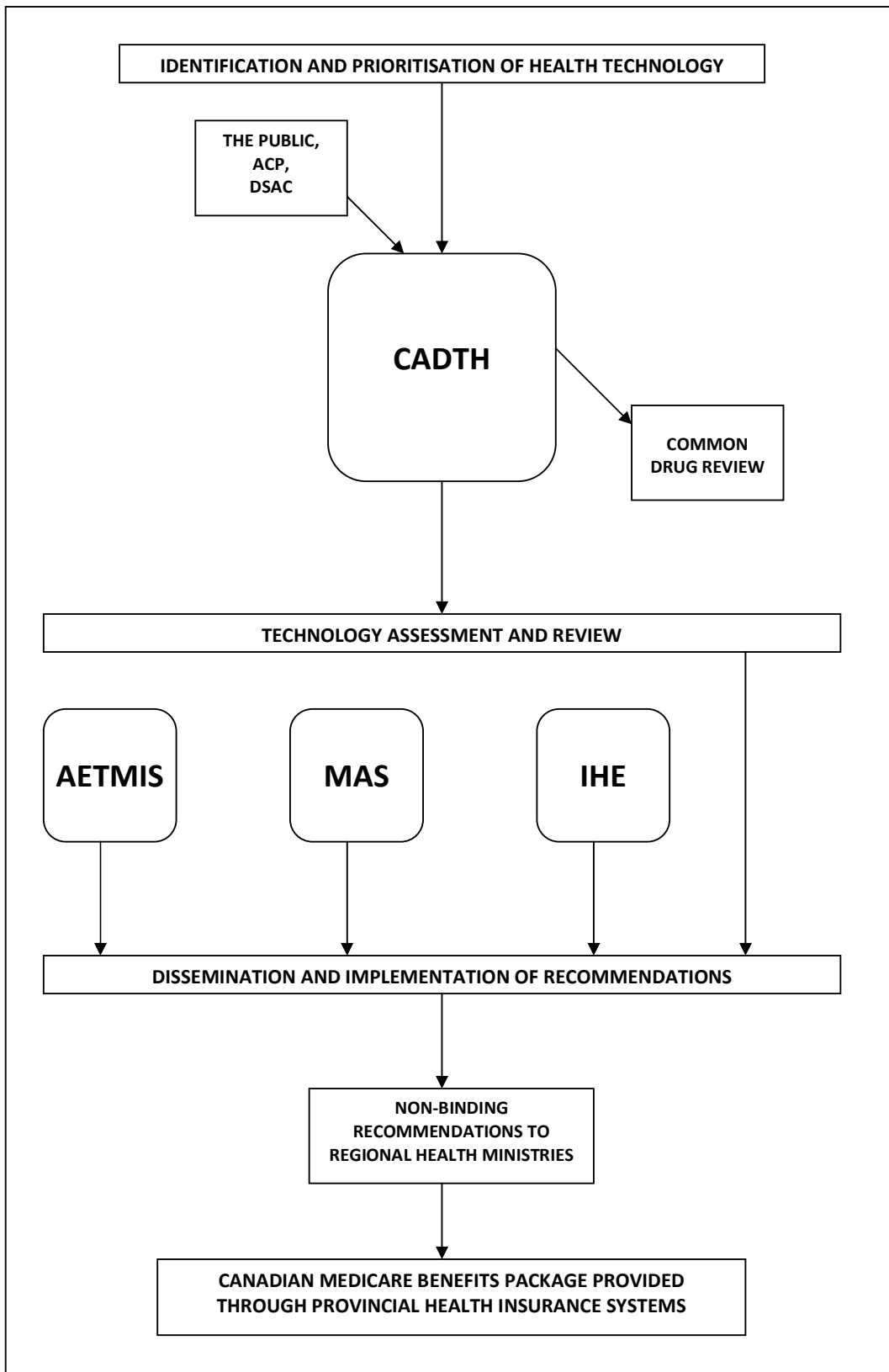
The Medical Advisory Secretariat

The Medical Advisory Secretariat (MAS), in Ontario, is a unit within the Ministry of Health and Long-Term Care in Ontario (MOHLTC), which it advises on the use of health technologies.

Institute of Health Economics

Institute of Health Economics (IHE) in Alberta took provincial responsibility for HTA through the consolidation of the HTA unit in the Alberta Heritage Foundation for Medical Research (AHFMR) into its own dedicated unit. IHE maintains a dominant position in HTA with the Department of Health and Wellness in Alberta, in line with the Alberta Health Technologies Decision Process (hereafter Decision Process), and yet maintains independence as a not-for-profit organisation, with aspirations to becoming an international centre of excellence for health economics.

Canadian HTA system



HTA Process

Identification and prioritisation of technologies

At CADTH, anyone can instigate an assessment of a particular health technology, with submissions possible through the organisation's website. CADTH states that "any proposal that aims to facilitate the appropriate and effective utilisation of drugs and health technologies within healthcare systems across Canada will be considered"³¹. In addition to this open submission procedure, CADTH also identifies technologies independently through a horizon scanning service, which actively scans literature for health technologies in early development and adoption stages, as well as others that may affect healthcare finances, facilities, operations and patient care.

The prioritisation of identified technologies is then performed with the assistance of the Advisory Committee on Pharmaceuticals (ACP) and the Devices and Systems Advisory Committee (DSAC), both of which are accountable to the CADTH Board of Directors. The ACP comprises of representatives of publicly-funded drug plans, from all government levels, and the DSAC includes representatives acting for the individual health ministries. The technologies are prioritised with the intention of choosing issues of national importance to the publicly-funded healthcare system and selecting specific research questions that an assessment must tackle.

At AETMIS, requests for new and existing technologies initiate mostly from the Québec Ministry for Health and Social Services and its decisional authorities, but it does have an open method for others to submit similar to CADTH. The prioritisation of technology submissions is executed by the AETMIS Board of Members, comprising of 14 independent members appointed by the Québec government.

In Ontario, it is the Ontario Health Technology Advisory Committee (OHTAC) that considers open submissions, based on a presentation by an MAS clinical epidemiologist. OHTAC consists of representatives of the Ontario Medical Association and the Ontario Hospital Association, as well as figures from hospital,

³¹ CADTH: *Suggest a Topic*. See <http://cadth.ca/index.php/en/hta/topic-proposal> (Accessed on 16 Dec. 08)

community and long-term care sectors, nursing and medical professions, and experts in health economics, ethics and technology assessment. The Assistant Deputy Minister from the Health System Information Management and Investment Division at MOHLTC appoints OHTAC members for two-year, renewable terms. *Ex-officio* members include the head of MAS and other senior MOHLTC officials. In addition, someone from the Local Health Integrated Networks, an Ontario network of 14 not-for-profit corporations that work with local health providers and community members to determine regional health service priorities, is also invited to become a member.

IHE has an open process of identifying new and existing technologies which focuses on collaborating with clinicians, researchers at educational institutes, and other experts to identify potential assessments, with requests also encouraged from other provinces and countries for cooperation on topics of mutual interest. Whilst a portion of prioritisation at IHE is done through internal and external review, most technology selection is executed through the Decision Process. This entails a review by the Alberta Advisory Committee on Health Technologies who's forwarding Committee submits advice and recommendations to the Alberta Ministry for approval.

Technology assessment and review

CADTH assessments are performed by project teams consisting of CADTH employees and external contractors. These teams must include researchers (in medicine, pharmacy, pharmacology, basic sciences, bioethics or health services), a project manager, economists, epidemiologists, an information specialist, a knowledge transfer specialist and two or more expert clinicians. Two members of CADTH's Scientific Advisory Panel (SAP) are assigned to each project to consider the protocol and to review the HTA report before it is published.

In Québec, AETMIS assessments are performed by Agency researchers with the necessary expertise. MAS researchers also perform the assessments in Ontario, after they have been submitted by OHTAC. IHE assessments are made by two

researchers and the HTA Reports produced are reviewed by the Director of the HTA programme, and by external experts.

Dissemination and implementation of recommendations

CADTH reports are written by a “research lead” who must follow the template set out in the *Guidelines for Authors of CADTH Health Technology Assessment Reports*³². Scientific data and research findings are translated into information that is relevant to healthcare decision makers. Before dissemination, the report is peer-reviewed, first by a senior HTA staff member, and then by at least two external experts, in addition to the two SAP members assigned to the project.

The knowledge transfer specialist assigned to the project team will have already identified partners, committed to using the findings of HTA reports, and they then develop dissemination strategies to ensure the most efficient interaction and collaboration with healthcare policymakers.

AETMIS reports are disseminated to the Québec health ministry, to the organisation that filed the application, and then made public. The Québec health ministry then uses the recommendations for the basis of the Regie de l'Assurance Maladie du Québec (RAMQ), the province’s health insurance system. MAS reports to OHTAC for review, who turn the assessment into recommendations that are conveyed to MOHLTC.

In dissemination, IHE makes an effort to reach more than just Alberta decision makers. Reports are published in the usual manner, through scientific journals, conference presentations, web-based communications, media releases, workshops, seminars and other educational activities. But in addition to this, distinctive dissemination activities are employed, including the publication of a health book series, the creation of an ambassador programme for knowledge transfer in Alberta, and the organising of “Consensus Development Conferences”, which perform jury trials on health policy or scientific issues to disseminate findings from research.

³² CADTH – *Guidelines for Authors of CADTH Health Technology Assessment Reports*. See <http://cadth.ca/media/hta/AuthorsGuidelines.doc> (Accessed on 06 Jan. 09).

Analysing the HTA system

Policymaking

Canada has by far the most decentralised healthcare system in the study and we can see that decisions about the use of new and existing technologies are made by a variety of actors at a regional level. Accordingly, the HTA system reflects the national health bodies, with a central agency that conducts HTA, but with publicly-funded agencies providing more local assessments for use by the regional health decision makers. There have been some examples where this decentralisation has created a discrepancy in healthcare provisions, for example the supplying of bariatric surgery for morbidly obese persons in Ontario but not in Québec³³.

Competence

The recommendations of the Canadian agencies depend on the regions where they are being performed. CADTH's recommendations are non-binding and so too are those of the regional HTA agencies. As a result, it is the role of the regional health ministries to decide on the use or not of health technologies, which they do upon the advice of the HTA agencies.

Accessibility

The process for identifying health technologies for assessment is a straightforward open process to which anybody is able to contribute. Similarly, at a regional level there is also an open process for identification. These procedures complement the more direct access that some policymakers have to suggest technologies, particularly at the regional level.

Functionality

Canadian HTA agencies receive a great deal of public funding, with CADTH receiving \$17.9m³⁴ per year - this reflects the more than 100 permanent staff³⁵ at CADTH - in

³³ *Canadian Business Online* - The Coalition against Morbid Obesity deplores that Ontario, and not Quebec patients benefit from bariatric surgeries in Quebec" (06/01/09). See http://www.canadianbusiness.com/markets/cnw/article.jsp?content=20090206_070503_5_cnw_cnw (Accessed on 19 May 09)

³⁴ The International Network of Agencies for Health Technology Assessment – List of members. See <http://www.inahta.org/Members/CADTH/> (Accessed on 27 Jan. 09)

³⁵ *Ibid*

addition to funding for regional HTA agencies. Assessments are also relatively prompt with the 20-24 assessments per year performed by CADTH taking on average around 6-12 months.

Perception

CADTH is not particularly prominent among the public beyond a number of surveys and reports that provide scientific expertise from the agencies^{36,37}. However, more regionally the public are aware of their respective HTA agencies and the decisions that they make which affect their healthcare services.

³⁶ Cancerfacts.com - Drugs to combat anemia boost risk of death (06/05/09). See http://www.cancerfacts.com/Home_News.asp?NewsId=2436&CB=14&CancerTypeId=4 (Accessed on 07 May 09)

³⁷ Le Devoir - Évaluation des technologies en santé - L'AETMIS cherche à "éclairer la prise de décisions en santé" (05/07/09). See <http://www.ledevoir.com/2008/07/05/196524.html> (Accessed on 07 May 09)

Germany

Overview

Healthcare in Germany is funded through a statutory contribution system dating back to Bismarck, which provides free healthcare for all through what are known as “sickness funds”. Insurance for healthcare is covered by either statutory health insurance schemes (SHI), of which there are around 240, or by private arrangements, of which there are 50 different companies. SHI schemes, which are compulsory for most, are the primary method and cover around 90% of the German population.

The Federal Joint Committee (G-BA), established in 2004, is the main policymaking body in German healthcare and is authorised by law to issue legally binding directives. The directives issued by the G-BA are legally binding for insured persons as well as for the providers and payers of healthcare: physicians, hospitals and sickness funds. By issuing directives the G-BA determines the benefit package of SHI and is also responsible for reimbursement decisions. The G-BA has 21 members and brings together the sickness funds and the healthcare providers, who are represented by nine members each. Monthly G-BA meetings are also attended by nine patient representatives with an advisory function.

Each of the German regions or *Länder* shares responsibility for the building and upkeep of hospitals with central government, whilst SHI providers increasingly exert control over some of the running costs³⁸. The German healthcare system prides itself on the principle of self-governance, which sees the Federal Health Ministry (BMG) setting the general rules with the details regulated by self-governing bodies.

The practice of HTA in Germany generally follows along these lines of healthcare decision making. The self-governing body, which maintains an independent role in deciding healthcare arrangements, has a central HTA body to assist it. This HTA body can instigate its own assessments, although since many of its recommendations

³⁸ Abel-Smith and Mossialos, *Cost Containment and Healthcare Reform*. (Elsevier Science B.V, 1994). See <http://www.sciencedirect.com/science/article/B6V8X-4BX36R6-2N/2/e07bb40d0fe8d686339f0f8f85b83106> (Accessed on 09 Feb. 09)

are intended to advise the G-BA on policymaking, it will rely on the G-BA for direction. It is also important to note that pharmaceuticals are mostly covered by social health insurance schemes once they receive market authorisation.

The influence over the healthcare system that is exerted by the BMG is also supported by the central HTA, as well as a separate HTA body. The German Bundestag also conducts its scrutiny and legislative role with the assistance of another separate HTA body. Overall, the government funds 76.9% of all healthcare expenditure in Germany and governmental healthcare spending stands at 10.6% of GDP (a 76.6% increase from 1970)³⁹.

HTA Agencies

Institute for Quality and Efficiency in Healthcare

G-BA decisions on the reimbursement of healthcare rely on the evidence provided to them by the Institute for Quality and Efficiency in Healthcare (IQWiG), created in 2004 as part of the Healthcare Reform as an institution of the Foundation for Quality and Efficiency in Healthcare. IQWiG is financed by a levy on inpatient and outpatient healthcare services, which are mainly reimbursed by SHI funds.

German Agency for Health Technology Assessment

The German Institute of Medical Documentation and Information (DIMDI), an institute of the BMG, was established in 1969 to provide information in life sciences to the German public. In 2000, the DIMDI established the German Agency for Health Technology Assessment (DAHTA@DIMDI) to specifically evaluate medical procedures and technologies. DAHTA@DIMDI reports are aimed at supporting all healthcare decision makers in Germany and it also commissions HTA work to IQWiG.

DAHTA@DIMDI is supported by a board of trustees, whose members are appointed by the BMG. This board, comprising of representatives from 18 different healthcare bodies, advises DAHTA@DIMDI on which new and existing technologies,

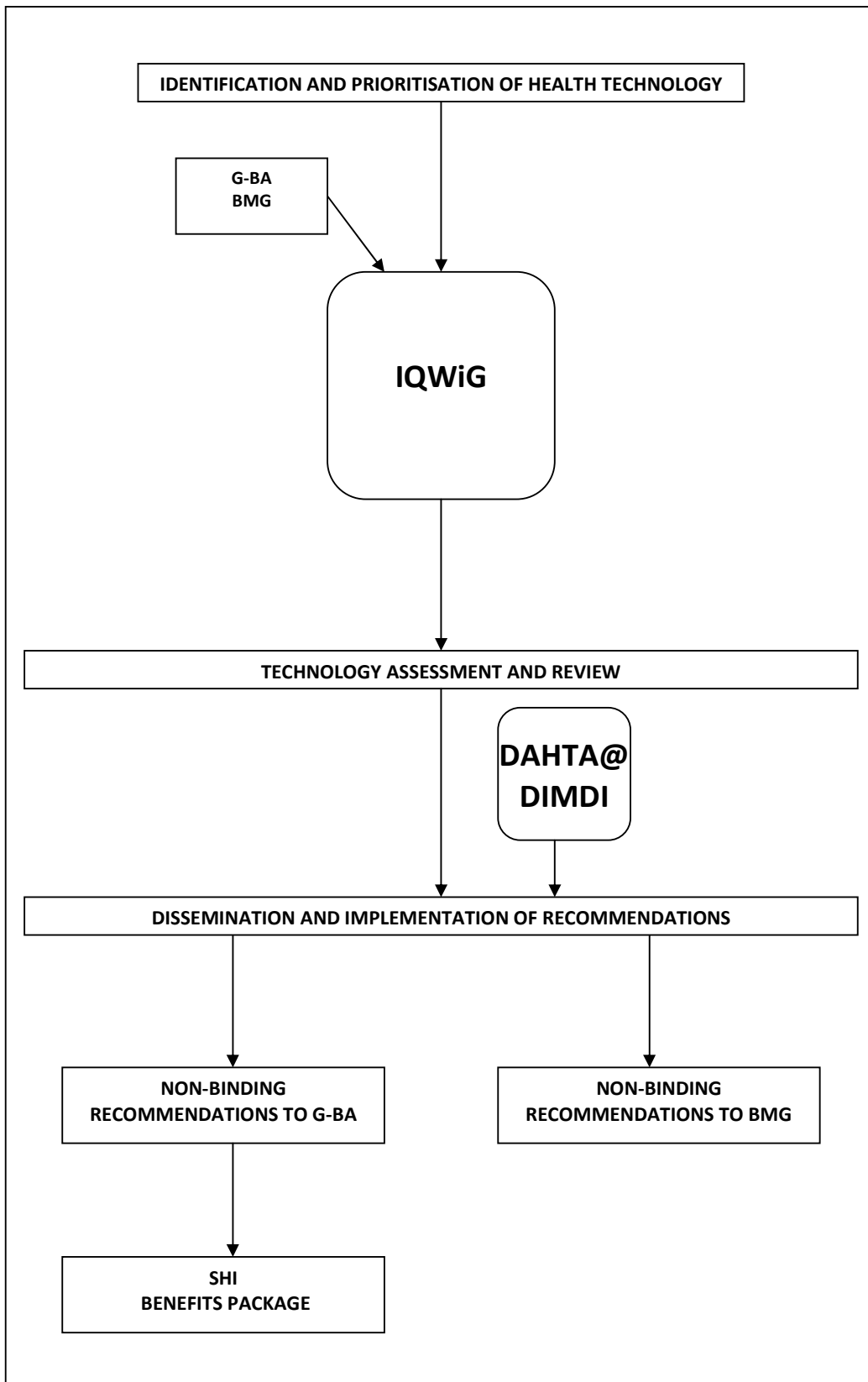
³⁹ OECD Health Data 2008, *op. cit*

submitted by a public open identification process, should be put forward for the production of a HTA report. DAHTA@DIMDI is also supported by a scientific advisory board, which comprises of representatives of the G-BA, the Association of the Scientific Medical Societies in Germany, as well as scientists of various disciplines, and counsels on scientific questions regarding methods and standards for the preparation of HTA reports, as well as reviewing the reports themselves.

Office of Technology Assessment

The German Bundestag also has a body that assists its policymaking relating to research and technology, namely the Office of Technology Assessment (TAB), created in 1990. TAB is operated by the Institute for Technology Assessment and Systems Analysis at the Karlsruhe Research Centre and its work is strictly oriented towards the information needs of the German Bundestag and its committees. The committee with the greatest interest in TAB's work is the Committee on Education, Research and Technology Assessment, which is made up of different parliamentary political groups and decides on the technologies that should be assessed. The scientific authority of the reports is the responsibility of the TAB's director.

The primary objective of TAB is not to provide early warning of technology-related risks, but rather to weigh opportunities and risks and to highlight possibilities for shaping new technological developments and their framework conditions.



HTA Process

Identification and prioritisation of technologies

Health technologies are commissioned to IQWiG by either the G-BA or the BMG, with IQWiG able to reject requests by the BMG as unfounded unless they fund the work themselves. IQWiG also undertakes projects and research work that is relevant for the healthcare system on its own initiative.

Health technologies are identified for DAHTA@DIMDI publicly, with anyone able to propose suggestions. The board of trustees then prioritises these suggestions. TAB technologies derive from suggestions made by the Bundestag.

Technology assessment and review

IQWiG assessments are performed by an internal project group and a project manager is appointed. The assessment process results initially in the creation of a preliminary report plan, outlining the specific research questions and scientific methodology of the assessment, and then in the creation of a preliminary report, which highlights initial recommendations based on the research. Both these reports are produced in consultation with external professional experts, individual affected persons or parties and relevant patient organisations. Both are also approved by IQWiG's Steering Committee and forwarded to the contracting agency, the Foundation's Board of Trustees and Board of Directors, as well as published on the IQWiG website. After the publication of these reports, the public are given four weeks to submit written comments and sometimes a scientific debate may be held.

Dissemination and implementation of recommendations

The final report is then produced, under the responsibility of the IQWiG project group, usually involving external experts. This report must also be approved by IQWiG's Steering Committee, and forwarded to the contracting agency and the Foundation's Board of Trustees and Board of Directors. If, after publishing the final report on their website, IQWiG receive comments that contain substantial evidence not considered, they will review the information and decide if a new commission on the topic is necessary or not.

In addition to these reports, IQWiG also produces a number of “rapid reports” that aim to provide information at short notice on relevant healthcare developments. These types of reports will often be on new technologies, but also on research questions that are not targeted at supporting decisions on directives of the G-BA. The process of producing rapid reports is shorter than ordinary reports because they do not create a report plan or a preliminary report, and no hearings are performed. The length of time required to produce these types of reports can be as little as two months.⁴⁰

TAB findings are made available through TAB working reports and final reports are published as printed papers of the Bundestag. Since 1996, final reports have also appeared in *Studies by the Office of Technology Assessment at the German Bundestag*.

Analysing the HTA system

Policymaking

German healthcare is mostly centralised, with decision making performed by the G-BA and, reflecting this, there is a central HTA agency in IQWiG that performs most of the advisory responsibilities for G-BA. There are also other central actors in healthcare, including the BMG and Bundestag, which capitalise on recommendations made by central HTA agencies.

Competence

Recommendations made by the central HTA agencies are offered to the relevant decision makers and are not binding on the decisions made relating to the allocation of health technologies.

Accessibility:

IQWiG operates a relatively closed process for identifying health technologies, with assessments triggered by recommendations from the BMG or the G-BA. However,

⁴⁰ For example, *IQWiG Vakuumversiegelungstherapie von Wunden*. See http://www.iqwig.de/download/N06-02_Rapid_Report_Vakuumversiegelungstherapie_von_Wunden.pdf (Accessed on 05 Feb. 09)

since 2004, IQWiG can initiate assessments itself and so there is potential for a more open system.

Functionality

German HTA agencies receive favourable levels of funding of \$19.3m⁴¹ per year and as a result IQWiG employs around 92 permanent staff⁴², which is relatively large. Assessments at IQWiG can take on average between 2-28 months. The agency also performs more assessments than most, with around 29 assessments per year⁴³.

Perception

IQWiG is known for its advisory role to the public and in particular its director is often quoted in the media⁴⁴. Much of the media interest tends to centre on new studies or reports that have been instigated by the body^{45,46}. However, public awareness of HTA in Germany is still low.

⁴¹ IQWiG in Numbers 2008. See http://www.iqwig.de/download/IQWiG_in_numbers_2004_2008.pdf (Accessed on 04 Feb. 09)

⁴² IQWiG Annual Report 2007 - *Jahresbericht 2007* (p34-40). See http://www.iqwig.de/download/jahresbericht_2007.pdf (Accessed on 04 Feb. 09)

⁴³ IQWiG in Numbers 2008. See http://www.iqwig.de/download/IQWiG_in_numbers_2004_2008.pdf (Accessed on 04 Feb. 09)

⁴⁴ *Der Tagesspiegel* – "Verhältnismäßig gesund". See <http://www.tagesspiegel.de/magazin/wissen/art304,2462995> (Accessed on 07 May 09)

⁴⁵ *Bild* – "Deutsche Ärzte und Kliniken sind viel besser als ihr Ruf". See <http://www.bild.de/BTO/tipps-trends/gesund-fit/topthemen/2006/gesundheit/bestnoten/ar-bestnoten.html> (Accessed on 05 May 09)

⁴⁶ *Der Spiegel* – "Alarm und Fehlalarm". See <http://wissen.spiegel.de/wissen/dokument/51/19/dokument.html?titel=Alarm+und+Fehlalarm&id=65089115&top=SPIEGEL&suchbegriff=iqwig&quellen=&qcrubrik=artikel> (Accessed on 05 May 09)

United Kingdom

Overview

The National Health Service (NHS) was founded in the United Kingdom in 1948 and quickly became the main funder of most healthcare services. Fundamentally, the NHS is a tax-financed organisation, with access to services available universally and free of charge at the point of entry. Most hospitals in the UK are state-owned and funds are allocated through a top-down process with central government determining the budgets of the primary care trusts (PCTs) which provide healthcare services⁴⁷. The main exception to this centralised process results from national devolution within the countries of the United Kingdom, which from the late 1990s onwards has seen separate healthcare bodies established in Scotland (NHS Scotland) and Wales (NHS Wales). A variation exists in independence between these two bodies, with the Scottish model having a far greater deal of autonomy through NHS Quality Improvement Scotland (NHS QIS), and with Scotland having its own Health and Community Care department. However, Wales does have its own HTA agency that advises the Welsh Assembly on its strategic healthcare planning, however its assessments are subordinate to those of NICE.

The United Kingdom is unique in that the recommendations offered by the central HTA agency directly influence health providers in the NHS. As such, when the central HTA body provides a set of “guidance” directly to providers in the NHS, it is deemed that this constitutes national policy and thus, any technology recommended by the central HTA agencies must legally be resourced and funded by the NHS provider.

This approach reflects the history of centralised decision making in healthcare in the UK in the post-war period, the only main exception being the existence of regional HTA agencies in Scotland and Wales which advise local healthcare policymakers. Overall, the government funds 87.3% of all healthcare expenditure in the UK and

⁴⁷ Department of Health - *Primary care trusts*. See <http://www.dh.gov.uk/en/Healthcare/Primarycare/Primarycaretrusts/index.htm> (Accessed on 05 May 09)

government healthcare spending stands at 8.4% of GDP (a 115.4% increase since 1960)⁴⁸.

HTA Agencies

National Institute for Health and Clinical Excellence

The National Institute for Health and Clinical Excellence (NICE) was originally established as the National Institute for Clinical Excellence, a Special Health Authority for England and Wales in 1999. A Special Health Authority is an independent NHS organisation that operates nationally, allowing NICE to fall under ministerial direction whilst also receiving supervision from the NICE board. The role of NICE is to produce guidance to the NHS on the use of selected new and existing health technologies. It does so after an appraisal of that technology through its Centre for Health Technology Evaluation. NICE does not approve all health technologies that are offered on the NHS, rather it provides assessments where there are different local prescribing or funding policies, or because there is confusion or uncertainty over a technology's value.

Scottish Medicines Consortium

The Scottish Medicines Consortium (SMC) was established to advise the NHS Scotland on the use of all newly licensed medicines, all new formulations of existing medicines and new indications for established products (licensed from January 2002). The SMC aims to be able to offer advice to NHS Scotland on all newly licensed medicines within 12 weeks of products being made available.

Membership of SMC is comprised of a variety of stakeholders and healthcare representatives, including two members from the Association of the British Pharmaceutical Industry (ABPI).

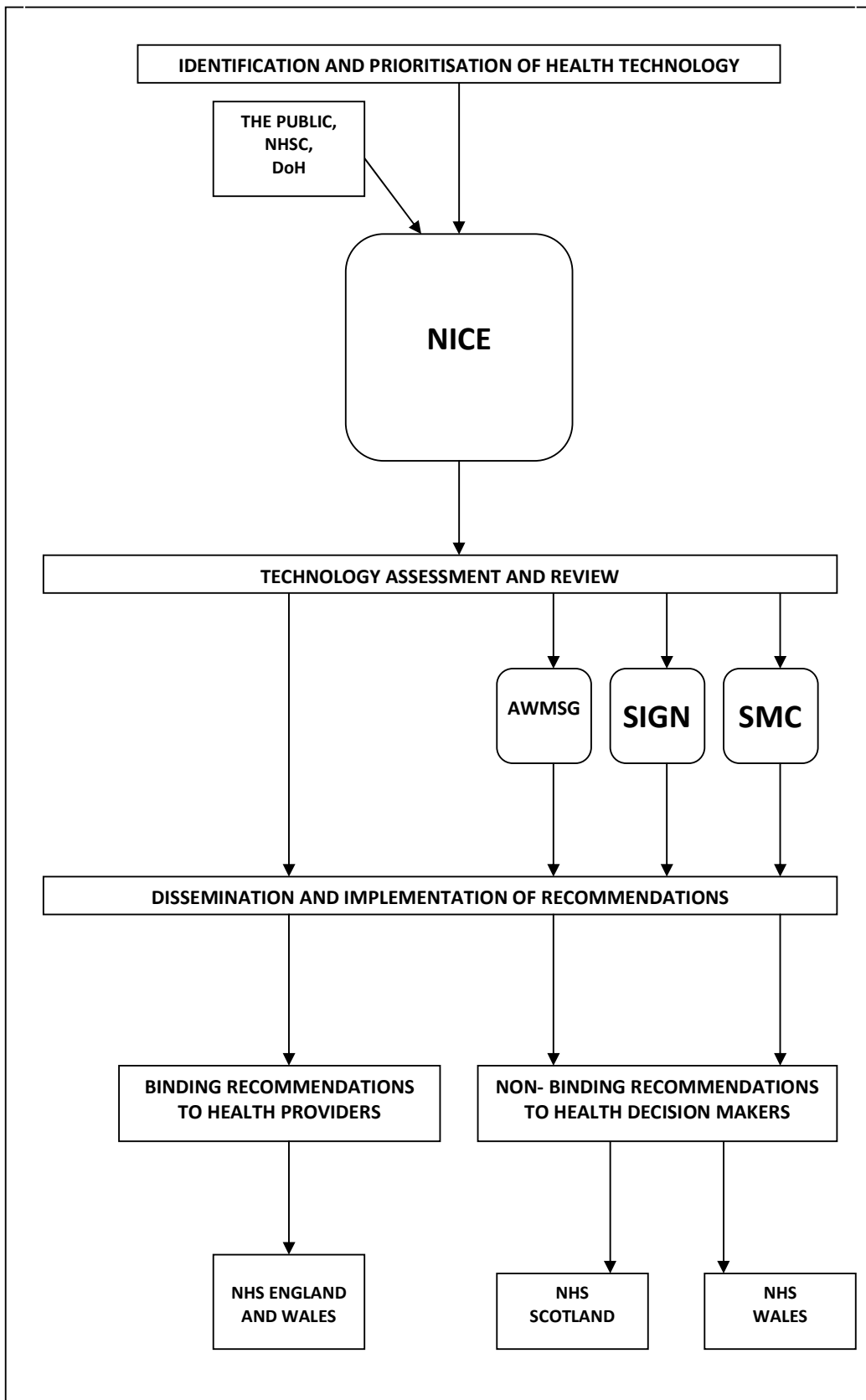
⁴⁸ OECD *Health Data 2008*, *op. cit*

Scottish Intercollegiate Guidelines Network

The Scottish Intercollegiate Guidelines Network (SIGN) was formed in 1993 to reduce variations in practice and outcomes for Scottish patients, by developing clinical guidelines containing recommendations for effective practice. These guidelines simply provide suggestions to local Scottish institutions, which are not compelled to follow SIGN's suggestions.

All Wales Medicines Strategy Group

The All Wales Medicines Strategy Group (AWMSG) was created in 2002 and provides advice on the management prescribing of medicines to the National Assembly for Wales' Minister for Health and Social Services, which now manages NHS Wales.



HTA Process

Identification and prioritisation of technologies

In early 2006, the Department of Health (DH) held a consultation which proposed that NICE should take responsibility for the management of the topic selection process, rather than the previous identification process that took place outside of NICE⁴⁹. In line with this consultation, it was outlined who could identify new and existing technologies and how these technologies would be prioritised to eventually become assessed by NICE.

Accordingly, it was established for the first time that anybody can suggest topics to NICE, in addition to the National Horizon Scanning Centre (NHSC) that regularly provides topic suggestions. The proposals submitted are assessed by NICE, who remove any that does not fulfil their remit and any that are inappropriate, based on a set of selection criteria set by the DH. NICE consideration panels, made up of health professionals and lay people, then prioritise topics and those chosen are then reviewed by a joint DH/NICE group, which draw up a priority list. DH ministers then make a final decision based on the topics submitted to it, which are then referred to NICE for assessment⁵⁰.

In Scotland, new and existing technologies can be proposed to SIGN by any group or individual, but submissions are only deemed suitable if there is evidence that a variation exists in practice, if there is a strong research base providing evidence of effective practice, and if the potential benefit to patients is sufficient to justify the resources invested in the development and implementation of a guideline.

At the SMC, the manufacturers of new pharmaceuticals must complete a New Product Assessment form that forms the basis of the assessment which advises whether a medicine should be used or not in the NHS Scotland.

⁴⁹ House of Commons Hansard Written Answers for 2 Dec 2005 (pt 12). See <http://www.publications.parliament.uk/pa/cm200506/cmhansrd/vo051202/text/51202w12.htm> (Accessed on 08 Jan. 09)

⁵⁰ NICE - *Frequently asked questions (FAQs) about topic selection*. See <http://www.nice.org.uk/media/49F/20/FAQsaboutTopicSelectionJan07.pdf> (Accessed on 05 May 09)

AWMSG conducts horizon-scanning in Wales to identify new medicines on an ongoing basis. It also invites pharmaceutical companies to make pre-marketing submissions to AWMSG for consideration. The AWMSG Steering Committee, which consists of Welsh Assembly representatives, Welsh Medicines Partnership representatives and the Chairman of AWMSG, then prioritises the technologies. It is important to note that AWMSG will not normally consider assessing a technology if NICE intends to evaluate the same technology within an 18 month period.

Technology assessment and review

Topics for assessment are referred to NICE in clusters, known as waves. Once a wave has been referred, NICE finalises a list of relevant people who are invited to consult (consultees) and commentate (commentators) on each assessment. The consultees are organisations invited to participate at most stages of the assessment and include the manufacturers of the technology, professional and patient bodies, and relevant NHS organisations. Commentators engage in the process but are not asked to prepare a submission dossier, and are involved only near the end of assessment, without a right of appeal. Commentators include manufacturers of comparator technologies and NHS QIS.

Each assessment is then assigned an assessment group, which is an independent academic team that is commissioned by the HTA Programme at the National Institute for Health Research (HTA Programme). Members of the assessment group come from one of seven academic centres based at universities in the UK. In addition to the assessment group, the Institute also outlines a programme director, a project manager; a technical lead, an executive lead, and a communications lead from within its own institute. An assessment is then undertaken, drawing from a variety of sources including the manufacturers and sponsors of the technology.

An assessment report is then produced by the assessment group, though this report does propose recommendations on the use of the technology for the NHS, as this is performed by NICE. Once NICE has received the assessment report they send it to the consultees and commentators who have 20 working days to review the report. The NICE Appraisal Committee, a standing advisory committee, then reviews all the

evidence. Members of NICE Appraisal Committees are appointed for a three year term and are drawn from the NHS, patient organisations, academia and the pharmaceutical and medical devices industries.

The result of this review is the creation of the appraisal consultation document (ACD), which summarises the evidence and views that have been considered by the Appraisal Committee and sets out preliminary recommendations. The ACD does not constitute NICE's final guidance for a technology, as recommendations made are provisional and may change in response to a further four week consultation. The Appraisal Committee meets again and begins to develop the Final Appraisal Determination (FAD), which is drafted by the project team and, after approval by a Guidance Executive, is distributed and posted onto the NICE website. Consultants then have 15 working days to appeal, but if there is no appeal or if an appeal is dismissed, NICE produce their guidance, which is published on the fourth Wednesday of each month, including a lay version, on NICE's website.

An SMC working group of health professionals, called the New Drugs Committee (NDC), uses available information to conduct rapid assessments of the evidence. The NDC offers recommendation to the SMC based upon the cost and benefits of using the medicine in Scotland. SMC advice is then made based on these recommendations.

SIGN assessments are performed by multidisciplinary working groups that are representative of the whole of Scotland, with member organisations of the SIGN Council consulting on the selection of assessment groups. SIGN guidelines are created after the assessment. Each guideline is graded, in order to highlight the strength of the supporting evidence, and a national open meeting is held to discuss each SIGN guideline in draft form, meetings are widely publicised and open to all. Guidelines are also independently reviewed by specialist referees prior to publication. Three years after publication the guideline is formally considered for review and is updated where necessary to take account of newly published evidence.

In Wales, key evidence, in addition to clinical and economic information submitted by pharmaceutical companies, is considered when performing an assessment. The New Medicines Group (NMG) of AWNSG provides a preliminary recommendation that is considered, along with responses from the pharmaceutical company, opinions of medical experts, and the perspective of patients. A final recommendation is then agreed by AWNSG.

Dissemination and implementation of recommendations

NICE guidance indicates a date on which a review will be made, which monitors its implementation. This review date varies depending on the anticipated rate of development in the evidence for the technology. NICE guidance is then considered national policy, with health professionals expected to take it into account, along with their legal and ethical duty to act in the best interests of their patients⁵¹.

Recommendations by SMC are offered to NHS Scotland and it is outlined that NHS Scotland should “take account of the advice and evidence from the SMC and ensure that recommended medicines are made available to meet clinical need”⁵².

There has been extensive work performed to ensure that there is as little duplication between the assessments of the SIGN and SMC as possible⁵³. From 2002 and 2007, SIGN had provided specific recommendations on a total of 57 individual medicines, whereas the SMC had issued advice on over 400. From these assessments there were ten occasions where recommendations from SIGN and SMC had been for the same medicine and on one occasion the recommendations made had been conflicting.

AWNSG recommendations are submitted to the Scottish Minister for Health and Social Services, who decides whether it should be ratified or not. Once endorsed, NHS Wales local health boards and trusts are expected to follow the recommendations from AWMSG within three months. If NICE guidance is issued on

⁵¹ National Prescribing Centre - *MeReC Bulletin*. See http://www.npc.co.uk/MeReC_Bulletins/2006Volumes/Vol16_No2.pdf (Accessed on 05 Feb. 09)

⁵² Scottish Medicines Consortium – FAQs. See <http://www.scottishmedicines.org.uk/smc/25.html> (Accessed on 20 May 09)

⁵³ Scottish Medicines Consortium (2007) - *Consistent SIGN and SMC Advice on New Medicines for NHS Scotland*. See <http://www.scottishmedicines.org.uk/smc/files/FINAL%20SIGN-SMC%20advice%2024907.pdf> (Accessed on 20 May 09)

a technology after AWMSG guidance has been set, the recommendations from NICE take precedence.

Analysing the HTA system

Policymaking

Centralisation has always been a key facet of healthcare coverage in the United Kingdom, ever since the creation of the NHS in 1948. However, recent devolution has allowed the system to become slightly more fragmented, by moving some healthcare decision making to Scotland and Wales. The relationship between these bodies is mixed and they mostly complement each other well, however there are a few of examples of conflicting healthcare recommendations, for example the decision by the SMC to approve sight-saving drugs that have been rejected by NICE⁵⁴.

Competence

NICE is by far the most influential body in regards to the recommendations it offers, as it has the ability to provide binding recommendations that NHS providers are obliged to follow. Importantly, this puts NICE in the position of being the key decision maker on behalf of the Secretary of State for Health in regards to health technologies in the NHS. The Scottish bodies are not as powerful in Scotland as NICE is in England and Wales, and NHS Boards and their Area Drug and Therapeutics Committees possess the decision making capacity.

Accessibility

New laws have been enacted to attempt to make the process of identifying and prioritising new and existing technologies in England and Wales more open. Where previously the process relied on the suggestion of topics from the minister based on a variety of committees, now a means of open submission is in place. However, the process ends with a decision by the Minister of Health who ultimately decides the technologies that are going to be assessed. In Scotland, SIGN allows for open

⁵⁴ Royal National Institute of Blind People (RNIB) - *RNIB accuses NICE of incompetence - risking blindness for 10,000 people* (08/08/07). See http://www.rnib.org.uk/xpedio/groups/public/documents/publicwebsite/public_pr080807.hcsp (Accessed on 20 May 09)

submissions, whilst SMC concern itself with all new medicines that are licensed for use in Scotland.

Functionality

NICE is the most highly-funded agency receiving \$48.6m⁵⁵ and, consequently, is also the biggest agency in the study, with over 270 permanent staff⁵⁶. However, the length of assessment by NICE on average seem to be longer than those of other agencies, with many assessments taking up to two years to be performed. However, NICE and DH have acknowledged this and new measures have recently been approved to shorten this length of time to no more than six months, as part of a recent reform to prevent private top-up payments from affecting a patient's entitlement to public healthcare⁵⁷. NICE completes around 44 assessments per year⁵⁸.

Perception

NICE's central role in UK healthcare policymaking is shown by the high-profile public reputation that it has and, subsequently, in the level of critical media coverage which guidance from NICE often receive. In particular, various articles have focused specifically on NICE and some have even questioned its existence. "Arrogant, illogical and totally out of touch, NICE must be scrapped...it's killing too many people"⁵⁹, "NICE decisions on drugs are flawed and tossing a coin is fairer, says academic"⁶⁰, "Charities lobby NICE over cancer drug"⁶¹, and "Cancer patients sentenced to an early death by bureaucrats"⁶² are just some examples of the intensity that media coverage has generated and the extent to which the public have become familiar with NICE's role.

⁵⁵ NICE Annual Report 2007/08. See <http://www.nice.org.uk/media/B60/8A/AnnualReport200708Volume1.pdf> (Accessed on 04 Feb. 09)

⁵⁶ NICE Annual Report 2007/08

⁵⁷ United Kingdom Parliament – MPs publish NHS top-up fees report (12/05/09). See <http://news.parliament.uk/2009/05/mps-publish-nhs-top-up-fees-report/> (Accessed on 20 May 09)

⁵⁸ Department of Health - NICE 18th, 19th, 20th Wave. See

http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_083774, http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_087104, http://www.dh.gov.uk/en/Healthcare/Medicinespharmacyandindustry/Prescriptions/DH_091238. (Accessed on 05 Feb. 09)

⁵⁹ Daily Mail – 12/08/08. See <http://www.dailymail.co.uk/news/article-1043688/Arrogant-illogical-totally-touch-NICE-scrapped-killing-people.html> (Accessed on 12 Jan. 09)

⁶⁰ Daily Telegraph – 28/10/08. See <http://www.telegraph.co.uk/health/3248107/Nice-decisions-on-drugs-are-flawed-and-tossing-a-coin-is-fairer-says-academic.html> (Accessed on 12 Jan. 09)

⁶¹ The Guardian – 29/10/08. See <http://www.guardian.co.uk/society/2008/oct/29/health-nhs> (Accessed on 12 Jan. 09)

⁶² The Times – 09/11/08. See http://www.timesonline.co.uk/tol/life_and_style/health/article5088756.ece (Accessed on 12 Jan. 09)

Conclusion and Policy Considerations

Comparative study allows for the understanding of different practices of HTA that could contribute towards promoting a “gold standard” for conducting HTA. Yet, this paper identified at the outset that there is not a single model for a Health Technology Assessment system, but rather a number of different procedures that attempt to serve the same purpose. Looking at four key countries which are established at performing HTA highlights the diverse systems that currently exist. Like it or not, as long as health systems continue to rely heavily on taxpayer funding then HTA is here to stay. Constructive studies should therefore focus on ensuring that HTA bodies function so that they are able to keep pace with medical innovation, as well as making difficult decisions about access to medicines for systems where resources are inevitably limited.

This study has shown that the rationale for HTA and the overall process used to conduct it in the four countries covered show a wide degree of consensus. Yet the countries begin to differ more prominently when looking at their individual systems of HTA in detail, reflecting as they do the values and funding of the wider healthcare system within which the HTA agencies perform. Therefore, as healthcare services continue to be provided in a variety of ways so too will HTA. There are a number of operational comments that can be made about the way in which HTA is conducted in the four countries studied, however, some criticisms that are made against particular HTA decisions can be more appropriately aimed at the national health system of a particular country rather than the HTA body *per se*.

To give an example we may consider the recent “top-up” debate which has caused some controversy in the United Kingdom and has led to a significant amount of criticism aimed at NICE. The “top up” debate opposed the practice that was happening in the NHS, which was denying patients who were paying for their own medicines privately (usually for cancer) from having access to publicly-funded care for the same illness. In this debate, NICE was seen as depriving patients of life-saving drugs as their decision to place a health technology on a negative list was directly prohibiting patients from having those treatments. However, in this example, and

indeed many similar examples, the problem stems mostly from the healthcare system itself and, in this case, the NHS's inability to accommodate a topping-up system. It is very often the case that a healthcare technology assessment body is only as good as its governing healthcare system.

Although this may be true, there are certainly a number of lessons that can be learnt about the conduct of HTA and in particular this study identifies certain “virtues” that a health technology assessment body should work towards, regardless of the health system that it performs within.

One such “virtue” is flexibility and the ability to appreciate local needs and individual concerns. Whilst some can see a particular benefit from having an uncompromising system that focuses on a rigid idea of cost-effectiveness, it is valuable for a system to be able to shape its recommendations around the needs of the population. The notion of a negative list, which many systems use, provides an indication of how inflexible these systems can be. It would be much more useful if HTA recommendations were used as a basis for trying to find ways of providing more expensive treatments. Rather than a HTA agency declaring that “this treatment is not cost-effective”, it would be better if it said “this treatment would be cost effective if...” and outlined circumstances where a technology could be allocated. Indeed, this allows for more flexible reimbursement arrangements which could detail that technologies could be allocated only to certain groups or only in certain circumstances. Furthermore, national health systems need to be able to offer patients a variety of means of paying for healthcare treatments. If a system is structured so that some patients can top-up their care, or if there is a helpful co-payments system, then the recommendations made by HTA agencies will not necessarily end in denial of treatment for patients.

HTA systems should also focus on becoming as accessible as possible, allowing their decisions and decision-making processes to be open for all to see. Transparency does not just provide the reassurance that a decision has been reached fairly and sensibly, it also allows for a more comprehensive and effective recommendation. By including health professionals, industry representations, lay people and patient

groups, an agency can ensure that the assessments it makes are relevant and will guarantee a smoother rolling out of its recommendations.

Finally, it needs to be kept in mind that HTA systems form part of the wider health system they conduct their assessments within. In other words, one cannot look at the HTA system (or its decisions) as being isolated from the overall health system in a given country. Accordingly, the policy actions and budgetary decisions that take place in the wider context of the national health system are likely to have a significant effect on the manner in which HTA decisions affect the ability of patients to gain access to new healthcare technologies. Decisions-makers and politicians cannot just hide under the "scientific veil" of HTA bodies. Rather both politicians and the public need to examine the HTA system with a more critical eye – to endorse its main points of strength but also to identify its limitations and weaknesses and to address them accordingly.

Health economics is having its moment in the sun and the expansion of HTA looks set to continue. In the absence of much greater pots of funding for healthcare or significant funding reforms – even more unlikely in the current economic climate – we are likely to see a further expansion of HTA in the future and a greater focus on companies being asked to prove their medicines are "worth it".

This will provide scant comfort to patients waiting on HTA decisions about new medicines and treatments for their conditions. But pressing for greater efficiency, more transparency and a mechanism for extending patient choice in self-funding when HTA bodies say "no", may be the least bad option in a highly pragmatic world of finite healthcare resources. In the meantime, we can but dream of a world in which we are able to look towards investing in the value of healthcare more broadly.

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Australia

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