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## **A model for best practice HTA**

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## **Abstract**

The aims of this paper are: to review and describe different approaches to HTA used in Australia and in other countries and to identify the features of best practice in HTA, particularly those likely to be most relevant to HTA at a local (ie state/regional) level.

There are a number of well-developed models of HTA at the national and local levels. Most information about the operation of these models, particularly about the type and number of evaluations conducted, the recommendations/decisions made and the reasons for these is available for national processes, but there is much less readily available documentation about local level HTA. Most HTA processes that operate nationally and internationally can be categorised in one of three ways: guidance (provides structured information about appropriate technologies), mandatory (provides mandatory information about technologies to be implemented) and funding and implementation (provides structured evidence-based advice about which technologies should be implemented, the level of funding required to implement them and the source of these funds).

The main factors which distinguish a high quality HTA process are that i) it is efficient in terms of setting priorities, the scope of the technologies to be assessed, avoidance of duplication and overall cost of the process, ii) the overall impact on utilisation and health budget is calculated as part of the HTA and iii) procedural justice occurs and is seen to occur; iv) it includes a comprehensive assessment of the impact on issues such as workforce, credentialing of providers and the ethical dimension of the technology; v) it influences decision making by being communicated appropriately and using trusted methods; vi) it influences adoption and diffusion of technology by ensuring that there is no diffusion prior to HTA, the results are incorporated into guidelines or recommendations, funding is linked to the decision, and remuneration arrangements and other characteristics of the HS facilitate the appropriate adoption and diffusion and vii) it influences health outcomes/efficiency/equity by ensuring that the methods and/or results are available and able to be used at a local level.

Firm recommendations for an ideal system for HTA at the local level are not possible as much of the necessary information and evidence is not available about the strengths and weaknesses of HTA practices and processes currently in use. However, it is likely that the operation of a successful model of HTA at a local level would require the development of a central organizational unit, a process for implementing the results of HTA and, crucially, the building of capacity to support both types of activities. Additional expertise and skills will be required for both providers of HTA evaluations and for the commissioners and users of HTA.

## **Introduction**

The challenge for health technology assessment (HTA) is to create policies that harness the benefits of technology and innovation while not encouraging the use of interventions for which the additional benefits are not worth their costs. The balance of benefits and costs has to be attained within a health system which has multiple objectives and complex funding and financing arrangements, where consumers do not face the full costs of services. Health technologies are considered by many to be a key driver of increasing health care costs in developed countries. HTA is broad in both its methods and applications. It can encompass assessments of safety, efficacy, effectiveness, cost, cost-effectiveness, as well as organisational, social, ethical and legal implications and be applied to drugs, devices, procedures and the organisational and support systems within which health care and health services are delivered (Busse, Orvain et al. 2002); it can encompass existing as well as new or emerging technologies.

HTA relies on the available research evidence. While it may develop new syntheses, including new decision analytic models, it does not conventionally include the generation of new primary research in the form of clinical trials or other studies. The purpose of HTA is to enhance efficient health care resource allocation, so the assessment of best practice in HTA must consider the impact of the process on subsequent technology diffusion.

HTA methods have been developed over a considerable period of time. In its earliest phase, many assessments were largely an academic exercise with outputs measured in journal publications. More recently, incentives for HTA evidence in policy formulation, particularly funding reimbursement, have been introduced. In most countries, these have taken the form of a regulatory hurdle, i.e. regulation has required the assessment of safety, effectiveness and cost-effectiveness as a precursor to marketing or funding approval.

Cost-effectiveness and other economic evaluation techniques address the question of efficient allocation of resources within a budget constraint. However, in most centralized approaches to HTA the budget constraint is not evident, so that it is not clear what alternative use of resources, and resulting health gains, will be foregone. Consequently, HTA evaluators and decision makers have tended to rely on an implicit shadow price; for example, interventions that have an incremental cost-effectiveness ratio (ICER) of \$70,000 per QALY or less may be seen as a good buy. It should also be noted that the use of a shadow price may or may not be explicit in the decision making process.

At a local level where budgets are defined, the opportunity cost should be clearer. This provides both an incentive and a disincentive for HTA. The incentive is that as the opportunity cost is explicit, and the budget constraint more binding, the gain in efficiency by applying HTA should be greater. The disincentive is that although the budget constraint is clear, the application of the technology is set within a context where differences in patient characteristics, disease severity, and the extent of uncertainty, lessen the precision of any ICER. At the same time, individual opinion leaders can be expected to hold greater sway, and there are peer pressures to ensure co-operative behaviour, particularly where authority and command structures are not defined. For these reasons, it is not surprising that HTA has proved more difficult to establish at local levels and may be less influential in decisions even when it has taken place.

Much of the international literature published on HTA is focussed at a national level (Lehoux, Denis et al. 2005);(Medical Services Advisory Committee 2005); (Organisation for Economic Co-operation and Development. 2005). It is much less clear how HTA could be operationalised at a more local level. The aims of this paper are: to review and describe different approaches to Health Technology Assessment (HTA) used in Australia and in other countries (section 2); to identify the features of best practice in HTA (section 3); and to use the evidence so generated to outline a model which is relevant to more local jurisdictions which

have responsibility for the delivery of health services in Australia such as state health systems, area/regional health services or hospital networks (section 4).

### **Overview of current HTA processes**

The best known HTA processes are those which are co-ordinated at a national level, often linked to national funding programs, and often widely promoted as exemplars by those involved. These include the National Institute for Health and Clinical Excellence (NICE) in England and Wales, the Canadian Agency for Drugs and Technologies in Health (CADTH) and New Zealand's PHARMAC, plus in Australia, the Pharmaceutical Benefits Advisory Committee (PBAC) and the Medical Services Advisory Committee (MSAC).

In a number of other countries with more fragmented funding programs, such as Canada, Spain and the United States, health technology assessment is undertaken at the funding agency level which might be a state/provincial health authority or a health insurer level. (Perry and Thamer 1997; The Canadian Agency for Drugs and Technologies in Health (CADTH) 2007) Canada has an extensive network of federal and regional organisations including nine major agencies/units. Spain has six regional agencies and in 1997 53 HTA agencies were operating in the United States (Perry and Thamer 1997).

Table 1 provides a summary of HTA processes in use at the national level in Australia (Australian Government. Department of Health and Ageing 2006); (Medical Services Advisory Committee 2005) and Canada (Canadian Agency for Drugs and Technologies in Health 2006); (The Canadian Agency for Drugs and Technologies in Health (CADTH) 2007), at the provincial level in one Canadian province, Ontario (Ontario Ministry of Health and Long-Term Care 2007) and one Australian State, Victoria (Victorian Department of Human Services 2006), and at a more local level in Sweden (Ostergotlund) (The Danish Centre for Evaluation and Health Technology Assessment 2005), Victoria (Southern Health Area, Melbourne) (Southern Health 2001) and New South Wales (New South Wales Health Department 2003).

Table 1 shows that there are a number of well-developed models of HTA at the national and local levels. Information about the operation of individuals models, particularly about the type and number of evaluations conducted, the recommendations/decisions made and the reasons for these is available for national processes, but there is much less readily available documentation about local level HTA. This limits the extent to which success and the features of best practice of HTA at a provincial or more local level can be judged. Nonetheless, it is likely that some features of best practice can be generalised to apply to local models. Further it seems that more consideration could be given to how national models can provide an information base for more local models, rather than categorising the two approaches as independent alternatives.

While HTA is broad in its scope, models vary across different HTA processes. While the most comprehensive cover all health services, many if not most models restrict their scope to procedures only, drugs only, or services requiring major capital items. In general, it seems that the approaches developed for drugs are more well-established and systematic than for other technologies. This is not surprising given the relatively simple nature of drugs (e.g. in terms of delivery and investigation of outcomes) compared to other technologies and the well developed and funded system of company-sponsored clinical trials which leads to more and better evidence being available for the HTA process.

Models also vary according to the process by which technologies are considered and prioritised for HTA. Some models are pro-active, determining priorities by a mix of seeking emerging issues and horizon scanning for new technologies; others are reactive and rely on submissions, often from interested parties.

All the models of HTA described in Table 1 except that in use in Ontario, Canada, were limited to the synthesis of existing evidence, and were not set up to generate new evidence or to fund new research. Therefore, where the evidence is inconclusive, there is little available to influence the funding and conduct of new research beyond moral persuasion and wishing. This is a limitation of existing models. However, some models do allow for the implementation and

impact of their recommendations to be monitored. Further, for any specific technology/condition, there is generally limited research evidence, particularly published randomised controlled trials. As all models draw on the same evidence there may be inefficiencies in having the same HTA repeated a number of times in different countries and jurisdictions. Yet it is possible for different processes to result in different recommendations, in part because the context and current alternative can vary from setting to setting. For example, the recommendation in relation to Herceptin® for early stage breast cancer, differ considerably across different countries - it has been funded in Australia and rejected in New Zealand (Barrett, Roques et al. 2006); (Breast Cancer Network Australia 2007). The increasing formalisation of HTA sets up new pressures to introduce new technologies based on their adoption in other countries, as advocates question the need to repeat HTA analyses.

A lack of explicit budgetary constraints is a problem for all national processes. The use of a shadow price for a unit of health gain does not mean that this ratio of marginal benefit to marginal cost will be achieved in practice. Further, the use of one shadow price rests on a number of assumptions, most importantly, a constant and divisible marginal social value of a health gain. For the more local HTA processes a budgetary constraint is more likely to be explicit. But it is not clear that the models we have identified take these into account, and if so what type of economic analysis was most useful. Nor were we able to assess the extent to which decisions made as a result of HTA have been implemented.

This review suggests that three general categories can be used to describe most HTA processes that operate nationally and internationally. To a large extent, these can describe local area processes also. For example, although funding and implementation models are commonly conducted at a centralised level, they could also be adopted at a local level.

- **Guidance:** HTA may be conducted at a centralised or a relatively decentralised level in the system to provide structured evidence-based advice about which technologies are appropriate and should be implemented (and

may provide advice about technologies that should not be used or should be stopped). However in this model there is no explicit mechanism for the guidance to be implemented. The Common Drug Review in Canada is an example of this approach (The Canadian Agency for Drugs and Technologies in Health (CADTH) 2007); (Mitton, McMahon et al. 2006).

- **Mandatory:** HTA may be conducted at a centralised or decentralised level in the system to provide structured evidence-based advice about which technologies must be implemented (and may provide advice about which technologies must not be used). In this model the advice is mandatory – there is a requirement for health service managers to implement the decisions and for providers to abide by the guidance. However, there is no explicit flow of funds attached to the recommendations, and therefore no explicit assessment of the financial or health services utilisation impacts of the recommendations. In particular, this has implications for what activities must be forgone to implement new technologies when there is no additional funding to support the recommendation. NICE is an example of this approach (Raftery 2006).
- **Funding and implementation:** HTA is conducted at a centralised level in the system to provide structured evidence based advice about which technologies should be implemented, the level of funding required to implement them and the source of these funds. The implication of this model is that there is a direct link between the HTA process and the implementation, via an identified source of funds. Most often this explicitly recognises that implementation of new technologies is likely to be expansionary for the health budget. Ideally such a model should allow for assessment of the social costs and benefits of this increase in funding. PBAC and MSAC in Australia are examples of this approach (Australian Government. Department of Health and Ageing 2006); (Medical Services Advisory Committee 2005).

Clearly there are many variations to these three broad categories, and particular models adopted may not fit neatly into one category. For example, the funding mechanism may vary.

## Features of Best Practice in HTA

Table 2 identifies the features used to describe the different HTA processes and the means by which the quality of the process can be judged. This makes clear that there are certain aspects that are common across the various models of HTA and others that are unique to particular models.

The features of HTA which would guarantee a high quality process as well as ensuring that decisions made on the basis of the HTA process are as well-informed as possible are summarised in the Box.

### Box: Features of a high quality HTA process

- the process for conducting HTA is efficient in terms of setting priorities, the scope of the technologies to be assessed, avoidance of duplication and overall cost of the process;
- the overall impact on utilisation and health budget is calculated as part of the HTA;
- procedural justice occurs and is seen to occur as evidenced by:
  - Robustness in technical evaluation (free from political influence)  
Leverage/authoritative in health system/authority. (e.g. NICE)
  - Transparency
- it includes a comprehensive assessment of the impact on issues such as workforce, credentialing of providers and the ethical dimension of the technology;
- it influences decision making by being communicated appropriately and using trusted methods;
- it influences adoption and diffusion of technology by ensuring that there is no diffusion prior to HTA, the results are incorporated into guidelines or recommendations, funding is linked to the decision, and remuneration arrangements and other characteristics of the HS facilitate the appropriate adoption and diffusion; and
- it influences health outcomes/efficiency/equity by ensuring that the methods and/or results are available and able to be used at a local level.

### **A model of HTA relevant to local jurisdictions in Australia**

Firm recommendations for an ideal system for HTA at the local levels are not possible as much of the information and evidence is not available about the strengths and weaknesses of HTA practices and processes currently in use. However, it is likely that the operation of a successful model of HTA at local levels would require the development of both a central organizational unit and a process for implementing the results of HTA and, crucially, the building of capacity to support both types of activities. Additional expertise and skills will be required for both providers of HTA evaluations and for the commissioners and users of HTA.

The functions of a state/provincial-based unit would include building capacity in HTA, supporting local initiatives by providing access to high level expertise and coordinating current and future HTA activities at both provincial and local levels. Coordination would encompass a number of activities. First, it would be necessary to develop priorities for HTA, identify developing technologies and develop priorities for assessment and identification of technologies which are becoming ineffective and obsolete. This function would be strengthened by providing a capacity to generate or at least influence new research, so that the information base for HTA was improved. Second, it would be important to develop a process by which decisions are made about which technologies are best assessed at a state/provincial level and which should be undertaken at a more local level. Third, it would be essential to develop processes that are efficient (ie avoided duplication, set priorities that reflect the needs at both provincial and more local levels), ensure procedural justice in terms of undertaking or commissioning high quality, independent evaluations and enabling the decision making processes to be transparent and authoritative. Finally, the expertise available at this level would be needed to assist local decision makers to translate the results of national- or provincial-level assessments to the appropriate level. This means developing the means to take into account the impact of the introduction of a technology on the population of a particular

geographical area (given the health and socio-demographic characteristics of the population), its workforce and budget.

A successful HTA process must also include a well-developed implementation process. First, decisions about which technologies should be implemented must be linked to the level of the health system that holds the responsibility for the budget. Without the right incentives in place, the introduction of technologies will be patchy, possibly resulting in inequity. Second, incentives should be aimed at encouraging active participation in the process of HTA in such a way that emphasis is placed on the provision of evidence about the technology under review. This will ensure that the outcome of the HTA process overall is evidence about the efficient use of resources. Third, it must be recognized that successful implementation will not occur unless accompanied by additional funding. However, it may be possible to obtain some additional funds through the removal from use of ineffective or obsolete technologies. Finally, ineffective and/or obsolete technologies should be discontinued and this should be taken into account in the determination of budgets.

It is likely that some HTA will need to be undertaken at a local (ie local administrative or hospital) level. Although evidence about best practice in HTA at this level is limited, it is likely to be most useful when technologies are being considered which seem likely to have a differential impact depending on the characteristics of the population (and therefore likely to be more or less efficient in different localities), where there are major implications regarding workforce issues (eg availability of particular types of clinicians, or the need for credentialing) or where consideration is being given to the expansion of a technology from one level of the health services another (eg from a tertiary to a district hospital).

## **Conclusion**

HTA is relatively well-developed at a national level in Australia. However, given that most health care services are planned, funded and delivered at the provincial and more local levels, there is scope for the processes of HTA to be developed more fully at these levels, creating advantages beyond those produced by current national processes. A comprehensive assessment of the impact of the introduction of the technology would be possible, including estimation of the overall impact of the technology on utilisation and the health budget. Issues such as workforce, credentialing of providers and the ethical dimension of the technology would be able to be taken into account. Health outcomes, efficiency and equity would be positively influenced by ensuring that the methods and/or results were available and able to be used at a local level. Finally, the potential would be developed for the results of HTA undertaken at both levels to be fed into an “information loop”. If developed successfully and implemented in a rigorous fashion, such a loop would enable “good” variation in terms of patterns of practice to be distinguished from “bad” variation. For example, it should be possible to distinguish between inequitable levels of care occurring as a result of where an individual resides versus acceptable variation which occurs in response to individual or local circumstances.

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**Table 1 Summary of selected HTA processes at national, state/provincial and local levels**

	<b>Scope</b>	<b>HTA process</b>	<b>Outcomes</b>	<b>Limitations</b>
<b>National</b>				
NICE (UK)	All technologies	Work commissioned by Dept. of Health. Systematic review + economic analysis. Undertaken by independent advisory bodies. Ineffective practice review (under development)	Mandatory recommendations for adoption. Budgetary implications estimated.	No budgetary responsibility = no financial constraints. Regional inconsistencies persist
CADTH (Canada)	All technologies	Topics identified though horizon scanning + independent proposals. Topics prioritised bi-annually. Effectiveness, economic evaluation, implementation, policy & health services impact.	Recommendations in the form of advice.	No enforcement of recommendations. Participation in process by provinces is voluntary. No links to funding. No means of ensuring that findings inform provincial decisions.
PBAC (Australia)	Pharmaceuticals	Sponsor prepares application (following guidelines). Effectiveness, cost-effectiveness, clinical benefit, availability of alternative treatment. Applications independently reviewed.	Recommendations for listing on the schedule (PBS). Recommendations re indications. Other restrictions can be imposed.	Applications “commercial-in confidence” Brief statement of justification only Negotiations re price not part of the process Few restrictions on volume.
MSAC (Australia)	Medical processes, procedures	Sponsor prepares application (following guidelines). Safety, effectiveness, cost-effectiveness. Applications reviewed under direction of the committee.	Recommendations for listing on the schedule (MBS). May also reject, recommend public or interim funding Full report published Directly determines scheduled payments to medical practitioners. Indirectly determines payment for all procedure costs.	No independent review May use non-trial evidence Open-ended program Interim funding may discourage research on long-term outcomes.
<b>Provincial/State</b>				
OHTAC	Procedures,	Meets once a month	Preliminary assessment used to	Recommendations not mandatory

(Ontario, Canada)	devices, equipment	Topics proposed by any publicly funded health facility in Ontario. Topics prioritised using algorithm Preliminary assessment Full assessment by experts including industry. Efficacy, safety, effectiveness, cost-effectiveness, budget impact, workforce implications. May request additional data be collected via field evaluations.	make recommendation or request full assessment. Recommendations + full analysis posted on website Recommendations can be appealed	
VPACT (Victoria, Australia)	Procedures, devices, clinical practices	Meets up to 4 times/year Submission must be completed for each technology/practice for which funding is requested. Collaboration required for proposal involving same technology/practice Clinical experts &/or time-limited panels may be involved.	Details not publicly available.	Criteria used to make assessments not clear Outcomes & justification not available publicly Not clear whether its role is that of peek advisory body or body controlling introduction of technologies.
<b>Local</b>				
Ostergottlund, (Sweden)	All technologies except drugs	Methods Board Aims to identify & evaluate technologies important to local services, make decisions about introducing/repealing technologies.	Short summary report including recommendations to inform the decisions of the county council.	Role not clear Criteria used to make assessments not clear Outcomes & justification not publicly available.
Southern Health, (Melbourne, Australia)	all technologies except drugs	New Clinical Procedures Committee Aims to assess introduction of new technologies at all levels of system Staff trained to use technologies safely & to high standard Application prepared by senior clinician, approved by senior management, submitted to NCP Efficacy, safety, costs & benefits	First approval for 12 months Written report re experience & benefits of new technology	Not clear what range of technologies is considered Outcomes & justification not available publicly Not clear about outcomes once the written report is received.

New South Wales (Australia)	dissemination of new interventional procedures	No production of HTA evidence in the form of comparative assessment of safety, effectiveness and cost-effectiveness. Evaluations conducted elsewhere may be reported. Appraisal and decision making delegated to AHS level	No information available	Explicitly excludes interventions new to the State for which it is expected there will be a centralised process for determining safety, effectiveness and appropriateness (cost-effectiveness not explicitly discussed). Not clear what the centralised process is or whether it has been implemented
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**Table 2. Key attributes of HTA**

<b>Attribute</b>	<b>Description</b>	<b>Measures of best practice</b>
<b>HTA Priority Setting</b>	Who sets priorities for assessment?  What is the process for setting assessment priorities, including any horizon scanning	Short time between innovation and assessment  High impact technologies prioritised  Assessment conducted before adoption/diffusion
<b>HTA/Technology scope</b>	What types of technologies are assessed?	Broad definition of technology that includes: <ul style="list-style-type: none"> <li>• Old and new technologies,</li> <li>• All health related technologies (drugs, procedures, services)</li> <li>• Can be disease-based</li> </ul>

<b>HTA Production</b>	<p><b>Who does it?</b></p> <p><b>Who funds it?</b></p> <p><b>Timelines?</b></p>	<p><b>Assessment is:</b></p> <ol style="list-style-type: none"> <li><b>1. of high quality and highly regarded</b></li> <li><b>2. produced efficiently</b></li> <li><b>3. in line with decision making timeframe</b></li> </ol>
<b>HTA Evidence</b>	<p>What level of evidenced is used/rejected?</p> <p>How is evidence merged?</p> <p>Are there guidelines on how to produce HTA?</p>	<p>Guidelines</p> <p>Consistency</p> <p>Comprehensive inclusion of evidence but appraisal of rigour and quality</p>
<b>HTA Content</b>	<p>What issues are covered? Safety/quality; efficacy, effectiveness, cost-effectiveness, total cost, utilisation, ethics, equity, incentives, risks, uncertainty</p>	<p>Comprehensive and broad</p>
<b>HTA Quality Assurance</b>	<p>What processes are in place to ensure that HTA content is of high quality?</p>	<p>Evidence of impact of the quality assurance process</p>
<b>HTA Appraisal</b>	<p>Who makes the final recommendation?</p> <p>How are the trade-offs between impact made (e.g. equity vs. efficiency)</p>	<p>Independent</p> <p>Peer review</p> <p>Expertise</p>

	<p>How prescriptive is the HTA appraisal recommendation?</p> <p>Does appraisal take funding issues into account/allocative efficiency?</p>	<p>Economic analysis includes – budget impact, societal perspective, service delivery issues including induced demand for use of equipment, crowding out of existing services, workforce – supply and training</p> <p>Basis for decision explicit</p>
<b>HTA Dissemination</b>	<p>Who is the target audience</p> <p>What strategies are used to disseminate the results of HTA?</p>	<p>HTA activities/results are widely known amongst target audience</p>
<b>Decision-making process</b>	<p>Who is involved?</p> <p>At what level of the health care system are resource allocation decisions made?</p>	<p>Adherence to notions of procedural justice (e.g. accountability for reasonableness framework)</p> <p>Are the appropriate decisions made at the appropriate level?</p>
<b>Decision implementation</b>	<p>How do decision-makers implement recommendations?</p> <p>What incentives are available to support decision implementation?</p> <p>How can decision-makers deal with uncertainty</p>	<p>Diffusion in line with HTA recommendations</p> <p>Prevents diffusion prior to HTA</p> <p>Feedback into primary research</p>