



A Proposed Health Technology Assessment Model for Victoria

SUBMITTED BY

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Executive Summary

Overview

This paper discusses the general approach to health technology¹ adoption within Victoria, examines leading overseas models and reviews the strengths of these models. A common element to these models is the use of cost-effectiveness analysis (more generally referred to as economic evaluation). Given none of the world's economies can afford the cost of meeting all demands for health care, it follows that health systems must prioritise funding decisions. Cost-effectiveness analysis enables a systematic approach to these purchasing decisions in a manner that maximises health gains. It identifies comparative measures of 'value-for-money' that provide an objective basis upon which to defend funding decisions, including rejections for funding, and may often indirectly assist Governments in meeting cost containment objectives during price negotiations with medical device manufacturers.

Based upon these observations, the paper suggests some changes to current arrangements to strengthen the overall quality of decision making. The health technology assessment (HTA) model proposed in this paper is still essentially at the conceptual stage. Its development follows consultation with DTF and Steering Committee meetings, and interviews with four Chairpersons of public health service 'new technology committees' (NTCs), one regional Medical Director, staff at DHS involved in HTA, and two Victorian Policy Advisory Committee on Clinical Practice and Technology (VPACT) members (plus attendance at a VPACT meeting). Information obtained from interviews was further informed by literature review.

Key findings

Briefly, the key findings of this paper are that:

- Health Services presently have a large amount of freedom in deciding what health technology they choose to purchase and/or implement;
- Both Health Services and VPACT have limited access to economic evaluation methods and advice;

¹ Health technology is defined as any prosthesis, implantable device, diagnostic test, medical procedure, surgical procedure or high cost pharmaceutical.

- Flexibility in technology purchases at the Health Service level allows uncoordinated and inequitable treatment across local communities;
- Except for very high cost health technology, the majority of new health technology entering Victoria's public health system enters through the Health Services without reference to VPACT / DHS;
- A range of other activities receive insufficient attention, most notably monitoring and follow-up (auditing of decisions), and;
- 'Best practice' HTA systems must incorporate rigour, independence, breadth, transparent and open communication, timeliness, enforcement/monitoring, and must also reflect community values.

While some weaknesses have been identified with the present institutional and policy framework for Victoria's HTA system, existing processes including VPACT provide a strong foundation on which to enhance the overall quality of decision making.

Key Recommendations

Briefly, the key reforms this paper proposes are:

- **Enhancing the cost effectiveness expertise and evaluation support for VPACT.**
While an enhancement of cost effectiveness expertise could take a number of forms, the simplest would be retaining the existing HTA processes in Victoria and enhancing the economic support for VPACT through increased resource capacity to undertake a broad range of rigorous evaluations.
- Maximising the impact of this increased evaluation effort by supporting it with:
 - lower thresholds for new funding submissions to VPACT/DHS;
 - a stronger process of enforcement and monitoring of compliance with decisions and their impacts; and
 - a more transparent and open communication process, so that evaluation methodologies and decisions are known and understood by all stakeholders.

Together these reforms are expected to lead to a more economically efficient health system through more rigorous and more consistent decision HTA making processes.

The Victorian HTA System

Introduction

Victorians are spending more on health care than ever before and one of the main drivers of rising expenditure is the adoption of new health technology. Within the public sector, decisions are routinely taken about the adoption of new technology, new procedures and new approaches as better information comes to hand and better health technologies become available. These decisions are made by health practitioners, by NTCs within hospitals and through VPACT. There is constant pressure to make the health budget go further.

These purchasing decisions have traditionally been based upon consideration of factors including clinical need, efficacy, safety, and affordability. Over the past decade, the evolution of HTA both Federally (through PBAC and MSAC processes) and internationally has been to extend the scope of the evaluation by including cost-effectiveness as a key criterion. However, estimating cost-effectiveness is a labour intensive process that would need to be resourced appropriately. Furthermore, the key discipline of health economics is a relatively new field and in relatively short supply in Australia, suggesting a centralised technical evaluation function for the State would be the only sustainable option. An inherent consideration here is the important trade-offs between the merits of decision-making at the local community level (Health Services) versus centralised decision-making, with greater consistency across the State of health care delivery.

VPACT is still a relatively new approach at the State level. It is similar to the approach taken to approval of new pharmaceuticals for the Commonwealth Pharmaceutical Benefits Schedule, with an independent committee making recommendations about the adoption of new technology to the Minister. VPACT makes high level recommendations involving significant funding on submissions made by NTCs of Health Services.

The Decision Making Environment

At present, requests for funding of new health technology are most often initiated by a clinician within one of the State's metropolitan hospitals. Funding of new health technology can be provided through either of two sources:

- from within the existing budgets allocated to the relevant Health Service, or;
- by submission to DHS for funding under the DHS New Technology Program, provided a favourable recommendation has been given by the VPACT (refer below).

Central to the management of these funding approval processes is an institutional framework comprising three main elements:

- Health Services
- VPACT
- Department of Human Services (including the Minister)

The general requirements of an HTA process may be distilled to key processes addressing:

- safety;²
- effectiveness;²
- value for money (cost-effectiveness) and;
- affordability.

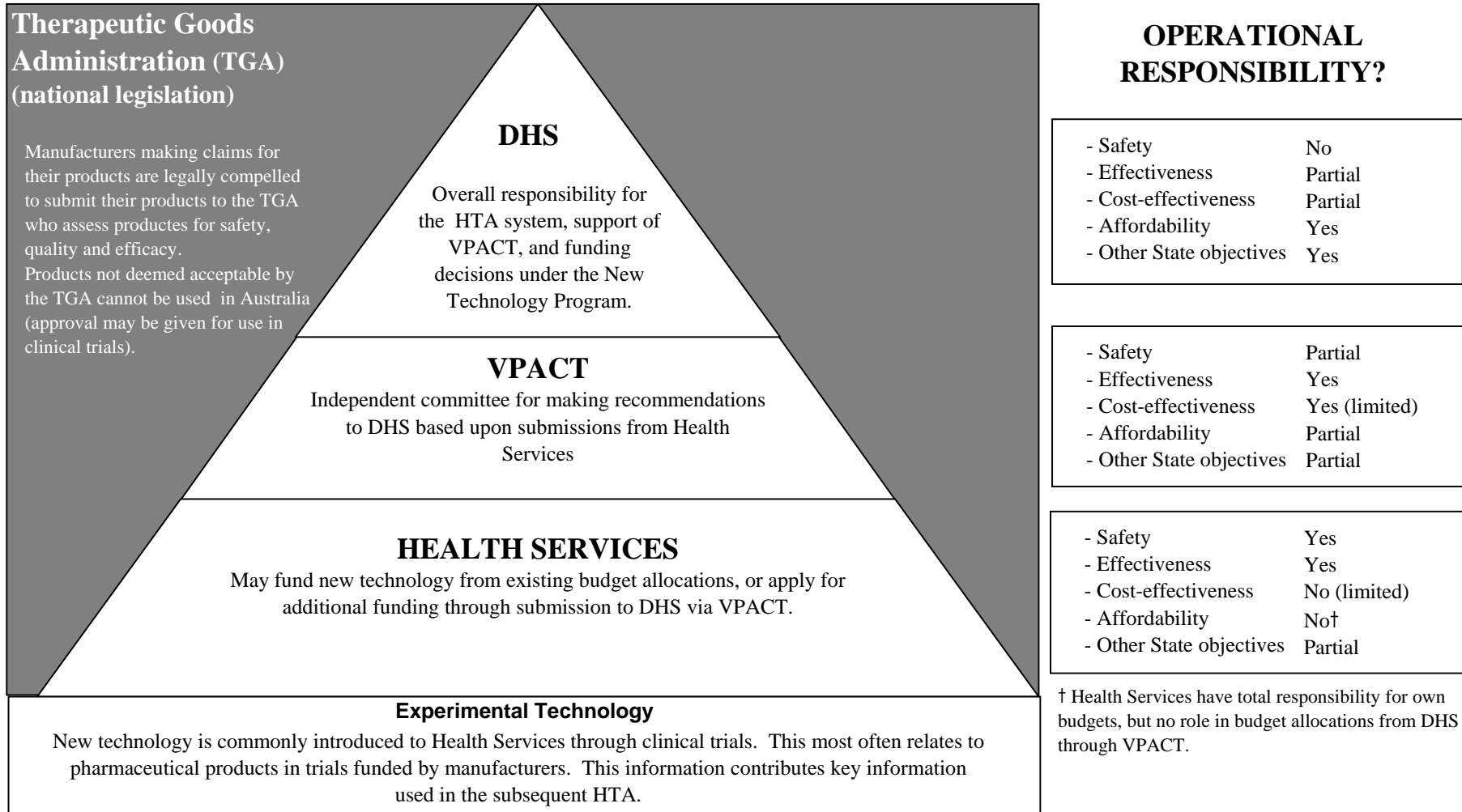
Figure one provides an overview of the HTA system in Victoria by relating these requirements of HTA systems to the Health Services, VPACT and DHS. Some explanatory comment is first provided to assist in the understanding of figure one.

- The National environment: Under national legislation, medical devices and pharmaceutical products being used for the therapeutic benefit of patients must have first been assessed by the Therapeutic Goods Administration (TGA). Unless such products have been assessed by the TGA for safety, quality and efficacy and deemed acceptable for listing on the Australian Register of Therapeutic Goods of the TGA, they cannot be marketed in Australia. This approvals process therefore precedes consideration of safety, quality and efficacy by the HTA system of Victoria. This approvals requirement does not apply to surgical procedures.

² Safety and effectiveness are important elements of the much broader responsibility of clinical governance. Remaining components comprise: clinical risk management; consumer participation, clinical audit, evidence based practice, credentialing/professional development and R&D.

- Safety & Effectiveness: While the TGA evaluates the safety of a technology and the production quality, safety is a broader issue at the State Health Service level. Safety at the State level includes the credentialing of clinicians approved to prescribe/apply the technology and compliance with storage, servicing or other requirements including any occupational health & safety issues. HTA assesses technology in the real world and is therefore a different assessment to that of the regulatory approval given by the TGA. That is, HTA establishes effectiveness (as opposed to efficacy) and the actual magnitude of the effect upon health outcomes. Safety and effectiveness are each essential parts of the clinical governance responsibilities of Health Services, but DHS has a responsibility to critically appraise all information contained in submissions from Health Services including estimates of effectiveness. This work is further reviewed by VPACT.
- Cost-effectiveness: Appropriately, Health Services are required to assess cost-effectiveness when preparing a submission for funding of new technology. However, economic evaluation is poorly understood by Health Services, and in most cases they are unable to correctly interpret the cost-effectiveness literature. VPACT / DHS have some knowledge of the field, but insufficient capacity greatly inhibits the analysis able to be undertaken.
- Affordability: Health Services have responsibility for the management of their budget. Submissions to VPACT are made where additional funding is sought from DHS. Thus responsibility for assessing affordability largely depends upon which of the alternative sources of funding is to be used (that is, the existing budget of Health Service or the New Technology / Clinical Practice Program of DHS). It should be noted though, that once a technology has been funded through the New Technology Program, it is planned for it to become 'mainstreamed' through funding streams such as casemix funding.
- Other Health Objectives: These include a range of objectives / policies applying at the time of HTA. These would include targeted programs giving priority to the treatment of specific diseases or 'at risk' populations, equity of access to health care etc.

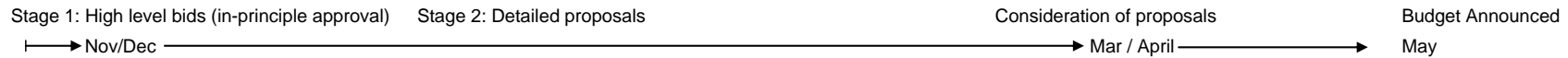
Figure 1: HTA System in Victoria



A broad overview of the current Victorian Government health care health technology approvals process is provided in Figure 2. This figure focuses upon the alternative processes for funding new health technology; that is, from within the existing budget of the Health Service, or to DHS through VPACT. It includes the role of the NTCs, within each Health Service, which serve as an initial filter for all applications to fund new technology.

Figure 1: Overview of the current Victorian Government health care technology approvals process

ERC PROCESS

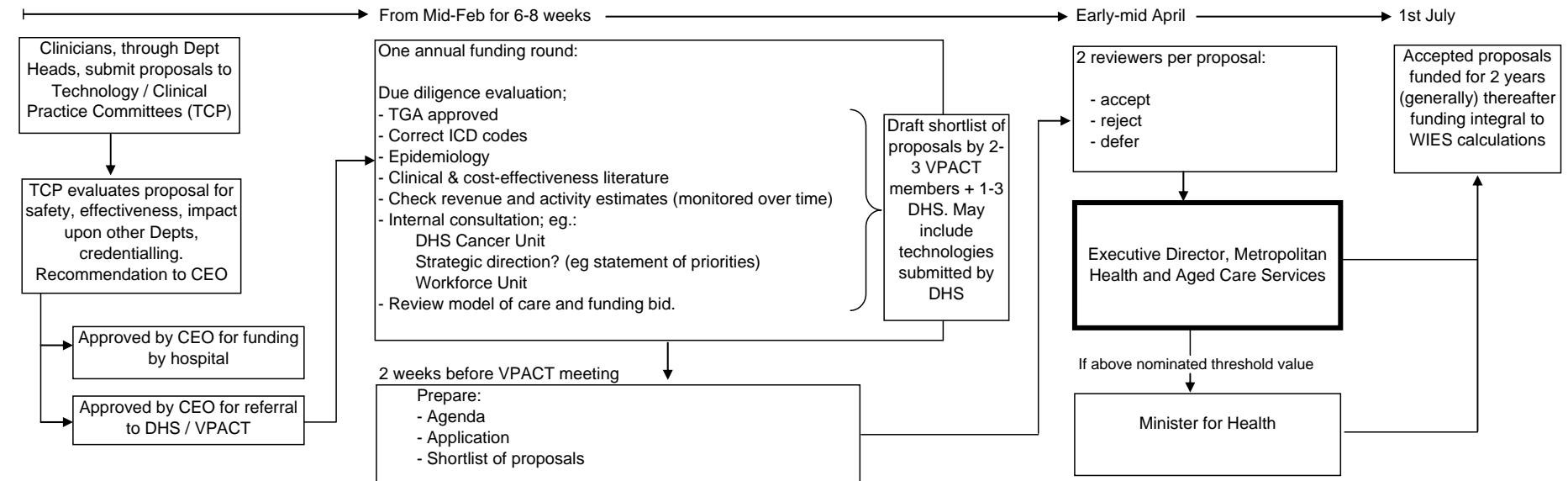


HEALTH SERVICES

DEPT OF HUMAN SERVICES

VPACT

FUNDING



Decisions at the Health Services Level.

Under the DHS New Technology Program, all metropolitan and regional health services are required to establish a NTC committee.³ As shown in Figure 1, the task of these committees is primarily to establish the safety, quality and effectiveness of proposed new health technologies. DHS lists the responsibilities as including:

- To establish criteria for assessment of applications to introduce a new technology;
- To assess applications to introduce a technology into a health service;
- To review referred existing technology used within a health service;
- To monitor new technology introduced into a health service; and
- To consider issues around the uptake of new or existing technology referred to it from within the Health Service.

The use of a standard application form is required by DHS to ensure consistency of information being presented to the NTCs. It is also relevant to this paper to note that Section 5 of the DHS Guidelines requests summary details of published cost-effectiveness evaluations. The robustness of the interpretation of these cost-effectiveness evaluations is questionable given the limited understanding of cost-effectiveness at the health service level.

NTCs provide an initial filter for all new technology funding requests. Where additional information is needed, a technology may be recommended for pilot use only. Where an NTC makes a favourable finding, a decision is made to either fund the technology internally or forward a submission to DHS / VPACT for consideration (as shown in figure two).

NTCs receive submissions for a wide range of commercially produced products, but also for therapies such as novel surgical procedures. During interviews with Chairpersons of NTCs for this project, the proportion of submissions relating to surgical procedures was estimated to be over 50 per cent. However, it was apparent that instances had been detected where a doctor had introduced a new surgical procedure without seeking the approval of their NTC.

³ To guide these committees, DHS developed the document ‘Guidance for Victorian public health services to establish new technology & clinical practice committees’ in which ‘new technology’ is defined as technology “considered by a reasonable body of medical opinion to *significantly different* from existing clinical practice” (ibid; p.4).

Without a systematic audit, it is difficult to know the extent to which overlooking the need for prior approval is an issue of concern for the HTA process.

Decisions by Department of Human Services and VPACT

Since 2004-05, VPACT has provided advice to DHS in relation to applications from Health Services for funding of new technology under the New Technology Program. It is now an integral part of the DHS funding allocation process. Membership comprises senior clinicians, health service managers, health economists and a consumer advocate.

VPACT provides an independent and systematic approach to the assessment of technologies and clinical practices in public health services in Victoria. New technology proposals must be sent, via DHS, to VPACT if the estimated budget impact:

- Is greater than \$250,000; and
- has state-wide relevance.

Additional requirements are that:

- all submissions to VPACT must be consistent with departmental and Health Service priorities; and
- if more than one Health Service seeks funding for the Health Technology, the Health Services concerned must confer and submit a single, combined application.

VPACT is a component of the Health New Technology Program managed by the Genetics & Health Technology Programs Unit within Programs Branch of the Metropolitan Health and Aged Care Services Division of DHS. This Genetics & Health Technology Programs Unit is modestly resourced with only 2-5 staff supporting HTA activities. The limited support capacity for VPACT has limited the scope of its activities to providing:

- An evidence-based assessment of clinical and cost effectiveness of new and existing health technologies and clinical practices; and
- Policies about new or modified health service delivery as required by introduction of new or changed health technology.

VPACT plays on very important role in the HTA process. However, resource constraints have meant that VPACT has been less active in certain areas of its charter. Some of these areas are:

- Mechanisms for early identification of new technologies and clinical practices with potential implications for public health services;
- Priorities for the introduction and use of new technologies and clinical practices;
- Policies and procedures for best practice for introduction and use of new and existing technologies and clinical practices in public health services;
- Dissemination of information on the introduction and use of new and existing technologies and clinical practices;
- Establishment of Nationally Funded Centre Applications; and
- Requirements for evaluating and monitoring the introduction and use of new technologies and clinical practices in public health services.

To date, DHS has accepted all VPACT recommendations, but it is not obliged to do so. Authority for these approvals rests with the Minister but with significant delegations to the Executive Director, Metropolitan Health and Aged Care Services Division and Health Service executives.

DHS approval of a new health technology is unlikely in the absence of a favourable recommendation from VPACT. Approval of the request for adoption of the new health technology usually attracts funding for up to 2 years. Thereafter, it is expected that the cost of the health technology will have become ‘mainstreamed’ appropriate funding mechanisms. The number of submissions considered by VPACT since its establishment have been:

- 2005-06: 26 submissions, 9 short-listed and 4 funded
- 2006-07: 12 submissions, 6 short-listed and 5 funded
- 2007-08: 14 submissions, 9 short-listed and 5 funded
- 2008-09: 13 submissions, 9 short-listed and 6 funded.
- 2009-10: 12 submissions (yet to be shortlisted)

It is important to note that an ‘approval’ of a submission does necessarily mean an unqualified approval. The case-study on drug-eluting stents (**Box 1**; page 15) for the treatment of coronary artery disease is an example of a restricted approval. Although occurring prior to VPACT, it was used by DHS as a pilot of the current approach.

Unlike a number of international approaches to HTA, the Victorian HTA system has addressed the need for ongoing monitoring, often referred to as 'post-marketing surveillance'. It is a DHS requirement of VPACT that it undertake ongoing monitoring of new and existing health technologies and clinical practices. Facilitating this task is mandatory six-monthly reporting by Health Services to VPACT. However, as pointed out earlier in discussion of the VPACT charter, it is understood that compliance with this requirement has been inconsistent.

Monitoring of clinical practice for compliance with restrictions, and against anticipated volumes and costs, appears reasonably comprehensive at the Health Service level. This is most likely a consequence of DHS funding policies which foster adoption of sophisticated clinical cost monitoring systems.

Box 1 : Case Study; Drug-Eluting Stents.

1. Background

Since the mid-1990's, bare metal stents (BMS) have been inserted in coronary arteries to restore blood flow where a build-up of plaque (atherosclerosis) has caused a clinically significant narrowing of the vessel. By 2004, these stents were coated with a slow-release drug that reduced the chances of restenosis (re-occlusion of the vessel). These stents are known as drug-eluting stents (DES), and cost approximately \$2,400 per stent compared to approximately \$800 for BMS.

2. Safety

Approval by the TGA was granted on the basis that DES were sufficiently similar to the already approved BMS.

3. Effectiveness

As for the safety of DES, efficacy of DES was accepted by the TGA on the basis that DES were sufficiently similar to the already approved BMS. DHS therefore conducted its own study comprising: a literature review; consultation with inter-State experience with DES, cardiologists representing 9 hospitals in Victoria offering the procedure, and clinical trial experience in Victoria.

4. Cost-effectiveness

The literature review included published economic evaluations of DES and which concluded DES offered acceptable cost-effectiveness.

5. Affordability

In 2004-05, 2,428 patients undergoing coronary artery stent implantation, in a public hospital, received at least one coronary stent. At an additional cost of \$1,900 per patient (allowing 1.2 stents per procedure), if DES were to be substituted for BMS all these patients, the additional cost to the State health system would be \$4.6 million per annum.

6. Equity / Other objectives

Any consideration of objectives other than: safety, efficacy / effectiveness, cost-effectiveness and affordability has not been formally reported. The minutes of the meeting were not reviewed for this case-study.

7. Decision

DES are a high cost item and the decision was made to approve restricted use. Agreement with all 9 hospitals was achieved to restrict use to a number of specific high-risk indications (the population of patients most at risk of developing a restenosis within 12 months of stent implantation), equivalent to 40% of the eligible population. This restriction saved a potential sum of \$2.52 million each year. By 2005-06, the funding of DES had been mainstreamed and was no longer supported under the New Technology Program.

It is relevant to note though that:

- as the health budget was not increased beyond CPI, the re-weighting of the WIES for stent implantation (F15Z) from the mainstreaming of DES meant that the increased cost needed to be absorbed across the total WIES funding allocation.
- some Health Services elected to place further restrictions upon the use of DES.

Strengths and Weaknesses of the Victorian HTA System

Observed Strengths of the Victorian HTA System

- The Victorian HTA framework mimics some of the elements of the Federal Medicare Services Advisory Committee (MSAC) and Pharmaceutical Benefits Advisory Committee (PBAC) processes. These systems are internationally recognised as leaders in the field of evaluation of health technologies. This in part relates to technical aspects of the evaluations themselves, but also relates to the process design including:
 - The ‘fourth hurdle’ of cost-effectiveness is included in the criteria for approval;
 - DHS receives recommendations from an independent committee (VPACT) of technical experts with consumer representation;
 - DHS provides analytical and secretarial support to VPACT, and;
 - Funding decisions are made by the DHS where the DHS may accept or reject the recommendation of VPACT.
- The first ‘three hurdles’ of safety, quality and efficacy/effectiveness are already reasonably well accommodated through a combination of TGA approval processes and the introduction of NTCs to Health Services.

Budget forecasting is an integral part of the evaluation. The reliability of this process though was not established for this study.

Observed Weaknesses of the Victorian HTA System

Observed weaknesses that can be addressed:

- DHS does not have a notional benchmark for funding approval. The New Technology Program receives an annual allocation and submissions from Health Services are made

against this budget in an annual cycle. Thus, the probability of receiving funding support for a given submission will depend to some degree upon the quality and cost of the technologies in competing submissions for that cycle. Being a rolling-budget ameliorates this problem, but does not solve it.

- If VPACT or DHS reject a submission for funding of new technology, Health Services can elect to fund it themselves. However, it seems inappropriate that a Health Service should be allowed override the decision of a peak body of experts (VPACT).
- The majority of new technology entering Victoria's public health system enters through the Health Services without reference to VPACT or DHS. The introduction of VPACT / DHS has reined this in but greater central control or at least coordination would be desirable.
- Related to the above weaknesses is the view of Adhealth that Health Services presently have too much freedom in deciding what technology they choose to purchase. Although the Health Services and DHS are in regular communication, there is no assurance that the criteria applied to decision-making in Health Services are those applied by the Minister / DHS. Furthermore, as Health Services generally have little understanding of economic evaluation methods, it follows that cost-effectiveness (correctly interpreted) is not routinely used in purchasing decisions. If the 'fourth hurdle' is not being applied to these decisions, the insights that this information provides will not be considered and optimum choices will not be made.
- Whilst decentralisation of decision-making authority is generally desirable, the current freedom in technology purchasing decisions at the Health Service level allows the emergence of uncoordinated and inequitable access to treatment across local communities. For example, although DHS had already restricted the use of drug-eluting stents (DES) for the treatment of coronary artery disease to nine categories of high risk patients (refer case-study provided in **Box 1**), some Health Services chose to further restrict access of patients to DES, thereby creating clear differences in access to this technology between the respective catchment populations. In supporting greater coordination of technology purchasing decisions, the scale of the complexity of this task must be acknowledged. Whilst a strong case can be made to further strengthen this aspect of the present system of HTA approval in Victoria, it will be well beyond the capacity of VPACT to consider all new technology proposals.

- VPACT includes two health economists. It must be noted though, that HTA expertise, and health economics in particular, is in short supply. Thus, this characteristic of members on HTA advisory groups can also be observed in England, Canada and Europe.

- As the effectiveness of NTCs will vary, a system of performance auditing of these committees would be desirable (this recommendation was also made in the Accenture, 2007 report).

- Whilst the framework of the system is sound, the main weaknesses arise from the under-resourcing of the system. From this single weakness, a number of consequences follow:
 - DHS does not employ a health economist (a scarce resource in the community) for HTA activities and lacks the capacity to provide independent analysis. HTA is restricted to a review of the available literature which, for most health technologies, will not include an economic evaluation that is applicable to the Victorian setting. VPACT consequently receives insufficient information by way of economic modelling and rigorous projections.

 - In recognition of the limited workload capacity of VPACT / DHS, restrictive criteria for submitting a proposal have been imposed.

 - A range of other activities receive insufficient attention, most notably monitoring and follow-up (auditing of decisions).

 - Details of VPACT / DHS decision-making do not appear to be formally communicated to Health Services. Even if formal and informal consultations during the process impart this knowledge, the system is then reliant upon corporate memory to understand what criteria were applied by VPACT / DHS in making a decision. This information is vital in lodging an appeal; the frequency of which is likely to increase as the system matures.

 - The distinction between current technology and new health technology can be arbitrary. It would be appropriate to extend the criteria for funding new technology to the replacement technology program of DHS. This is currently a separate funding process, although with some on-going consultation between the relevant officers of DHS.

- Another weakness Victoria shares with all other jurisdictions is difficulty in grappling with the political challenge of “disinvestment”. In Victoria, disinvestment tends to be left to occur by natural attrition as older less effective therapies are replaced by newer more effective (though usually more costly) therapies.

Best Practice HTA Systems

The inclusion of 'fourth hurdle' (cost-effectiveness) evaluations as an integral component of HTA purchasing decisions is now well accepted. In general, the closer the HTA is to decision-makers, the greater the impact of an evaluation. The challenge is to create a funding system that integrates the HTA whilst maintaining the independence of HTA.

However, beyond these general principles, it is emphasised that there is no one model of best practice in HTA. Although the scientific foundations of HTA are still evolving, particularly for the application of the cost-effectiveness criterion, the primary reason for the variation in HTA systems is the variation in the health systems they serve. For example, the UK health system is dominated by the government funded NHS under the central management of the national Department of Health. Australia by contrast has fragmented funding between Federal and State Governments with significant contribution from private health care providers. Thus, whilst both the UK system 'National Institute for Clinical Excellence' (NICE) and the PBAC (Australia) are very well regarded internationally, they are very different in structure, process and scope of technologies. NICE could not be applied in Australia, nor would the PBAC be relevant to the NHS.

HTA systems in Europe, Canada and Australia that incorporate cost-effectiveness exhibit common characteristics:

- The health department is usually the dominant body, overseeing the selection and appraisal process, making decisions, funding and managing implementation.
- Evaluation is usually done independently.
- Transparency and accountability, including explicit decision-criteria, are not well documented in many instances.⁴

⁴ Hutton, J., McGrath, C., Frybourg, J., Tremblay, M., Bramley-Harker, E., Henshall, C. (2006) Framework for describing and classifying decision-making systems using technology assessment to determine the reimbursement of health technologies (fourth hurdle systems) *In J Technol Assess Health Care* 22(1):10-18.

A summary of some of the key strengths of these systems, from the perspective of Victoria's aspirations, is given below. More detailed comments upon all five jurisdictions are provided against criteria in an appendix.

Overview of the National Institute for Clinical Excellence (NICE)

Strengths of NICE

In common with the PBAC, MSAC and VPACT processes, NICE in the UK has integrated evidence based HTA into the funding paradigm.

Whereas in Australia, the evaluation of effectiveness is undertaken by multidisciplinary teams as part of the economic evaluation, in the UK a distinction is made between effectiveness (assessment) and economic evaluation (appraisal) with the two functions undertaken by separate institutions (National Institute for Health Research and NICE respectively). This is claimed as a feature of the UK system which further protects independence of the scientific evaluation of effectiveness before proceeding to appraisal, which often involves degrees of judgement.

The process of identifying technologies for appraisal is rigorous and involves a number of advisory groups acting as filters. This process is described as a 'needs led' approach as it can provide for the inclusion of old technologies. This is harder to achieve if the system is only reactive to submissions.

It has been reported that the HTA system (NIHR & NICE) produces around 50 assessments per year and 15 - 20 technology appraisals each year. Given the number appraisal reports listed on the NICE website, this estimate is considered to be conservative. To complete these reports, the competencies of the scientific community have been well harnessed. The methodological standard of evaluation is very high.

NICE actively use the results of their appraisals to develop guidelines on the appropriate treatment and care of patients with specific diseases and conditions that are broader than just the optimum use of the technology.

NICE has also made a greater effort to engage the public than in Australia. In Australia, it is usual for a consumer representative to be included on advisory committees involved in HTA.

NICE however have a range of initiatives including surveys and focus groups as part of NICE's "Patient, carer and public involvement policy". To guide those making recommendations, they have published the document "Social Value Judgements; Principles for the development of NICE guidance".⁵ NICE appraisal findings are also disseminated in patient-friendly versions.

Weaknesses of NICE

The scale of the process and the rigour of the evaluation leads to two predictable weaknesses:

- The length of time it takes for an evaluation (approximately 12 months)‡
- The cost of NICE (£37 million p.a.)

‡ To assist reducing the time-frame of evaluations, NICE has introduced a single appraisal approach. This approach requires the manufacturer or sponsor to prepare an evaluation which is then critically reviewed through NICE. This effectively shifts the onus of proof to the manufacturer, but does accelerate the process.

Where a positive recommendation has been made, NICE have no responsibility in monitoring compliance. However, it must be noted that the purchaser / provider type system operating (Primary Care Trusts) provides incentives for this work to be undertaken elsewhere.

NICE has been criticised for its decisions. However, the existence of these criticisms is not regarded as a significant weakness, as the process is about rationing of health care; a process by which there will always be 'winners and losers'.

Overview of the Canadian Agency for Drugs and Technology in Health (CADTH)

Canada, with health care delivery provided by Provincial Governments under a Federal government regulatory system, has more in common with the Australian health system than the UK, but it does not have the major complication of separation of funding between State

⁵ (<http://www.nice.org.uk/aboutnice/howwework/socialvaluejudgements/socialvaluejudgements.jsp>).

and Federal governments confronted by Australia. Compared to the Canadian and Australian health systems, the advantage for NICE is that it can take a more corporate view of the health system given the structure of the NHS / Department of Health, and adopt a national agenda with uniformity of approach.

CADTH is funded by Provincial governments and is accountable to a Board comprising Provincial Deputy Ministers of Health. Quebec has elected not to be involved in CADTH.

Strengths of CADTH

Despite CADTH only having an advisory role, studies have reported a high response rate of Provincial governments to the HTA advice received (it should be noted though that this experience has not been shared internationally when HTA is only an advisory function). To the extent advice is accepted from this single agency, it does enhance the prospects of equity across Provinces in the provision of health care.

National coordination: A protocol has been developed for exchanging information between CADTH and Provincial HTA agencies (including Quebec). Since 2004 this group of national and regional HTA agencies have also operated under a national health strategy approved by the health ministers.

The scope of CADTH's work is much broader than the evaluation of specific technologies, encompassing a range of issues relating to the organisation and operation of health services including the use and impact of HTA decision making.

Rather than being purely reactive to clinicians and manufacturers, the selection of issues for study is determined by the Board (effectively the clients) and thus provides opportunity for disinvestment or to address issues of importance.

Weaknesses of CADTH

Because Provincial health systems are autonomous on health care coverage decisions, the link between HTA advice and national policy is weak.

Despite the evidence for compliance with CADTH advice, the limitation of CADTH's role to advisory only is seen as weakness for other jurisdictions.

Overview of the Oregon Health Services Commission (OHSC)

OHSC is a system of HTA with unique approach that serves a State Government operating within a Federal government health care program (Medicaid). The strengths of this system are that:

- the approach to prioritisation is highly transparent with economic principles being applied to decisions (while the rigour of the evaluation is low, the approach is well publicised);
- the approach to prioritisation is comprehensive, covering all treatments including procedures;
- the development of the process entailed enormous consultation with the community (although subsequent consultation has been reduced);
- prioritisation takes into account final outcomes (as much as possible with the brief time allowed); and
- having ranked all therapies, budget control is achieved by “ruling off” funding at the lowest priority above the funding line. Funding thus becomes a technical decision rather than a political one.

Overview of the Pharmaceutical Benefits Advisory Committee (PBAC)

The PBAC represents an alternative approach to evaluating technologies when constrained to a specific health care program (the Pharmaceutical Benefits Scheme) within a federal system of government with fragmented funding of health care. The strengths of PBAC are that:

- the overall approach to prioritisation is highly transparent (however in the application of the process to individual drugs commercial-in-confidence restrictions imposed by companies inhibit deliberations);
- the process is a world leader in technical aspects of pharmacoeconomic evaluation, and the management of pricing & listing on the national formulary;
- evaluations and recommendations are independent of the Dept of Health and Ageing; and
- at approximately 9 months, the process is relatively short with a ‘fast-tracking’ option for highly valued drugs.

Establishing a cost effectiveness methodology

It is important that the assessment process is underpinned by a clear and commonly understood cost effectiveness methodology.

The precise estimation of a cost effectiveness threshold is difficult, given uncertainties arising from the clinical and epidemiological data available. In practice, results are used differently depending upon the reliability of the analysis. Other health care objectives remain also. It is uncommon for governments to publicly announce a threshold. An exception is the NICE who published a threshold of £20,000-£30,000 per QALY.

Nevertheless, studies of past decisions have revealed indications of actual thresholds.

In Australia, the National Health and Medical Research Council (NHMRC) has developed criteria as shown in the following table. The NHMRC approach has the attractive feature of adjusting the threshold according to the level of evidence on both outcomes and costs.

An analysis of PBAC decisions was undertaken by George et al. (2001).⁶ The study relates to old data from 1992 to 1996. It was concluded that the PBAC were unlikely to recommend a drug for listing if the additional cost per life-year exceeded \$76,000 (1998/1999 values) and was unlikely to reject a drug for which the additional cost per life-year gained was less than \$42,000. Importantly, the cost-effectiveness ratio is not the only factor determining the reimbursement decision as other policies (eg rule of rescue) may have influenced decisions. .

⁶ George, B., Harris, A., Mitchell, A. (2001) Cost-Effectiveness Analysis and the Consistency of Decision Making: Evidence from Pharmaceutical Reimbursement in Australia (1991 to 1996) *Pharmacoeconomics* 11:1103-1109

Table 1 : NHMRC's criteria: Assessing evidence using shadow prices

	Ranking of evidence on effects	
Ranking of evidence on costs	<i>High</i>	<i>Low</i>
<i>Strong</i>	Recommend if: < \$70,000 per life year Do not recommend if > \$100,000 per life year	Recommend if < \$30,000 per life year Do not recommend if >\$70,000 per life year
<i>Weak</i>	Recommend if < \$30,000 per life year Do not recommend if > \$70,000 per life year	Recommend if < \$30,000 per life year Do not recommend if >\$30,000 per life year

Source: *How to compare the costs and benefits: evaluation of the economic evidence* (NHMRC)
Table 6.1

http://www.nhmrc.gov.au/publications/synopses/cp106/_files/chapter22cp106.pdf - 110k - [pdf]

Best Practice features of HTA systems

Whilst no one system represents best practice, and there are often trade-offs between features of a model, it is possible to identify key preferred features of HTA systems based on collective assessment of the previously discussed HTA systems:

1. **Rigour:** thorough economic/cost effectiveness evaluations are undertaken
2. **Independence:** economic results and funding decisions are separated
3. **Breadth:** broad scope of technologies chosen for evaluation
4. **Transparent and open communication:** transparent evaluation methodology, decision making process and communication of decisions
5. **Timeliness:** timely evaluation & decision making
6. **Enforcement/monitoring** of compliance with decisions and their impact
7. **Reflects community values** and is **accepted by stakeholders**

Proposed Victorian Model

While some weaknesses have been identified with the present institutional and policy framework for Victoria's HTA system, existing processes including VPACT provide a strong foundation on which to enhance the overall quality of decision making. Considering the existing strengths of the Victorian system, and best practice features of HTA systems more generally, a number of suggested changes to current arrangements are proposed.

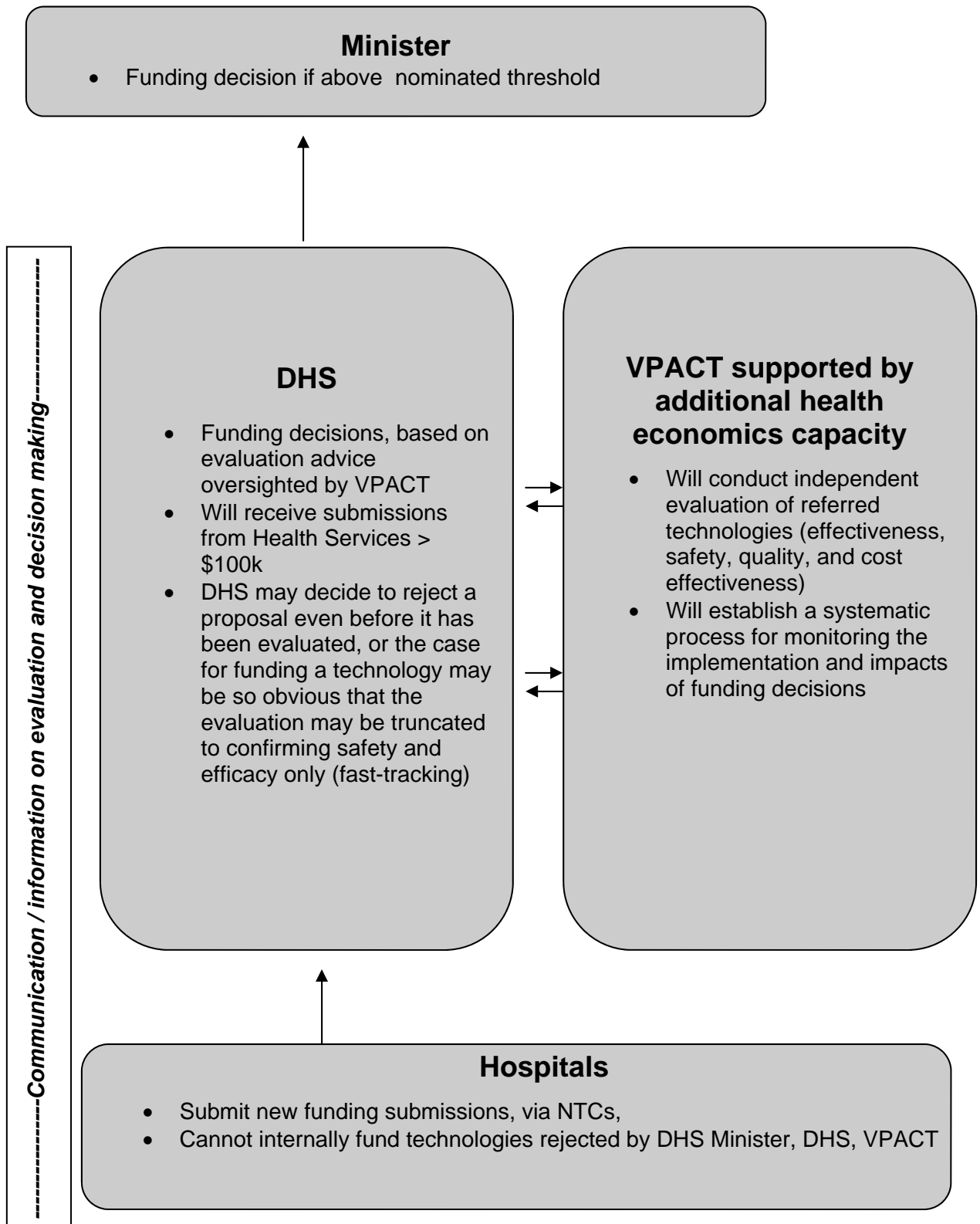
Given the shared interest in this field with other States, an ideal long term solution would be a national body. However, there are significant challenges in gaining universal agreement amongst States for adoption of a national approach to the evaluation of State funded health care. Nevertheless, it is envisaged that any approach to developing a national model could build upon a Victorian model. That is, the Victorian model outlined below does not preclude a future initiative to develop a national body.

The key reforms this paper proposes are:

- **Enhancing the cost effectiveness expertise and evaluation effort of VPACT.**
While an enhancement of cost effectiveness expertise could take a number of forms, the simplest would be retaining the existing HTA processes in Victoria and enhancing the technical support of VPACT and its resource capacity to undertake a broad range of rigorous cost-effectiveness evaluations.
- Maximising the impact of this increased evaluation effort by supporting it with:
 - **lower thresholds for new funding submissions to VPACT/DHS;**
 - **a stronger process of enforcement and monitoring of compliance** with decisions and their impacts; and
 - **a more transparent and open communication process**, so that evaluation methodologies and decisions are known and understood by all stakeholders.

Together these reforms are expected to lead to more rigorous and more consistent decision HTA making processes. The acceptability of this strengthening of the HTA to Health Services would be enhanced by the provision of support training to NTCs in the application of cost-effectiveness principles. The proposed model is summarised in the following Figure.

Figure 2: Overview of Proposed Enhanced Victorian Government Health Care Technology Approvals Process



Outline of key changes proposed

Enhancing the cost effectiveness expertise and evaluation effort of VPACT

The rigour of information already provided in submissions means that VPACT need only verify the safety, quality and efficacy/effectiveness of proposals. However, given the short supply of HTA expertise, and health economics in particular, VPACT currently receives limited information on economic modelling (cost-effectiveness analyses) and projections.

Recommendation

Enhance the assessment of cost effectiveness and overall evaluation effort by VPACT by a commensurate increase in VPACT resources, particularly of specialist health economic resources.

Lower thresholds for new funding submissions to VPACT/DHS

Whilst there is a strong argument that decisions should be made as locally as possible to enhance the prospects of health care reflecting local community values, the reality is that the limited availability of qualified personnel in relevant fields of HTA necessarily point to a centralised process. A centralised system also provides efficiency gains for the HTA process itself by avoiding duplication of effort.

Recommendation

Redirect more new technology purchasing decisions through VPACT/DHS. VPACT presently reviews items referred to it if the budget impact is at least \$250,000 and the technology has State wide relevance. This threshold could be adjusted downward, for example to make it compulsory to submit for health technologies with a total cost >\$100,000.

Under this recommendation, it is possible that the work load associated with the development and review of submissions to an NTC could be simplified given the efficacy and cost of the technology concerned would, in any event, be the subject of rigorous evaluation by VPACT.

Enforcement of decisions and appeals mechanisms

Under current funding policy, if VPACT or DHS reject a submission for funding of new technology, Health Services may revert to funding the technology themselves. As previously noted in the discussion of weaknesses of the Victorian HTA system, it seems inappropriate that a Health Service should be allowed to fund it and override the decision of a peak body of experts (VPACT) in this manner.

Recommendation

Provide VPACT / DHS with greater authority over purchasing decisions by preventing the funding of technologies rejected by VPACT / DHS. The rights of stakeholders including appeal mechanisms would need to be clearly established

Stronger monitoring and evaluation of decisions and impacts

While it is already a requirement of VPACT to undertake ongoing monitoring of new and existing technologies and clinical practices, it is understood that the application of this task has been inconsistent.

Reliable growth estimates from approved purchases should be a key part of the evaluation and approvals process. Thus any unexplained growth would represent a failure of either (a) the forecasting or (b) compliance with restrictions.

Predictions should be monitored and variations from actual growth reviewed for methodological improvements or policy changes required (e.g. unit pricing). If the process is reliable, there should be no technology driven surprises in overall costs.

A related issue is that, as the effectiveness of NTCs will vary, a system of performance auditing of these committees would be desirable (this recommendation was also made in the Accenture, 2007 report).

Recommendation

VPACT / DHS establish a systematic process for monitoring the implementation and impacts of technology funding decisions.

Greater transparency and communication of decision making (criteria, process and final decisions)

Evaluations should ideally be available publicly, thereby enabling clinicians, patients and the public more broadly to gain a better understanding of the basis of the decisions.

It would also be useful for NTCs to have a broad understanding of the principles of economic evaluation in order to better understand the logic and basis for subsequent funding decisions by DHS, and secondly perhaps to better screen proposals before they are submitted to DHS / VPACT.

Greater centralisation and communication of decisions is likely to lead to more rigorous and more consistent decision HTA making processes. This would help support stakeholder acceptance of the process. While at times some stakeholders may not agree with the final decisions, it is important that they understand the process and see it as having a legitimate role.

Recommendation

DHS publish information on cost-effectiveness evaluations, decision making criteria and processes, and final decisions. This information should in the first instance be made available to hospital NTCs.

Consolidation of new and replacement technology purchasing decisions over the longer term

The separation of ‘new’ technology purchasing decisions from replacement technology should be reviewed as the distinction between the two can be arbitrary. It would be appropriate to over time extend the criteria for funding new technology to the replacement technology program of DHS. This is currently a separate funding process, although with some on-going consultation between the relevant officers of DHS.

Recommendation

At a later stage of reform, consider combining the DHS replacement technology and new technology units into a capital purchasing program where the same criteria are applied to decisions.

Operation of the proposed model

Proposals for new health technology assessments

Proposals for new health technology assessments could be submitted to VPACT by: hospitals (through their NTC); the Minister/DHS; manufacturers/ sponsors; and potentially through VPACT's own independent scanning.

Once Health Service proposals have been screened by NTCs, they would continue to be submitted to DHS for review and referral to VPACT. Health services should also still be required to coordinate submissions where more than one health service seeks funding for the technology. Whilst all proposals could be referred directly to VPACT rather than via DHS, an interim step that might be considered would be an initial review by DHS. The purpose of this review would be to take advantage of efficiency gains by avoiding the need for evaluation where:

- DHS decides to reject a proposal even before it has been evaluated on grounds unrelated to cost-effectiveness. Alternatively, on selective occasions the case for funding a technology may be so obvious that the evaluation may be truncated to confirming safety and efficacy only (fast-tracking). In both instances, it would be wasteful to commit evaluation resources to full appraisal of such proposals.
- DHS may wish to consider the overall budget impact of the technology and thus impose guidelines on the evaluation. For example, it may restrict the sites to receive funding, and/or restrict patient eligibility for the technology, both of which may affect the cost-effectiveness results.
- DHS may wish to comment upon aspects of the evaluation such as the choice of comparator for the economic evaluation.

From the initial review and screening by DHS, proposals would be forwarded to VPACT for evaluation.

An illustration of the benefits of this interim step of submitting health service proposals to DHS broadly follows the practice by NICE. The selection of technologies for evaluation by NICE is supported by a comprehensive structure of committees deliberating over some months in relation to the relative priority of the technology and affordability. The process envisaged for Victoria though would be a process of internal consultation within DHS and thus represents a much truncated version of the process adopted by NICE.

Any such initial review by DHS step was not uniformly supported by the Adhealth project team given the potential for political interference; a feature of 'best practice' HTA systems is transparency and independence of evaluations. The project team was unanimous in supporting the need for very careful consideration of the boundaries and criteria that would apply to DHS were this option implemented.

Timing

The overall time-frame for the HTA process may need to be reviewed to allow for the inclusion of enhanced economic evaluation.

Depending upon the complexity of the technology and the extent of the data available, the time-frame needed for an evaluation will vary and may require individual negotiation.

If manufacturers or sponsors were expected to submit proposals for review by VPACT, as opposed to VPACT preparing an evaluation, the time-frame could be shortened as it usually takes less time to critically assess a submission than to prepare the submission. This would also shift the onus of proof to the manufacturer.

An overall period of 6-12 months for evaluations is likely to be generally tolerated by stakeholders. This view is based upon current HTA practices as there is no generally accepted threshold. Industry will always want reduced timelines and budget holders have an incentive to delay. The PBAC process takes up to 9 months to implement by the time a medication is available to clinicians for prescribing from the PBS whilst MSAC can often take more than 12 months. These timeframes are comparable to those observed in 'fourth hurdle' systems internationally.

Scope of the independent evaluation report to DHS

The evaluation report prepared by VPACT and submitted to DHS for funding decision making should comprise:

- A review of effectiveness and safety;
- A review of the costs and cost consequences;
- Consideration of the optimal clinical place of the technology, including the optimum diffusion of the technology within the State health system;
- An estimate of the cost-effectiveness of the technology, and the degree of uncertainty;
- Estimate of utilisation, given optimum use, and the associated budget impact including allowance for cost-offsets;
- Funding recommendations.

Funding decisions by Minister/DHS

It is not envisaged that positive findings in favour of the technology by VPACT should be binding upon the Minister for Health / DHS. The report would serve to provide the Minister and DHS with an objective and defensible basis upon which to make decisions. Victoria's health system objectives are broader than just prioritisation by cost-effectiveness and thus other criteria may, on occasions, override VPACT recommendations regarding 'value-for-money'.

Appendix: Assessment of HTA systems

During discussions with the Department of Treasury and Finance (DTF) leading to this paper, a list of key characteristics of priority setting systems that are uniformly desirable was developed:

1. Supports Government's health care objectives (incorporates equity objectives)
2. Elicits and reflects community values
3. Broad scope of technologies chosen for evaluation
4. Rigorous evaluation undertaken
5. Independence: Economic results and funding decisions are separated
6. Governance: Accountability and functions are clearly specified
7. Transparent decision making
8. Timely evaluation & decision making
9. Appeals mechanism provided
10. Enforcement / monitoring of decisions
11. Control of overall budget retained
12. Administration cost affordable
13. Acceptability by stakeholders

This Appendix assessed each of six HTA systems against these criteria.

In assessing HTA systems against these criteria, it is relevant to note the review by Hutton et al., (2006) which included an assessment of the extent to which information was available. They used a matrix that assessed:

- the decision process in three stages :

[1] making the assessment, [2] making the decision, [3] the outputs and implementation)

- against four criteria :

[1] legal constitution & governance. [2] methods & processes, [3] use of evidence, [4] transparency and accountability.

The results are show in the table below as averages for the countries studied (Europe, Canada and Australia).

Proportion of Required Information Publicly Available; Hutton et al., 2006

Characteristics	Stage		
	1. Assessment (44%)	2. Decision (58%)	3. Outputs & implementation (36%)
1. Constitution and governance (47%)	Consultation and involvement of stakeholders (38%)	Who makes the decision (88%)	Appeal & dissent (39%)
2. Methods, processes (63%)	Methodology (60%)	Decision making process (78%)	Implementation and communication (54%)
3. Use of evidence (46%)	Evidence-base for assessments (50%)	Evidence-base and additional influences for decisions (31%)	Monitoring and reappraisal (58%)
4. Transparency and accountability (21%)	Presentation and communication of assessment results (17%)	Content and documentation of the decisions (50%)	Evidence of impact of the decisions (0%)

Evaluation methodology:

- 0% = absent
- 50% = partially present
- 100% = present

Systems evaluated : Australia (Federal), Canada (Federal), United Kingdom, Europe (including France, Belgium, Netherlands, Germany, Italy, Portugal, Denmark, Spain, Hungary and Poland).

The overall average score was 45% highlighting the difficulty in making judgements in many instances. The range of results was from 29% for Germany to 61% for Australia. This information is included as it illustrates the difficulty in many instances of establishing a clear understanding of the operations of these HTA systems. The assessments provided below are made on the basis of the incomplete information available supplemented at times by first hand experience of the authors.

In providing these assessments, the problem also arises that modern health systems are characterised by constant reform, particularly the NHS. Each system generally exhibits one or all of the following:

- reforms currently underway
- reforms being enacted
- reforms being planned.

The information represents our understanding of the operation of these systems as of 2007-08.

1. Supports Government's health care objectives

The primary objective of all health systems is straightforward; they exist to prevent / treat disease in the general population. Limitations in medical science and strict limitations in budgets though mean that choices must be made. In Victoria, these choices are made, either explicitly or implicitly, each time a health care resource is consumed. These choices should be guided by Government through a subordinate set of objectives that reflect community values and preferences for health care for the population. These relate to equity objectives including access, preferences in the treatment of sub-populations or diseases, etc.

Institution	Ranking	Description of Approach to Key Characteristic
International		
National Institute of Clinical Excellence (NICE); United Kingdom	****	Operating within the goals and objectives of the Department of Health, NICE has a short list of objectives relating to improving health care and reducing inequalities (http://www.nice.org.uk/aboutnice/whatwedo/niceandthenhs/fasteraccesstomodernreatment/objectives.jsp). These objectives are supported by numerous operational policies.
Canadian Agency for Drugs and Technologies in Health (CADTH)	-	CADTH is funded by multiple 'clients' (Provincial Governments). Although the health system must comply with Federal legislation, there is no single set of objectives uniformly adopted by each Province. The stated objectives of CADTH relate to mostly to professional standards (http://cadth.ca/index.php/en/cadth/corporate-profile).
Health Services Commission (State of Oregon)	*	The Health Services Commission has developed a set of objectives however the limited capacity and time-frame within which HTA must occur limits the extent to which it can address objectives other affordability, safety and efficacy.
Australian		
Pharmaceutical Benefits Advisory Committee (PBAC)	***	The link between Australian health system objectives and the PBAC not explicit.
Medicare Services Advisory Committee (MSAC)	***	Australian health system objectives not well developed. MSAC has developed some policies which reflect perceived community values, but is less publicised than for PBAC.
Department of Human Services, Victoria	***	DHS has a list of current objectives on its website. (http://www.dhs.vic.gov.au/about-the-department/annual-reports/meeting-our-objectives). The awareness of officers of DHS of these objectives in their day to day operations though is less clear. The Government also commits to specific policy and service delivery objectives each election period and is accountable for these to parliament and the electorate.

2. Elicits and reflects community values

Developing a well defined and interpretable set of subordinate objectives as described above is complex and it is not surprising that few governments, if any, possess a complete set of such objectives. It is therefore important that health care decision-makers are at least informed of community values and preferences for health care. For instance, community surveys suggest that there is a strong community preference for treatment of those whose quality of life is severely compromised ahead of other patients, even if the magnitude of benefit from the treatment for other patients may be slightly greater. This is important information for decision-makers in deciding the how to allocate a health care budget.

Institution	Ranking	Description of Approach to Key Characteristic
International		
National Institute of Clinical Excellence (NICE); United Kingdom	****	Operating within the goals and objectives of the Department of Health, NICE is guided by an extensive number of independent advisory groups made up of health professionals, patients, their carers and the public. NICE has published the document <i>Social Value Judgements: Principles for the Development of NICE Guidance</i> (http://www.nice.org.uk/aboutnice/howwework/socialvaluejudgements/socialvaluejudgements.jsp). It describes the principles that these advisory bodies should apply when making decisions about the effectiveness and cost effectiveness of interventions. Community participation is encouraged through the process.
Canadian Agency for Drugs and Technologies in Health (CADTH)	*	CADTH has community representation on advisory committees but does not appear to systematically seek to identify community values and preferences.
Health Services Commission (State of Oregon)	*	The Health Services Commission has developed a set of objectives however the limited capacity and time-frame within which HTA must occur limits the extent of assessment.
Australian		
Pharmaceutical Benefits Advisory Committee (PBAC)	****	PBAC has developed some policies (eg. when rule-of-rescue applies) which reflect perceived community values. The committee includes consumer representation
Medicare Services Advisory Committee (MSAC)	***	Australian health system objectives not well developed. MSAC has developed some policies which reflect perceived community values, but is less publicised than for PBAC. The committee includes consumer representation
Department of Human Services, Victoria	***	DHS has a list of current objectives on its website. (http://www.dhs.vic.gov.au/about-the-department/annual-reports/meeting-our-objectives). Although VPACT has one consumer representative, reliance is placed upon the committee members having an understanding of community values and preferences. The membership of VPACT includes a consumer representative. Broader communication and elicitation of community values through surveys and submissions is not systematically pursued.

3. Broad scope of technologies chosen for evaluation

More technologies undergoing HTA before being funded is obviously preferred to less and is therefore listed as criteria against which HTA systems should be assessed. It is noted, though, that earlier papers developed for this study highlighted the trade-off between the number of technologies undergoing a full HTA and the rigour of the HTA.

Institution	Ranking	Description of Approach to Key Characteristic
International		
National Institute of Clinical Excellence (NICE); United Kingdom	*****	NICE has a very broad mandate for HTA producing 'guidance reports' across public health, health technologies and clinical practice.
Canadian Agency for Drugs and Technologies in Health (CADTH)	***	CADTH has a broad mandate for HTA but is heavily biased towards pharmacoeconomic evaluation.
Health Services Commission (State of Oregon)	*****	Complete coverage of all treatments.
Australian		
Pharmaceutical Benefits Advisory Committee (PBAC)	**	Only evaluates pharmaceuticals to be listed on the Pharmaceutical Benefits Schedule
Medicare Services Advisory Committee (MSAC)	**	Only evaluates medical services to be listed on the Medicare Benefits Schedule.
Department of Human Services, Victoria	****	Health Services responsible for all technology purchased. DHS/VPACT defines technology as prostheses, implantable devices, diagnostic tests, medical and surgical procedures and high cost pharmaceuticals. The range of technologies that may be considered by VPACT is thus very wide. The scope is limited though by the application of stringent limitations (i.e. a budget impact of \$250,000 and Statewide application) and by the ability of Health Services to by-pass VPACT by funding the technology themselves. The HTA system in Victoria is reactive to requests (in common with most approaches internationally) with the vast majority of new technology being adopted by Health Services themselves without reference to DHS governance processes for new technology.

4. Rigorous evaluation undertaken

In general, the more rigorous the HTA, the more reliable the findings. As for the previous criteria relating to the breadth of criteria evaluated, it is again noted a trade-off exists between the number of technologies undergoing a full HTA and the rigour of the HTA.

Institution	Ranking	Description of Approach to Key Characteristic
International		
National Institute of Clinical Excellence (NICE); United Kingdom	*****	NICE commissions full economic evaluations of all technologies listed for HTA.
Canadian Agency for Drugs and Technologies in Health (CADTH)	*****	CADTH undertakes full economic evaluations of all technologies listed by the Board of Governors
Health Services Commission (State of Oregon)	*	The HSC reviews published information for each technology over a 4-6 week period and prepares a summary report for the 11 members of the Commission.
Australian		
Pharmaceutical Benefits Advisory Committee (PBAC)	*****	Full economic evaluations are prepared for all submissions to the PBAC, and comprehensively reviewed by DHA through contracted universities
Medicare Services Advisory Committee (MSAC)	*****	Full economic evaluations are prepared by universities contracted to DHA and submitted to MSAC for all submissions to MSAC. Preliminary evaluations are also undertaken as part of MSAC's Horizon Scanning function
Department of Human Services, Victoria	*	TCP committee and VPACT documentation list cost-effectiveness as a criterion for approval of technology purchases (and this criterion is a focus for this study). VPACT though comprises voluntary membership with limited technical support from DHS. TCPs lack both technical support and an understanding of economic evaluation theory and practice. Cost-effectiveness is usually thought to mean simply cost-saving rather than the correct concept of value-for-money

5. Independence: Economic results and funding decisions are separated

The funding of health care is highly political. Having evaluations undertaken independently protects Governments and the executive from accusations of ulterior motives in making decisions (eg. purely cost saving; political reasons, etc.).

Institution	Ranking	Description of Approach to Key Characteristic
International		
National Institute of Clinical Excellence (NICE); United Kingdom	****	NICE commissions independent organisations to undertake evaluations, although a project officer from NICE is assigned to monitor the evaluation
Canadian Agency for Drugs and Technologies in Health (CADTH)	***	Most evaluations are done internally, however CADTH is itself nominally an independent organisation (although under the direction of a Board comprising Provincial Ministers of Health).
Health Services Commission (State of Oregon)	*	The Secretariat to the Health Services Commission is a unit within the Office for Oregon Health Policy & Research of the Dept of Administrative Services. The 11 member commissioners though, who decide upon the evidence are independent.
Australian		
Pharmaceutical Benefits Advisory Committee (PBAC)	*****	The membership of each of MSAC and the PBAC is independent of Government and the evaluators of the submissions from industry are also independent, although under some direction from the administration (DHA).
Medicare Services Advisory Committee (MSAC)	*****	
Department of Human Services, Victoria	*	The introduction of VPACT was a positive initiative and enables an independent evaluation. This committee structure is consistent with preferred models of international practice

6. Governance: Accountability and functions are clearly specified

The importance of this criteria is largely self evident, but warrants listing. The importance of accountable, transparent, responsive, effective and efficient, equitable and inclusive processes and consistent with legal responsibilities.

Institution	Ranking	Description of Approach to Key Characteristic
International		
National Institute of Clinical Excellence (NICE); United Kingdom	*****	NICE Board and senior management team set the Institute's strategic direction and oversee delivery, provide financial stewardship and ensure corporate governance. Primary Trusts have 3 months in which they must commence funding technology that has been the subject of a positive findings by NICE.
Canadian Agency for Drugs and Technologies in Health (CADTH)	****	CADTH is accountable to Canada's Conference of Deputy Ministers of Health through a 13-member Board of Directors. Program-specific Advisory Committees assist the Board as well as members of staff. A five-member Executive Management Group oversees the day-to-day operations of CADTH.
Health Services Commission (State of Oregon)	*****	HSC comprises 3-4 staff making governance less complicated than for other institutions such as NICE.
Australian		
Pharmaceutical Benefits Advisory Committee (PBAC)	****	Governance has been an issue in the past. Whilst the PBAC has responsibility for determining cost-effectiveness, the role of the PBAC in relation to affordability was not clear. High profile legal challenges to PBAC authority led to clarification and clearer governance arrangements exist today.
Medicare Services Advisory Committee (MSAC)	****	MSAC was created after PBAC and continues to benefit from the experience of DHA and the PBAC itself, including issues relating to governance.
Department of Human Services, Victoria	**?	Considerable detail is provided on the DHS website about the roles and responsibilities of the different entities within the HTA system of Victoria but TCPs in particular are still in their development phase. Governance requires further development, but it must be noted that the New Technology Program is still evolving, and VPACT itself is still clarifying its functions.

7. Transparent decision making

This criteria is a component of many definitions of governance, although listed separately here.

Institution	Ranking	Description of Approach to Key Characteristic
International		
National Institute of Clinical Excellence (NICE); United Kingdom	****	NICE operates under a relatively open and transparent process. Priorities for HTA are developed through a series of advisory groups with decisions on the public record. The final prioritisation is less public and involves negotiation between the Dept of Health and NICE. Once chosen for evaluation, the full HTA report is available.
Canadian Agency for Drugs and Technologies in Health (CADTH)	***	Comprehensive technical reports from CADTH evaluations can be downloaded from the CADTH website and which frequently includes recommendations. Decisions though are made by Provincial Governments and these have not been reviewed.
Health Services Commission (State of Oregon)	****	The philosophy of the HSC is that all patients should have access to care, and that there should be an open and reasoned process for determining the list of covered treatments. The approach to decision making has been well documented and studied over the past decade. The only potential for lack of transparency is in relation to the interpretation of evidence relating to a medical service in consideration.
Australian		
Pharmaceutical Benefits Advisory Committee (PBAC)	**	The PBAC has often been criticised for a lack of consistency and transparency in its recommendations. Specific criticisms include: the cost-effectiveness threshold which companies must meet is not explicit; there is no opportunity to address any issues in dispute directly with the decision-makers; the PBAC may use information in assessing a product, of which the company is unaware. These issues are difficult for the PBAC to counter as the companies are very protective of the information contained in submissions.
Medicare Services Advisory Committee (MSAC)	****	The MSAC process is more open as the evaluation is normally undertaken by entities contracted to DHA (most often academic groups). These reports are made available to manufacturers for comment before being released on the MSAC website.
Department of Human Services, Victoria	**	Although considerable communication occurs between DHS officers and Health Services during the period leading up to a decision, as far as the consultants are aware, detailing the reasons for a decision do not appear to be systematically recorded and disseminated. Internal decision-making processes are not transparent to Health Services. The main criteria applied under the New Technology / Clinical Practice program are those of safety, effectiveness, cost-effectiveness and affordability. When consulting with the relevant portfolio area of DHS in relation to recurrent funding, other criteria must come into play. Similarly, decisions within the Health Services are not always transparent. This applies to both approvals and rejections.

8. Timely evaluation & decision making

Delays in decision-making cause delays in the delivery of beneficial health care to patients.

Institution	Ranking	Description of Approach to Key Characteristic
International		
National Institute of Clinical Excellence (NICE); United Kingdom	**	From the time of listing for assessment, the NICE process of HTA is a detailed and moderately complex process. Completion of an appraisal normally takes around 12 months although a 'fast-track' option exists for new technology that potentially very important for patients. NHS then has a further 3 months in which to adopt the technology
Canadian Agency for Drugs and Technologies in Health (CADTH)	**	CADTH have a variable time-frame for appraisal, but it appears to be commonly a few months only reflecting the less rigorous approach to evaluation compared to NICE, PBAC and MSAC.
Health Services Commission (State of Oregon)	*****	The HSC receives advice about new procedure codes in late November and must complete the evaluation and make a decision on these codes by 1 January each year. Clearly only very quick appraisal of the literature is possible for a range of codes in this short time-frame.
Australian		
Pharmaceutical Benefits Advisory Committee (PBAC)	***	The evaluation process and PBAC recommendation is made in about 5-6 months from the closing date for submissions. Listing on the PBS itself can take a further 2-3 months.
Medicare Services Advisory Committee (MSAC)	**	MSAC has a more flexible approach. The website states "The time taken for an application to be assessed depends on a number of factors, including the completeness of the application form, the quality of available evidence and the complexity of the medical service, treatment or procedure....". A period of at least 12 months would be common.
Department of Human Services, Victoria	***	DHS has an annual round of submissions for new technology. The general dates are known in advance (Error! Reference source not found.) and span a period of approximately 6 months. This is an acceptable time-frame, particularly given the limited staffing available in DHS, and compares favourably with other HTA systems. Anecdotally though, it has been suggested that final negotiation with DHS, following a positive recommendation from VPACT, can 'drag-on'.

9. Appeals mechanism provided

In the interests of ensuring due process and fairness.

Institution	Ranking	Description of Approach to Key Characteristic
International		
National Institute of Clinical Excellence (NICE); United Kingdom	****	A formal, independent appeals process has been established by NICE. Patients and carers, healthcare professionals and manufacturers can appeal against final advice given by the independent advisory committee on a specific medicine or treatment. Since 2000, 38% of appraisals conducted have gone to an appeal hearing.
Canadian Agency for Drugs and Technologies in Health (CADTH)	**?	In December 2007, a recommendation was made to introduce an appeals process for the drug reviews by CADTH. It is not known if this is being acted upon.
Health Services Commission (State of Oregon)	?	Insured members have a right of appeal (Medicare), however the rights of manufacturers could not be established.
Australian		
Pharmaceutical Benefits Advisory Committee (PBAC)	****	An independent review option has been available following rejection by the PBAC for 2-3 years, but has been use rarely to date.
Medicare Services Advisory Committee (MSAC)	**	Following a review of MSAC in 2005, a recommendation was made to create an independent appeals mechanism. The status of this recommendation was not established for this paper.
Department of Human Services, Victoria	**	<p>Unsuccessful applications to VPACT have 60 days from receiving written notification of the decision to appeal the decision. Any such appeal needs the endorsement of the CEO/s. Importantly, the review is not independent. DHS undertakes to clarify the issues; actions may include seeking further independent expertise and, if considered appropriate, further review by VPACT.</p> <p>The sponsor/s of an unsuccessful application within a Health Service may appeal to the Chair of the TCP Committee or to the CEO of the Health Service.</p>

10. Enforcement / monitoring of decisions

Compliance with decisions to restrict or otherwise control the diffusion of new technology through the health care system should not be assumed. Post-approval monitoring / auditing of clinical practice to ensure compliance, and to test the validity of forecast expenditures, is highly a desirable feature of a HTA system.

Institution	Ranking	Description of Approach to Key Characteristic
International		
National Institute of Clinical Excellence (NICE); United Kingdom	*	Although NHS has a legal responsibility to implement NICE decisions, NICE itself does not audit or otherwise monitor Primary Trusts of the NHS to ensure compliance.
Canadian Agency for Drugs and Technologies in Health (CADTH)	-	CADTH is a technical group providing evaluation with no role in decision making. Some contribution to public policy is made through its research activities, but auditing and compliance are not functions of CADTH.
Health Services Commission (State of Oregon)	*****	The Prioritized List is a legally enforceable list of entitlements to those covered by Medicaid.
Australian		
Pharmaceutical Benefits Advisory Committee (PBAC)	****	The PBAC itself is an advisory body (although the Minister cannot approve a drug without a positive recommendation from the PBAC). The committee structure though includes the Drug Utilisation Sub-Committee which monitors utilisation. Larger sales than forecast are drawn to the attention of the pricing authority for potential re-negotiation of unit prices.
Medicare Services Advisory Committee (MSAC)	***	As with the PBAC, MSAC is an advisory body without responsibility for compliance. The approach to managing costs on the MBS is different such that increases in utilisation can be accommodated by reducing the benefit paid.
Department of Human Services, Victoria	**	DHS has identified the need for post-approval monitoring and specified this as a function of the New Technology Program. Compliance though with post-implementation evaluation has been reported to be weak (<i>Accenture Health Options Review; Demand Management Project</i> . January 2007). Once funding is mainstreamed, reliance upon conformity with restrictions for use of technology to achieve cost control becomes subsumed with overall budget control.

11. Control of overall budget retained

Cost containment of health care is an important objective of all governments. The process of HTA should enable careful consideration of budget implications and ensure that recommended / approved technology is affordable.

Institution	Ranking	Description of Approach to Key Characteristic
International		
National Institute of Clinical Excellence (NICE); United Kingdom	***	Positive recommendations from NICE must be implemented by Primary Trusts of the NHS within 3 months. Budget control comes from review of the affordability of a technology at the time of short-listing for appraisal.
Canadian Agency for Drugs and Technologies in Health (CADTH)	*	CADTH provides advice on likely costs, but does not have responsibility for cost containment.
Health Services Commission (State of Oregon)	***	The Prioritised List for the Oregon Health Plan comprises over 700 'lines' or groups of conditions / treatment pairs ranked in order of priority. Budget control is achieved by re-calculating each year how many lines are affordable. The cut-off for funding is the last item considered affordable within the budget allocated by the Oregon legislature.
Australian		
Pharmaceutical Benefits Advisory Committee (PBAC)		The PBAC does not have direct responsibility for control of the pharmaceutical budget. However, indirect control arises from determination of the acceptable cost-effectiveness threshold as variations in the threshold have flow-on effects for overall expenditure. The Minister of Health has authority to approve listing of drugs on the PBS up to \$10 million p.a. Above \$10 million, decisions must go to Cabinet.
Medicare Services Advisory Committee (MSAC)		As for the PBAC, MSAC does not have direct responsibility for control of the budget. For technical reasons, the cost-effectiveness threshold applied should be the same as for the PBAC, however the different approach to managing the MBS schedule means there is a weaker association between the threshold and total expenditure on medical services. For medical services, a budget is allocated to each item on the MBS, the likely number of services estimated, and the fee calculated = [budget ÷ No. Items].
Department of Human Services, Victoria		Funding decisions made under the New Technology Program/ Clinical Practice Program is capped, but have long term funding implications for Health Services who would be expected to fund the technology once mainstreamed. To ensure affordability, the due diligence process (refer Error! Reference source not found.) includes a review of the recurrent funding implications, and acceptance of those implications, by the relevant area of DHS with portfolio responsibility for the technology concerned. Restrictions to both the diffusion of new technology amongst Health Services and the approved indications are also used to contain costs (refer Drug-Eluting Stent case-study, Error!

Institution	Ranking	Description of Approach to Key Characteristic
		Reference source not found.).

12. Administration cost affordable

The HTA process itself needs to be both efficient and affordable.

Institution	Ranking	Description of Approach to Key Characteristic
International		
National Institute of Clinical Excellence (NICE); United Kingdom	*	NICE employs over 200 people directly and has contracts with 7 academic centres to provide appraisal reports. The current annual budget is \$68million
Canadian Agency for Drugs and Technologies in Health (CADTH)	***	Approximately \$9.5 million on HTA activities. The number of employees could not be ascertained.
Health Services Commission (State of Oregon)	*****	Approx 3-4 staff support the Commissioners. An actuarial firm is engaged each to provide utilisation and budget estimates for each new technology
Australian		
Pharmaceutical Benefits Advisory Committee (PBAC)	**	Not divulged
Medicare Services Advisory Committee (MSAC)	**	Not divulged
Department of Human Services, Victoria	*****	Approx 3 staff engaged in HTA under the New Technology / Clinical Practice program, and voluntary membership of VPACT, results in the cost of the system being very low relative to that of the PBAC, MSAC and most overseas HTA systems. The costs at the Health Service level are difficult to estimate as the TCP committee system engages a diverse group of clinicians and managers who undertake a variety of activities only part of which relate responsibilities with TCP committee.

13. Acceptability by stakeholders

It is clearly desirable that all stakeholders understand and accept the goals of the HTA system and the process adopted. Funding of health care is inherently controversial. At the margin of funding, decisions to fund, or more particularly not to fund, will always attract criticism from interested parties. The executive of NICE has been quoted in a recent journal article as saying “..If we spend a lot of money on a few patients, we have less money to spend on everyone else. We are not trying to be unkind or cruel. We are trying to look after everybody.”, from which the authors suggest “..NICE can be viewed as either a heartless rationing agency or an intrepid and impartial messenger for the need to set priorities in health care.”(Steinbrook, 2008)⁷ . These comments apply to all jurisdictions listed below.

Institution	Ranking	Description of Approach to Key Characteristic
International		
National Institute of Clinical Excellence (NICE); United Kingdom		Generally accepted
Canadian Agency for Drugs and Technologies in Health (CADTH)		Maintains continued support of all Provincial Governments with the exception of Quebec.
Health Services Commission (State of Oregon)		Widely accepted
Australian		
Pharmaceutical Benefits Advisory Committee (PBAC)		Australia is regarded as an international leader in the field of pharmacoeconomic evaluation and reimbursement policy.
Medicare Services Advisory Committee (MSAC)		The MSAC process is, like the PBAC process, highly regarded internationally, but has a lower profile.
Department of Human Services, Victoria		During discussions with TCP committee representatives, VPACT members and most clinicians, the Victorian HTA system, including the criteria applied, appeared to be accepted appears well accepted, though not without scope for improvement. No discussions were held with manufacturers affected.

⁷ Steinbrook, R. (2008) Saying No Isn't NICE — The Travails of Britain's National Institute for Health and Clinical Excellence. *NEJM* 359:19;1980-81.