The Queensland Policy and Advisory Committee on New Technology (QPACT) decision-making framework for health technology investment in Queensland Health: A guidance document

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Section A: QPACT scope and process

The purpose of this guidance document is to describe the components and process of decision-making used by the Queensland Policy and Advisory Committee on New Technology (QPACT) in developing its recommendations for Queensland Health concerning investment in and the introduction of new health technologies in Queensland’s public health services.

QPACT value transparency in decision-making and strive to be accountable to all stakeholders, including patients, the people of Queensland, healthcare providers, policy-makers and executives. A transparent decision-making process will ensure that stakeholders will have a better understanding of how QPACT make its recommendations concerning new health technology investment, uptake and monitoring in Queensland’s public health services.

Scope

The scope of Queensland’s Health Technology Assessment (HTA) program includes therapeutic interventions such as prostheses, implantable devices, medical and surgical procedures. The scope of the technology assessed by the process might also include some high cost equipment and other devices used in the treatment and care of patients (e.g. interventional radiology or new diagnostic equipment).

Major bodies of work related to the scope of the program include:

- Overseeing the New Technology Funding Evaluation Program.
- Commissioning field evaluations/pilots of technologies where there is potential clinical benefit but some clinical and cost-effectiveness questions remain.
- Commissioning Health Technology Assessments (HTAs) (either in-house by the HTA Secretariat or by an external group with the appropriate HTA expertise).
- Policy and strategy – policy and planning for the introduction of new and emerging technologies into Queensland Health.
- Horizon scanning for new and emerging technologies.
- Providing advice on statewide superspecialty services including the designation of new services and reviewing currently designated services to ensure they continue to meet the criteria.

Governance

QPACT provides advice to the Director-General of Queensland Health on the adoption, diffusion, implementation and evaluation of new health technologies into Queensland Health’s acute care facilities. QPACT’s reporting pathways include:

- Integrated Policy and Planning Executive Committee (IPPEC) for policy and strategy approval and clinical service planning
- Health Infrastructure and Projects Executive Committee (HIPEC) for funding approval

QPACT is comprised of a range of clinicians and administrators who represent the various disciplines within which health technology is a core component of a service.

The HTA team is part of the Access Improvement Service in the Centre for Healthcare Improvement and reports to the Chief Executive Officer of the Centre for Healthcare Improvement. The HTA team is the secretariat to both QPACT and the four District Advisory Committees for New Technology.

QPACT principles

QPACT follows a set of principles that underpin its deliberations and recommendations, which are articulated in its Terms of Reference. These principles include:

- Providing a level of evidence which influences how policy development, planning and resource allocation occurs.
- Identifying evidence or lack of evidence, on the costs and benefits of health interventions and new and emerging treatments/diagnostics.
- Providing a vehicle for review and monitoring of new clinical interventions.
- Evaluating the economic implications and cost-effectiveness of new health technologies prior to adoption in Queensland Health.
- Appraising social, ethical and access implications of the new clinical practice and technology as well as their organisational implications for service delivery across Queensland Health.
- Ensuring appropriately credentialed and trained staff are in place when introducing new technologies.
- Ensuring health and safety for patients, clinicians and the community.
Ensuring broad-based stakeholder consultation is considered.
Ensuring ethics procedures are in place to protect patients, clinicians, and the community.
Ensuring risk management procedures are in place to reduce adverse events.

Objectives
The following objectives will be considered when assessing technologies under the New Technology Funding Evaluation Program:
- Ensuring equitable patient access to health services
- Improving patient flow through acute health services
- Decreasing elective surgery waiting lists for acute health services
- Enhancing service delivery for the major hospital redevelopment projects underway across the State

The New Technology Funding Evaluation Program process
There are seven phases of the annual New Technology Funding Evaluation Program cycle which include:

Phase 1: The pre-Expression of Interest (EOI) phase
During this phase, which represents the development of an EOI by a health service(s), the decision-making framework criteria and the QPACT Terms of Reference (inclusion and exclusion criteria) will be used to help inform health services and clinicians about the appropriateness of developing an EOI, using the criteria and considering potential safety issues, knowledge gaps, and collaborators.

Phase 2: The Expression of Interest short-listing phase
EOIs are considered by QPACT at a face-to-face meeting and are short-listed according to the inclusion and exclusion criteria of the committee’s Terms of Reference. EOIs that are short-listed will progress to the next phase where applicants will be invited to prepare a Full Submission on the technology.

Phase 3: The due diligence phase
During this phase, which represents departmental review of Full Submissions (by the HTA Secretariat), all evidence and information presented in a Full Submission will be reviewed according to the decision-making framework criteria. The HTA Secretariat will present a comprehensive due diligence document on each technology to QPACT for its assessment.

If, during the due diligence phase, it is identified that insufficient information was provided in the Full Submission, the HTA Secretariat will consult or meet face-to-face with the applicant to obtain further information.

More information on the components considered in the due diligence process is provided in Section B.

Phase 4: The recommendation development phase
During this phase, the evidence will be reviewed by QPACT at a face-to-face meeting in accordance with the decision-making framework criteria in order to formulate a recommendation regarding the implementation of the health technology under review. QPACT employs a deliberative decision-making process.

QPACT recommendations inform policy for Queensland Health regarding the support of new health technologies which have significant potential based on QPACT’s decision making criteria.

At any time, QPACT may seek additional information to inform its decision-making process and reach a recommendation.

QPACT provides recommendations to either fund, fund with conditions, or not fund particular technologies. QPACT will commit funding for a 12-24 month period to collect evaluation data. The Health Service District will be required to consider the recurrent costs of the technology for mainstream funding after the QPACT funding period. Technologies that are not supported by QPACT could be referred to Queensland Health Clinical Networks, one of the four District Advisory Committees on New Technology or the Health Technology Equipment and Replacement (HTER) Program for advice and/or funding consideration.

A field evaluation will be commissioned when a new technology appears to show potential clinical benefit but there remain some clinical questions, or questions regarding its feasibility or value for money. A project officer could be appointed where necessary to collect data and support a formal evaluation for 12-24 months.

A pilot of a new technology will be undertaken in the public health sector when strong evidence exists to support its use, including experience from other jurisdictions or the private health sector.
Phase 5: The departmental endorsement phase

During this phase, the HTA team will seek departmental endorsement of the QPACT recommendation. This process will consider the decision-making framework criteria in the context of relevant strategic, policy and planning issues relevant to the department.

Phase 6: The health service engagement phase

Should the department endorse implementation of the new health technology, the HTA team will meet with the clinicians and relevant health service staff to discuss funding, implementation, monitoring, reporting and evaluation (including key performance indicators) of the technology in light of the decision-making framework criteria. The QPACT recommendation and departmental endorsement decision will be emailed to the applicant, placed on the HTA website and announced in the quarterly HTA newsletter compiled by the HTA Secretariat.

Phase 7: Post recommendation phase - appeal process

During this phase, any new evidence introduced during the appeal process will be evaluated by QPACT using its appeals policy and the decision-making framework criteria.
**Section B: The development of a decision-making framework**

**QPACT’s approach to decision-making**

In developing this decision-making framework and guidance document, information was used from a variety of sources including a review of other decision-making methodologies from national and international HTA agencies and discussions with experts in evidence-based medicine, health economics and health policy. It was agreed that QPACT’s decision-making should be evidence-based, fair and transparent, consider access and equity of access for Queensland public patients, and align with existing policy. In order to ensure that these objectives can be achieved, QPACT has adopted a deliberative decision-making process to date.

According to a report by the Organisation for Economic Cooperation and Development (OECD), decisions on the implementation of technologies are more likely to be acceptable to a diverse range of stakeholders if the decision-making process is regarded as transparent, evidence-based and includes an appeals mechanism (OECD, 2005).

QPACT’s decision-making framework provides the basis for its deliberations throughout the six phases of the New Technology Funding Evaluation Program and in developing recommendations to Queensland Health on the adoption and diffusion of new health technologies. The due diligence process that is undertaken by the HTA Secretariat is aligned with this framework to ensure consistency. Each technology is appraised individually, as particular components of the decision-making criteria may have more applicability than other components.

A deliberative process, as defined by the Ontario Ministry for Health and Long Term Care is “a tool for producing guidance based on heterogeneous evidence. It is a participatory process that includes representation from experts and stakeholders, face-to-face interaction, criteria for the sources of scientific evidence and a mechanism for eliciting colloquial evidence while making it subsidiary to the science” (Medical Advisory Secretariat, 2009).

The key concepts of the decision-making framework which QPACT has adopted are based on the decision-making criteria originally developed by the Ontario Health Technology Advisory Committee (OHTAC, 2010). OHTAC is the single portal for providing advice to the Ontario health care system, including the Ministry of Health and Long-Term Care regarding the uptake, diffusion and distribution of new health technologies and the removal of obsolete health technologies.

OHTAC’s decision-making framework considers the following components:

- Clinical need
- Clinical benefit (safety and effectiveness)
- Value for money
- Feasibility of adoption (economic and organisational feasibility)
- Consistency with expected societal and ethical values

By employing the key concepts and framework of the decision-making process used by the Ontario Health Technology Advisory Committee (OHTAC), the Queensland HTA Program aims to consider all disciplines within the HTA process in order to provide equitable access to health services for all populations, improving patient access to services and enhancing service delivery throughout the State.

QPACT will continue to develop and adapt its decision-making process by considering other frameworks and approaches, such as The Accountability for Reasonableness Framework (A4R) for priority setting, and in developing guidelines for optimising its processes and communication. It is anticipated that its approach to decision-making will be reviewed every 12 months.

**Components of decision-making**

The above components are used throughout the due diligence process on applications to inform decisions made by QPACT (Refer to Appendix 1 for a tabular representation of the criteria and sub-criteria for decision-making).

**The clinical need and clinical benefit**

After defining the policy or research question the HTA Secretariat gathers information about the target condition, target group and the technology to be assessed. A comparator and the intended (improved) outcome/s are provided by the applicant. This information helps translate the policy question into a research question so evidence can be gathered from and substantiated by the literature.

Specific information required from the applicant regarding the new technology:

- Nature of the health problem or disease
- Epidemiology and burden of disease
- Treatment alternatives for the disease - a comparator technology currently widely diffused
- Technology status – regulatory approval by the Therapeutic Goods Administration (TGA) for use in Australia and level of diffusion (in Australia and internationally)
- Safety - identify all harms caused by the use of the technology and adverse events recorded

Sources used by the secretariat:
- Research literature (search strategies listed)
- Routinely collected data
- Guidelines
- Special sources such as disease registries, clinical expert opinion, information from manufacturers, and other sources available on the internet.
- Health Technology Assessment reports which are searchable through the International Agency for Health Technology Assessment (INAHTA) database or the websites of HTA agencies.

A critical appraisal of the evidence is performed using the tool in Appendix 2.

QPACT’s recommendations on a health technology will outline the specific demographic characteristic (e.g. age, gender, and ethnicity) only if there is clear evidence of differences based on such characteristics. Queensland Health has some unique challenges in terms of geography, population settlement patterns and cultural considerations. QPACT may consider "need" on the basis of providing access or assisting a particular health professional group to provide an improved service to a particular demographic.

Value for Money

While an economic evaluation on a new technology is often rare, where a cost-effectiveness analysis has been completed an appraisal of the literature will be undertaken using the checklist suggested by Drummond et al (2005) (Appendix 3).

In some instances, an economic evaluation will have been conducted on the new technology. However, with new technologies this is often rare. Where a cost-effectiveness analysis has been completed an appraisal of the literature will be undertaken using the checklist suggested by Drummond et al (2005) (Appendix 3).

In any Full Submission on a new technology, the applicant will be required to state the direct costs of the technology and any associated consumables. The due diligence process will then investigate if there is a potential cost offset from the technology (and evidence of potential cost-effectiveness), such as reduced length of stay, potential for the technology to reduce inpatient stay to a day surgery procedure, reduced complications and quality of life factors (e.g. reduced pain, increased mobility). Where possible, a health care provider perspective is used when assessing the value-for-money of new technologies.

Feasibility of adoption

According to the decision-making criteria developed by OHTAC, feasibility of adoption is defined as a measure with which the health technology can be adopted into the health care system (OHTAC, 2010). This is divided into economic and organisational feasibility.

Economic Feasibility

Economic feasibility takes into account the following considerations:

- The number of eligible patients likely to be treated in each year.
- The actual unit cost of the new technology and the unit costs of the comparator.
- Consideration of the direct and indirect costs associated with the adoption of the technology, including net medical costs involved for new and comparator treatments, any costs of training required to acquire the skills, and the proposed number of patients to be treated by the technology.

In the case of diagnostic/screening technologies, it is important to include the risks of false-positive and false-negative results, costs (and risks) for the treatment of false-positive cases, costs (and risks) for delays in treating false-negative cases and the treatment of sequelae of undetected disease.

Organisational Feasibility

Organisational feasibility takes into account the following considerations:

- Summary of the impact of adopting the technology on other clinical units or technologies, and on properties and facilities (e.g. capital works).
- Software requirements.
- Training requirements and if the manufacturer will provide the initial training.
Consultation with all relevant stakeholders including information technology services, patient safety officers, business manager of the relevant clinical department, capital works project officer(s) and biomedical technology services representatives. This is considered essential to the process and is subsidiary to the scientific evidence.

Alignment with the Clinical Services Capability Framework (CSCF) to determine if the new technology will impact on the clinical service area and the capability of the level of services provided in this area. The CSCF outlines the minimum support services, staffing and safety standards required in both public and private health facilities to ensure safe and appropriately supported clinical services.

Maintenance requirements beyond the funding provided under the New Technology Funding Evaluation Program.

Social and ethical considerations in HTA decision-making

Although ethics have been on the Health Technology Assessment (HTA) agenda since the 1970s, many assessments have focused exclusively on critically appraising the evidence in terms of safety and effectiveness. Cost analyses and cost-effectiveness studies have also become increasingly important when undertaking HTAs. More recently, other considerations such as social, ethical and legal aspects of technologies have become part of the HTA agenda. This is particularly relevant to HTA as there can be moral consequences associated with choosing one technology over another, which may lead to a reallocation of resources within health care or between wider sectors of society.

Despite the general agreement that ethical and social considerations are an important part of HTA decision-making, there is a lack of accepted and practical methods for incorporating social and ethical values within HTA reports. Systematic searches of the scientific literature for publications reflecting the ethical or social implications of a technology are difficult (Saarni et al, 2008).

Ethical and social analysis within the HTA decision-making process can assist decision-makers in interpreting information in a policy relevant way. Some aspects of social and ethical values that are considered in the due diligence and decision-making process (adapted from Hofmann, 2005), include:

- Does the technology in any way violate or interfere with basic human rights?
- How does the implementation of the technology affect the distribution of healthcare?
- Can the technology harm the patient?
- What patient group is the beneficiary of the technology?
- Are there third-party agents involved?
- What are the interests of the users of the technology?
- What are the interests of the producers of technology (industry, universities)?
- Are the users of the technology in the studies representative of studies to be included in the HTA?

Appeals process

QPACT invites any applicant who believes that QPACT has misinterpreted or overlooked any crucial evidence in arriving at its recommendations to bring that evidence to its attention after the results have been released by the Committee.

An applicant who disagrees with the recommendations of QPACT on the grounds that relevant evidence has been overlooked or misinterpreted is invited to complete the QPACT Appeals Form and forward to the Committee through the QPACT Secretariat within 60 days of notification of QPACT’s recommendations.

The QPACT Secretariat will review the information contained in the appeal and again apply due diligence on the application which will then be provided to QPACT. Applicants may be invited to make a 10 minute presentation to the QPACT members regarding the matter of concern to them and answer questions from the Committee for a further 5 minutes.

The Committee will communicate the outcome of the appeal in writing to the applicant within 7 days after the meeting.

The Secretariat will communicate any impending appeals by providing a report to QPACT.
### Appendix 1

QPACT’s decision-making criteria and subcriteria are detailed below:

<table>
<thead>
<tr>
<th>Criteria</th>
<th>Subcriteria</th>
<th>Definition/Considerations</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>Clinical Need</td>
<td>Burden of Illness</td>
<td>- The burden of illness on society of the target condition to which the technology is applied (e.g. incidence, prevalence, Years of Life Lost, Years Live with Disability, Disability Adjusted Life Years)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Need</td>
<td>- The need for the technology compared to the availability of alternatives to manage the target condition</td>
<td></td>
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</table>
| Clinical Benefit          | Effectiveness                         | - Effectiveness compared to available alternatives (measured in terms of relative risk, odds ratios; increased survival or progression-free survival; reduced mortality, morbidity or length of stay, etc).  
- The magnitude and direction of the technology’s effect should be considered.                                                                                                                                                                                                                                                                                                                                                                                                                               |          |
|                           | Safety                                | - Frequency and Severity of adverse events specific to the technology compared to available alternatives.                                                                                                                                                                                                                                                                                                                                                                                                                                             |          |
| Value for Money           | Value for Money                       | - A measure of the net cost or efficiency of the technology compared to available alternatives (note that Queensland Health does not use a value-for-money threshold)  
- Can be assessed in many ways including additional cost per unit of outcome,  
- Experience from international/ other jurisdictions can be used.                                                                                                                                                                                                                                                                                                                                                                           |          |
| Feasibility of adoption   | Economic Feasibility                  | - The net budget impact of the new technology  
- Costs for other system enablers (e.g. information technology, capital works, workforce remuneration/recruitment/training)  
- Funding implications (Statewide/Superspecialty status, etc)                                                                                                                                                                                                                                                                                                                                                                                                                          |          |
|                           | Organisational feasibility            | - The ease with which the health technology can be adopted by looking at other enablers and/or barriers to diffusion  
- Infrastructure/geography/clinical services capability framework/impact on other service streams (e.g. rehabilitation services)/workflow issues  
- building space or special requirements  
- ability of applicant to perform field evaluation (where relevant)                                                                                                                                                                                                                                                                                                                                                     |          |
| Consistency with Expected Societal/Ethical Values | Psychological/ Social Considerations | - Broadly shared values in society that bear on the appropriate use and impact of the technology                                                                                                                                                                                                                                                                                                                                                                                                                                                          |          |
|                           | Ethical Considerations                | - The potential ethical issues inherent in using or not using the technology  
- Please list any ethical issues identified.                                                                                                                                                                                                                                                                                                                                                                                                                                                    |          |

**Recommendation (tick one box):**

<table>
<thead>
<tr>
<th>Recommendation</th>
<th>Comments</th>
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<tbody>
<tr>
<td>Fund – conditional to Key Performance Indicators with Health Service Districts</td>
<td></td>
</tr>
<tr>
<td>Not fund – more evidence required</td>
<td></td>
</tr>
<tr>
<td>Not fund (already funded through other sources e.g. MBS)</td>
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<tr>
<td>Full Health Technology Assessment</td>
<td></td>
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</tbody>
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**Panel Chair Signature:**

**Date:**

8
## Appendix 2  Study quality checklists

| Quality checklist for systematic reviews  
(Source: NHMRC 2001) |
<table>
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<tr>
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<tbody>
<tr>
<td><strong>Quality criteria</strong></td>
</tr>
<tr>
<td>Was an adequate search strategy used (e.g. search years, databases, search terms, other sources)?</td>
</tr>
<tr>
<td>Were the inclusion criteria appropriate and applied in an unbiased way?</td>
</tr>
<tr>
<td>Was a quality assessment of included studies undertaken?</td>
</tr>
<tr>
<td>Were the characteristics and results of the individual studies appropriately summarised?</td>
</tr>
<tr>
<td>Were the methods for pooling the data appropriate?</td>
</tr>
<tr>
<td>Were sources of heterogeneity explored?</td>
</tr>
<tr>
<td><strong>Quality criteria</strong></td>
</tr>
<tr>
<td>Yes, No, Unsure, N/A</td>
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</table>

| Quality checklist for randomised controlled trials  
(Source: NHMRC 2000) |
<table>
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<tbody>
<tr>
<td><strong>Quality criteria</strong></td>
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<tr>
<td>Was the study double blinded?</td>
</tr>
<tr>
<td>Was the randomisation method for assignment of patients to treatment reported?</td>
</tr>
<tr>
<td>Was allocation to treatment groups concealed from those responsible for recruiting the subjects?</td>
</tr>
<tr>
<td>Were all randomised participants included in the analysis?</td>
</tr>
<tr>
<td>Were patients analysed in the groups to which they were randomised?</td>
</tr>
<tr>
<td>Aside from the intervention, were the groups treated equally?</td>
</tr>
<tr>
<td><strong>Quality criteria</strong></td>
</tr>
<tr>
<td>Yes, No, Unsure, N/A</td>
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</table>

| Quality checklist for cohort studies  
(Source: NHMRC 2000) |
<table>
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<tbody>
<tr>
<td><strong>Quality criteria</strong></td>
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<tr>
<td>How were subjects selected for the 'new intervention'?</td>
</tr>
<tr>
<td>How were subjects selected for the comparison or control group?</td>
</tr>
<tr>
<td>Does the study adequately control for demographic characteristics, clinical features and other potential confounding variables in the design or analysis?</td>
</tr>
<tr>
<td>Was the measurement of outcomes blinded to group assignment?</td>
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<tr>
<td>Was follow-up long enough for outcomes to occur?</td>
</tr>
<tr>
<td>Was follow-up complete?</td>
</tr>
<tr>
<td>Were there exclusions from the analysis?</td>
</tr>
<tr>
<td><strong>Quality criteria</strong></td>
</tr>
<tr>
<td>Yes, No, Unsure, N/A</td>
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</tbody>
</table>

| Quality checklist for case-control studies  
(Source: NHMRC 2000) |
<table>
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<tr>
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<tbody>
<tr>
<td><strong>Quality criteria</strong></td>
</tr>
<tr>
<td>How were cases defined and selected?</td>
</tr>
<tr>
<td>How were controls defined and selected?</td>
</tr>
<tr>
<td>Does the study adequately control for demographic characteristics and important potential confounders in the design or analysis?</td>
</tr>
<tr>
<td>Was measurement of exposure to the factor of interest (e.g. the new intervention) adequate and kept blinded to case/control status?</td>
</tr>
<tr>
<td>Were all selected subjects included in the analysis?</td>
</tr>
<tr>
<td><strong>Quality criteria</strong></td>
</tr>
<tr>
<td>Yes, No, Unsure, N/A</td>
</tr>
</tbody>
</table>

| Quality checklist for case-series  
(Source: Khan et al 2001) |
<table>
<thead>
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<tbody>
<tr>
<td><strong>Quality criteria</strong></td>
</tr>
<tr>
<td>Is the study based on a representative sample selected from a relevant population?</td>
</tr>
<tr>
<td>Are the criteria for inclusion explicit?</td>
</tr>
<tr>
<td><strong>Quality criteria</strong></td>
</tr>
<tr>
<td>Yes, No, Unsure, N/A</td>
</tr>
<tr>
<td>Quality checklist for diagnostic test accuracy studies</td>
</tr>
<tr>
<td>------------------------------------------------------</td>
</tr>
<tr>
<td><strong>Quality criteria</strong></td>
</tr>
<tr>
<td>Were eligible patients identified before the index test and standard were applied?</td>
</tr>
<tr>
<td>Is the reference standard likely to correctly classify the target condition?</td>
</tr>
<tr>
<td>Were test results interpreted without knowledge of the results of other tests?</td>
</tr>
<tr>
<td>Did all patients (or a random selection) receive verification using a reference standard of diagnosis?</td>
</tr>
<tr>
<td>Did patients receive the same reference standard regardless of the test result?</td>
</tr>
<tr>
<td>Was the time period between the index test and reference standard short enough to be reasonably sure that the target condition did not change between the two tests?</td>
</tr>
<tr>
<td>Were uninterpretable and/or indeterminate test results reported?</td>
</tr>
<tr>
<td>Were withdrawals from the study explained?</td>
</tr>
<tr>
<td>If two or more tests are compared, were they assessed independently of each other on all patients (or in randomly allocated patients)?</td>
</tr>
</tbody>
</table>

(Source: Bossuyt, Irwig, & Glasziou 2003)
Appendix 3

Drummond’s check-list for assessing economic evaluations


1. Was a well-defined question posed in answerable form?
   1.1. Did the study examine both costs and effects of the service(s) or programme(s)?
   1.2. Did the study involve a comparison of alternatives?
   1.3. Was a viewpoint for the analysis stated and was the study placed in any particular decision-making context?

2. Was a comprehensive description of the competing alternatives given (i.e. can you tell who did what to whom, where, and how often)?
   2.1. Were there any important alternatives omitted?
   2.2. Was (should) a do-nothing alternative be considered?

3. Was the effectiveness of the programme or services established?
   3.1. Was this done through a randomised, controlled clinical trial? If so, did the trial protocol reflect what would happen in regular practice?
   3.2. Was effectiveness established through an overview of clinical studies?
   3.3. Were observational data or assumptions used to establish effectiveness? If so, what are the potential biases in results?

4. Were all the important and relevant costs and consequences for each alternative identified?
   4.1. Was the range wide enough for the research question at hand?
   4.2. Did it cover all relevant viewpoints? (Possible viewpoints include the community or social viewpoint, and those of patients and third-party payers. Other viewpoints may also be relevant depending upon the particular analysis.)
   4.3. Were the capital costs, as well as operating costs, included?

5. Were costs and consequences measured accurately in appropriate physical units (e.g. hours of nursing time, number of physician visits, lost work-days, gained life years)?
   5.1. Were any of the identified items omitted from measurement? If so, does this mean that they carried no weight in the subsequent analysis?
   5.2. Were there any special circumstances (e.g., joint use of resources) that made measurement difficult? Were these circumstances handled appropriately?

6. Were the cost and consequences valued credibly?
   6.1. Were the sources of all values clearly identified? (Possible sources include market values, patient or client preferences and views, policy-makers’ views and health professionals’ judgements)
   6.2. Were market values employed for changes involving resources gained or depleted?
   6.3. Where market values were absent (e.g. volunteer labour), or market values did not reflect actual values (such as clinic space donated at a reduced rate), were adjustments made to approximate market values?
   6.4. Was the valuation of consequences appropriate for the question posed (i.e. has the appropriate type or types of analysis – cost-effectiveness, cost-benefit, cost-utility – been selected)?

7. Were costs and consequences adjusted for differential timing?
   7.1. Were costs and consequences that occur in the future ‘discounted’ to their present values?
   7.2. Was there any justification given for the discount rate used?

8. Was an incremental analysis of costs and consequences of alternatives performed?
   8.1. Were the additional (incremental) costs generated by one alternative over another compared to the additional effects, benefits, or utilities generated?

9. Was allowance made for uncertainty in the estimates of costs and consequences?
   9.1. If data on costs and consequences were stochastic (randomly determined sequence of observations), were appropriate statistical analyses performed?
   9.2. If a sensitivity analysis was employed, was justification provided for the range of values (or for key study parameters)?
   9.3. Were the study results sensitive to changes in the values (within the assumed range for sensitivity analysis, or within the confidence interval around the ratio of costs to consequences)?

10. Did the presentation and discussion of study results include all issues of concern to users?
    10.1. Were the conclusions of the analysis based on some overall index or ratio of costs to consequences (e.g. cost-effectiveness ratio)? If so, was the index interpreted intelligently or in a mechanistic fashion?
    10.2. Were the results compared with those of others who have investigated the same question? If so, were allowances made for potential differences in study methodology?
10.3. Did the study discuss the generalisability of the results to other settings and patient/client groups?
10.4. Did the study allude to, or take account of, other important factors in the choice or decision under consideration (e.g. distribution of costs and consequences, or relevant ethical issues)?
10.5. Did the study discuss issues of implementation, such as the feasibility of adopting the "preferred" programme given existing financial or other constraints, and whether any freed resources could be redeployed to other worthwhile programmes?
References


National Health and Medical Research Council (NHMRC), 2010. NHMRC additional levels of evidence and grades for recommendations for developers of guidelines. Australian Government. Available at: www.nhmrc.gov.au


OHTAC Terms of Reference [updated 2006], available www.health.gov.on.ca/english/providers/program/ohtac/terms.html#3


Victorian Policy and Advisory Committee on Technology (VPACT). 2010. ‘VPACT decision-making framework for health technology investment in Victorian public health hospitals’.