

PROPOSAL FOR THE STATEWIDE INTRODUCTION OF A NEW HEALTH TECHNOLOGY

ITEMS TO NOTE:

- All relevant sections must be completed in short, well-spaced paragraphs.
- Enquires can be directed to the following Department of Health (DoH) staff:
 - Siegi Schmidmaier, phone 9096 1296, email siegi.schmidmaier@dhs.vic.gov.au
 - Luisa Chaves, phone 9096 1410, email luisa.chaves@dhs.vic.gov.au
 - Paul Fennessy, phone 9096 2142, email paul.fennessy@dhs.vic.gov.au.
- Standing requirements for completing submissions:
 - Applicants will not canvas Victorian Policy Advisory Committee on Technology (VPACT) members.
 - Health services seeking funding for the **same** new health technology for the **same** clinical indication should collaborate to prepare a joint submission, with one health service nominating to take the lead role.
 - Cancer-related submissions must be signed off by all partners of the relevant Integrated Cancer Service.
 - High cost pharmaceuticals: VPACT will only consider those drugs that are typically reserved for use in hospitals and are generally not used in community practice (such that the drugs are not candidates for inclusion on the PBS).
 - A business case and full life cycle costing is required to be completed if seeking funding for procurement or lease of capital medical equipment costing more than \$100,000.
 - The health service New Technology Committee Chair and Chief Finance Officer must also endorse each submission prior to forwarding to DoH.
- Completed submissions are to be forwarded by close of business on **Friday 11 December 2009** to Siegi Schmidmaier (Programs Branch Level 19, 50 Lonsdale St, Melbourne 3000):
 - Submission - three (3) double-sided unbound copies and an electronic copy (Word format; PDF of signature pages)
 - Capital medical equipment business case and full life cycle costing - three (3) double-sided unbound copies and electronic copies (Word for business case, Excel for full life cycle costing, PDF of signature pages).
- Health services may be contacted by DoH for additional information.
- VPACT will consider full submissions at its March 2010 meeting for funding in 2010-11.

SECTION 1: SUMMARY INFORMATION

Health Service (name all if a joint submission)	
Hospital campus (name all if a joint submission)	
Name of new health technology	
Principal clinical discipline/service (e.g. cardiology, neurosurgery, oncology)	
Number of cases for which funding is sought	
Funding requested per case	
Total funding requested	

Lead Organisational contact(s):

Title & Name	
Position	
Phone	
Fax	
Email	

Referees

Please specify **two** referees from interstate or overseas with experience in the new health technology you are proposing to introduce for external assessment:

Referee #1	
Title & Name	
Position	
Phone	
Fax	
Email	

Referee #2	
Title & Name	
Position	
Phone	
Fax	
Email	

Endorsement by health service New Technology Committee Chair:

Health service	
Name	
Signature	
Date	

(Repeat as necessary if a joint submission)

Endorsement by health service Chief Finance Officer:

Health service	
Name	
Signature	
Date	

(Repeat as necessary if a joint submission)

Endorsement by health service Chief Executive Officer:

Health service	
Name	
Signature	
Date	

(Repeat as necessary if a joint submission)

SECTION 2: OVERVIEW OF NEW HEALTH TECHNOLOGY

1. Description of New Health Technology

Provide a brief plain language statement describing the proposed new health technology.

2. Classification of New Health Technology

Specify classification of proposed new health technology (refer Appendix Item A).

3. Category of New Health Technology

Specify category of the proposed new health technology (refer Appendix Item B).

4. Statewide Application of New Health Technology

Indicate the statewide application for the proposed new health technology and consultation undertaken with relevant health services (refer Appendix Item C).

5. Clinical Setting – is the New Health Technology for:

Specify whether the proposed new health technology is to be used in the following settings:

- Inpatients
- Outpatients (include all streams, e.g. MACS, MBS, private)
- Mix of inpatient and outpatient (specify proportion as a %)
- Other (specify, e.g. research)

6. Use of New Health Technology Elsewhere

Identify and describe use of the proposed new health technology elsewhere, both nationally and internationally.

7. Relevant DRG, ICD codes and/or other coding classification

You **must** specify relevant i) DRG and ii) ICD procedural and/or diagnostic codes.

8. Additional information for High Cost Pharmaceuticals

Please provide additional details as specified at Appendix Item D.

9. Clinical Pathway

The clinical pathway represents the patient journey through related episodes of care to treat a specific disease/clinical problem and incorporates the following:

- Care from primary through to quaternary providers
- Care from medical, allied health and nursing personnel
- Inpatient and non inpatient care
- Different types and quanta of care at different stages of the clinical problem
- Various treatment settings.

Please **detail** the clinical pathway for the patients proposed to receive the new health technology taking into account, but not limited to, the above.

SECTION 3: CLINICAL NEED

10. Clinical Indication/Disease/Condition

- 10.1. Specify the clinical indication/condition that the new health technology will treat or diagnose.
- 10.2. Provide a brief description of the clinical indication/condition and its clinical progression and prognosis.
- 10.3. Specify whether the clinical indication/condition is severe, progressive and expected to lead to premature death.
- 10.4. Provide details concerning the incidence and prevalence of the clinical indication/condition in Australia.

11. Patient Population(s)

- 11.1. What are the demographic characteristics of the patient population(s) with the clinical indication/condition (e.g. age range, median and mean, gender, ethnicity, occupation, socio-economic status)?
- 11.2. What is/are the subgroup/s of the patient population(s) that will benefit from the new health technology?
- 11.3. What factors are taken into account when considering patient selection for use of the proposed new health technology?
- 11.4. Specify the numbers of paediatric and adult patients who will receive the proposed new health technology per annum.
- 11.5. If this number is expected to increase over time and/or have a cumulative component due to ongoing follow-up, please specify the predicted numbers of new and follow-up patients by year for 5 years.

12. Comparison With Existing Approach(es) To Clinical Intervention

- 12.1. What existing clinical technology or practice is/are used for this clinical indication/condition?
- 12.2. Describe how the new health technology differs from this/each of these:
 - Significant clinical advantages over existing treatment
 - No worse than existing treatment in terms of effectiveness/toxicity or
 - Less effective than the existing treatment, but has less toxicity.
- 12.3. How will implementing this new health technology impact on the existing clinical technology or practice?

13. Opportunities for Disinvestment

Introducing a new health technology often provides an opportunity to substitute for a proportion of existing treatment or diagnostic paradigms (e.g. introducing EBUS for lung cancer staging has reduced the need for mediastinoscopy by > 80%). Please identify and detail the impact that the new health technology will have on existing paradigms and indicate how this impact might be measured.

14. Health Outcomes

- 14.1. What are the health outcomes that will be achieved by the proposed new health technology? How will these be measured and over what time frame will these occur?

SECTION 4: EVIDENCE OF SAFETY, EFFICACY & CLINICAL EFFECTIVENESS

15. Regulatory Approval

- 15.1. You **must** provide documentary evidence of approval for the new health technology for use in Australia for the identified clinical indication by the Therapeutic Goods Administration.
- 15.2. If a high cost pharmaceutical, you **must** provide additional information as detailed at Appendix Item E.

16. Evidence of Safety

- 16.1. **Provide documentary evidence** of safety (e.g. TGA approval) associated with the use of the new health technology for the proposed clinical indication.
- 16.2. List nature and incidence of side effects, contraindications, cautions, warnings and adverse effects for the proposed new health technology and the proposed indication, and source of this information.
- 16.3. What are the main differences in the indications, contra-indications, cautions, warnings and adverse effects between the proposed new health technology and existing treatments, and the source of this information?

17. Evidence of Efficacy and Clinical Effectiveness

Evidence of efficacy and clinical effectiveness must exist for the proposed new health technology. Please summarise the best available evidence, outlining key aspects, for clinical effectiveness of the new health technology for the defined clinical indication.

If the new health technology is a diagnostic test, you must provide information about the comparative effectiveness against the current gold standard (i.e. provide information about sensitivity, specificity, diagnostic accuracy).

You must address the strength of evidence, size of effect & relevance of effect in your response (refer to Appendix Item F for further information).

As a bare minimum, you should identify whether such evidence has been published by those agencies listed at Appendix Item F.

18. Clinical Guidance/Clinical Practice Guidelines/Other

Specify briefly, and provide, any Clinical Guidance, Clinical Practice Guidelines, WHO classifications for the proposed new health technology.

19. Health Service Assessment

- 19.1. Your health service's New Technology Committee (or equivalent) must endorse this submission prior to forwarding to the department. You **must** provide documented proof of your New Technology Committee's endorsement (Committees if a joint submission).
- 19.2. Please provide details of any health service ethics committee consideration regarding the proposed new health technology.

SECTION 5: EVIDENCE OF COST EFFECTIVENESS

20. Evidence of Cost Effectiveness

You are not expected to analyse the cost effectiveness of the proposed new health technology.

It is unlikely that published evidence of cost effectiveness regarding the proposed new health technology will exist, but any available evidence of cost effectiveness for the proposed new health technology must be provided.

Please summarise any available evidence of cost effectiveness and identify any real and/or potential cost efficiencies (i.e. gains/losses for the health service) associated with introducing the proposed new health technology. Please provide any supporting documentation.

As a minimum, those websites detailed in Appendix G should be searched for any evidence of cost effectiveness.

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SECTION 6: CLINICAL FEASIBILITY

21. Bed Utilisation

- 21.1. Specify whether use of the new health technology will require patients to be managed in Intensive Care, multi day beds or same day beds.
- 21.2. What is the estimated average length of stay per annum for patients receiving the proposed new health technology at each health service?
- 21.3. What bed numbers are required per annum at each health service?
- 21.4. Will bed utilisation be increased or decreased, and by how much with the proposed new health technology?
- 21.5. Will this occur within existing capacity? If not, detail the proposed solution for this.
- 21.6. How will the introduction of the proposed new health technology affect demand management and access to existing elective and emergency patients?

22. Clinical Personnel and Expertise

- 22.1. Specify the type of clinical personnel required to implement the new health technology.
- 22.2. Detail existing clinical personnel and expertise available to implement the new health technology.
- 22.3. Is additional clinical personnel and expertise required to implement the new health technology? If so please specify.

23. Operator Competency

- 23.1. Specify what credentialing and competency assurance is needed to ensure safe implementation of the new health technology.
- 23.2. Has this been undertaken? If not, how and when will this occur?

24. Associated Service Utilisation

- 24.1. Specify all other services (e.g. ICU, OR, imaging, pathology, outpatients) that will be utilised for the changed health technology.
- 24.2. Are these available within existing capacity, and if not, why not?
- 24.3. If additional services are required to implement the new health technology (refer Appendix Item H), identify and detail how you propose to source.

25. Future Service Impacts

- 25.1. Specify the existing health technology(ies) that the proposed new health technology is likely to replace setting (refer to Appendix Item I).
- 25.2. Are there emerging trends with this new health technology that may have substantive future impacts on services? If so, please specify and describe.

SECTION 7: GOVERNANCE

26. Clinical Governance

The submission must also demonstrate, where appropriate, that existing appropriate governance structures have considered the proposed new health technology (e.g. ethics/research/DTC committees).

Describe the clinical governance arrangements and processes overseeing the implementation of the new health technology.

27. Monitoring And Evaluation

- 27.1. Specify how your health service will monitor the new health technology once it is introduced into the clinical setting (refer to Appendix Item J which details elements for consideration).
- 27.2. Specify an evaluation protocol, including all relevant performance indicators and defined time points, for the new health technology.

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SECTION 8: ESTIMATED FINANCIAL IMPACT

28. Existing Costs for Current Practices

Provide details of existing costs for current clinical practices and treatment in this patient population, as detailed at Appendix Item H.

29. Existing Revenue for Current Practices

Provide details of revenue and its sources for the care continuum for current clinical practices in this patient population, as detailed at Appendix Item K.

30. Projected Costs for Proposed New Health Technology

30.1. If the proposed new health technology is a prosthesis, implantable device, high cost pharmaceutical or diagnostic test:

- What is the **unit cost**?
- What is the average number of units administered/used per case?

30.2. Indicate if additional costs are required to implement the NTCP not covered by usual revenue sources, as detailed in Appendix L.

30.3. What are the inpatient and outpatient costs per case?

30.4. What is the total cost of the new health technology per case?

30.5. Specify source of costing data for each element.

31. Additional recurrent budget requirement

If applicable, detail and justify additional recurrent budget requirements per case.

32. One-Off Establishment Costs

If applicable, detail and justify one-off establishment costs for the proposed new health technology.

33. Projected Revenue for Proposed New Health Technology

Provide estimates of revenue and its sources for the new health technology for the care continuum.

34. Alternative Funding Sources

You must identify and detail alternative sources of funding obtained or being sought regarding the proposed new health technology (e.g. capital costs, operating costs, philanthropic funds, MBS revenue, research).

35. Summary of funding requested

35.1. Number of cases for which funding is sought (at each health service).

35.2. Funding requested per case.

35.3. Total funding requested (at each health service and total).

SECTION 9: IMPLEMENTATION OF THE NEW HEALTH TECHNOLOGY

36. Implementing the proposed new health technology

Provide a detailed implementation plan and timeframe for introducing the new health technology in your health service. Include milestones, timeframes and managing the implementation of the new health technology (especially if the new health technology will be implemented across more than one health service). Where related to capital medical equipment, also provide a payment/milestone schedule or plan.

NB: Notification by DoH that it endorses the VPACT recommendation and approves a funding allocation towards the new health technology should be considered as Week Zero.

Should this submission be recommended and endorsed, DoH officers will make arrangements to meet with the lead contact to discuss processes, funding, reporting requirements and other issues around implementing the new health technology.

Due to the financial implication around allocating additional funding, it is a requirement that the Chief Finance Officer, or their delegate, will participate in this meeting.

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SECTION 10: CAPITAL MEDICAL EQUIPMENT BUSINESS CASE

Note: *This section is to be completed when the New Health Technology submission seeks funding for capital medical equipment procurement > \$100,000 or as requested by DoH.*

If not relevant to your submission, please delete this page prior to forwarding to DoH.

This section utilises the business case and full life cycle costing templates that health services are requested to complete related to capital medical equipment procurement.

This requirement under the New Technology Program is only required for submissions seeking related capital medical equipment funding and aligns with and supports existing DoH policy.

Any funding sought for capital medical equipment through the 2010-11 New Technology Program is not guaranteed, but will be considered by VPACT and DoH.

If relevant, please complete this section.

If this section is relevant to this submission, you must also complete:

1. the *Medical equipment business case* template
2. a full life cycle cost analysis.

The full submission proforma is available at <http://www.health.vic.gov.au/newtech/funding.htm>.

The *Medical equipment business case* template is available at <http://www.health.vic.gov.au/newtech/funding.htm>.

Contact DoH for the Excel spreadsheets regarding the full life cycle cost analysis to be emailed to you.

For more information regarding completion of the *Medical equipment business case* template, please refer to Appendix M and <http://www.health.vic.gov.au/med-equip/mebcp.pdf>.

APPENDIX (NB: delete the Appendix prior to forwarding to DoH)

This Appendix provides additional information for applicants preparing a submission for VPACT consideration. Applicants are strongly encouraged to review Items in drafting their submissions.

A. A New Health Technology is classified as one of the following:

- New health technology/clinical practice
- Substitute or replacement for an existing technology/practice
- Extended use of an existing technology/practice or
- Other (please specify).

B. Categories of New Health Technology:

- Prosthesis
- Implantable device
- Diagnostic technique
- Medical procedure
- Surgical procedure
- High cost pharmaceutical
- Other therapeutic intervention

C. Statewide application of proposed New Health Technology:

The proposed new health technology is expected to have one of the following statewide applications:

- Highly specialised service at a single hospital (e.g. Paediatric Lung Transplantation)
- Specialised service provided at major tertiary hospitals (e.g. cerebrovascular coils)
- Specialised service provided in metropolitan and regional Health Services/hospitals (e.g. drug-eluting stents) or
- Less specialised service provided in metropolitan and rural/regional Health Services/hospitals (e.g. administration of chemotherapeutic agents).

Where the new health technology is expected to have broad application across the system, indicate what consultation has been undertaken with all relevant health services.

D. If submission is for a High Cost Pharmaceutical, the following additional information is required:

- Generic name
- Trade name
- Dosage form
- Dosage strength
- Pack/vial/bottle size
- Normal dosage schedule
- Normal duration of treatment
- Restrictions recommended
- Specify line therapy (i.e. first line, second line, etc.)

E. Regulatory approval of proposed New Health Technology:

If a high cost pharmaceutical, please provide the following information:

- Documentary evidence of approval for use by local Drug Therapy Committee(s)
- Has manufacturer/distributor sought listing on the PBS (Section 85 or Section 100), Commonwealth Chemotherapy Pharmaceutical Access Program or Highly Specialised Drugs Program for this indication? If so, indicate when and provide documentary evidence of outcomes of PBAC recommendation(s) and
- List other indications for this drug that are funded by existing programs.

F. Evidence of clinical effectiveness of proposed New Health Technology:

The following three dimensions of evidence must be addressed in your submission:

- Strength of evidence (which considers the level of evidence, the quality of that evidence and the statistical precision of that evidence)
- Size of effect (which the clinical importance, as opposed to statistical significance, of the primary outcomes of each included study) and
- Relevance of effect (assess the relevance of the results of an individual study with respect to the appropriateness of the outcomes, the appropriateness and generalisability of the study population and the generalisability or applicability to the proposed new health technology)

Further information about these dimensions of evidence is at http://www.nhmrc.gov.au/consult/files/levels_grades05.pdf.

Health services preparing a submission for VPACT consideration are expected to identify whether Health Technology Assessments (HTAs) produced by the agencies listed below support their submission. This list of agencies is not exhaustive and other agencies may have published relevant HTAs.

Australia

- Medical Services Advisory Committee <http://www.msac.gov.au>
- Australian Safety and Efficiency Register of New Interventional Procedures – Surgical (Royal Australasian College of Surgeons) <http://www.surgeons.org/asernip-s/>
- National Health and Medical Research Council <http://www.nhmrc.gov.au>
- Australia and New Zealand Horizon Scanning Network <http://www.horizonscanning.gov.au>

Europe

- National Institute for Health and Clinical Excellence (UK) <http://www.nice.org.uk>
- National Coordinating Centre for Health Technology Assessment (UK) <http://www.ncchta.org>
- EuroScan (European Consortium) <http://www.euroscan.bham.ac.uk/>
- Cochrane Library <http://www.thecochranelibrary.org/>

North America

- Canadian Agency for Drugs and Technologies in Health (Canada) <http://www.cadth.ca/index.php/en/home>
- Evidence-based Practice Centres (USA) <http://www.ahrq.gov/clinic/epcix.htm>
- Medical Advisory Secretariat (Canada) (http://www.health.gov.on.ca/english/providers/program/mas/mas_mn.html)
- Blue Cross Blue Shield Technology Evaluation Center (USA) (<http://www.bcbs.com/blueresources/tec/>)

G. Evidence of cost effectiveness of proposed New Health Technology:

Since published evidence of cost effectiveness regarding new health technology is limited, you should identify whether any evidence of cost effectiveness exists. As a bare minimum, you should review the websites listed in Appendix F above for evidence of cost effectiveness.

H. Recurrent operational input costs for proposed New Health Technology:

Consideration of the following elements should inform proposed costs for clinical and other services concerning Pre-admission assessment, Inpatient care and Post-discharge care (e.g. EFT and any other associated costs):

- Specialist Medical Practitioner
- Allied health by type
- Pharmacy
- Theatre (Surgical, Anaesthetist, Other)
- ICU
- Imaging
- Pathology
- Specialist Consumables
- Dietary supplements
- Outpatient Organisational overheads
- Other

I. New Technology/Clinical Practice replacing existing technology/practice:

This section seeks to identify what existing health technology or clinical practice can be replaced by introducing the proposed new health technology. For example:

- CT- or endobronchial ultrasound-guided FNA can replace mediastinoscopy for lung cancer staging
- Drug-eluting stents can replace bare metal stents in patients considered at high risk of restenosis
- Double-balloon enteroscopy can replace exploratory laparoscopy for idiopathic upper GI bleeding.

J. Monitoring And Evaluation:

Elements that might be considered as part of the monitoring process following the introduction of a new health technology within the clinical setting:

- Learning curve for operator(s)
- Credentialing
- Experience
- Quality plan
- Stopping rule

K. Revenue for existing practice and proposed New Health Technology:

Revenue sources for the care continuum for existing practice and the proposed new health technology can include, but are not restricted to, the following:

- WIES
- VACS – medical
- VACS – allied health
- Specified grants
- Alternative funding mechanisms (e.g. Highly Specialised Drugs, Section 100, Nationally Funded Centre)
- Other

L. Projected recurrent costs for proposed New Health Technology:

Costs for the proposed new health technology throughout the care continuum can include, but are not restricted to, the following:

- Staffing and salaries (you should specify each type and number of clinicians by session/hours/EFT as appropriate)
- Administration (staffing and salaries by EFT)
- Staff/salary overheads (provide breakdown)
- As appropriate for (i) Pre-admission assessment, (ii) Inpatient care and (iii) Post-discharge care and follow-up, for each clinical and other service specify how the costs are derived (refer to Appendix Item I for a non-exhaustive list of services).

M. Business Case Template to procure capital medical equipment for proposed New Health Technology:

Should the submission include a proposal to procure capital medical equipment with a value > \$100,000, a business case and full life cycle costing **is required**. This information articulates the qualitative and financial analysis of several viable options around procuring the proposed capital medical equipment. These options could include outright capital purchase, periodic payment plan over the course of the new health technology funding agreement, outsourcing and bundling.

You are referred to the DoH policy/publication *Medical equipment asset management framework - Medical equipment business case package September 2007* for further information. This has informed this new requirement in the 2010-11 New Technology Program submission process, which has been formally requested by VPACT.

Why does the Medical Equipment Business Case and full life cycle costing need to be completed?

- To align with existing DoH policy
- At the request of VPACT
- To inform VPACT decision-making regarding submissions for the 2010-11 New Technology Program to procure additional (versus replacement) equipment with a value in excess of \$100,000.

It is acknowledged that the VPACT decision-making process on capital medical equipment needs occurs separately from other DoH funding opportunities or calls for funding submissions.