



Department of Health
Government of Western Australia

**POLICY FOR THE INTRODUCTION OF HIGH-COST
NEW HEALTH TECHNOLOGIES
INTO THE WESTERN AUSTRALIAN
PUBLIC HEALTH SYSTEM**

May 2005

Policy for the Introduction of High-Cost New Health Technologies into the Western Australian Public Health System

1. *Purpose*

New diagnostic and therapeutic devices and procedures have at times been introduced into the health system without proper assessment of their utility and cost. This policy provides a consistent State-wide framework for the introduction of new health technologies into clinical practice so that patients, clinicians and managers can be assured that new technologies are supported by evidence of appropriateness, efficacy, safety and effective resource utilisation. The policy includes a process for monitoring the outcomes.

2. *Definitions*

New health technologies are technologies which have not previously been used in the State of Western Australia or which are significant variations of existing technologies. They include the following¹:

- **Devices:** non-diagnostic equipment; drug delivery systems; monitoring systems; therapeutic inserts (i.e. through existing body cavities); prostheses, tissue regeneration and bioengineered products used on the surface of the body; non-diagnostic imaging, and biomaterials; and implantable devices.
- **Diagnostics:** diagnostic imaging methods and equipment, diagnostic testing methods, diagnostic implants, interventional diagnostic procedures (e.g. new biopsy techniques), gene-based diagnostics, genetic markers, tumour markers, and screening tests.
- **Procedures:** surgical procedures and techniques, medical interventional and therapeutic procedures, rehabilitation and other allied health techniques, modifications of existing procedures.

Procedures will not be addressed on a Statewide basis at this stage but may be included at a later date if it is thought necessary. Pharmaceuticals are specifically excluded since the Western Australian Drug Evaluation committee has the responsibility of assessing new drugs.

3. *Scope*

The scope of this State-wide policy will be limited to technologies that are expected to cost more than \$10 thousand per patient or if adopted across the State will incur estimated costs of over \$1 million annually. It is expected that individual hospitals, health services and area health services will maintain local policies to address the introduction of new health technologies which fall under this threshold.

4. *National Context*

There are a number of organisations and committees involved in health technology assessment and approval at the national level. These are:

Therapeutic Goods Administration (TGA)

The Therapeutic Goods Administration (TGA) is a unit of the Australian Government Department of Health and Ageing (DOHA). The TGA carries out a range of assessment and monitoring

¹ Australian Horizon Scanning Network Definitions, 2003

activities to ensure therapeutic goods available in Australia are of an acceptable standard with the aim of ensuring that the Australian community has access, within a reasonable time, to therapeutic advances.

Medicare Services Advisory Committee (MSAC)

MSAC is a Commonwealth committee. The terms of reference of the Medical Services Advisory Committee are to:

- 1) advise the Minister for Health and Ageing on the strength of evidence pertaining to new and emerging medical technologies and procedures in relation to their safety, effectiveness and cost effectiveness and under what circumstances public funding should be supported;
- 2) advise the Minister for Health and Ageing on which new medical technologies and procedures should be funded on an interim basis to allow data to be assembled to determine their safety, effectiveness and cost effectiveness;
- 3) advise the Minister for Health and Ageing on references related either to new and/or existing medical technologies and procedures; and
- 4) undertake health technology assessment work referred by the Australian Health Ministers' Advisory Council (AHMAC), and report its findings to AHMAC

Health Policy Advisory Committee on Technology (HPACT)

HPACT is a Commonwealth committee. HPACT advises MSAC. Membership is drawn from States and Territories, MSAC, DOHA, ASERNIP-S (see below) and other relevant technology assessment organisations.

- 1) Provides policy and planning advice to MSAC and the Australian Government on the potential impact of the introduction of new technology into the Australian health care system.
- 2) Oversees the operation of the National Horizon Scanning Unit.

National Horizon Scanning Unit (HSU)

The HSU is a Commonwealth funded unit which is located in the Department of Public Health at the University of Adelaide. The HSU alerts the Health Departments of the Australian Commonwealth, States and Territories, and New Zealand, of new and emerging health technologies that may impact on the Australian public health care system. Potentially significant new health technologies are also assessed by the HSU for safety, effectiveness, cost effectiveness and on ethical grounds, to assist policy makers. The HSU also performs work directly for ASERNIP-S and MSAC.

Australian Safety and Efficacy Register of New Interventional Procedures - Surgical (ASERNIP-S)

ASERNIP-S is a Commonwealth-funded venture of the Royal Australasian College of Surgeons (RACS). Services provided include systematic and accelerated reviews of the peer literature, the establishment and facilitation of clinical and research audits or trials, the identification and assessment of new and emerging techniques and technologies by horizon scanning, and the production of clinical practice guidelines.

New and Emerging Techniques – Surgical (NET-S)

NET-S was developed with the aim of providing an early warning system for identification of new and emerging surgical techniques and technologies prior to their introduction into routine clinical practice. NET-S is administered by ASERNIP-S in conjunction with RACS.

5. *State Context*

Medical Director's Forum (MDF)

The Directors of Medical Services meet monthly as the Medical Director's Forum. The forum considers items of interest to all public hospitals and advises the Chief Medical Officer on issues requiring a Statewide response.

Statewide Policy Division

The Statewide Policy Division receives information from the national bodies and informs the Department of Health, including the MDF, of any issues which are expected to impact upon the Western Australian Health Sector in the near future. The Statewide Policy Division concentrates particularly upon high cost and/or resource intensive items and provides advice on appropriate strategies for their controlled evaluation and introduction. The Division has links to HPACT.

6. *Process*

1. All new technology or new applications of current technology which fit the criteria must undergo a formal approval process, which will be managed by the Medical Director's Forum (MDF), assisted by the Statewide Policy Division, of the Department of Health.
2. Decisions will be based upon advice from all relevant stakeholders, independent expert opinion and published evidence. Clinical, economic, equity and any other relevant issues will be considered. **No submission will be considered unless accompanied by an independent literature review commissioned by the proponents of the technology.**
3. The MDF's decision on the introduction of new health technologies which fit the criteria will be ratified by the State Health Executive Forum (SHEF) Chief Executive's committee. The decision of the SHEF Chief Executives committee is final. Funding is not implied or guaranteed until agreed by the Chief Executives committee.
4. All Area Health Services are expected to have policies and guidelines in place with the relevant Committees established to assess and approve submissions on the introduction of new health technologies.
5. Submissions by the area health service to the MDF for the introduction of new technology must first be approved by the area health service relevant Committees and endorsed by the Chief Executive Officer or his delegate. Area Health Services may choose to make joint submissions. The MDF may choose to broaden the scope of an application to include any other area health services in its determination based on its assessment of the likely spread of a technology.
6. The MDF may also choose to assess a particular technology to which it has been alerted by clinicians, administrators, the Clinical Policy Branch or any other body without specific referral from an area health service.

7. Submissions for the introduction of new technology or new applications of current technology must be completed by the proponents of the technology using the attached proforma, "Submission for the Introduction of New Technology" and endorsed by the health service CEO or his delegate (Attachment 2). Submissions should be sent to:

Chairman, Medical Directors Forum
c/o Group Director Statewide Policy Division
Department of Health
189 Royal Street
EAST PERTH WA 6004
8. Proponents will be informed of the outcome of the submission in a timely manner.
9. Where a proponent of a new technology is unhappy with the conclusions and recommendations of the MDF, the unsuccessful proponent may appeal to the Chief Medical Officer who will review the decision prior to ratification by the SHEF Chief Executives committee.
10. Following approval, regular progress reports must be submitted to the relevant health service committees and clinical bodies and a copy of the reports forwarded to the MDF. The MDF will recommend the frequency and duration of reporting.
11. Problems with any new technology must be reported immediately to the relevant health service committee and clinical bodies and to the MDF. A Medical Device Incident Report must be forwarded to the TGA. Report forms are available at:

<http://www.tga.gov.au/problem/index.htm>
12. A register of all submissions and subsequent reports from all Committees will be maintained by the MDF.

7. Guiding Principles

Existing Mechanisms

The Department of Health, Western Australia, through the Clinical Policy Branch, is guided by the determinations of the national bodies mentioned in section four. Western Australia nevertheless reserves the right to make its own determinations in the interest of the local population even though these may be at variance with those of Commonwealth bodies. The single exception is the determinations of the TGA since technologies cannot be sold or distributed in Australia without TGA approval.

Health and Safety

The provisions of this policy are set out with a view to the health and safety of:

- consumers
- clinicians
- non-clinical staff
- the general community

Costs and benefits

There is an opportunity cost associated with the introduction of any new procedure. The resources consumed by the new procedure need to be weighed against the benefits of performing the procedure and the effects of redirecting these resources away from existing services.

Evidence based practice

Most technologies will have been evaluated or implemented elsewhere. This experience provides valuable evidence for the evaluation of the new procedure or technology. The evidence should be considered in relation to the particular environment and conditions in which the procedure or technology was introduced. Levels of evidence should be quoted according to the international standard.

Risk management

A risk management approach according to Australian Standard AS/NZS 4360: 2004 (Risk Management)² is essential in managing the introduction of new interventions into clinical practice to reduce the risk of adverse outcomes.

Ethics and Research

Any information relating to Ethics Committee approvals or research protocols must be included with the submission to the MDF.

Credentialing

The safe and effective introduction of new technology demands a high level of clinical skills and competence, adequate resources and appropriate infrastructure to ensure safety, effectiveness and efficiency for patients, care teams and the broader health service. Effective credentialing systems must be in place at the health service to ensure that individual clinicians and the clinical teams are competent and properly supported to perform the procedure³.

Training

Training should include all professionals who will be involved in the new procedure such as trainee medical staff, nurses, allied health and any support staff (eg. those involved in setting up and sterilising the equipment).

Conflicts of interest

There must be full disclosure of:

- a) any relationship between the clinician and the supplier concerned
- b) any relationship between the clinician and any other significant party
- c) involvement in prior assessment or development of the technology
- d) any financial interest in the technology that could result in a conflict of interest.

Patient information and informed consent

Patient information and consent forms must be developed at the time of application outlining the potential risks as accurately as possible, including any areas of uncertainty. The criteria for selection of patients for the new procedure should also be included in the information and consent forms.

Monitoring

Any new procedures must be monitored after their introduction. Systems to collect data should be established prior to introduction and data should be peer reviewed and independently reviewed. Any adverse events are to be reported and the causes reviewed according to current Department of Health policy⁴.

² AS/NZS 4360:2004 Risk Management. Standards Australia/Standards New Zealand. 3rd edition. 2004

³ Credentialling: An Introduction. Office of Safety and Quality in Health Care. WA Department of Health.

⁴ Incident Reporting and Management Policy. Office of Safety and Quality in Health Care. WA Department of Health.

Equipment and supplies

New equipment and supplies that may be required for the procedure and their maintenance are to be approved through the appropriate committees as set out by Health Supply WA Guidelines.

8. *Acknowledgements*

Royal Australian College of Surgeons and Australian Safety and Efficacy Register of New Interventional Procedures - Surgical (ASERNIP-S), General Guidelines for Assessing, Approving and Introducing New Procedures into a Hospital or Health Service.

New South Wales Health, Model Policy for the Safe Introduction of New Interventional Procedures into Clinical Practice. October 2003.

Commonwealth Department of Health and Ageing, Draft Policy for the Introduction of New Health Technology into the Public Health System, February 2002.