Government of Western Australia
Department of Health

Policy Frameworks
MP 0072/17
Effective from: 3 February 2021

Health Technology Governance Policy

1. Purpose

This Policy specifies the clinical governance, safety and quality requirements for health technologies introduced into and used within the WA health system.

Clinical innovation through the introduction of health technologies, including procedures, diagnostic techniques and medical devices, can bring significant benefits to WA patients. Health Service Providers are responsible for ensuring that health technologies used are safe, clinically effective and cost effective.

This Policy is consistent with the statement and purpose of the *Clinical Governance, Safety and Quality Policy Framework* which is to ensure that patients receive care that is safe, effective and efficient, and that clinical governance structures and processes are maintained across the WA health system.

This Policy should be read in conjunction with the *Procurement Policy Framework.*

This Policy is a mandatory requirement under the *Clinical Governance, Safety and Quality Policy Framework* pursuant to section 26(2)(a) and (c) of the *Health Services Act 2016*.

2. Applicability

This Policy is applicable to the following Health Service Providers:

- Child and Adolescent Health Service
- East Metropolitan Health Service
- North Metropolitan Health Service
- PathWest Laboratory Medicine WA
- South Metropolitan Health Service
- WA Country Health Service.

To the extent that the requirements contained within this Policy are applicable to the services purchased from contracted health entities, Health Service Providers are responsible for ensuring these requirements are accurately reflected in the relevant contract and managed accordingly.

3. Policy requirements

Health Service Providers must:

- ensure the safe introduction of appropriate, clinically effective health technologies
- ensure the discontinuation of health technologies where there is lack of evidence of effectiveness or evidence of potential harm
- have local governance processes and procedures in place, either through a dedicated health technology committee or equivalent local authority, to:
    - prior to introduction, evaluate health technologies with respect to safety, efficacy and cost-effectiveness. Health Service Providers may utilise information from national health technology assessment or request advice from the WA Policy Advisory Committee on Health Technology (WAPACT) if required.
    - authorise and manage the safe introduction of health technologies, including monitoring, evaluating and reporting patient safety events associated with the technology or its use as per Therapeutic Goods Administration requirements.
    - ensure that staff members seeking to use a health technology hold the appropriate qualifications and credentials to competently utilise the technology and that its use is within their scope of clinical practice as per Credentialing and Defining Scope of Clinical Practice Policy MP 0084/18
    - consider disinvestment in health technologies through regular review, as appropriate.

- notify WAPACT of an intention to implement a new or significantly extended health technology that is high risk in terms of patient safety or which has statewide planning implications.

4. Compliance monitoring

Health Service Providers are responsible for complying with this Policy. Health Service Providers are responsible for ensuring they remain informed regarding the introduction and use of health technology within their health service, including monitoring patient outcomes.

To monitor compliance with this Policy, the System Manager may request information:

- on health technology governance arrangements within Health Service Providers, including assurance that Health Service Providers have established local governance processes and procedures to meet the requirements of the Policy
- to confirm the rigour of health technology evaluation, monitoring and reporting in response to safety concerns, and that where appropriate, notification of health technologies to WAPACT was undertaken, as required by this Policy.

5. Related documents

The following documents are mandatory pursuant to this Policy:

- N/A

6. Supporting information

The following information is not mandatory but informs and/or supports the implementation of this Policy:

- N/A

7. Definitions

The following definition(s) are relevant to this Policy.

Term	Definition
Diagnostic Techniques	Includes but is not limited to diagnostic imaging and testing methods, equipment, implants, interventional diagnostic procedures, genetic markers, gene-based diagnostics, tumour markers and screening tests.
Health Technology	A health technology is broadly defined as a procedure, diagnostic technique or medical device. For the purpose of this Policy, emerging health technologies such as novel biological therapies and gene therapies are considered in scope. For the purpose of this Policy, the following technologies are generally considered out of scope: • pharmaceuticals (including radiopharmaceuticals) unless a device also delivers a pharmaceutical • information communications technology (ICT), unless it is integral to the clinical application of the health technology • public health activities and programs • primary health technologies.
Health Technology Committee	Health technology committees (or otherwise named) evaluate, advise and oversee the introduction of health technologies into clinical practice.
High-risk Health Technology	A health technology that is high risk in terms of patient safety (clinical risk) and where either: • the long-term outcomes have not yet been fully assessed and still require close monitoring • the heath technology is highly specialised and of low case volume, or • centralisation has potential safety and quality benefits.
Medical Device	A medical device is any instrument, apparatus, appliance or other article that (whether used alone or in combination, and including the software necessary for its proper application): • is intended to be used in, on, or for human beings for a therapeutic purpose • does not achieve its principal intended action in or on the human body by pharmacological, immunological, or metabolic means, but may be assisted in its function by

	such means. This includes any accessory that is intended to be used with the instrument, apparatus, appliance or other article. For the purpose of this Policy, examples of medical devices include drug delivery systems, non-diagnostic equipment, 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.
Procedure	Surgical procedures and techniques, medical interventional and therapeutic procedures, rehabilitation and other allied health techniques, modifications of existing procedures.
Staff Member	Staff Member of a Health Service Provider as defined by the *Health Services Act 2016*, means: (a) an employee in the health service provider; (b) a person engaged under a contract for services by the health service provider.
Statewide Planning Implications	A health technology for which planning at the state level is required. This includes health technologies for which: • the cost of the new health technology exceeds the current Health Service Provider budget allocation or • centralisation has: ○ potential safety and quality benefits, or ○ the potential to maximise cost effectiveness.

8. Policy contact

Enquiries relating to this Policy may be directed to:

Title: WAPACT Secretariat

Directorate: Patient Safety and Clinical Quality Directorate

Email: wapact@health.wa.gov.au

9. Document control

Version	Published date	Effective from	Effective to*	Amendment(s)
MP0072/17	26 October 2017	26 October 2017	16 November 2017	Original version
MP0072/17 v 1.1	16 November 2017	16 November 2017	16 November 2017	Removal of hyperlink to supporting document, in development
MP0072/17_ v 1.2	16 November 2017	16 November 2017	3 February 2021	Change of hyperlink

MP0072/17 v 2.0	3 February 2021	3 February 2021	Current	Minor Amendments

10. Approval

Initial approval	Rebecca Brown, Acting Director General, Department of Health 2 October 2017
Current Version approved	Dr Michael Levitt, Acting Assistant Director General, Clinical Excellence Division, Department of Health 26 December 2020

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