



Health Technology Governance Policy

1. Purpose

Clinical innovation through the introduction of health technologies including procedures, diagnostics and devices can bring significant benefits to the WA health system. Health Service Providers are responsible for the safe introduction of clinically effective health technologies into their organisation.

This policy outlines the governance requirements for health technologies to be introduced to the WA health system, including when a referral to the [Western Australian Policy Advisory Committee on Health Technology \(WAPACT\)](#) is required.

The 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 supersedes Operational Directive 0541/14 – *Introduction of High-Cost Health Technologies*.

2. Applicability

This policy is applicable to all Health Service Providers (excluding Health Support Services).

3. Policy Requirements

Health Service Providers must:

- ensure the safe introduction of health technology across their organisation, as well as the discontinuation of technologies where there is evidence of inefficiency, ineffectiveness or potential harm to patients
- have governance processes in place to:
 - appraise, authorise and manage the introduction of health technology into their organisation
 - monitor and evaluate patient safety events associated with technology integration, either through a dedicated Health Technology Committee or otherwise named, or via other established committees or groups
 - ensure that health professionals seeking to incorporate a technology within their scope of clinical practice undergo a credentialing and scope of practice process compliant with the *Clinical Governance, Safety and Quality Policy Framework*, and that training for other health professionals on the technology that is being introduced has been considered.
- decide whether a health technology proposal requires referral to WAPACT prior to the health technology being procured/introduced. Application to WAPACT is required for any health technology that:

Before referencing this mandatory policy please ensure you have the latest version of this document from the [Policy Frameworks website](#)

- is high risk in terms of patient safety (clinical risk) where either the long term outcomes have not been fully assessed and require close monitoring or there are potential quality and safety benefits in only one Health Service Provider providing the service to maintain throughput and proceduralist expertise, OR
- is new to the WA health system and high cost with a predicted expenditure exceeding \$1 million in annual or single acquisition (capital) costs, OR
- may involve more than one Health Service Provider and there are potential cost and service delivery efficiencies via a single provider approach and/or benefits in having a Whole of Health procurement contract, OR
- integrates with, or has some Information and Communications Technology (ICT) elements that require referral or notification with ICT Governance Bodies to ensure compliance with WA health system technical standards, OR
- has other WA health system planning implications including a specialist workforce, a case for service reconfiguration, or equity of patient access, social and ethical factors.

Submissions for consideration by WAPACT must be endorsed by the governing body of the Health Service Provider. Please refer to Section 6 for information on the submission process and WAPACT review process.

- comply with procurement governance and process requirements outlined in the *Procurement Policy Framework*, as well as the *Information and Communications Technology Policy Framework* when procuring health technology with an ICT element. The latter includes the Patient Safety Risk Assessment which requires a collaborative clinical and technical approach to identify and mitigate potential harm that may arise as a result of the use and deployment of ICT systems and applications
- comply with the *Research Policy Framework* where the procedure/technology proposed is being implemented as a clinical study and may need to undergo scientific and ethical review, and/or approval and monitoring by a Human Research Ethics Committee.

4. Compliance monitoring and evaluation

Health Service Providers are required to monitor their compliance with this mandatory policy. Health Service Providers are responsible and accountable for their own outcomes and for ensuring they remain informed regarding the introduction of health technology within their organisation.

To monitor compliance with this policy the Policy Owner will liaise with Health Support Services regarding procurement of health technologies meeting WAPACT referral criteria and may contact governing bodies of Health Service Providers on an annual basis requesting information on health technology implementation and disinvestment in the Health Service Provider within the preceding 12 months.

The System Manager may also seek information regarding the governance processes for health technology within Health Service Providers as well as request reports on compliance with this policy. These may be used to evaluate policy compliance and determine the effectiveness of the policy in guiding robust health technology governance.

5. Related documents

The following documents are required to give affect to this policy (i.e. the documents included are mandatory):

- N/A

6. Supporting information

The following documents inform this policy (i.e. documents that are not mandatory to the implementation of this policy but may support the implementation of the policy):

- [Western Australian Policy Advisory Committee on Health Technology Terms of Reference](#)
- *Guideline for health technology governance in Western Australia (in development)*

Further information on the submission process and WAPACT review process can be obtained from the WAPACT Secretariat by emailing wapact@health.wa.gov.au.

7. Definitions

Term	Definition
Device	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.
Diagnostic	Diagnostic imaging and testing methods, equipment, implants, interventional diagnostic procedures, genetic markers, gene-based diagnostics, tumour markers and screening tests.
Health Professional	Includes but not limited to, doctors, dental professionals, nurses, midwives and allied health professionals.
Health technology	A health technology is broadly defined as a procedure, diagnostic or device. For the purpose of this policy the following technologies are generally considered out of scope: <ul style="list-style-type: none">• pharmaceuticals (including radiopharmaceuticals) unless a device also delivers a pharmaceutical• ICT unless it is integral to the implementation 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.

Procedure	Surgical procedures and techniques, medical interventional and therapeutic procedures, rehabilitation and other allied health techniques, modifications of existing procedures.
Procurement	A term used to cover activities in which WA health system contracts or funds the delivery of goods and/or services.
WA Policy Advisory Committee on Health Technology (WAPACT)	WAPACT is an advisory committee reporting to the Department Executive Committee (DEC). WAPACT supports the Department (as System Manager) and Health Service Providers and their governing bodies by providing independent health technology advice and contributing to the central governance of health technologies that are high risk, high cost or have implications for the WA health system. WAPACT has representation from Health Service Providers, PathWest, Imaging and the Department of Health. The Chief Medical Officer is Chair of WAPACT and acts as the Technology Sponsor to DEC.

8. Policy Owner

Assistant Director General
Clinical Excellence Division
WA Department of Health

Enquiries relating to this mandatory policy may be directed to WAPACT Secretariat at:
wapact@health.wa.gov.au

9. Review

This mandatory policy will be reviewed as required to ensure relevance and recency. At a minimum it will be reviewed within 3 years after first issue and at least every 3 years thereafter.

Version	Effective from	Effective to	Amendment(s)
MP0072/17	4 October 2017	26 November 2017	Original version
MP0072/17 v.1.1	26 November 2017	16 November 2017	Removal of hyperlink to supporting document, in development
MP0072/17 v.1.2	16 November 2017	4 October 2020	Change of hyperlink

The review table indicates previous versions of the mandatory document and any significant changes.

10. Approval

This mandatory policy has been approved and issued by the Director General of the Department of Health.

Approval by	Rebecca Brown, Acting Director General, Department of Health
Approval date	2, October, 2017
Published date	16, November, 2017
RMR#	F-AA-50303



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