

## New Health Technologies and Specialised Services

**Summary** This Guideline outlines the process for reviewing and assessing health technologies that are new to the NSW public health system. It indicates clear eligibility criteria for new health technologies for the Ministry consideration and sets responsibilities of districts, networks and the Ministry in relation to new health technology processes.

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**Distributed to** Ministry of Health, Public Health System, NSW Ambulance Service

**Audience** All Staff of NSW Health

## New Health Technologies and Specialised Services

### Guideline Summary

This Guideline outlines the approach to introduce new health technologies and specialised services in NSW to support contemporary high quality clinical service provision. It describes the state-wide level responsibilities in the identification, assessment, planning and implementation of new health technologies in NSW and information on when local, inter-district processes intersect with those of the NSW Ministry of Health.

### Key Principles

NSW Health is committed to exploring opportunities to support new and emerging health technologies that improve provision of healthcare for patients and clinicians.

The level of impact a new health technology and specialised service is likely to have on the health system will determine the most appropriate approach to service planning and provision. This ranges from local and inter-district planning by local health districts (districts)/specialty health networks (networks) to state-level planning by the NSW Ministry of Health (the Ministry).

The districts and networks should have local processes in place to identify, assess, fund, implement and evaluate new health technologies that meet the needs of their community.

The districts and networks must advise the Ministry of new and emerging medical technologies and services that meet the eligibility criteria for statewide assessment.

The Ministry is responsible for considering new and emerging medical technologies and services that require specialised service planning, governance, oversight, evaluation and/or monitoring across NSW.

To enable identification, assessment and implementation of appropriate new health technologies across the NSW health system, the Ministry's health technology process is underpinned by the following principles:

- Evidence-based assessment and advice
- Decision making in the context of NSW Health resources
- Collaboration among key NSW Health stakeholders
- Flexible and responsive approaches which will be adapted to the issue/service
- Alignment with the governance structures and roles of the Ministry, pillar organisations and districts/networks
- Alignment with the annual budget cycle and overall budget parameters.

The processes for new technologies led by the Ministry does not replace district and network decision making regarding the provision of local and inter-district services. The Ministry continues to support local innovation and clinical referral pathways across district boundaries to ensure our patients have access to the appropriate clinical care.

## Revision History

Version	Approved By	Amendment Notes
GL2024_008 June-2024	Deputy Secretary, Health System Strategy and Patient Experience	Guideline updated to reflect changes to the health technology assessment process. Some content has moved from the Guideline to the NSW Health website for access.
GL2022_012 October-2022	Deputy Secretary, Health System Strategy and Planning	Guideline updated to reflect the contemporary policy environment and changes to the new health technology nomination process.
September 2018 (GL2018_023)	Deputy Secretary, Strategy and Resources	Revised Guideline
January 2017 (GL2017_020)	Deputy Secretary, Strategy and Resources	Revised Guideline
December 2016 (GL2017_001)	Deputy Secretary, Strategy and Resources	New Guideline

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## 1. Background

New health technologies have the potential to significantly impact the experience of giving and receiving care, improve outcomes and enhance efficiency and effectiveness of clinical services.

The introduction of new health technologies and services in NSW requires balanced consideration of the available evidence, cost implications and the requirement of the health system to provide contemporary high quality clinical services across all areas of service provision.

The NSW Ministry of Health (the Ministry) is responsible for system-wide planning of services. The Ministry's role in planning lies along a continuum from setting broad directions in healthcare provision to leading specific planning processes such as the planning and oversight of new health technologies.

Planning future capacity for NSW Health services is underpinned by robust clinical service planning. The [Clinical Services Planning Analytics \(CaSPA\)](#) portal provides a range of tools and resources for local health districts (districts) and specialty health networks (networks) users for service and capital planning purposes.

The level of impact a new medical technology and service is likely to have on the health system will determine the most appropriate approach to service planning and provision. This ranges from local and inter-district planning by districts and networks to state-level planning by the Ministry.

### 1.1. About this document

This Guideline describes a coordinated approach to manage the increasing number of complex new medical technologies and services with the potential to significantly impact the way in which healthcare is delivered in NSW.

It also supports a transparent process for the identification, assessment, planning and implementation of new health technologies in NSW at a local and statewide level.

### 1.2. Key definitions

<b>Health Technology</b>	<p>Health technologies are broadly defined as interventions that substantially change the way care is delivered. They may take the form of a new test, device, procedure, therapy or program substantially different from the alternative.</p> <p>Health technologies significantly change clinical practice in the prevention, diagnosis, treatment, and/or rehabilitation of disease.</p>
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**Health Technology Assessment (HTA)**

The purpose of a HTA is to inform health policy and decision-making to promote an efficient, sustainable, equitable and high-quality health system<sup>1</sup>.

It is a multidisciplinary process that uses explicit and scientifically robust methods to assess the value of using a health technology at different points in its lifecycle.

## 2. Introduction of New Health Technologies in NSW

### 2.1. Local assessment and implementation

NSW Health supports local assessment and implementation of new health technologies to meet the needs and context of the local environment and community.

Local health districts (districts) and specialty health networks (networks) are to develop local processes to identify, assess, fund and evaluate new health technologies.

The suggested process for districts and networks includes 5 steps to effectively progress new health interventions in a framework that does not compromise patient safety or quality of care:

1. Identify and investigate
2. Assess
3. Service planning
4. Implement
5. Monitor and evaluate.

[A factsheet](#) detailing the suggested process for districts and networks to introduce a new health technology is available.

Districts and networks must advise the NSW Ministry of Health (the Ministry) of new and emerging health technologies that meet the eligibility criteria for statewide assessment listed in Figure 1.

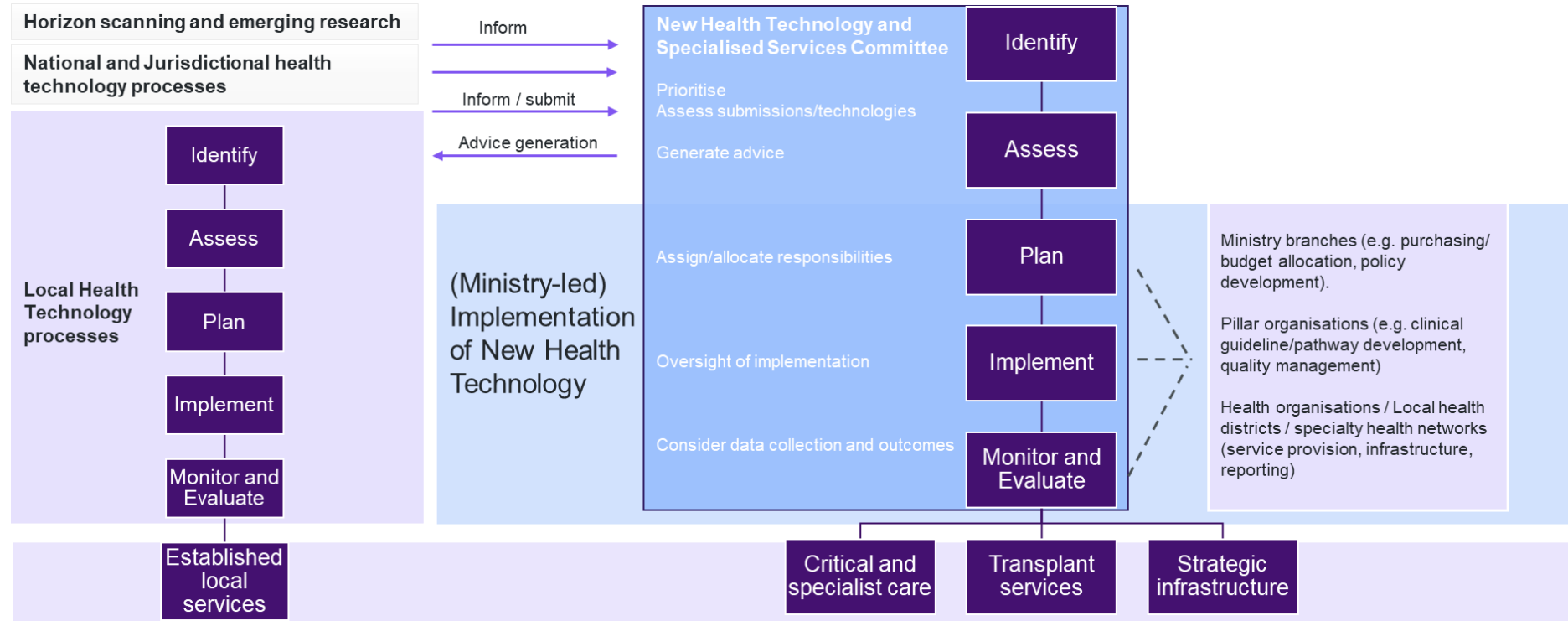
The processes for new technologies led by the Ministry does not replace district/network decision making regarding the provision of local and inter-district services. The Ministry continues to support local innovation and clinical referral pathways across district boundaries to ensure our patients have access to the appropriate clinical care.

<sup>1</sup> [The International Network of Agencies for Health Technology Assessment](#)

## **2.2. Statewide assessment and implementation**

The Ministry is responsible for considering new and emerging health technologies that may require centralised planning, governance, purchasing, oversight, evaluation and/or monitoring across NSW.

**Figure 1. Local and statewide processes for introduction of a new health technology**





### 3. Identification

Eligible new health technologies may be identified for consideration through several channels:

- Local health district (district)/specialty health network (network) submission following local health technology assessment processes.
- National and jurisdictional health technology processes.
- Horizon scanning arising from clinical networks and work program of pillars.
- System performance monitoring processes.

Districts and networks are responsible for advising the NSW Ministry of Health (the Ministry) of new and emerging health technologies that may require centralised planning, governance, purchasing, oversight, evaluation and/or monitoring across NSW.

The [NSW Health New Health Technology Submission Form](#) is available for submission for consideration by the Ministry.

The eligibility criteria for new or emerging health technologies include:

- The intervention is complex to deliver safely and effectively in NSW. This may include a highly skilled workforce, highly specialised infrastructure and/or procedure.
- The cost of service provision is of significance to the NSW Health system. This may include the requirement for a flexible and/or individualised purchasing approach.
- The patient volume is low and requires only selected sites to meet safety and quality outcomes and achieve service proficiency in NSW.

New health technologies in scope include:

- implantable devices
- medical and surgical procedures
- treatment and diagnostic technologies
- gene-based diagnostics
- gene and cell therapies, or
- existing technologies for new/emerging indications.

New health technologies not in scope for the Ministry consideration include:

- medicines<sup>2</sup>, including radiopharmaceuticals

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<sup>2</sup> Medicines are excluded due to existing processes in place within NSW. A process for off-label use of unapproved drugs (including radiopharmaceuticals) is set out in the NSW Health Policy Directive *Approval Process for Medicines and their Use* ([PD2022\\_056](#)). Hybrid technologies such as drug eluting stents are considered by the Committee.

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- information and communication technologies (such as lifestyle apps/software that do not meet the definition of a medical device<sup>3</sup>)
  - public health activities and programs
  - primary health technologies, and
  - technologies not approved by the Therapeutic Goods Administration (TGA)<sup>4</sup>.

## 4. Assessment and Review

The New Technologies and Specialised Services Committee (the Committee) provide governance and strategic oversight to the NSW Ministry of Health's (the Ministry) new technology processes.

The Committee brings together executive-level membership from the diverse areas of NSW Health with responsibilities in the review, assessment and purchase of new health technologies and specialised services for NSW public patients. This includes:

- The Ministry, which is responsible for technology evaluation and specialised services planning, system purchasing and performance reporting, health and medical research, and population and public health.
- The NSW Agency for Clinical Innovation, Cancer Institute NSW and the Clinical Excellence Commission who provide expert clinical input.

The Committee provides an authorising environment for the following activities:

- Advising on new and emerging health technologies that may significantly impact provision of clinical care in NSW.
- Prioritising submissions of new health technologies to determine those for further consideration or health technology assessment.
- Providing advice on disinvestment opportunities to improve efficiency and effectiveness in health technology.
- Overseeing the assessment of new health technologies, including:
  - clinical need
  - clinical effectiveness
  - economic feasibility
  - safety
  - ethical and equity considerations

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<sup>3</sup> Medical devices are defined under section 41BD of the *Therapeutic Goods Act 1989* (Commonwealth).

<sup>4</sup> As a general principle, the routine use of non-TGA approved products outside of a dedicated clinical trial is not supported in NSW public health facilities. However, it is acknowledged that there are some technologies that will not have or require TGA approval (such as islet cell transplantation) or may not be amendable to clinical trials. In such cases, there may be a need to consider such technologies through the Committee. This may include those that are being routinely used under the Special Access Scheme and Personal Importation Scheme or Authorised Prescriber schemes.

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using the best available evidence.

- Leveraging available national and jurisdictional mechanisms.
- Considering and recommending innovative options for providing new health technologies (such as preferred implementation model).
- Providing guidance to facilitate local and/or networked service implementation.
- Making recommendations on whether a new health technology should be considered for state-wide implementation in NSW to relevant Ministry branches to inform decision making on purchasing/budget allocation.
  - Note the Committee does not offer the authorising environment to fund the new health technology.
- Making recommendations to the Secretary, NSW Health should the new health technology require Ministry led implementation.
- Providing oversight to new health technologies, approved by the Secretary, NSW Health, requiring governance, purchasing, oversight, evaluation and/or monitoring across NSW.
- Making recommendations to the Secretary, NSW Health should the health technology no longer require Ministry led oversight (for example health technology is successfully established and embedded in the health system).

## 5. Implementation

### 5.1. Local/Networked adoption

In many instances submissions to the New Technologies and Specialised Services Committee (the Committee) may be considered suitable for local adoption without the requirement for NSW Ministry of Health (the Ministry) led oversight.

Recommendations for new health technologies considered appropriate for local and/or networked adoption will be referred to the submitting local health district (district)/specialty health network (network) and/or agency/pillar organisation. The Committee may refer or recommend linkage to relevant Ministry branches and agency/pillar organisations to further support local and/or networked service planning and delivery.

The Ministry will provide support consistent with its executive and statutory role, including regulatory functions, public health functions (such as disease surveillance, control and prevention) and public health system manager functions in statewide planning, purchasing and performance monitoring and support of health services. Further information is available in the NSW Health Policy and Procedure Manual [Corporate Governance and Accountability Compendium](#).

The Committee may recommend further local evidence generation under a research framework, or further local health technology assessment to support future decision making for adoption of the new health technology.

## 5.2. Ministry-led implementation

Recommendations for new health technologies requiring Ministry-led planning require approval of the Secretary, NSW Health, before proceeding with the established process to plan and purchase services.

If implementation is approved by the Secretary, NSW Health, the Ministry will lead a process to determine the purchasing approach and parameters for introducing the new health technology.

The Ministry will assign responsibilities for further planning and implementation including:

- clinical requirements
- service delivery
- staffing
- monitoring
- evaluation, and
- reporting for a defined duration.

It is to be noted that where a district/network has made a submission for a new health technology that is recommended for Ministry-led adoption, they may be required to enter a competitive expression of interest process to determine the service provider.

All new health technologies recommended for Ministry-led adoption are considered in the annual service agreement cycle managed by the Ministry's System Sustainability and Performance Division.

All purchasing decisions are made in the context of the overall NSW Health budget.

Purchasing decisions will focus on system strategic priorities and system issues such as:

- patient need
- number of sites required
- geographic location
- infrastructure and equipment requirements
- workforce considerations, and
- evidence-based patient selection criteria.

## 6. Monitoring and Evaluation

Monitoring and evaluation are critical elements to assess the impact of the health technology on clinical outcomes, patient experience, cost effectiveness, and equity of access.

The NSW Ministry of Health (the Ministry) will develop a monitoring and evaluation plan that measures the impact of the health technology across the domains of experience, outcomes and effectiveness and efficiency.

Health outcome evaluation is included as a way of monitoring the longer-term impact of the new health technology on relevant health outcomes and quality of life. Evaluation methodology is guided by the [NSW Government evaluation guidelines](#) primarily through the coordinated use of process and outcome evaluation.

Reporting will be aligned to existing data collections to minimise additional reporting requirements. Reporting requirements may need to expand in some cases depending on measures outlined in the monitoring and evaluation plan (such as, efficiency, carbon reporting, and so on).

The local health districts (districts)/specialty health networks (networks) are responsible for service level monitoring consistent with local policies and procedures for clinical governance. This includes clinical aspects, adverse events and patient outcomes. Any proposed expansion to the agreed clinical indications will require review, and approval, by the Ministry, clinical lead and service providers.

Projected service demand assumptions outlined in the plan are to be reviewed regularly against activity data to minimise deviation.

## 6.1. Established health technologies

The monitoring and evaluation outcomes will flag successful service establishment, maturity and sustainability.

Recommendations for health technologies no longer requiring Ministry-led oversight require approval of the Secretary, NSW Health.

If transition to local oversight is approved, the Ministry will work collaboratively with the Agency for Clinical Innovation and the districts/networks until new health technologies are successfully established and embedded in the health system. This will include the:

- policy
- procedures
- guidelines
- finance
- performance management
- clinical and corporate governance structures,

required to maintain safety, quality and proficiency of services.

## 6.2. Specialised services

Health technologies may require ongoing strategic governance from the Ministry. This includes infrastructure/services that continue to be complex to deliver safely and effectively, are of significant cost, and/or of a volume necessitating site selection to deliver proficiency in NSW.

These services will be subject to annual reporting requirements to ensure services are meeting the expected outcomes and providing equitable access to the people of NSW.

The services will be required to report any changes to clinical evidence, model of care or updates to technology which may alter service delivery and/or influence future demand. Any proposed expansion to the agreed clinical indications will require review, and approval by the Ministry.

Reporting will also inform purchasing decisions for specialised services during the annual service agreement negotiations with the host district/network.

Specialised service categories are listed in the Service Agreements, for example Transplant Services.