AUSTRALIAN COMMISSION
ON SAFETY AND QUALITY IN HEALTH CARE

Guidance for health service organisations

Introduction of new interventional procedures and clinical practice innovations

December 2024

Published by the Australian Commission on Safety and Quality in Health Care

Level 5, 255 Elizabeth Street, Sydney NSW 2000
Phone: (02) 9126 3600
Email: **mail@safetyandquality.gov.au**
Website: **www.safetyandquality.gov.au**

The Commission's preference is that you attribute this publication (and any material sourced from it) using the following citation:

Australian Commission on Safety and Quality in Health Care. Guidance for health service organisations: Introduction of new interventional procedures and clinical practice innovations. Sydney; ACSQHC, 2024.

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Context

Health service organisations need robust processes to assess the safety, value and sustainability implications of new interventional procedures and clinical practice innovations. A rigorous evaluation process can ensure that appropriate decisions are made so that resources are only allocated to support innovations most likely to benefit patients, and that processes are implemented to ensure that safety and quality are assessed and monitored. This evaluation process also supports environmental sustainability by early consideration of where the innovation is indicated in a model of care and the characteristics of the population that is expected to benefit most. It is a powerful tool for setting parameters to reduce subsequent low value care.

Purpose

This guidance supports public and private health service organisations to develop local policy and processes for the safe introduction of new interventional procedures and clinical practice innovations. It is intended to complement, but does not supersede, existing jurisdictional requirements, policies, and procedures.

The objectives of this guidance are to support:

- Consideration of clinical context and appropriateness and related factors that will impact the health service organisation due to the introduction of new interventional procedures and clinical practice innovations
- Regular individual or specific evaluation of approved procedures and innovations
- Safe transition between research and acceptance as evidence-based clinical practice
- Clinical innovation.

A process for new interventional procedures and clinical practice innovations assists clinicians and health service managers by:

- Providing a structured process with known milestones so that there is clear understanding of what is expected
- Providing supportive steps to help guide clinicians and managers so that all relevant information is included at the beginning of the process to avoid repeated requests for additional information
- Identifying potential role delineation impacts so that consideration can be given to additional requirements prior to application
- Ensuring the intervention/innovation is presented in a way that targets local population needs and therefore build a stronger case for implementation.

Scope

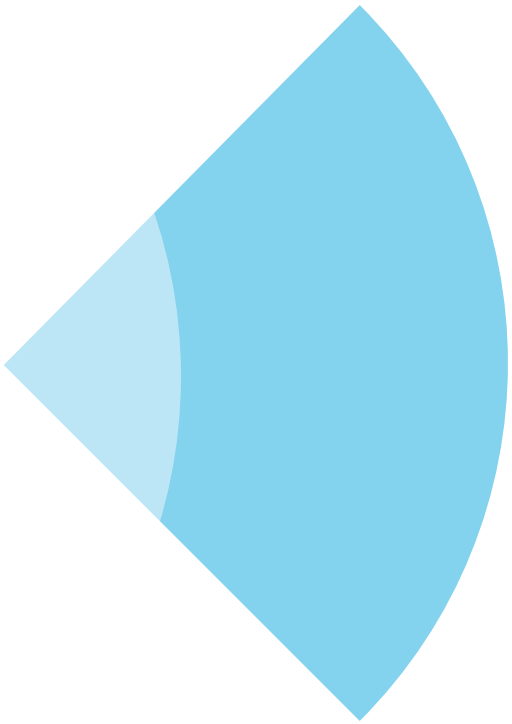
The new interventional procedures and clinical practice innovations that are in scope for this guidance are surgical, medical, biological, diagnostic, or therapeutic procedures and software as a medical device that have been not previously undertaken or used within the health service organisation. These procedures and practices may include new techniques for established procedures and trialling of new equipment or procedures, or they may be new to the specific health service.

Health service organisations should consider use of this guidance for the introduction of artificial intelligence (AI) enabled processes. More information on the safe use of AI in hospitals is available in the **literature review and environmental scan report** on the website of the Australian Commission on Safety and Quality in Health Care (the Commission.)

The scope of this guidance excludes introduction of:

- Research and clinical trials of new interventions and clinical practice innovations. These should be under the governance of research ethics and governance entities and are not the remit of new interventional procedure/clinical practice innovation governance processes
- New medicines and **boundary or combination products**, unless they are associated with a new procedure or clinical practice innovation and their introduction has been endorsed by the appropriate quality use of medicines committee
- Devices that still require evaluation and approval by the **Therapeutic Goods Administration** (TGA)
- Changes related to stepwise quality improvement
- Policies in the instance of a recall or a medical device shortage
- New interventional procedures and clinical practice innovations that are new to the jurisdiction or that require state-wide/national planning.

Operational considerations for the introduction of new interventional procedures and clinical practice innovations are included in **Appendix 1**.



Governance

The governance arrangements for new interventional procedures and clinical practice innovations should ensure that patients, clinicians, and managers can be confident that their introduction is supported by evidence of efficacy, safety, and effective resource utilisation.

The protocol for the introduction of new interventional procedures or clinical practice innovations requires approval by an appropriate governance committee. This may be a Clinical Ethics Committee or a formally constituted committee that oversees the introduction of new interventional procedures or practices their organisation clinical governance body. The governance arrangements should:

- Be consistent with the requirements of the **National Safety and Quality Health Service Clinical Governance Standard** and other relevant national safety and quality standards
- Be consistent with the requirements of the **National Clinical Trials Governance Framework** where applicable
- Be consistent with jurisdictional requirements for implementation of new interventional procedures and clinical practice innovations
- Include documentation on the importance of adopting clinical innovation in a structured and safe way in the health service organisation's clinical governance framework, and a risk management plan that accommodates circumstances for both planned and urgent review
- Include an appropriately skilled and representative committee (referred to as the New Interventional Procedures [NIP] Committee in this document)*, which reports to the overarching clinical governance or quality committee, to review proposals for the introduction of new interventional procedures or clinical practice innovations, monitor the implementation of approved proposals and approve requests for transfer to routine care. Consumer representatives should be included in the NIP Committee, especially from the target patient cohort for the new procedure or practice
- Have clearly established pathways for the NIP Committee to receive feedback/referrals from research ethics committees (if it is determined that they are not research but a new intervention/ innovation that should be considered by the NIP Committee instead), clinical ethics committees, and Medical and Dental Appointments Committees
- Include the interface with the Executive Management, which plays a key role in assessing need and financial implications of introduction of new procedures or innovations
- Be supported by standard policies and processes for assessment, approval and post-introduction evaluation
- Be considered in the context of the level of the facility (see **Appendix 2** Part B).

* It is acknowledged that health service organisations will likely already have committees in existence within their governance arrangements that perform the functions recommended to support the introduction of new interventional procedures and clinical practice innovations.

Credentialing and training

Once new procedures are assessed to be safe, policies, procedures, training, and other resources should be developed to support clinical practice. Arrangements should be in place to ensure adequate training and competence for all relevant clinicians, clinical teams and supporting staff as part of the health service organisation's existing credentialing systems.

The Medical and Dental Appointments Committees should be consulted to see if the clinicians named in the application, including those providing proctoring assistance, have been previously credentialed to carry out the work that is proposed in the new intervention/innovation. There will also be a need for clinicians to apply to the credentialing committee to ensure skills gained after appointment to the health service organisation are consistent and sufficient with the skills needed to carry out a new intervention/innovation. Once the credentialing committee is satisfied that the clinicians have the requisite skills, the NIP Committee should be informed.

Colleges and specialised societies that auspice training programs should be engaged in the development of credentialling and training processes. For submissions where an external proctor/s is training local staff to gain experience and expertise, the submission should include the training and background of the proctor/s and they must have local credentialing before undertaking training or providing services in the new intervention/innovation. Health service organisations should ensure they have appropriate policies and procedures in place, including for patient consent, where training is provided by representatives of the sponsor of the new interventional procedure.

Assessment and monitoring of new interventional procedures and clinical practice innovations should include the review of the training requirements and the number of interventions needed for clinical staff to stay adequately skilled.

Ongoing or periodic training requirements should be considered as should the number of interventional procedures that need to be undertaken for staff to remain competently skilled. Appropriate records should be maintained for training and made available to members of the team that will be supporting implementation of the new procedure or practice.

Legislative framework

The introduction of new devices for a new intervention requires the prior evaluation and approval of the device by the **TGA** for a specified intended purpose consistent with use in that intervention.

The introduction of new procedures should ideally be predicated by devices that are included in the Australian Register of Therapeutic Goods (ARTG). Clinicians are able to use a medical device that has been included in the ARTG for a purpose it is not indicated for. This is known as off-label use.

Access to unapproved medical devices can also be legally obtained through:

- The Special Access or Authorised Prescriber Schemes
- The Clinical Trial Notification (CTN) or Clinical Trial Approval (CTA) Schemes.

Problems with medical devices should be reported to the **TGA Incident Reporting and Investigation Scheme** and as per local jurisdictional requirements. From March 2025, it will be mandatory to **report adverse events** related to medical devices to the TGA.

Evidence

High quality evidence should form part of the application to ensure that health service managers and the NIP Committee can make an informed decision. Clinicians should be encouraged to seek evidence from the medical literature and sources such as health technology assessments as part of making the submission. While the device manufacturer or sponsor may also provide relevant information, this alone should not be the supporting evidence for the submission.

Monitoring and evaluation

The implementation of new interventional procedures and clinical practice innovations must be monitored and evaluated to assess the impact in relation to clinical outcomes, patient experience, cost effectiveness and equity of access. The NIP Committee should have a formal monitoring and evaluation procedure in place with clearly set out requirements and nominated responsibilities for reporting back once approval is given. This should occur every six months. When an adverse event occurs these should be reported to the **TGA**. The NIP Committee should also define the principles and criteria for determining when a procedure should be paused or stopped.

Adverse events should be reported immediately to the Chair of the NIP and in accordance with the organisation's incident management system. The Chair should ensure that the NIP Committee reviews the adverse event against the principles that are established for determining when a procedure should be paused or stopped. Adverse events should be categorised and investigated in accordance with the health service organisation's policy for investigation of adverse events.

Appendix 3 includes an example progress review form for monitoring approved new interventional procedures and clinical practice innovations.

Transition to evidence-based care

The timing of transition is likely to vary considerably between interventions and occur over months or even years. Not all new procedures may ultimately transition to routine evidence-based practice, and decisions about acceptance as standard clinical care require careful evaluation.

A formal submission should be presented for consideration by the NIP Committee, and would include: a further literature review, comparative data from any other health services also providing the procedures, data on activity, clinical outcomes, patient-reported outcomes and experience, training and credentialing implications, costs, effectiveness, and equity of access based on monitoring and evaluation reports. The decision should be based on the outcome of regular reviews and monitoring and evaluation.

Proposals endorsed by the NIP Committee for transition to routine evidence-based practice should be reviewed by the relevant overarching clinical governance or quality committee and recommendations should be made to the health service organisation Chief Executive (or equivalent). Processes should also be established for communication with local primary care providers to support appropriate post-discharge care.

Model policy and process for new interventional procedures and clinical practice innovations

Figure 1 is a flow chart that sets out a model process for introduction of new interventional procedures or clinical practice innovations. It is an example that can be adapted by health service organisations to reflect their local arrangements.

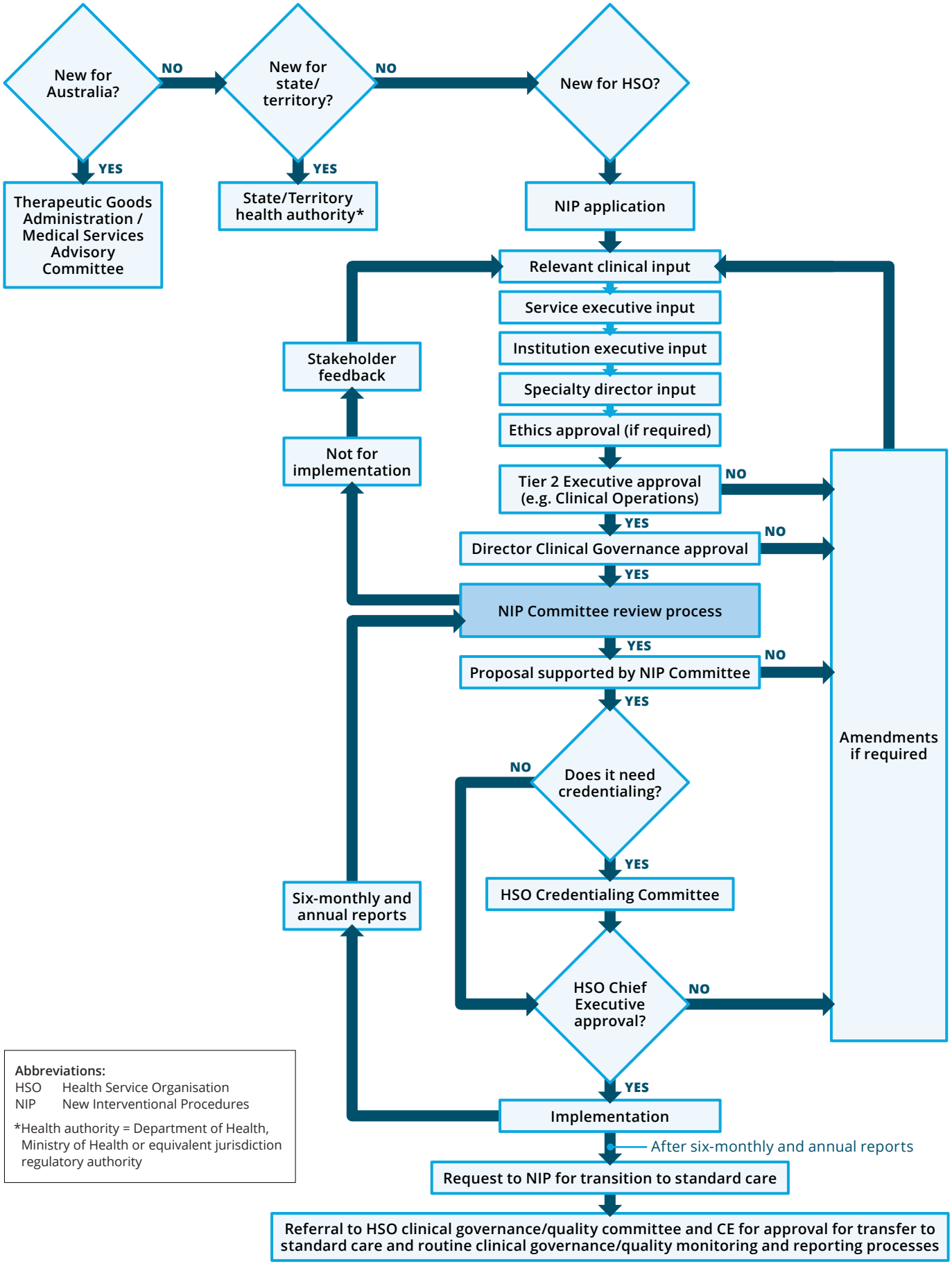
Policies for introduction of new interventions/ innovations should include:

- A general and detailed application form completed by the lead clinician. An example of a template form that can be adapted by health service organisations if they do not already have their own application form is provided at **Appendix 2**
- A description of the health service organisation processes and criteria for review and approval of proposals and a local flow chart for this process (see **Figure 1** for an example)
- Information on key health service organisation stakeholders in the development, review, and approval of proposals and any consultation with other health service organisations
- Roles and responsibilities of the committees and positions responsible for review and approval of proposals and for monitoring of implementation of approved proposals
- Requirements for a risk assessment
- Patient information and informed consent processes
- Patient selection, indications, and exclusion criteria
- Credentialing for clinicians who will be performing the procedures
- Information, education, and training for members of the workforce who will be supporting implementation of the new interventional procedures or clinical practice innovations
- Requirements for a business case for implementation including areas for investment/disinvestment
- Requirements for recordkeeping, and use of electronic forms and systems, where possible
- Requirements for monitoring and evaluation processes, including adverse events and documentation and reporting on the outcome of implementation process
- Communication processes
- Requirements for approval to transition to routine practice, including clinical governance/quality monitoring and reporting processes suggested in the example at **Appendix 3**
- Relevant legislative requirements, such as mandatory reporting of adverse events related to medical devices to the TGA from March 2025
- Consideration of sustainability issues – environmental, economic, workforce.

Useful information and resources

- ***National Safety and Quality Health Service (NSQHS) Standards***
- ***NSQHS Standards User Guide for governing bodies***
- ***National Model Clinical Governance Framework***
- ***General Guidelines for Assessing, Approving & Introducing New Surgical Procedures into a Hospital or Health Service***
- ***Royal Australasian College of Surgeons position on credentialing and scope of practice for surgeons***
- **Australian Commission on Safety and Quality in Health Care guidance on health and human research**
- **Therapeutic Goods Administration**
- **Medical Services Advisory Committee**
- **Prostheses List Advisory Committee**
- **Pharmaceutical Benefits Advisory Committee**
- **Independent Hospital and Aged Care Pricing Authority**
- **Australian Commission on Safety and Quality in Health Care – Informed Consent**
- **National highly specialised therapies (HST) framework**
- ***TGA Guidance on Adverse Event Reporting***
  Sustainable procurement guide from HealthShare Victoria
- **Sustainable procurement guide from Practice Greenhealth**
- ***A Review of Sustainable HealthCare***
- **Australian Digital Health Agency Digital Health Standards Catalogue**

Figure 1: Model process flow chart – Introduction of new intervention/clinical procedure



Abbreviations:
HSO Health Service Organisation
NIP New Interventional Procedures

*Health authority = Department of Health, Ministry of Health or equivalent jurisdiction regulatory authority

Appendix 1

Key considerations for the introduction of new interventional procedures and clinical practice innovations

The following considerations apply for the introduction of all new interventional procedures and clinical practice innovations.

Health and safety

Health and safety issues must be considered for patients, clinicians, other members of the workforce, and the community.

Risk management

The introduction of new interventional procedures and clinical practice innovations should be informed by a risk management approach. This includes evaluation of procedures and technologies prior to their introduction and monitoring and review of patient safety and clinical adverse events following their introduction. There should be clear benefit(s) that outweigh risks and clear alignment to the local role-delineation framework and health service plan.

Evidence-based practice

Most procedures and clinical practice innovations will have been evaluated or implemented elsewhere and the assessments of the procedure need to be considered in relation to the reliability of the evaluation as well as the context and population in which the procedure is being introduced.

Patient information and informed consent

Patient information and informed consent should be a process of communication, discussion and shared decision making. This process should include the treatment options available (including not having the intervention in the recommended model of care for the patient), potential outcomes (neutral, positive, and negative) and the risks and benefits. There should not be a reliance on the device manufacturer or sponsor's standard form as these may not be consistent with health service organisation's requirements. Clinicians applying for a new intervention or innovation should consider if the consent form should be reviewed by an ethics committee, as they are often experienced in reviewing consent forms to ensure that they are transparent in providing information on risks and benefits to the patient and their context.

The information and consent documentation should include the selection criteria the patient has met to be considered for the new intervention and proposed longer term monitoring of the patient. Informed consent is to be obtained in a legal and ethical manner that supports person centred care. **Informed consent** practices should align with local policies and procedures for informed consent.

Costs and benefits

The introduction of any new procedure or practice innovation will have an opportunity cost and resource implications. Consideration should be given to the range of direct and indirect costs associated with the new procedure or innovation, and the clinical benefits. There should also be consideration and clear articulation of the cost impact of disinvestment if the new intervention is approved.

Conflicts of interest

There must be full disclosure of any relationship between the clinician and device supplier or other significant party. There should be disclosure of involvement in prior assessment of the procedure or innovation and any financial involvement that could result in a conflict of interest. A process should be established for management of disclosed conflicts as part of the decision-making process.

Environmental sustainability

The introduction of any new procedure or innovation should involve consideration of its contribution to the climate resilience and carbon footprint of the health service organisation. This includes its impact on reducing carbon emissions, waste, energy use and low value care to deliver safe and high-quality models of care that are environmentally sustainable. The ***National Health and Climate Strategy*** developed by the Department of Health and Aged Care includes steps for developing a sustainable net zero and high value care health system. When introducing new procedures or innovations it is important to assess these considerations.

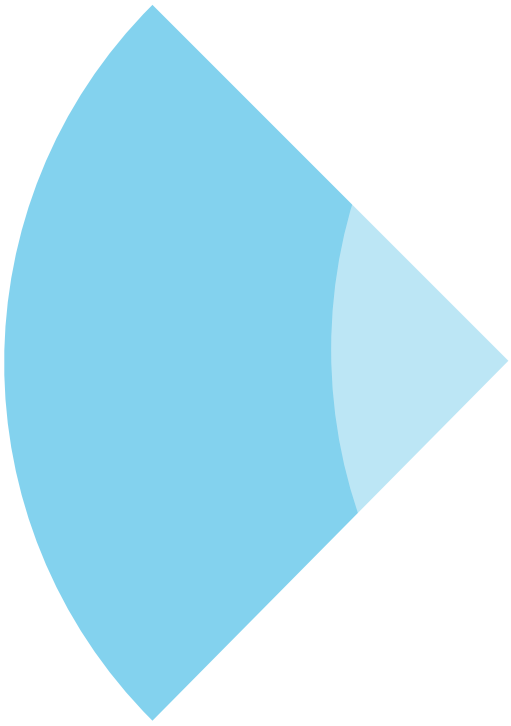
Equipment and supplies

Local arrangements should be developed for approval, procurement, reprocessing and maintenance of new equipment and consumables that may be required for the procedure or the technology. This will require consideration of existing jurisdictional procurement arrangements.

Investment/disinvestment

Consideration of areas of investment need to be evaluated against the health service organisation's objectives and the needs of the population base that it serves.

Disinvestment should be considered when introducing a new intervention or clinical innovation. Opportunities to cease ineffective, low-value or inappropriate practices, technologies or interventions should be actively explored as part of the approval process.



Appendix 2

Example application form for proposals for the introduction of new interventional procedures and clinical practice innovations

This example form is divided into two parts to distinguish between information on the scientific merit of the new procedure or innovation (Part A) and the information required for the business case (Part B).

Health service organisations may wish to establish a two-stage process that first considers the scientific merit prior to requiring the information for the business case. In this case, applicants would not be required to submit Part B until Part A has been approved. Part A will help to inform Part B submission.

Health service organisations that choose to use this form should modify it as necessary to fit their local and jurisdictional requirements.

Instructions for completing the Proposed Intervention/Innovation Application Form

Save this template and complete all fields, providing as much detail as possible (use as much space as required to address the questions). If additional space is required to respond in detail, please attach as a separate document. If a field is not relevant, please note as being 'N/A'.

Ensure all relevant parties are consulted in the development of your application.

Attach all relevant supporting documentation when submitting your application.

Ensure that the appropriate approvals are obtained before submitting your application (electronic approvals/scanned signatures will be accepted).

Part A

1. General details of the new or altered procedure, diagnostic, technology, or treatment (the 'intervention' or 'innovation')

1.1	**Title of the intervention/ innovation**	
1.2	**Date of application**	☐☐ / ☐☐ / ☐☐☐☐
1.3	**Facility name and location**	
1.4	**Stage of technology development** (see table below)	☐ Emerging ☐ Experimental ☐ Investigational ☐ Nearly established ☐ Established ☐ Established but changed indication or modification of the technique

Stages of technology development

Stage	Aim/purpose of studies	Study types	Approval pathway
Emerging	Proof of concept study, clinical safety and efficacy	Case report(s) or case series less than five patients	Research
Experimental	Clinical studies aimed at identifying the appropriate patient population for the technology and clinical safety and efficacy within this patient group	Case series	Research
Investigational	1. Comparative studies investigating new technology against existing treatment options 2. Feasibility studies which assess proof-of-concept in a hospital setting	1. Observational studies (non-randomised comparative studies, interrupted time series) 2. Registry-style case series within a hospital setting	Research
Nearly established	1. Comparative studies with large patient numbers evaluating new technology against existing treatment options in a hospital setting 2. Registry studies with a long duration of follow-up and large patient numbers (i.e. post-marketing or multi-site registries) in multiple sites assessing long-term safety	1. Randomised controlled trials 2. Multi-site case series with large patient numbers (registry studies)	Clinical Ethics Committee *and either* Health Authority *or* Health Service *then* NIP Committee
Established	The above data and studies in addition to hospital and clinical trial data within Australia	The above studies publishing Australian data	Health Authority *or* Health Service *then* NIP Committee
Established but changed indication or modification of the technique	This situation happens sometimes for mesh dressings, vascular stents, etc.	N/A	Health Authority *or* Health Service *then* NIP Committee

2. Applicant details

2.1	**Name**	
2.2	**Department or service**	
2.3	**Contact telephone**	
2.4	**Email**	

3. Description of the service/department/location

3.1 **Provide a brief statement regarding your service/specialty, and why you wish to introduce this intervention/innovation?**

3.2 **What are the organisational benefits associated with the new intervention/innovation?**

3.3 **How does performing this intervention/innovation fit with the recognised scope of the service and the designated level of service of the facility?**

3.4 **What are the proposed governance arrangements for the intervention/innovation?**

✚ Include the name and position of the person(s) responsible for managing/overseeing the intervention/innovation.

3.5 **Is the item on a state/territory or local procurement contract or is a tender required?**

4. Description of the intervention or innovation

4.1 **Provide a detailed overview of the intervention/innovation**

- Address any surgical and rehabilitation processes, additional equipment that is required, and any other relevant information such as disinvestment implications if applicable.
- Attach the clinical protocol if one has been developed.

Will the intervention/innovation have a likely impact on Emergency Department (ED) presentations and has a discussion occurred with the Director of ED as to the ED's role if a patient presents post-intervention?

Where is the procedure expected to be performed (e.g. procedure room, operating theatre, etc.)?

What procedures are currently performed in the area where the intervention/innovation will take place and how will you balance starting this procedure with the demand for that space?

What is the expected length of stay for the patient?

Continued over

4. Description of the intervention or innovation (continued)

4.1 cont. **Will the patient require post intervention/innovation follow-up?**

Is there an expectation that the activity undertaken by the new intervention/innovation will supersede current activities being undertaken (e.g. can you disinvest in something if you begin this new intervention/innovation)?

Will the new intervention/innovation replace an existing procedure, technology, or treatment? What are the disinvestments that can be made if introducing this new intervention/innovation?

4.2 **What are the comparator technologies/procedures? If there are none, what is current model of care?**

4.3 **Has the proposed new intervention/innovation been submitted as a research project to a Human Research Ethics Committee (HREC)?**

☐ Yes ☐ No

If YES, provide the name of HREC that has reviewed the project:

✚ Attach a copy of all HREC and research governance documents (e.g. HREC Approval Letter, National Ethics Application Form, Site Specific Assessment Form, all documents approved by the HREC, curriculum vitae of study personnel, and documentation of training and credentialing).

Continued over

4. Description of the intervention or innovation (continued)

4.4 **Has the new intervention/innovation been reviewed by the Health Insurance Commission (HIC), Medical Services Assessment Committee (MSAC)?**

☐ Yes ☐ No, not required

If YES, provide details, including any conditions placed on the use of the modality:

4.5 **Does the intervention/innovation involve the use of a device?**

☐ Yes ☐ No – Go to section 5

If YES, is the device listed on the Australian Register of Therapeutic Goods (ARTG) for the intended use in the proposed intervention/innovation?

☐ Yes, listed on the ATRG ☐ No, not listed on the ARTG

If YES, provide details from the ARTG:

If NO, provide details of the research/trial setting and access approval process to import or use the device in Australia and rationale for moving from research to new intervention/innovation:

Continued over

4. Description of the intervention or innovation (continued)

4.6 **If the intervention/innovation involves the use of the device, is the use of the device consistent with the TGA intended purpose?**

☐ Yes, listed on the TGA ☐ No, not listed on the TGA

If YES, provide details from the TGA:

If NO, provide details of the research/trial setting and access approval process to import or use the device in Australia and rationale for moving from research to new intervention/innovation:

4.7 **If the intervention/innovation involves the use of the device, are consumables required?**

☐ Yes ☐ No, does not require consumables

If YES, provide details of consumables and costs:

If the intervention/innovation involves the use of the device, will the device need to be reprocessed (disinfected or sterilised)?

☐ Yes ☐ No, does not require reprocessing (disinfection/sterilisation)

If YES, provide details of required reprocessing or sterilisation requirements:

4.8 **Has the item been implicated in TGA recalls?**

Continued over

4. Description of the intervention or innovation (continued)

4.9 **If the intervention/innovation involves use of a device, is the device identified using a Unique Device Identifier (UDI)?**

☐ Yes ☐ No, the device does not have a UDI

If YES, provide details of the UDI of the specific devices involved:

4.10 **Provide details of any previous briefs, risk assessments or minutes which have referenced or discussed this intervention/innovation**

5. Patient population

5.1 Provide a detailed overview of the patient population for this treatment

- Address patient population, patient selection, exclusion criteria and total patient numbers expected per annum.
- Attach the clinical protocol if one has been developed.

What is the process for patient selection (e.g. criteria led screening)?

How will the patient enter the organisation (e.g. day surgery, clinic)?

Is it expected that the patient will be an outpatient or inpatient?

What are the likely numbers that may qualify for this procedure? Is there likely to be a subpopulation within this group that would not proceed with the intervention/innovation?

What additional consent requirements might here be for this patient population?

Continued over

5. Patient population (continued)

5.2 What is the expected number of interventions/innovations that will be performed each year?

Identify the number of patients, number of treatments and expected frequency of intervention/innovation (e.g. three patients completed in half-day operating list every two months for a total of 18 patients per year).

5.3 Is there a registry that will capture patient outcomes including patient-reported outcome measures (PROMs) and patient-reported experience measures (PREMs)?

5.4 What are the criteria for ceasing the intervention/innovation early if patient outcomes are not beneficial as expected or patient harm is suspected? How will this be tracked?

6. Processes

6.1 **Has the proposed new intervention/innovation been used elsewhere?**

☐ Yes ☐ No

If YES, provide details of where this has been used – within Australia or internationally:

✚ Information/details may also be attached as an appendix.

6.2 **Have there been any reviews of the intervention/innovation by independent national bodies (e.g. Australian Safety and Efficacy Register of New Interventional Procedures, Medical Services Advisory Committee [MSAC], National Institute for Health Care Excellence [UK], Food and Drug Administration [USA], National Institute of Clinical Studies)?**

☐ Yes ☐ No

If YES, provide details of the reviews:

✚ Information/details may also be attached as an appendix.

6.3 **Have any systematic reviews of the intervention/innovation been undertaken?**

☐ Yes ☐ No

If YES, provide details of the reviews:

6.4 **Are there any other reviews and/or observational studies or clinical series reports relating to the intervention/innovation?**

☐ Yes ☐ No

If YES, provide details of the reviews, observational studies or clinical series reports:

7. Risks/benefits

7.1 What are the expected benefits from the new intervention/innovation?

For patients?

For the facility?

For clinicians?

For finances?

For the environment?

7.2 Are there any social, ethical or cultural considerations that may raise additional risks or barriers to access for particular populations?

Have these been explored through an ethics committee?

Continued over

7. Risks/benefits (continued)

7.3 **Are there any side effects or complications related to the new intervention/innovation?**

Consider how it compares to existing procedure(s), if applicable.

☐ Yes ☐ No

If YES, list all side effects or negative consequences and their reported frequency:

7.4 **Are there any potential risks to patients and/or staff, including infection, chemical or radiation safety issues?**

Consider work health and safety (WH&S) factors and the need for a WH&S consultation.

☐ Yes ☐ No

If YES, how will these factors (including WH&S) be addressed?

7.5 **Has a patient information sheet been developed to inform patients about risks/potential risks?**

☐ Yes – Attach a copy ☐ No

Explain how patients/consumers were involved in the design and/or review of the patient information sheet:

7.6 **Are there any strategies that will/should be put in place to minimise risk?**

☐ Yes ☐ No

If YES, provide details of the strategies:

8. Quality and safety

8.1 **Outline the plan for monitoring and evaluation of the new intervention/innovation?**

8.2 **If the proposed new intervention/innovation, diagnostic, technology, or treatment carries with it a risk of adverse events, are there criteria for reviewing outcomes before any further procedures are performed?**

☐ Yes ☐ No

If YES, describe the process for review:

If NO, explain how an adverse event will be added into the safety event management system for further review and tracked:

What are the criteria for stopping the treatment?

8.3 **What are the criteria or safety issues that would bring the introduction to an immediate stop?**

Continued over

8. Quality and safety (continued)

8.4 **If the procedure requires the introduction of a device or item that requires sterilising, does the Central Sterile Supply Department have the necessary equipment and capability?**

☐ Yes ☐ No

If YES, provide details of the procedure:

8.5 **What are the sustainability considerations for the proposed change (e.g. sustainable procurement practices, use of efficient and renewable energy sources, merits of the intervention/innovation in reducing waste or improving efficiency)?**

What are the environmental impacts of the innovation or procedure (e.g. expected carbon emissions, energy use or waste outputs)?

If there is a negative consequence, detail mitigation strategies to reduce any negative environmental impacts from the implementation:

Part B

9. Staffing, resources, and costs

9.1 **Are there any expected costs (e.g. staffing, education and or training of staff, consumables, prostheses, high-cost disposables, equipment/machines, space, impact on length of stay, additional theatre time medications and post-discharge follow-up)?**

☐ Yes ☐ No

If YES, provide a business case for any initial and ongoing costs, and any expected savings:

Attachment number:

9.2 **Have all staff groups that will be affected been consulted (e.g. operating theatre staff, nursing, allied health, etc.)?**

☐ Yes ☐ No

If YES, provide details of any consultations that have occurred:

9.3 **Which specialists in your department have experience performing the intervention/innovation?**

- Include information regarding appropriate credentialing and training for medical, nursing, allied health, and technical staff.
- Provide any specific qualifications as an attachment.

Continued over

9. Staffing, resources, and costs (continued)

9.4 **Do you have a specialist recognised for the teaching of the new intervention/innovation?**

☐ Yes ☐ No ☐ N/A

If NO, answer the following:

(a) Provide details of any specialists that are accredited to proctor (teach) other staff:

(b) Provide details of affiliations of the specialist with the vendor/product sponsor:

(c) Provide any qualifications as an attachment, if applicable:

9.5 **Is there an established credentialing process for the clinical, nursing and allied health staff?**

☐ Yes ☐ No ☐ N/A

If YES, outline the plan for developing the skills required for these staff:

✚ Include details of timeframes, staff involved and the training process. Post-procedure care of the patient should also be considered.

Continued over

9. Staffing, resources, and costs (continued)

9.6 **If external proctor(s) are required to come from another site (including internationally), what is involved, what are the costs, what are the arrangements/logistics?**

How will external proctor(s) be credentialed to help train local staff?

9.7 **Are you aware of an AR-DRG code and any anticipated revenue for which this procedure would be compensated?**

☐ Yes ☐ No

If YES, provide details of the code and revenue expectations:

10. Conflict of interest

10.1 **Do you have or have you had any relationship with the supplier of the device/intervention, or other significant party identified in this application?**

☐ Yes ☐ No

If YES, provide details of the relationship:

10.2 **Have you been involved in any prior assessment of the device/intervention?**

☐ Yes ☐ No

If YES, provide details of the prior assessment:

10.3 **Do you (or a member of your immediate family) have any financial interest in the device/intervention supplier or manufacturer?**

☐ Yes ☐ No

If YES, provide details of the financial interest:

10.4 **Have you, or the organisation, received any financial incentive to use the proposed device/intervention?**

☐ Yes ☐ No

If YES, provide details of the financial incentive:

Continued over

10. Conflict of interest (continued)

10.5 **Have you benefited by receiving any training, travel or accommodation related to the proposed device/intervention?**

☐ Yes ☐ No

If YES, provide details of the training, travel or accommodation:

If YES to any of the above (questions 10.1–10.5), please provide a plan on how this conflict will be managed:

11. Additional comments

11.1 **Provide any additional information/comments relevant to your application:**

12. Facility approvals

Approvals at the facility required by, for example, Business Manager, Director of Medical Services and the General Manager

Applicant			
Name		Signature	
Date	/ /		

Department Head or Stream Head			
Comments			
Name		Signature	
Date	/ /		

Facility Business Manager			
Comments			
Name		Signature	
Date	/ /		

Facility Executive Director of Medical Services or Director of Clinical Governance			
Comments			
Name		Signature	
Date	/ /		

12. Facility approvals (continued)

Facility General Manager/Chief Executive Officer (CEO)			
Comments			
Is there a capped number of procedures or restricted period this can be used? ☐ Yes ☐ No If YES, provide details:			
Name		Signature	
Date	☐☐ / ☐☐ / ☐☐☐☐		

13. District/Health Service advice

For completion by District/Health Service Executive Director of Medical Services or Director of Clinical Governance

Are there credentialing and specific scope of practice requirements? ☐ Yes ☐ No			
Comments			
Name		Signature	
Date	☐☐ / ☐☐ / ☐☐☐☐		

14. District/Health Service General Manager/CEO advice

For completion by General Manager or CEO of the Health Service

Is the proposal for the introduction of the new interventional procedure/innovation supported?

☐ Yes ☐ No

Comments	
Name	
Date	☐☐ / ☐☐ / ☐☐☐☐
Signature	

15. District/Health Service NIP Committee approval

For completion by Chairperson of NIP Committee

Is the new interventional procedure approved?

☐ Yes ☐ No

Comments	
Name	
Date	☐☐ / ☐☐ / ☐☐☐☐
Signature	

Communication of outcome

Date applicant notified of outcome to applicant ☐☐ / ☐☐ / ☐☐☐☐

✚ Copy of notification to be provided to the Facility General Manager/CEO and Executive Director Medical Services, with copy forwarded FYI to Executive Director Quality/Clinical Safety and other relevant executives (e.g. Director of Nursing, Executive Director Finance, Performance and Planning and Executive Director Operations).

Appendix 3

Example progress review form for approved new interventional procedures and clinical practice innovations

Health service organisations that choose to use this form should modify it as necessary to fit their local and jurisdictional requirements.

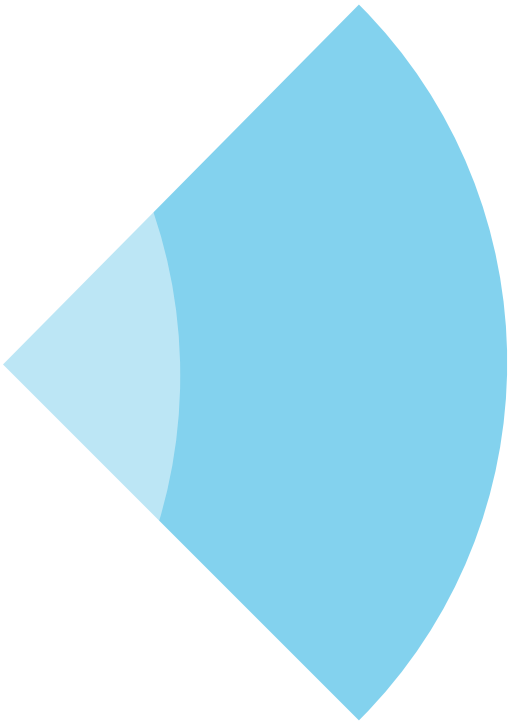
Instructions for completing the Progress Review Intervention/Innovation Application Form

Save this template and complete all fields, providing as much detail as possible (use as much space as required to address the questions). If additional space is required to respond in detail, please attach as a separate document. If a field is not relevant, please note as being 'N/A'.

Ensure all relevant parties are consulted in the development of your application.

Attach all relevant supporting documentation when submitting your application.

Regular reviews should include dimensions of clinical effectiveness; safety, costs, and economic implications; ethical, social, cultural, environmental and legal issues; and organisational and environmental aspects, as well as wider implications for the patient and the population. The overall value may vary depending on the perspective taken, the stakeholders involved, and the decision context. Additionally, the process of transitioning to routine care is one that should include multiple dimensions of clinical effectiveness with assurance that practice can be safe sustained beyond the period of regular monitoring through a new intervention pathway.



New intervention/innovation details

Name of new intervention/innovation	
Name of submitting clinician	
Department/service/area where new intervention/innovation was introduced	
Contact telephone for lead clinician	
Date new intervention/innovation introduced	☐☐ / ☐☐ / ☐☐☐☐

Provide a brief statement regarding how the introduction occurred

What organisational benefits have been realised?

Are there any that have not yet been realised? Why?

Have there been any issues with procurement, recalls or Therapeutic Goods Administration (TGA) updates?

New intervention/innovation details (continued)

Provide any additional information to support assessment of the impact of the intervention/innovation

Has there been an impact on Emergency Department presentations?

Were there any unexpected deaths or coroner's cases from the patient cohort for which the new intervention/innovation was implemented?

Were there any unexpected service impacts (e.g. procedure room, operating theatre, etc.)?

What is the length of stay (LOS) for the patients who had the intervention/innovation compared to those that did not (or pre-new intervention)?

Did the patient cohort go to the expected disposition post-procedure (e.g. post-anaesthesia care unit [PACU], intensive care unit [ICU], ward, home)?

New intervention/innovation details (continued)

Were there any issues in post intervention/innovation follow-up (e.g. lost in system, failure to attend)?

What activity was superseded (e.g. where were the disinvestments) and by what volume?

Provide a detailed overview of the patient population that received the new intervention/innovation (patient selection process, total numbers, total number of failed procedures

✚ Ensure that you cover any on any variation to the patient population, patient selection, or inclusion/exclusion criteria.

Were there any side effects or complications related to the new intervention/innovation that were not anticipated or occurred in numbers great than anticipated?

Were there any Work Health and Safety issues noted during the delivery of the new intervention/innovation?

What was the total cost associated with the new intervention/innovation? (Consider staffing, education and or training of staff, consumables, prostheses, high-cost disposables, equipment/machines, space, impact on length of stay, additional theatre time, medications and post-discharge follow-up.)

New intervention/innovation details (continued)

Outline who is credentialed to undertake this new procedure?

Are there any additional training needs?

Are you applying for this intervention/innovation to become routine care?

☐ Yes ☐ No

If YES, outline why and provide the evidence for this recommendation:

Follow-up actions

Follow-up actions

Action 1

Action 2

Approval letter to applicant Date ☐☐ / ☐☐ / ☐☐☐☐

Progress Review Form #1

Date due ☐☐ / ☐☐ / ☐☐☐☐ Date received ☐☐ / ☐☐ / ☐☐☐☐

Progress Review Form #2

Date due ☐☐ / ☐☐ / ☐☐☐☐ Date received ☐☐ / ☐☐ / ☐☐☐☐

Progress Review Form #3

Date due ☐☐ / ☐☐ / ☐☐☐☐ Date received ☐☐ / ☐☐ / ☐☐☐☐

AUSTRALIAN COMMISSION
ON SAFETY AND QUALITY IN HEALTH CARE

Level 5, 255 Elizabeth Street, Sydney NSW 2000
GPO Box 5480, Sydney NSW 2001
PHONE: (02) 9126 3600
EMAIL: mail@safetyandquality.gov.au

safetyandquality.gov.au