

Clinical Practice - Model Policy for Safe Introduction of New Interventional Procedures

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Summary Procedures to assist clinicians to introduce new interventional procedures.

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**Model Policy for the Safe Introduction of New Interventional Procedures
into Clinical Practice**

The attached model policy has been developed to assist Area Health Services to develop a policy specific to their Area. The policy is considered to be important in assisting clinicians to introduce new interventional procedures so that patients, clinicians and managers may be confident that any new interventional procedures introduced into facilities are supported by evidence of efficacy, safety and effective resource utilisation. It will also ensure that there is an agreed process for the monitoring of outcomes.

The policy needs to be implemented within the framework of national and state guidelines such as:

Medical Services Advisory Committee (2000) *Funding for new medical technologies and procedures: application and assessment guidelines*. Department of Health and Aged Care, Canberra.

NSW Health (2002) *Guide to the Role Delineation of Health Services*. NSW Department of Health, Sydney.

NSW Health (2002) *Guidelines for the credentialing of visiting practitioners and staff specialists*. NSW Department of Health, Sydney.

RACS/ASERNIP-S *General Guidelines for Assessing, Approving and Introducing New Procedures into a Hospital or Health Service*. Royal Australasian College of Surgeons, Melbourne.

Area Health Services are required to develop their own policy based on the model policy and forward a draft copy to NSW Health Department by 26 March 2004. The policy is to be implemented by 27 September 2004.

Robyn Kruk
Director-General

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In accordance with the provisions incorporated in the Accounts and Audit Determination, the Board of Directors, Chief Executive Officers and their equivalents, within a public health organisation, shall be held responsible for ensuring the observance of Departmental policy (including circulars and procedure manuals) as issued by the Minister and the Director-General of the Department of Health.

MODEL POLICY
for
**THE SAFE INTRODUCTION OF NEW
INTERVENTIONAL PROCEDURES INTO CLINICAL
PRACTICE**

**A model policy for Area Health Services and other
Public Health Organisations**

October 2003

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Introduction

This model policy *The Safe Introduction of New Interventional Procedures into Clinical Practice* has been developed in response to an identified need for a consistent state-wide approach to the introduction of procedures and treatments that have not previously been undertaken in an Area Health Service or health facility.

The purpose of the Model Policy is to assist clinicians to introduce new interventional procedures by providing a standard process for the assessment and approval of such procedures, so that patients, clinicians and managers may be confident that any interventional procedure that is introduced is supported by evidence of efficacy, safety and effective resource utilisation, and can be safely performed given the available resources. It will also ensure that there is an agreed process for monitoring the outcomes of the new intervention. The policy also applies where a procedure is already performed in an area health service and where approval is sought to perform it at another facility within that Area Health Service.

This model policy is **not** intended for the introduction of new interventional procedures that require state-wide or national planning. For example, some interventional procedures or treatments which are low volume, high cost and require concentrated clinical expertise due to its expected low demand, such as paediatric heart transplantation, or require the investment of significant capital works, eg radiotherapy.

Nationally, the Medical Services Advisory Committee (MSAC) advises the Commonwealth Minister for Health and Ageing on evidence relating to the safety, effectiveness and cost-effectiveness of new medical technologies and procedures. Applications to MSAC can be made by the medical profession, medical industry and others with an interest in seeking Australian government funding for a new medical technology or procedure.

At a state level, requests for funding for new technology that are provided at limited centres can be considered by the NSW Department of Health through the Funding of State-wide Services Steering Committee. In addition, through the Department's "budget holding" policy, Area Health Services that wish to commence a new service, eg renal dialysis, are in the position to negotiate with other Area Health Services for funding transfer that would be associated with the projected patient flow reversals.

This policy is also not intended for the introduction of a totally new (to NSW) surgical technique. It is intended that there will be a centralised process for determining the safety, effectiveness and appropriateness of a totally new technique, for its broad use in NSW health services.

Nor does this policy apply to emergencies where a procedure or intervention is considered by an attending clinician to be required urgently to prevent or minimise harm to a patient.

This policy **is** for Area Health Services that are considering introducing an intervention that has been undertaken in other facilities in NSW but has not been undertaken in a particular facility in the Area Health Service previously. The decision to undertake such an intervention should take into consideration not only a clinician's ability to do the procedure but also the structural requirements and clinical support

systems required to safely implement that procedure as outlined in the NSW Health (2002) *Guide to Role Delineation of Health Services*, and NSW Health (2002) *Guidelines for the credentialing and delineation of clinical privileges of visiting clinicians and staff specialists (Draft)*.

In addition, the introduction of new devices for procedures require prior evaluation and approval by the Therapeutic Goods Administration (Commonwealth Department of Health & Aged Care). Problems with medical devices need to be reported to the Therapeutic Goods Administration as part of the Australian and New Zealand Medical Device Incident Report Investigation Scheme.

The committees required to implement this policy may be considered within structures that are already in place eg Area Quality Council, Credentialing committee, or a committee formed specifically for review of a new intervention to a facility.

Name of this Policy

This policy may be cited as the *[name of Public Health Organisation] Policy on the Safe Introduction of New Interventional Procedures into Clinical Practice in [Name of Public Health Organisation]*.

Purpose of this Policy

The purpose of this policy is to assist clinicians to introduce new interventional procedures so that patients, clinicians and managers may be confident that any new interventional procedures introduced into *[name of Public Health Organisation]* facilities are supported by evidence of efficacy, safety and effective resource utilisation. Moreover, it will ensure that there is an agreed process for monitoring outcomes.

Objectives

1. To provide a framework for the safe introduction of new interventional procedures into clinical practice.
2. To encourage and protect innovation in clinical practice.
3. To promote clinical improvement.
4. To provide mechanisms for monitoring the efficacy, safety and efficiency of new interventions.

Definitions

Expressions used in this policy are defined in the dictionary at the end of the policy.

Background

Clinical Governance

Public Health Organisations have a responsibility for the quality of care provided to

consumers of the organisation.¹ This is referred to as “clinical governance”. Clinical governance means that the Board of *[name of Public Health Organisation]* must ensure that an effective health system is in place that provides an environment that fosters quality, identifies deficiencies in the quality of care and effectively addresses those deficiencies. The successful implementation of clinical governance requires the development of partnerships between clinicians and managers for the safe and effective provision of health care.

Local managers and clinicians have a joint responsibility for safety, quality, activity, budget and staff morale in the clinical workplace. While it is intended that local managers will be the key managers of this process, this will be achieved through liaison with the clinicians.

[Name of Public Health Organisation] is responsible for managing the safe introduction of new procedures into clinical practice to maximise safety to patients and staff. Provision of a formal approval process is necessary in order to protect the patient, the clinician and the health service. The intent is to encourage and to protect innovation and to promote clinical improvement by outlining a framework for the assessment of new interventional procedures before they are introduced into the *[name of Public Health Organisation]*.

Credentialing

The safe and effective introduction of new technology requires that skills, resources and infrastructure be aligned to ensure safety, effectiveness and efficiency for individual patients, care teams and the broader health service.

As well as assessing new procedures to ensure they are safe and that there are appropriate resources to support them, it is necessary to determine that individual clinicians and the clinical teams who will perform them are competent to do so, and properly supported. This is achieved through the area's credentialing systems. (Describe AHS credentialing system; refer to Guidelines for the credentialing and delineation of clinical privileges of visiting clinicians and staff specialists (Draft 2002).)

Existing Mechanisms

The policy also applies where a procedure is already performed in a *[name of Public Health Organisation]* facility and where approval is sought to perform it elsewhere within the *[name of Public Health Organisation]*. The policy seeks to provide a local effector arm for Professional College initiatives and other initiatives such as the Australian Safety and Efficiency Register of New Interventional Procedures – Surgical (ASERNIP-S), the International Network of Agencies for Health Technology Assessment (INAHTA) and the Commonwealth Medicare Services Advisory Committee (MSAC).

In addition, the introduction of new devices for a procedure require prior evaluation and approval by the Therapeutic Goods Administration (Commonwealth Department of Health & Aged Care). Problems with medical devices need to be reported to the Therapeutic Goods Administration as part of the Australian and New Zealand

¹ NSW Health (1999) A Framework for Managing the Quality of Health Services in NSW.

Medical Device Incident Report Investigation Scheme.

General Principles

Regardless of the type of new interventional procedure to be introduced or by whom, certain principles shall apply:

- a) **Health and safety.** The primary motivating concern of the actions described in this policy is the health and safety of:
 - consumers
 - the individual clinician
 - colleagues and other staff
 - the community.
- b) **Risk management.** This policy emphasises a risk management approach. The aim is to manage the introduction of new interventions into clinical practice, and thereby reduce the risk of adverse outcomes. Systems for support during the early stages of the introduction of the procedure should be given consideration.
- c) **Evidence based practice.** Most techniques will have been evaluated or at least implemented elsewhere and the assessments of the procedure need to be considered in relation to the reliability of the evaluation as well as taking into consideration the particular conditions in which the procedure is being introduced. Where there is no evidence a well reasoned scientifically based argument in support of the proposed innovation is required.
- d) **Ethics.** Information regarding the current universal level of application and the results of findings need to be included with the application for the approving committee to review. If there are any concerns regarding the need for ethics approval then the application will be forwarded to the ethics committee for consideration who will decide if ethics approval is required.
- e) **Patient information and informed consent.** Patient information and consent forms need to be developed at the time of application outlining the potential risks as accurately as possible and including any areas of uncertainty. The criteria for selection of patients for these procedures should also be included in the information and consent.
- f) **Costs and benefits.** The introduction of any new procedure will have an opportunity cost. The new procedure will consume resources that need to be evaluated against the benefits of performing the procedure and the effect of taking these resources from existing services.
- g) **Conflicts of interest** must be disclosed. There must be full disclosure of any relationship between the clinician and supplier concerned or other significant party or involvement in prior assessment of the procedure and any financial involvement that could result in a conflict of interest.
- h) **Training.** Training needs to take into consideration all professionals who will be involved in the new procedure. This includes junior medical staff, nursing staff, allied health and support staff who may be involved in the sterilising or setting up of the equipment.

- i) **Monitoring.** Any new procedures need to be monitored after their introduction. Systems to collect data should be established prior to introduction and then reviewed by peer groups as well as an independent group. Any adverse events are to be reported and the causes reviewed at the local level.
- j) **Equipment and Supplies.** New equipment and supplies that may be required for the procedure are to be approved through the appropriate committees. Systems to obtain and maintain the equipment and supplies are to be established also.

Summary of the Policy

1. All new procedures or new applications of current procedures must be formally approved.
2. Where a clinician is unsure whether a procedure falls within the scope of this policy, advice should be sought from local management in the first instance.
3. *An Application Form for the Introduction of a New Interventional Procedure* must be completed and supporting evidence provided.
4. The application is reviewed through an approval process that has been approved by the Board of the Area Health Service
5. *An Approval for the Introduction of New Interventional Procedures* will be forwarded to the nominated person of a craft group when approval has been granted.
6. Each clinician who will be performing the new procedure must be credentialed to do so. This means where the new procedure requires training in new skills and the use of equipment then evidence of this training should be provided.
7. Local Consumer Health Councils and Networks will be informed of applications and of their outcomes.
8. If a problem occurs with a medical device then a *Medical Device Incident Report* must be completed and reported appropriately.
9. Progress reports are to be submitted at 6 monthly intervals, or, if not appropriate, at clinically relevant intervals.

Policy

- 1) All new procedures or new applications of current procedures must be formally approved by the *[Name of Public Health Organisation] Health Service [New Interventions Assessment] Committee* before being used in *[Name of Public Health Organisation]* health facilities.
- 2) Where a clinician is unsure whether a procedure falls within the scope of this Policy, advice should be sought from local management in the first instance. Local management has discretion to obtain further advice from the *[Name of Public Health Organisation] Health Service [Name of Clinical Governance*

Committee].

- 3) An *Application Form for the Introduction of a New Interventional Procedure* must be completed (Appendix A).
- 4) The clinician/s or unit wishing to introduce the new interventional procedure should answer the questions on the Application Form, which functions as a checklist.
- 5) Each clinician who will be performing the new procedure must be credentialed to do so. This means where the new procedure requires training in new skills and the use of equipment then evidence of this training should be provided.
- 6) The completed Application Form (Appendix A) should be forwarded with a copy of the *Approval for the Introduction of a New Interventional Procedure* (Appendix B) for approval as indicated on Appendix B.
 - a) The clinician/s or unit making the application should forward it to their departmental head.
 - b) The application should then be forwarded to the *[Line Manager as determined by the CEO]*.
 - c) The application should then be forwarded to the Chair of the *[New Interventions Assessment]* Committee.
 - d) The application will be registered and submitted to the next *[New Interventions Assessment]* Committee meeting for final approval.
 - e) The Chair of the *[New Interventions Assessment]* Committee will advise the Health Services *[Name of Planning]* Committee of the application.
 - f) The *[New Interventions Assessment]* Committee will implement the credentialing process as outlined in *[Name of Public Health Organisation] Health Service – [Names of Local Policy for the credentialing of Visiting Medical Clinicians and Staff Specialists]* where appropriate.
 - g) Applicants will be informed of the outcome of the application by a returned copy of the Approval Form with the reference number and date for reporting.
 - h) The Departmental Head will be responsible for liaising with the relevant clinician and / or clinical team at regular intervals appropriate to the procedure in question re progress. A proforma that can be used in this context is attached to this policy (Appendix C).
 - i) Progress reports should be forwarded to the *[New Interventions Assessment]* Committee and to the Health Services *[Planning]* Committee at regular intervals, appropriate to the procedure in question.
 - j) The sponsor/s of an unsuccessful application may appeal to the Chair of *[New Interventions Assessment]* Committee or to the Chief Executive Officer.
- 7) Local Consumer Health Councils and Networks will be informed of applications and of their outcomes.
- 8) If a problem occurs with a medical device then a *Medical Device Incident Report*, available at www.health.gov.au/tga/forms.htm, must be submitted and a copy forwarded to the *[Name of Appropriate Committee or Unit]*.
- 9) Progress reports are to be submitted to the *[New Interventions Assessment]* Committee at 6 monthly intervals, or as agreed between the committee and the

clinicians (Appendix B).

10) A register of applications and approved procedures is to be kept and maintained by the (*New Interventions Assessment*) Committee.

Dictionary

Adverse event An unintended injury or complication resulting in disability and/or death and/or extended length of stay that is caused by the health care intervention and not by the patient's disease.

Clinician – a health clinician or health service provider (whether or not the person is registered under a health registration act), eg nurses, medical clinicians, allied health clinicians, social workers etc.

Craft Group – A group of specialists or professionals eg paediatricians, physiotherapists.

Health service – includes the following services:

- Medical, hospital and nursing services
- Dental services
- Psychiatric and psychological services
- Pharmaceutical services
- Ambulance services
- Community health services
- Health education services
- Services provided by podiatrists, chiropractors, osteopaths, optometrists, physiotherapists, acupuncturists, occupational therapists, speech therapists, audiologists, audiometrists, radiographers, social workers, nutritionists and dieticians, orthoptists, environmental and public health professionals, prosthetists and therapeutic counsellors
- Services provided in other allied or alternative health care fields
- Welfare services necessary to implement any services referred to above

Interventional Procedure A procedure involving any invasive contact with the patient. Examples include surgical operations, endoscopy, certain radiological procedures, chemical or other therapies, eg ventilation.

Local health organisation – *[list of hospitals and other affiliated organisations within the Area Health Service/Public Health Organisation.*

New Interventional Procedure A procedure not previously performed within a *[Name of Public Health Organisation]* health facility or one that is performed within a *[Name of Public Health Organisation]* health facility and for which approval is sought for its performance at another *[Name of Public Health Organisation]* health facility. This will include variations on an existing procedure and treatment where a new device, equipment or medication is introduced.

(New Interventions Assessment) Committee – This committee may be a separate committee or the requirements for approving new interventions may be a part of the role of another committee such as the Credentialing Committee. Any committee

considering the application for the introduction of new interventions should include experts who may be co-opted as required but includes at least the Director of Medical Services (or delegate), a clinician with no conflict of interest and a clinician with expert knowledge of the procedure.

Performance – refers to the knowledge and skill possessed and applied by the clinician in the course of their duties. Performance is also influenced by experience, application and attitude.

Public health organisation – an area health service, statutory health corporation or affiliated health organisations in respect of its recognised establishments and recognised services.

Public health system – consists of all the area health services, all the statutory health corporations and all the affiliated health organisations in respect of their recognised establishments and recognised services.

Appendices

Appendix A

APPLICATION FORM / CHECKLIST FOR THE INTRODUCTION OF A NEW INTERVENTIONAL PROCEDURE IN THE [Name of Public Health Organisation] HEALTH SERVICE

Date: / /

Name of

Procedure: _____

Name of Individual or Group making the application: _____

1 Has this procedure been used elsewhere? YES NO
If YES, please attach details

2 Does this new procedure replace current procedures? YES NO

3 If YES, does this new procedure have advantages over current procedures?
If YES, please attach details. YES
NO

4 Has this procedure been evaluated elsewhere? YES NO
for example: ASERNIP-S, SERNIP, Professional Colleges or Sections thereof;
Medicare Services Advisory Committee, Cochrane Collaboration, publications,
clinical trials, information from internal and/or external peers.
If YES please attach details

5 If the procedure involves the use of a new medical device, has the device been approved for this purpose by the Therapeutic Goods Administration (Commonwealth Department of Health & Aged Care)? YES NO

6 Are there discrete training requirements for the proposed procedure? YES NO

If YES, please attach details

On a separate sheet please list:

the name/s

qualifications

evidence of relevant training and courses attended

Of those individuals who wish to be credentialed for this procedure

**APPLICATION FORM / CHECKLIST FOR THE INTRODUCTION OF A NEW
INTERVENTIONAL PROCEDURE IN THE [Name of Public Health Organisation]
AREA HEALTH SERVICE**

Date: /...../

Name of Procedure

Name of Individual or Group making the application:

7 Has a patient information sheet been developed? YES NO
If YES, please attach (*the patient must indicate their understanding of the procedure by signing and dating the patient information sheet*)

8 Have specific risks arising from this procedure been considered and will patients be explicitly informed about these? YES NO

9 Will outcomes be monitored by a database / register? YES NO
If YES, please attach details

10 Will outcomes be reviewed regularly? YES NO
If YES, please attach details

11 If the procedure carries with it a risk for adverse events are there criteria for reviewing outcomes before any further procedures are performed? YES NO
If YES, please attach details

12 Have direct and indirect costs been considered? YES NO
If YES, please attach details

13 Have staffing requirements been considered? YES NO
If YES, please attach details

14 Has the impact on other departments been considered? YES NO
If YES, please attach details

15 Have Occupational Health & Safety requirements been addressed? YES NO
If YES, please attach details

16 Please indicate the number of cases anticipated to be performed per year
_____ cases

Please note that approval will only be granted when Questions 7 - 14 are answered by ticking the YES box and the appropriate information is attached.

Appendix B

APPROVAL FOR THE INTRODUCTION OF A NEW INTERVENTIONAL PROCEDURE

Name of Procedure:

Name of Individual or Group making the application:

Name of Facility/ies at which procedure is approved:

Head of Clinical Unit:

_____ **Date:** _____
Signature

Sector General Manager:

_____ **Date:** _____
Signature

Chair of the (New Interventions Assessment) Committee:

_____ **Date:** _____
Signature

Reference No _____

Date for first progress report _____

Appendix C

PROGRESS REPORT FOR A NEW INTERVENTIONAL PROCEDURE IN THE [Name of Public Health Organisation] AREA HEALTH SERVICE.

(The completed form is to be sent to the

- a) Department Head, who will sign and forward to the**
- b) [New Interventions Assessment] Committee who will sign and forward to the**
- c) Health Services (Planning) Committee,**
- d) a copy will be kept with the original application by the [Name of Public Health Organisation]**

Name of Procedure

Reference Number _____

Date: _____

1. Has the procedure been introduced? YES NO
If yes, please give commencement date.....
If no, please give reasons:

2. Is it continuing? YES NO

3. How many procedures have been performed? _____

4. Have outcomes been measured? YES NO
Please list a summary of progress and key outcomes on a separate page

5. Have there been any adverse outcomes or significant problems? YES NO
If yes, please list details on a separate page

6. Is the procedure to continue to be employed? YES NO

This Progress Report was:

Completed by (name):

Reviewed by:

Department Head (name & date):

.....

[Name of Public Health Organisation] (name & date):.....

Health Services (Planning) Committee (name & date):

.....

References and Resources

Hunter Area Health Service Policy Number 01/05, March 2001. *Policy for the introduction of new interventional procedures involving patients in the Hunter Area Health Service.* (Executive responsible for policy monitoring and review: Director of Clinical Governance).

NSW Health (1999) *A Framework for Managing the Quality of Health Services in NSW.* NSW Department of Health, Sydney.

Royal Australasian College of Surgeons/ASERNIP-S. (2002) *General Guidelines for Assessing, Approving and Introducing New Procedures into a Hospital or Health Service.* Royal Australasian College of Surgeons, Melbourne.

NSW Health (2002) *Guide to the Role Delineation of Health Services.* NSW Health Department, Sydney.

NSW Health (2002) *Guidelines for the credentialing and delineation of clinical privileges of visiting clinicians and staff specialists,* (Draft). NSW Health Department, Sydney.

Recommended Reading

Gorman, D 'Introduction of new technologies. Inquiry by the Medical Board of Western Australia in the matter of Dr Philip Hardcastle. *United Journal* Issue 1 2001.

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Royal Australian College of Surgeons (2000) *Credentials Committees, Surgical Appointments and Complaints Procedures - A Guide* by the Royal Australasian College of Surgeons, Melbourne.

Royal Australian College of Surgeons (1994) *The Implications of New Technology for Surgical Practice, Quality Assurance, Accreditation and the Delineation of Responsibilities.* Royal Australasian College of Surgeons, Melbourne.

Commonwealth Therapeutic Goods Act (1989) Therapeutic Goods Administration, Commonwealth Department of Health & Aged Care,
www.health.gov.au/tga/devices/devices.htm.

Commonwealth of Australia (2000) *Funding for new medical technologies and procedures: application and assessment guidelines*. Medical Services Advisory Committee, www.health.gov.au/haf/msac.

Rogers v Whitaker (1992) 175 CLR 479 -regarding informed consent & duty of disclosure.

Chappel v Hart (1998) HCA 55 - regarding informed consent & duty of disclosure.

Acknowledgements

This policy has been developed by Quality and Clinical Policy Branch, NSW Health following the successful introduction of this approach within the Hunter Area Health Service.

We would like to acknowledge the Clinical Governance Unit, Hunter Area Health Service for providing the concept and the original policy and the Royal Australian College of Surgeons/ASERNIP-S for providing copies of the *General Guidelines for Assessing, Approving and Introducing New Procedures into a Hospital and Health Service* for distribution and referencing in the model policy.

We would also like to thank the following members of the working party who considered the responses from the Area Health Services and decided the approach to take for this policy for NSW.

Professor Allan Spigelman (Chair)	Hunter Area Health Service/University of Newcastle
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Dr Kevin Hanel	RANZ College of Surgeons
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Dr Noel Young	RANZ College of Radiologists
Dr Peter Holman	RANZ College of Surgeons
Rebecca Fox	NSW Operating Theatre Association
Mrs Eon McDonall	Consumer
Mrs Colleen Loder	Consumer
Dr Peter Finlayson	New England Area Health Service
Dr Roger Allan	RANZ College of Physicians – Cardiac Society
Maureen Robinson	NSW Health Department
Gaylene Parsell	NSW Health Department

Frequently Asked Questions for “Model Policy for the Safe Introduction of New Interventional Procedures into Clinical Practice”.

When is an intervention a ‘new intervention’?

The definition in the model policy of a ‘new intervention’ is “ A procedure not previously performed within an AHS health facility or one that is performed in the AHS and for which approval is sought for its performance at another facility. This will include variations to an existing procedure or treatment where a new medication, device or medication is introduced.” ...”Any intervention that is new to the state is **not** covered in this policy. It is intended that there will be a centralised process for determining the safety, effectiveness and appropriateness of a totally new technique for its broad use in NSW health services.”

Any new interventions that are undergoing development and trial are to be considered as experimentation or research and will need to be addressed through the appropriate ethics committee.

The purpose of this policy is to provide a process for when a clinician who has learnt how to perform a new procedure or to vary a procedure using a new device, equipment, etc (either overseas, in a different AHS, or at a different facility within an AHS) and wishes to introduce it into the facility at which they are working.

It is about ensuring that the ramifications of the new procedure are considered at all levels, in all departments and that the appropriate training is provided to all staff so that the new procedure and handling of the new equipment is performed safely and that the patient is cared for safely and appropriately throughout the episode of care.

Why are new devices not given the same emphasis in this policy?

The policy applies equally to the introduction of a new device or a new treatment such as a medication. These fall within the definition of a “new intervention” used in this policy.

Some AHS have equipment or medication committees that review all new devices or medications. The committees that review devices and medication should be included in the process for approval of a new intervention as appropriate.

Does the local policy have to keep to the Model Policy or can it be adapted for local implementation?

The model policy can be used as a guideline so that each AHS can develop their own policy or it can be used with minimal modifications so that it meets the structures within the organisation.

The purpose of the model policy is to provide a framework for the AHS so that they did not have to develop a policy from the start and to ensure that there is some level of consistency across the state. It is expected that there will be local variations to the policy however there are parts of the policy such as the checklist and monitoring after introduction that should be considered essential to be included in the local policy.

Who really needs to sign off the implementation of a new interventional procedure or device?

This will depend on variables such as location, type of new intervention or ramifications of the new interventions, such as risk or cost. A flowchart of the process within the organisation identifying who is responsible at each step may assist in the understanding of the requirements for the application of a new intervention and who has the responsibility for sign off. Ultimately the Area Quality Council needs to be informed of the introduction of the new intervention and how the outcomes achieved from the new intervention will be evaluated.

Communication regarding the introduction of new procedures and new devices needs to take place with the affected parties before they are introduced. This may take place informally or formally. In the first instance a clinician who wants to introduce a new procedure may be encouraged to discuss this with the most appropriate line manager/clinical director. This person should be able to determine who should be involved in further investigation or approval before going to the approval committee.

Does a credentialing committee need to be responsible for this process?

The credentialing committee is a part of the process as it will be necessary to determine that the persons who are undertaking the new intervention are competent.

New standards and policies are being developed at National and State level that address Credentialing and Clinical Privileges. These documents include developing processes for the introduction of new clinical services, procedures and technologies and the involvement of the committee and/or individuals responsible for credentialing. A review of credentials is also recommended when new technology or clinical interventions are introduced by a practitioner or to a health facility.

Does a person with a conflict of interest have to be excluded from the process?

The model policy indicates that any conflict of interest must be disclosed.

The parties involved in the approval process will need to decide whether the person will need to be excluded or whether they can contribute to the overall process and in what capacity.

What is required to monitor the outcomes of the new intervention?

A progress report is to be provided at a frequency determined by the approval committee on the numbers of procedures, if it is going to continue, outcomes that have been achieved as well as any adverse events or significant problems.

This report is broader than the reporting of adverse events or safety of the procedure as it includes the efficacy and effectiveness of the procedure.