



## **The Safe Introduction of New Clinical Interventions into Ambulance Practice**

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**Division** State Headquarters

**Summary** Process for the introduction of new clinical interventions and clinical innovations

**Applies to (bold indicates selection)** **All Ambulance Service of NSW staff**  
All Operational Staff  
All Administration staff  
All Headquarters staff  
Division staff (select Aero medical, Northern, Southern, Sydney, Western)  
Operations Centres (select All, Aero medical, Northern, Southern, Sydney, Western)

**Review date** May 2011

**Previous reference** SOP2007-025

**Status** Active

**Approved by** Chief Executive

**Compliance with this policy directive is mandatory.**



## **Introduction**

The purpose of this policy is to enable Ambulance to introduce new clinical interventions so that patients, clinicians and managers can be confident they are supported by evidence of efficacy, safety, encourage innovation and promote clinical improvement.

The Aims of this policy compliance procedure are:

- To provide a framework for the safe introduction of new clinical interventions into ambulance practice;
- To ensure the clinical context and appropriateness, scientific evidence, clinical ethics, resource implications, credentialing and training aspects are all integrated in decisions relating to the introduction of new clinical interventions;
- To ensure regular evaluation of individual approved clinical procedures occurs;
- To ensure that best evidence and safe transition between new clinical interventions and routine clinical practice; and,
- To encourage innovation in clinical practice.

## **Policy**

Regardless of the type of new clinical intervention/procedure to be introduced or by whom, the key principles associated with the introduction of new clinical interventions/procedures should apply. These include the clinical context and appropriateness of care, scientific rationale, patient safety, informed consent, clinical ethics, resource implications, credentialing and scope of practice, and training and education.

All new clinical procedures or new applications of current procedures should be formally endorsed by the New Clinical Intervention Procedures Committee and authorised by the Chief Executive, before being used in the Ambulance Service.

Where an employee 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 Ambulance Service's Manager Clinical Professional Development or refer to the new clinical intervention fact sheet.

Any operational clinician(s) or manager may submit an application for the introduction of a new clinical intervention/procedure using Procedure Form 26 to the Chair of their respective Divisional Clinical Quality Committee. In the case of an application originating from the Ambulance Clinical Advisory Committee (ACAC), Research or Equipment Review Group the completed form should be endorsed by the Chair of the Committee, at which point the Committee will become the sponsor for the proposed new clinical intervention. Non-operational staff may submit an application directly to the Chair, New Clinical Intervention Procedures Committee.

The chair of the sponsoring committee is responsible for the initial phase of evaluation, referral or rejection (refer to the flow diagram appendix 1).

Strong supporting evidence should be provided with the application form along with an in depth analysis of costing, training, health, safety and clinical risk assessments or estimates. If the proposed new clinical intervention has been evaluated elsewhere and the evidence is considered adequate the chair of the sponsoring committee will forward the proposal to the New Clinical Intervention Procedures Committee for "in-principle" support to enable the proposal to proceed to the next phase of the evaluation.



Any proposed new clinical interventions that have gained “in-principle” support will be forwarded to the relevant functional units for an analysis of the quantities, unit price, overall costs, timing for the introduction and sustainability of the new intervention e.g. maintenance, replacements, storage, carriage, compatibility with other equipment, staff training and identification of a funding source are considered.

Functional units will have until the deadline (this will depend on the complexity of the application however will ideally be a minimum of 4 weeks to a maximum of 12 weeks) to submit their position to the Chair of the New Clinical Intervention Procedures Committee.

The final phase of the process involves the Chair of the New Clinical Intervention Procedures Committee submitting a briefing paper that addresses all areas of the general principles, inclusive of any recommendations to the Ambulance Executive Management Board, which will decide on one of the following outcomes:

- i Application approved;
- ii Application has merit but inadequate evidence to proceed. The Ambulance Executive will refer the application to the sponsoring Committee, who will seek further assistance / advice (as required) to resolve concerns prior to final approval. Application should be reconsidered at the next scheduled Ambulance Executive meeting for further consideration; or,
- iii Application rejected outright – reasons should be clearly documented and the applicant advised in writing.

### **Implementation, monitoring and reporting**

Pre-implementation is the responsibility of the General Manager, Clinical Development who will delegate to the appropriate Clinical Development Manager the responsibility of preparing a comprehensive implementation plan inclusive of monitoring, audit/evaluation, communication strategy and reporting systems. The General Manager, Clinical Development prior to implementation, should approve the patient safety and clinical quality aspects of this plan.

Once the General Manager, Clinical Development approves the plan there should be consultation with the General Manager, Operations who is responsible for its implementation. The nominated Clinical Development Manager will provide an on-going liaison/support role to operations during implementation.

Each clinician who will be performing the new clinical intervention must be credentialed to do so. The General Manager, Clinical Development delegates the responsibility of the credentialing process for clinicians (where appropriate) to the Manager Education.

Clinical Development will be responsible for co-coordinating progress reports at quarterly intervals. Progress reports should be forwarded to the General Manager, Clinical Development and to the Ambulance Executive at regular intervals, appropriate to the procedure in question.

### **Urgent or Emergency Situations involving New Clinical Interventional Procedures**

Where a new clinical interventional procedure is considered to be required urgently to prevent or minimise patient harm such requests should be discussed with the General Manager, Clinical Development via the contact person(s) for this policy compliance procedure.



### **Appeal process**

Unsuccessful applicants may appeal to the Chair, New Clinical Intervention Procedures Committee in the first instance, in order to ensure that there are no procedural issues, or that there is no further relevant information to be considered.

In the event that the applicant is still not satisfied with the outcome of the Committee's deliberations, they may lodge an appeal with the General Manager, Clinical Development.

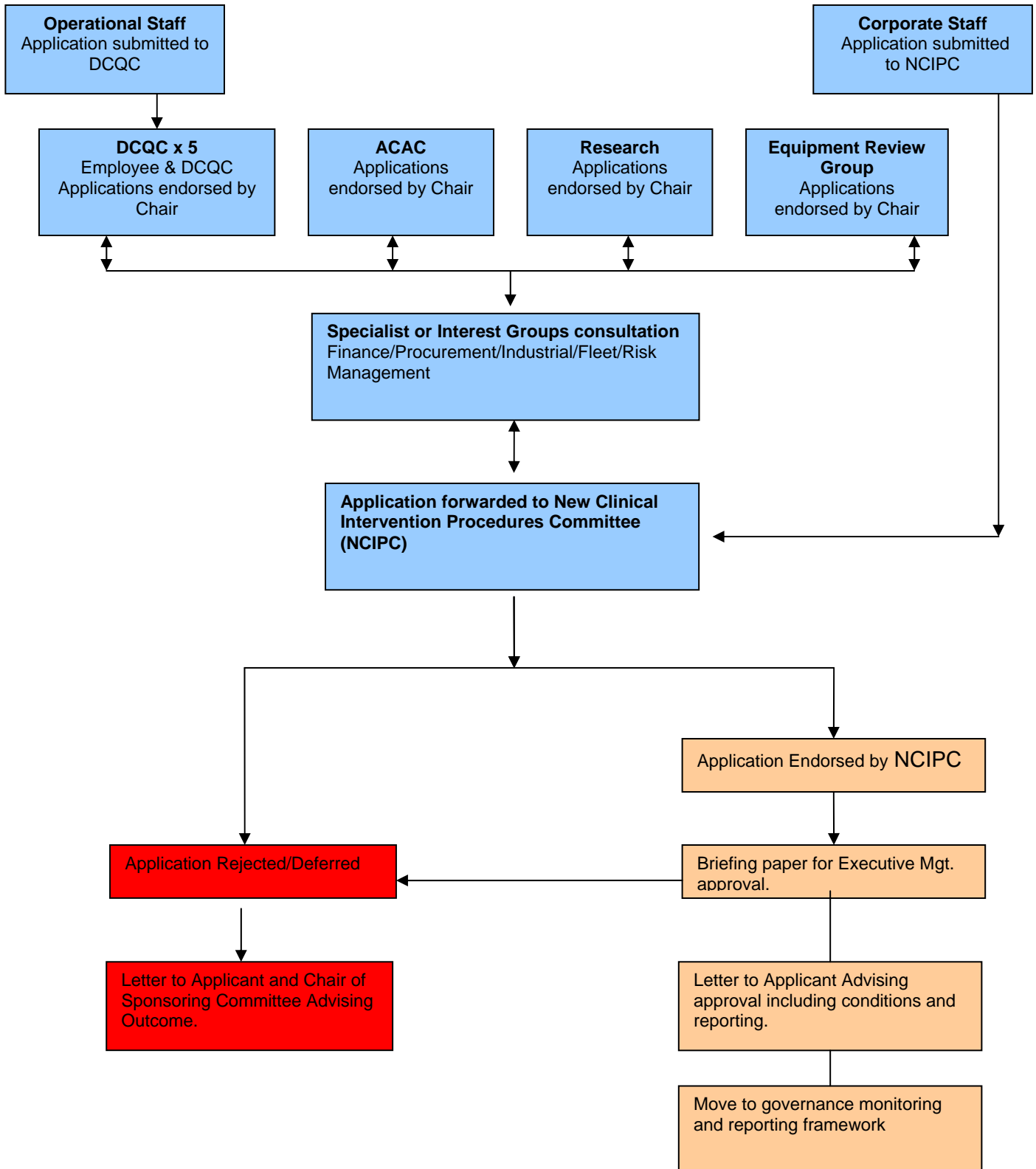
### **Organisational Responsibility**

This policy compliance procedure and its associated guidelines are managed and administrated on behalf of the Ambulance Service of NSW by the General Manager, Clinical Development.



**The safe introduction of new clinical intervention procedures application**

**Flowchart No 1**





## Definitions and key principles associated with the introduction of new clinical interventions

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**New Clinical Interventions Procedure:** A medical, diagnostic or therapeutic procedures and equipment not previously performed within the Ambulance Service of NSW. This will include variations on an existing procedure and treatment where a new device, procedure or medication is introduced.

**New Clinical Intervention Procedures Committee:** The role of this Committee is to provide expert advice to the General Manager, Clinical Development on the framework for the introduction of new clinical procedures in Ambulance and to ensure that clinical practice innovation is encouraged, while being introduced safely and effectively. The recommendations of this Committee for the introduction of new clinical interventions into Ambulance practice are submitted to the Chief Executive for approval. The Committee is chaired by the Manager, Clinical Professional Development.

**Ambulance employee:** Any employee may submit an application outlining a proposed new clinical intervention. Applications must be referred to the employee's respective Divisional Clinical Quality Committee (DCQC) for initial assessment. Once the DCQC confirms the application satisfies all of the principles, the chair of the DCQC should endorse the application and forwarded to the New Clinical Intervention Procedures Committee for final evaluation.

**Divisional Clinical Quality Committee, Ambulance Clinical Advisory Committee, Research and Equipment Review Group:** Depending on the type of new intervention, these committees play an integral role in the submission of applications and/or evaluation of proposed new clinical interventions. These committees have a dual role and either assesses and/or may be the point of origin for applications for the introduction of new clinical intervention. The relevant committee/group must ensure the application addresses costing, training, health, safety, clinical risk and procurement.

**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.

**Evidence based practice.** Most techniques will have been evaluated or at least implemented elsewhere and the assessment of the procedure needs 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.

**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.

**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.

**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.

**Training.** Training needs to take into consideration all employee's who will be involved in the new procedure. This includes support staff who may be involved in the maintenance or setting up of the equipment.

**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.

**Equipment and Supplies.** New equipment and supplies that may be required for the procedure are to be approved by the Ambulance Executive. Systems to obtain and maintain the equipment and supplies are to be established.



## Clinical Intervention Fact sheet

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### What is a new clinical intervention?

A new clinical intervention procedure may be a surgical or medical procedure. It may be diagnostic, therapeutic or new equipment. It is considered new if it has either not been previously used within the Ambulance Service of NSW. When assessing whether a procedure or equipment falls into the classification of a new clinical intervention procedure consider if the following questions.

Does it have:

1. Associated potential risks that are not fully defined?
2. Credentialing, training or supervisory implications?
3. Financial implications for the service?
4. A change to paramedic scope of practice?

Examples of new clinical interventions include:

- Laryngeal Mask Airway (LMA) - note the key issue is assessment of the technology and the operator's expertise to use this technology and therefore applies to most airway management procedures. It would include an airway procedure that is an adjunct to oral, nasopharyngeal or endotracheal intubation.
- Controlled Infusion Device (eg IMED/Syringe drivers) – These devices would enable paramedics to monitor patient medications during inter-facility transfers utilising a light, compact and robust infusion management device. They incorporate active and passive safety features configurable to local practice and protocols which are lockable to prevent use or change by unauthorised personnel. The introduction of any new procedure will have an opportunity cost to the Health system. 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.

### Why does an application need Executive sign off?

New clinical interventions usually have resource implications. These may be in terms of staffing, costs, or competing access for current resources. Whether they are positive or negative the technology needs to be considered within the strategic plan for the organisation.

### What is the role of the New Clinical Intervention Procedure Committee?

New clinical interventions often but not always require a new level of expertise for their safe undertaking. The role of this committee is to ensure there is sufficient proficiency to introduce a new clinical intervention and a plan is in place to ensure the adequate training of future operators interested in performing the procedure.



## Proposed New Clinical Intervention Application/Forward Directive

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Complete each question and submit to the Chair of your relevant DCQC, Research, Equipment, Protocol or ACAC Committee.

1. **What is the proposed new equipment device/procedure/medication product to be considered for evaluation/implementation?**

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2. **Who is seeking to develop this clinical practice guideline?**

Individual/Committee:

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Contact:

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Position:

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Location:

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Phone:

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Email:

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3. **How has the need for the development/review of this proposed new clinical intervention procedure been identified? Please tick most appropriate box:**

- New market / substitution
- Legislative changes / requirements
- Clinical Risk Management Plan
- Recommendations from RCA's
- IIMS Data
- Actions from complaints management
- Systems review or clinical audit
- Review of existing clinical procedure or in response to new information or organisational need
- A discrete clinical need being recognised by clinician or manager
- Other



**Please provide a brief explanation:**

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**4. What relevant existing policies/procedure in Ambulance will be considered when introducing this new clinical intervention?**

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**5. What additional information will be considered when developing the clinical practice guideline?** *(eg external policies, evidence-based best practice, legal/ethical considerations, industry standards)*

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**6. What is the proposed purpose and scope of this new clinical intervention procedure?**

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**This section to be completed by the Chair of the DCQC, Equipment, Protocol or Research committee.**

Is device, procedure or medication recommended for "in-principle" support by the Chair of the appropriate Committee?  Yes /  No

Comments \_\_\_\_\_  
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\_\_\_\_\_

Name \_\_\_\_\_ Signature \_\_\_\_\_  
Date \_\_\_\_\_

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**Please fax, post or email to:**

Executive Assistant  
Clinical Development Unit  
Ambulance Service NSW  
State Headquarters

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Rozelle NSW 2039  
Fax: 02 9320 7814  
Email: [nsmoore@ambulance.nsw.gov.au](mailto:nsmoore@ambulance.nsw.gov.au)

**Date received:** \_\_\_\_\_

**Date reviewed:** \_\_\_\_\_

**Date returned:** \_\_\_\_\_

**Clinical Practice Improvement Committee "in-principle" support.**  Yes /  No

Comments \_\_\_\_\_  
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\_\_\_\_\_  
\_\_\_\_\_

Name \_\_\_\_\_ Signature \_\_\_\_\_ Date \_\_\_\_\_