Justice Health and
Forensic Mental Health Network

Justice Health NSW Policy

Safe Introduction of New Interventional Procedures into Clinical Practice

Issue Date: 04 July 2024

Together for
Healthier Tomorrows

Safe Introduction of New Interventional Procedures into Clinical Practice

Policy Number 5.123

Policy Function Safe Practice and Environment

Issue Date 04 July 2024

Next Review Date 04 July 2028

Risk Rating Medium

Summary This policy ensures the Justice Health and Forensic Mental Health Network (Justice Health NSW) has a clear and effective process for introduction, spread and monitoring of new interventional procedures within health facilities.

Responsible Officer Director, Nursing Midwifery and Clinical Governance

Applies to
☐ Administration Centres
☒ Community Sites and programs
☒ Health Centres - Adult Correctional Centres or Police Cells
☒ Health Centres - Youth Justice Centres
☒ Long Bay Hospital
☒ Forensic Hospital

CM Reference POLJH/5123

Change summary
- Minor Review
- Align with NSW Health Policy, hyperlinks and new template

Authorised by Chair, Policy Steering Committee

Revision History

#	Issue Date	Number and Name	Change Summary
6	July 2024	5.123 Safe Introduction of New Interventional Procedures into Clinical Practice	• Minor Review • Align with NSW Health Policy, hyperlinks and new template
5	December 2019	5.123 Safe Introduction of New Interventional Procedures into Clinical Practice	• Policy 1.020 *Medication Management* adequately provides guidelines and procedures for the safe and quality use of all medication in Justice Health and Forensic Mental Health Network. Therefore, medication procedures

			and trials are no longer covered in this policy. • Title change
4	September 2015	5.123 Safe Introduction of New Interventional Procedures and Medications into Clinical Practice	• Renaming of Clinical Products and Equipment Committee to Equipment and Products Imprest Committee • Position titles changes
3	June 2012	5.123 Safe Introduction of New Interventional Procedures and Medications into Clinical Practice	• The establishment of the Clinical Products and Equipment Committee necessitates a thorough review, and the existing flowchart and forms in this policy no longer apply • Interim process incorporated • Reference to the Former Products Evaluation Committee edited • Title change
2	March 2008	5.123 Safe Introduction of New Interventional Procedures into Clinical Practice	• Minor updates • Title change
1	June 2005	5.123 Safe Introduction of New Interventional Procedures	• New policy

PRINT WARNING

Printed copies of this document, or parts thereof, must not be relied on as a current reference document.

Always refer to the electronic copy for the latest version.

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1. Preface

This policy relates to clinicians and services that are considering introducing an interventional procedure that has not previously been undertaken within Justice Health and Forensic Mental Health Network (Justice Health NSW). This policy also applies where an interventional procedure is already performed in one facility and where approval is sought to perform it elsewhere within Justice Health NSW.

The decision to undertake such an intervention must take into consideration not only the clinicians' ability to perform the interventional procedure but also the structural requirements and clinical support systems required to safely implement that interventional procedure. Additionally, the introduction of new devices for interventional procedures requires prior evaluation and approval by the Therapeutic Goods Administration.

Within Justice Health NSW, the Medical and Dental Appointments Advisory Committee (MDAAC) will approve clinical consumables or equipment followed by the evaluation of Equipment Products and Imprest Committee (EPIC). This policy is a component of the *Clinical Governance Framework* within which quality clinical services are provided safely, effectively and efficiently, for both patients and workers within Justice Health NSW.

2. Policy Content

2.1 Mandatory Requirements

Justice Health NSW is committed to delivering health outcomes and experiences that matter to patients, families and carers, and the community. Regardless of the type of new interventional procedure to be introduced by Justice Health NSW recognises that health technologies play an important role in driving value-based healthcare, which means continually striving to deliver care that improves:

- Health outcomes that matter to patients, families and carers.
- Experiences of receiving care.
- Experiences of providing care.
- Effectiveness and efficiency of care.

2.2 Key Concepts

2.2.1 Risk Assessment and Management

This policy emphasises a risk management approach. The aim is to appropriately manage applications to introduce new interventions into clinical practice, and thereby reduce the risk of adverse outcomes. Systems for support and monitoring during the early stages of the introduction must be given consideration.

2.2.2 Evidence Based Practice

Most practices will have been evaluated or at least implemented elsewhere. Assessment of the practice needs to be considered in relation to the reliability of the evaluation as well as taking into consideration the conditions in which the interventional procedure or medication is being introduced. Where there is no evidence, a well-reasoned scientifically based argument in support of the proposed intervention is required for consideration.

2.2.3 Ethics

Information regarding the current universal level of application and the results of findings need to be included in the application for the approving committee to review.

If there are any concerns regarding the need for ethics approval, then the application must be forwarded to the Justice Health NSW Human Research and Ethics Committee to determine if ethics approval is required

2.2.4 Patient information and informed consent

Patient information and consent forms must be developed at the time of the application for the introduction of the new interventional procedure outlining the potential risks as accurately as possible. If applicable, the criteria for selection of patients for the new interventional procedure must be included in the information and consent, along with information about where the patient should submit any complaint about the interventional procedure. Consent and provision of patient information must be documented in the patient's health record.

2.2.5 Costs and benefits

The introduction of any new interventional procedure will have an opportunity cost. The new interventional procedure will consume resources that need to be evaluated against benefits of performing the interventional procedure and the effect of taking these resources from existing services or applying for additional funding.

2.2.6 Declarations of interests

There must be full disclosure of any relationship between the staff member and supplier or other significant party, or of involvement in prior assessment of the interventional procedure or medication, including any financial involvement that could result in interest.

2.2.7 Training

Training must be provided for all workers who will be using the interventional procedure to ensure that they are able to perform the task safely and competently. Workers include clinicians, allied health and support staff who may be involved in the using, sterilizing and/or setting up of the equipment.

2.2.8 Monitoring

Any new interventional procedure must be monitored after their introduction. Systems to collect data must be approved by the relevant Committee, established prior to introduction and then reviewed. Any adverse events are to be reported in the Incident Management System (ims+), investigated and remedial actions taken as necessary in accordance with NSW Health PD2020_047 *Incident Management*. Actions taken to address adverse incidents may result in the need to cease the interventional procedure.

2.2.9 Equipment, Consumables and Procurement Compliance

New equipment and consumables that may be required for the interventional procedure must be approved through the appropriate Committee i.e., the Equipment Products & Imprest Committee for interventional procedures. Systems to obtain and maintain the equipment and supplies must be identified and if necessary established in accordance with Justice Health NSW policies and procedures. Any equipment that may be required

will need to comply with the requirements of the Procurement and Contract Implementation Team and with NSW Health Procurement Policy Framework.

3. Procedure Content

3.1 Governance and Oversight of New Interventional Procedures

Implementation of a new interventional procedure or application of current interventional procedures to other facilities within Justice Health NSW requires formal approval before they are introduced. Approval is obtained through the following committees:

- MDAAC for interventions to be carried out by Medical and/or Dental Officers
- Equipment Products & Imprest Committee (EPIC) for interventions involving new equipment
- Clinical Governance Committee for any other new interventional procedures.

Approval by more than one of these Justice Health NSW Committees may be required for relevant interventions.

3.2 Making an Application to Introduce a New Interventional Procedure

Any staff member wishing to make an application to introduce a new interventional procedure must seek approval from their General Manager in the first instance. Once approved by their General Manager, the General Manager will contact the Executive Director, Nursing, Midwifery and Clinical Governance, who will advise in writing on what information is to be provided. NSW GL2024_008 *New Health Technologies and Specialised Services* (Table 1, p.10) has a suggested inclusion criteria to provide a rationale for the introduction of a new technology, and or intervention.

The Executive Director, Nursing, Midwifery and Clinical Governance who will then coordinate communication with the relevant committee on receipt of information.

Where a clinician is unsure whether an interventional procedure falls within the scope of this policy, advice must be sought from the Executive Director Nursing, Midwifery and Clinical Governance in the first instance.

3.3 New Device or Equipment

In situations where a new interventional procedure is introduced that involves the introduction of a new device or equipment, approval by each of the below Committees may be required.

- MDAAC for interventions to be carried out by Medical and/or Dental Officers
- Equipment Products & Imprest Committee (EPIC) for interventions involving new equipment
- Clinical Governance Committee for any other new interventional procedures.

3.4 New Medication to Justice Health NSW Medication Formulary

Where the new interventional procedure or intervention requires a medication to be included in the Justice Health NSW Medication Formulary, refer to policy NSW Health PD2022_056 *Approval Process for Medicines and Their Use*. Additional approval will be required from the Drugs and Therapeutics Committee.

3.5 Credentialing and training in the New Interventional Procedure

Each Medical Officer who will be performing the approved New Interventional Procedure must be credentialed by the MDAAC to do so. Approval is required for other clinicans by the relevant General Manager, and the Director of Allied Health if it is an Allied Health Professional or the Executive Director, Nursing, Midwifery and Clinical Governance.

Training must be provided for all workers who will be using the interventional procedure to ensure that they are able to perform it safely and competently, this is the responsibility of the General Managers. Documentation of training should be maintained for record keeping and evidence to support that training has been provided.

3.6 Incident Reporting

If a problem occurs with a medical device this must be notified on the Incident Management System (ims+) under No Person in the category of Devices, Gases and Consumables. However, if the incident directly relates to a negative patient outcome, then it must be notified on the ims+ clinical category.

Progress reports must be submitted to the relevant committee/s at 6 monthly intervals, or at a date specified by that committee.

4. Definitions

Clinician

Includes all clinical staff (doctors, dentists, nurses and allied health professionals) involved in the direct care and treatment of patients.

Workers

Includes clinicians, allied health assistant and technicians, dental assistants and other support staff who may be involved in the use, sterilizing and/or setting up of the equipment.

Interventional Procedure

Defined as a procedure involving any invasive contact with the patient. Examples include surgical operations, endoscopies, some radiological procedures, chemical and other therapies e.g., ventilation.

New Interventional Procedure

A procedure not previously performed within the Justice Health NSW facility or one that is performed within a Justice Health NSW facility and for which approval is sought for its performance at another Justice Health NSW facility.

This will include variations on an existing procedure and treatment where a new device, equipment or medication is introduced.

Adverse Event

Defined as an unintended injury or complication resulting in a 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.

Must

Indicates a mandatory action to be complied with.

Should

Indicates a recommended action to be complied with unless there are sound reasons for taking a different course of action.

5. Related Documents

Legislations	*Therapeutic Goods Act 1989* *Work Health and Safety Action 2011*
Justice Health NSW Policies, Guidelines and Procedures	*Clinical Governance Framework*
Justice Health NSW Forms	
NSW Health Policy Directives and Guidelines	GL2024_008 *New Health Technologies and Specialised Services* PD2020_047 *Incident Management* PD2022_056 *Approval Process for Medicines and Their Use*
Other documents and resources	*National Safety and Quality Health Service (NSQHS) standards:* *Action 1.23 Credentialing and Scope of Clinical Practice* *Action 3.14 Clean and Safe Environment* *National Clinical Trials Governance Framework*