Safe Introduction of New Intervenotional Procedures and Medications into Clinical Practice

Policy Number  5.123

Policy Function  Safe Practice and Environment

Issue Date  3 September 2015

Summary  This policy ensures Justice Health & Forensic Mental Health Network has an effective and ongoing monitoring process for interventional procedures or medications introduced within facilities

Responsible Officer  Executive Director Governance and Commercial Services

Applicable Sites
  - Administration Centres
  - Community Sites (e.g. Court Liaison Service, Community Integration Team, etc.)
  - Health Centres (Adult Correctional Centres or Police Cells)
  - Health Centres (Juvenile Justice Centres)
  - Long Bay Hospital
  - Forensic Hospital

Previous Issue(s)  Policy 5.123 (June 2012)

Change Summary
  - Renaming of Clinical Products and Equipment Committee to Equipment and Products Imprest Committee
  - Minor amendments

TRIM Reference  POLJH/5123

Authorised by  Chief Executive, Justice Health & Forensic Mental Health Network
1. Preface

This policy relates to clinicians and services that are considering introducing an interventional procedure or medication including clinical trials, that has not previously been undertaken or prescribed within Justice Health & Forensic Mental Health Network (JH&FMHN). This policy also applies where an interventional procedure is already performed in one facility and where approval is sought to perform it elsewhere within JH&FMHN. Introduction of a new interventional procedure requires the clinician to be granted appropriate credentials to perform the procedure by Medical & Dental Appointments Advisory Committee.

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

Within JH&FMHN, approval is required from the appropriate committee, the Equipment and Products Imprest Committee, Drugs and Therapeutics Committee and/or Medical & Dental Appointments Advisory Committee (MADAAC).

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 of JH&FMHN.

2. Policy Content

2.1 Mandatory Requirements

Regardless of the type of new interventional procedure or medication to be introduced or by whom, the following principles will be applied:

Health and safety – the primary concern of the actions described in this policy is the health and safety of:

- Patients,
- Workers (includes clinicians and anyone who may use the procedure), and
- The community.

2.1.1 Risk Management – this policy emphasises a risk management approach. The aim is to appropriately manage applications to introduce new interventions and medications 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.

2.1.2 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 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.

2.1.3 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 JH&FMHN Human Research and Ethics Committee to determine if ethics approval is required.
2.1.4 **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 procedure outlining the potential risks as accurately as possible. If applicable, the criteria for selection of patients for the new procedure must be included in the information and consent, along with information about where the patient should submit any complaint about the procedure.

2.1.5 **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 benefits of performing the procedure and the effect of taking these resources from existing services or applying for additional funding.

2.1.6 **Conflicts of interest** – there must be full disclosure of any relationship between the clinician and supplier or other significant party, or of involvement in prior assessment of the procedure or medication, including any financial involvement that could result in a conflict of interest.

2.1.7 **Training** – training must be provided for all identified workers who will be using the 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, sterilising and/or setting up of the equipment.

2.1.8 **Monitoring** – any new interventional procedure or medication must be monitored after their introduction. Systems to collect data must be established prior to introduction and then reviewed. All data must be stored in TRIM. Any adverse events are to be reported in the Incident Information Management System (IIMS), investigated and remedial actions taken as necessary in accordance with JH&FMHN policy 2.030 Incident Management. Adverse medication events are monitored by the Drugs & Therapeutics Committee. Actions taken to address adverse incidents may result in the need to cease the procedure or medication.

2.1.9 **Equipment and supplies** – new equipment and supplies that may be required for the procedure are to be approved through the appropriate committee i.e. the JH&FMHN Equipment and Products Imprest Committee (EPIC) for interventional procedures and the Drugs & Therapeutics Committee for medications (D&TC). Systems to obtain and maintain the equipment and supplies are to be identified and if necessary established.

### 3. Procedure Content

Implementation of a new interventional procedure or medication, or application of current procedures to other facilities within JH&FMHN, requires formal approval before they are introduced. Approval is obtained through either of the following committees:

- MADAAC for interventions to be carried out by medical and/or dental officers,
- D&TC for interventions involving medications, and/or
- EPIC for interventions involving new equipment

Progress reports and evaluations will be required to be tabled at the Clinical Governance Committee when requested.

Any other new procedures fall within the remit of the Clinical Governance Committee. Approval by more than one of these committees may be required for relevant interventions.
Any staff member wishing to make an application to introduce a new interventional procedure must contact the Director Clinical & Corporate Governance (DCCG), who will advise on the information which is required to be provided in writing. The DCCG will liaise with the Executive Director of the relevant clinical directorate and Director Medical Programs, and coordinate communication with the Clinical Governance Committee and MADAAC. The DCCG must ensure that all information in relation to the new procedure and/or intervention is stored in a central container on TRIM.

Where a new medication is being proposed for inclusion in the JH&FMHN Formulary, the Drugs and Therapeutics Committee must review and approve the introduction of this medication before it can be used. Refer to policy 1.020 Medication Management.

Further information on the introduction of clinical trial medications for example, can be found in the JH&FMHN Medication Guidelines (2015).

In a situation where a new procedure is introduced that also involves the introduction of a new medication and/or new device or equipment, both of the above processes apply. Where a clinician is unsure whether a procedure falls within the scope of this policy, advice must be sought from the DCCG in the first instance.

Each medical officer who will be performing the new procedure must be credentialed by the MADAAC to do so. Approval is required for nurses by the relevant Executive Director Clinical Operations on recommendation from the Service Director Operations Nursing, Service Director Long Bay Hospital or Director of Nursing for The Forensic Hospital, Service Director Community Mental Health and Service Director Adolescent Health & Diversion Programmes. Training must be provided for all workers who will be using the procedure to ensure that they are able to perform it safely and competently. Learning and Development (L&D) should be involved in the planning for delivery of this training. Documentation of training should be maintained by the L&D Training Convenor in TRIM for record keeping as well as evidence to support that training has been provided.

If a problem occurs with a medical device this must be notified on the Incident Information Management System (IIMS) in the category of property, security, hazard, incident type, medical device. However if the incident directly relates to a negative patient outcome, then it must be notified on the IIMS clinical form. Medication-related incidents must be notified in the category of medication.

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

4. Definitions

**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.

**Clinician**
Includes all staff (that is doctors, dentists, nurses and allied health staff) involved in the direct care and treatment of patients

**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. This definition can
also equally apply to a device or a treatment such as a medication. However, when seeking approval for a new medication, refer to the process outlined in JH&FMHN policy 1.020 Medication Management.

**Must**
Indicates a mandatory action or requirement.

**New Interventional Procedure**
A new interventional procedure refers to a procedure not previously performed within a JH&FMHN facility or one that is performed within a JH&FMHN facility and for which approval is sought for its performance at another JH&FMHN facility. This will include variations on an existing procedure and treatment where a new device, equipment or medication is introduced.

**Workers**
Workers include clinicians, allied health and support staff who may be involved in the use, sterilising and/or setting up of the equipment.

**Should**
Indicates an action that needs to be followed unless there are sound reasons for taking a different course of action.

### 5. Legislation and Related Documents

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