High-Risk Medicines Management

Summary The High-Risk Medicines Management has been revised with updated with information that is relevant to NSW Health clinicians. The individual standards within PD2020_045 have been removed as they will be placed on the CEC High-Risk Medicines webpage.

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Author branch Clinical Excellence Commission

Branch contact (02) 9269 5500

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Applies to Local Health Districts, Board Governed Statutory Health Corporations, Specialty Network Governed Statutory Health Corporations, Cancer Institute, Community Health Centres, NSW Ambulance Service, Public Hospitals

Distributed to Ministry of Health, Public Health System, Divisions of General Practice, Government Medical Officers, NSW Ambulance Service, Private Hospitals and Day Procedure Centres, Tertiary Education Institutes

Audience Clinicians;Administration;Medical Services;Nursing Staff;Pharmaceutical

Secretary, NSW Health

NSW Health

POLICY DIRECTIVE

High-Risk Medicines Management

POLICY STATEMENT

All NSW Health organisations must have systems in place for the safe management and use of high-risk medicines.

SUMMARY OF POLICY REQUIREMENTS

All public health facilities are to have a high-risk medicines management program.

As part of the high-risk medicines management program, public health facilities are to maintain a high-risk medicines register. This register is to include medicines or medicine groups used locally within the facility identified to be at 'high-risk' of misadventure.

The local high-risk medicines registers are to as a minimum, include medicines or medicine groups for which a state-based high-risk medicine standard is available on the CEC High-Risk Medicines webpage. Compliance with the state-based individual high-risk medicine standards is a **mandatory requirement** for all NSW Health facilities.

For medicines that appear in the local high-risk medicines register and a state-based high-risk medicine standard is not available, local standards are to be prepared in consultation with relevant specialists.

The local standards are to be aligned with NSW Health Policy Directive *Medication Handling* (PD2022_032) and approved by the respective local Drug and Therapeutics Committee. Local standards must also include a timeframe for review.

All public health facilities are to employ strategies to mitigate the risk of medicines on their mandatory local high-risk medicines register.

Adverse incidents involving high-risk medicines must be reported in the facility incident management system and reviewed through local quality management systems.

REVISION HISTORY

Version	Approved By	Amendment Notes
PD2024_006 February 2024	Deputy Secretary, People, Culture and Governance	Revised to clarify requirements and remove all individual high-risk medicine standards, which have been made available on CEC website. New standards for 'Anticancer medicines' and 'Insulin' developed.
PD2020_045 November-2020	Deputy Secretary, People, Culture and Governance	Revised to incorporate an Opioid Standard.
PD2019_058 December-2019	Deputy Secretary, People, Culture and Governance	Revised to incorporate a Hydromorphone Standard.
PD2015_029 August-2015	Deputy Secretary, Governance, Workplace and Corporate	Revised to a) incorporate hydromorphone, methotrexate (oral), neuromuscular blocking agents, paracetamol; b) update potassium (intravenous), vincristine and anticoagulants. Replaces PD2012_003, PD2009_009 and PD2005_624.
PD2012_003 January-2012	Director-General	High-Risk Medicines Management
PD2009_009 February-2009	Director-General	Paracetamol Use
PD2005_624 September-2005	Director-General	Methotrexate – Safe Use of Oral Methotrexate

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1. BACKGROUND

1.1. About this document

This Policy sets out the requirements for a local high-risk medicines management program at each location, facility, or group of facilities within NSW Health.

This Policy supports requirements for Standard 4 (Medication Safety) of the National Safety and Quality Health Service Standards. Although most medicines have a wide margin of safety, there are some medicines that have a high risk of causing patient injury or death if they are inadvertently misused or administered incorrectly. Errors with these high-risk medicines may not be more common than those from other groups but their consequences can be significant.

Although the principles may be relevant, this Policy and the associated standards may not be applicable to all medication handling and administration practices by paramedics and flight nurses employed by NSW Ambulance.

Medication handling and administration within NSW Ambulance is mandated in the Medications Management Policy Directive and Operating Procedure endorsed by the NSW Ambulance Chief Executive.

1.2. Key definitions

Drug and Therapeutics Committee (DTC)	The Committee with delegated responsibility for the governance and quality of the medication management system and for ensuring the appropriate, safe and effective, and cost-effective use of medicines in the health facility, Local Health District or Specialty Health Network under their jurisdiction. For further information on the role and operation of Drug and Therapeutics Committees, refer to the: • NSW Health Policy Directive *Medication Handling* (PD2022_032) • Council of Australian Therapeutic Advisory Groups' (CATAG) *Achieving effective medicines governance: Guiding Principles for the roles and responsibilities of Drug and Therapeutics Committees in Australian public hospitals*. Some health facilities may have an equivalent committee (such as a Quality Use of Medicines Committee) that governs such quality use of medicine functions. For this Policy, equivalent committees are considered to have the same roles and responsibilities as Drug and Therapeutic Committees, and the same governance and quality responsibilities apply.

Electronic Medication Management (eMM)	The software and associated hardware (such as computer terminals and screens) used to create and document the entire medication process, from the authorised practitioner's (authorised prescriber's) medication order to the pharmacist's review of the medication order and supply of medication, to the clinician's record of administration of the medication, and all the processes in-between.
High-Risk Medicine	High-Risk Medicines are those that have a high risk of causing injury or harm if they are misused or used in error. Error rates with these medications are not necessarily higher than with any other medicines, but when problems occur, the consequences can be more significant.
Therapeutic Drug Monitoring	Refers to the individualisation of dosage by maintaining plasma or blood drug concentrations within a target range (therapeutic range or window).

1.3. Related documents

This Policy is to be read in conjunction with the following NSW Health Policies and other related documents.

Table 1: Related NSW Health Policy Documents

Document Number	Document Title
PD2022_032	Medication Handling
PD2020_047	Incident Management
PD2019_057	Prevention of Venous Thromboembolism
PD2023_021	Preparation of Pharmaceutical and Advanced Therapeutic Products

Table 2: Other Related Documents

Organisation	Document Title
Australian Commission on Safety and Quality in Health Care	National Safety and Quality Health Service Medication Safety Standard
Clinical Excellence Commission	Medication Safety Self Assessment for Australian Hospitals

2. HIGH-RISK MEDICINES MANAGEMENT PROGRAM REQUIREMENTS

All public health facilities are to have a high-risk medicines management program in place.

The high-risk medicines management program is to include the following minimum elements.

2.1. A high-risk medicines register

A high-risk medicines register consists of a list of medicines or medicine classes used within the health facility considered to be at 'high-risk' of causing harm due to misadventure. The register is to raise awareness of additional vigilance required when a high-risk medicine is used and is to be maintained at each location, facility, or group of facilities.

2.1.1. Minimum requirements

The local high-risk medicines registers are, at a minimum, to include the high-risk medicines or medicine groups for which a standard is available on the CEC website.

The determination of high-risk medicines or medicine groups for inclusion in the local high risk medicines register may be informed by analysing notifications made in local Incident Management System or based on literature. A local safety assessment is to be completed to identify the risk of patient harm and suitability for inclusion in the local high-risk medicines register. All NSW Health clinical staff must be aware of the local high-risk medicines register. The register is to be readily accessible. For example, on the facility or LHD/SHN intranet page.

2.1.2. Drug and Therapeutics Committee responsibilities

The local Drug and Therapeutics Committee (or equivalent committee) is responsible for:

- assessing and determining the medicines to be included in the register
- maintaining the register and associated standards.

2.1.3. Additions to the register

Before a new medicine is introduced for use within a NSW Health facility, the potential for error with that medication is to be investigated and a risk assessment completed. If the assessment identifies that there is a high risk of death or serious harm to the patient if the medicine is inadvertently selected, misused, prescribed or administered incorrectly, the medicine is to be included in the high-risk medicine register with an appropriate local standard developed.

When a new medicine or medicine group is added to the local register, the Drug and Therapeutics Committees is to determine whether an independent second person check is required for administration (if not mandated by the Medication Handling (PD2022_032) or a CEC High-Risk Medicine Standard).

2.1.4. Review of the register

The local Drug and Therapeutics Committee is to have a mechanism in place to regularly review the local high-risk medicines register. When new medicines are introduced for use within the health service, it should be assessed for addition to the register, if appropriate.

2.1.5. Development of local standards

This Policy is to be viewed in conjunction with the high-risk medicine standards available on the CEC website. Compliance with the individual high-risk medicine standards is a **mandatory requirement** for all NSW Health facilities.

These standards address risks related to prescribing, dispensing, administration, supply and storage of specified high-risk medicines or medicine groups. It also addresses risk mitigation strategies to prevent errors related to high-risk medicines.

For medicines that appear in the local high-risk medicines register and a state-based high-risk medicine standard is not available, local standards are to be prepared in consultation with relevant specialists, aligned with NSW Health Policy Directive *Medication Handling* (PD2022_032), and approved by local Drug and Therapeutics Committee.

2.1.6. Prescribing and administering high-risk medicines

The NSW Health Policy Directive *Medication Handling* (PD2022_032) is to be followed when prescribing, supplying and administering high-risk medicines (refer to Section 3, 4 and 6).

2.2. Strategies to minimise risk with high-risk medicines

The Drug and Therapeutics Committee are to develop strategies related to high-risk medicine management.

Strategies related to high-risk medicines handling are to include:

- providing access to pre-measured medicine doses in a form that requires minimal manipulation prior to administration where possible
- limiting access to multiple concentrations of the same medicines in solution to clinical areas to minimise selection errors
- consideration of dose adjustments when prescribing for patients who are overweight, obese, or underweight, and patients with existing clinical conditions (such as renal or hepatic impairment) that may affect drug metabolism and excretion
- considerations and additional guidance for clinicians surrounding use of these medicines in high-risk patient groups such as paediatric, pregnant and older persons
- use of clinical guidelines where dosing is complex, and duration of therapy substantially increases risk of toxicity. For example, aminoglycosides
- conducting therapeutic drug monitoring, laboratory tests and dose amendments to enhance drug efficacy and reduce toxicity

- mechanisms to ensure electronic (mechanical) infusion devices default to the safest setting
- alerting clinicians in clinical handover to the use of any high-risk medicines
- additional patient monitoring, for example, clinical observations to ensure timely response to adverse events or side effects associated with the treatment
- implementing second person checks prior to administration of high-risk medicines (refer to NSW Health Policy Directive *Medication Handling* (PD2022_032) and CEC High-Risk Medicine Standards for information)
- prioritisation of medication reconciliation processes for patients prescribed high-risk medicines where appropriate. For example, elderly patients and patients with poor health literacy
- use of shelf reminders, physically separating look alike and sound alike products and ensuring medicines are stored in a non-cluttered orderly manner to prevent selection errors
- use of alerts in information technology systems, for example, automated dispensing cabinets and in electronic Medication Management (eMM) systems. Ensuring state recommendations regarding safety in eMM systems are considered and implemented where appropriate
- regular review of local and wider system incidents and near-misses and the use of prospective analysis and re-design of workflows and systems to prevent reoccurrence of the same errors.

The Committee is to consider the environmental impacts to reduce waste and/or emissions for example, utilising biodegradable materials where appropriate.

2.3. Staff education

Clinicians (where relevant to their scope of practice) are to receive education on the safe use of high-risk medicines. Health Education and Training Institute (HETI) eLearning modules may be available to assist for this purpose.