SESLHD PROCEDURE COVER SHEET

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EXECUTIVE SPONSOR or EXECUTIVE CLINICAL SPONSOR	Director, Clinical Governance and Medical Services
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FUNCTIONAL GROUP(S)	Medicine Pharmacy/Pharmaceutical
KEY TERMS	High Risk, Medicines
SUMMARY	A procedure for the implementation of NSW Health Policy Directive PD2020_045 - High-Risk Medication Management Policy.

1. POLICY STATEMENT

This procedure has been developed to support compliance with NSW Health Policy Directive PD2020_045 - High-Risk Medicines Management.

2. BACKGROUND

This procedure provides a standard for the management of high-risk medicines and aims to address the risks associated with the prescribing, storage, dispensing and administration of high-risk medicines.

Although most medicines have a wide margin of safety, a number of medicine classes have a high risk of causing patient injury or death if they are inadvertently misused or administered incorrectly. Errors with these medicines are not necessarily more common than those from other classes but outcomes associated with them, can be more serious. This procedure aims to support the implementation of the NSW Policy Directive PD2020_045 High-Risk Medicines Management within SESLHD.

3. RESPONSIBILITIES

3.1 Employees will:

- **Registered Nurses, Registered Midwives and Enrolled Nurse without Notation** will ensure that the correct policy and procedure is adhered to in accordance to legislative requirements on the management of high-risk medicines within the SESLHD.
- **Pharmacy Staff** will ensure that the correct policy and procedure is adhered to in accordance to legislative requirements on the management of high-risk medicines within the SESLHD.
- **Medical Staff** will ensure that the correct policy and procedure is adhered to in accordance to legislative requirements on the management of high-risk medicines within the SESLHD.

3.2 Line Managers will: ensure that staff adhere to the correct policy and procedures in accordance to legislative requirements on the management of high-risk medicines within the SESLHD.

3.3 District Managers/ Service Managers will: monitor policy adherence and allocate resources accordingly to facilitate compliance.

4. PROCEDURE

4.1 SESLHD High-Risk Medicines Register

- A register consisting of a list of drugs considered to be high-risk medicines (HRM) must be maintained in SESLHD. These clinical risks should ideally be recorded within ERMs, or other risk registers.
- The SESLHD Quality Use of Medicines Committee (QUMC) is responsible for determining which medicines are to be included on the SESLHD High-Risk Medicines Register. It will review the list for relevance and completeness as a regular agenda item and accept submissions from local site/service medication related committees.
- The local site/service medication related committees will:
    - review reports on HRM incidents, policy compliance rates and formulate corrective actions,
    - document risk minimisation strategies which have been implemented as well as ongoing challenges with planned actions, and;
    - submit requests to SESLHD QUMC for additions to the SESLHD High-Risk Medicines Register.
- Clinical staff will be made aware of medicines on the list and the need to take extra care in their safe storage, handling, prescribing, dispensing and administration.
- Prior to any new medicine being placed on the SESLHD Formulary by the SESLHD Quality Use of Medicines Committee, the potential for error with that medication should be assessed. 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 must be included in the High-Risk Medicine Register with an appropriate protocol developed.
- The SESLHD High-Risk Medicines Register is made available on the Quality Use of Medicines intranet. Clinical staff must be made aware of medicines on the register.

South Eastern Sydney Local Health District (SESLHD) High-Risk Medicines List has adopted the NSW Health definition:

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.

High-Risk Medicines are represented by the acronym – "A PINCH" (and others):

- Anti-infective agents
- Potassium and other concentrated electrolytes **Intravenous (not oral)**
- Paracetamol
- Insulin
- Narcotics and other sedating agents (S8s and S4Ds)
- Neuromuscular blocking agents (NMBAs)
- Chemotherapeutic agents
- Heparin and other anticoagulants
- Other medicines considered high-risk within SESLHD, refer to High-Risk Medicines Register.

4.2 High-Risk Medicines Risk Mitigation Strategies

4.2.1. High-Risk Medicines Procedure Development and Implementation

SESLHD will develop individual protocols aimed at reducing the risks associated with high risk medicines and these must be followed at all times by staff. These protocols will be available for staff on the intranet. The SESLHD QUMC will be responsible for notifying relevant clinical staff of changes to the register and the associated protocols.

Protocols are to clearly articulate:

- Responsibilities and restrictions for prescribing and administration of high-risk medicines;
- Additional considerations for high-risk patient groups such as paediatric, pregnant and elderly patients;
- Additional considerations for patients with conditions that may affect drug excretion or metabolism such as renal or hepatic impairment;
- Additional patient monitoring, for example, clinical observations, required to ensure a timely response to adverse events or side-effects associated with the treatment;
- Therapeutic drug monitoring requirements, including laboratory tests and dose adjustment;
- Any specific training, qualifications, skills or competencies required to prescribe or administer the medicine;
- Specific storage requirements to minimise selection error;
- Patient and/or carer information or education requirements.

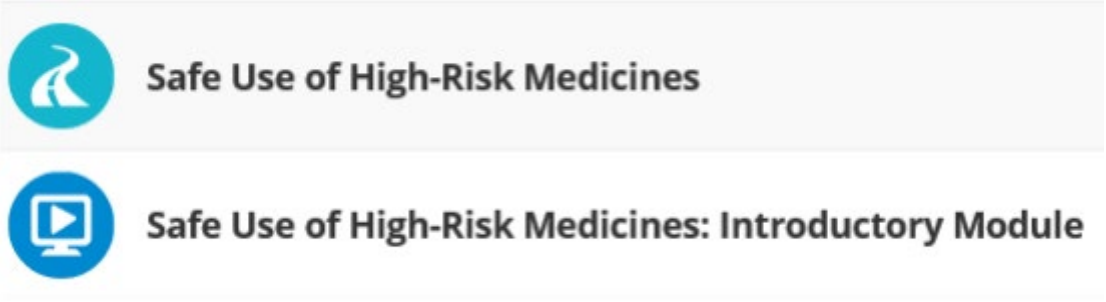
4.2.2. Staff Education

SESLHD will provide staff will ongoing education about high risk medicines and whenever a new high risk medicine is identified education aimed at lowering the identified risks will be supplied. Clinical staff must:

- ensure they are familiar with the high risk medicines register

- ensure they are familiar with the safe storage, prescribing, dispensing, and administration of high risk medicines in accordance with policies, procedures and local protocols
- ensure they consider the additional risks associated with managing high risk medicines e.g. at the time of storing, prescribing, dispensing, administering, and providing patient information about a high risk medicine
- report incidents involving high risk medicines via appropriate pathway (refer to section 4.2.9)
- participate in education or training to ensure they maintain a knowledge base relevant to their area of practice and their role in the safe management of high risk medicines.

My Health Learning has the following over-arching education modules:



Clinical Excellence Commission provides tools and information supporting the safe and quality use of high-risk medicines.

Additional medication resources are also available to staff via CIAP.

4.2.3. Response to NSW Safety Alerts / Notices

Whenever a safety alert / notice is issued by NSW Health regarding a high-risk medicine, the Pharmacy Department will act, along with nursing and medical staff to implement all appropriate recommendations.

4.2.4. Ensure Correct Prescribing of High-Risk Medicines

- A thorough medication history should be taken for all patients on high risk medicines, including previous allergic / adverse drug reactions. This should be continuously updated throughout the patient's stay as required.
- The route of administration must be clearly identified. For high risk drugs the use of multiple routes of administration in the one prescription must be avoided (e.g. IV/Oral).
- The strengths of medicines must be clearly visible in terms of the dosage unit or dose per volume of liquid e.g. mg / mL.
- The approved eMR eMEDs system must be used to prescribe medicines except in designated areas where other paper-based or electronic prescribing systems have been specifically authorised, with relevant cross-referencing for high risk medicines e.g. intravenous therapy or pain management.
- The indication section should be documented.

- High risk medicines should be reviewed with particular caution during transitions of care, such as between environments of different acuity levels or between units that use different electronic medication management systems.
- High risk medicines are commonly administered intraoperatively. It is critically important that all intraoperative medicines given are recorded on the Anaesthetic Record, supported by consistent and complete handover when patients return to the ward environment.

4.2.5. Ensure the Correct Administration of High Risk Medicines

- Select medicines in a dosage form that requires minimal manipulation prior to administration.
- When measuring and administering medicine doses, ensure any devices are used according to manufacturer's specifications and that they are used according to their stated purpose.
- When second checks are required at the point of administration, ensure a fully independent check is undertaken by both staff members.
- Where medication errors are made involving high risk medications, supervising clinicians and managers should consider the individual's need for education, procedural re-training and/or other supports to prevent similar high risk errors.
- Use oral/enteral dispensers to prepare and administer all liquid medicines by routes other than injection (refer to NSW Health Safe Administration of Liquid medicines by Routes other than Injection PD2012_006)
- Ensure that additional care is taken when administering the following dose forms.

Transdermal patches

- Confirmation from the prescriber should be sought if multiple patches are required to achieve a prescribed dose.
- Before applying a patch, check that the medicine and strength details are clearly visible on the patch itself
- Write the date of application on the patch using a marker, and record the time of application and site of application on the medication chart.
- Ensure patch is not exposed to temperature extremes.
- Opioid transdermal patches MUST NOT be cut or only partially applied to achieve a smaller dose.
- Ensure safe and secure disposal when relevant (e.g. opioid patch).
- Always check for existing patches prior to applying a new patch. (NOTE: the eMEDs system does not have a "patch removal order" for all patches).

Modified release oral medicines

- Never dissolve, divide (unless scored) or crush for administration. MIMS Online offers "Don't Rush to Crush" a comprehensive guide to administering oral medicines to patients who are unable to swallow or have swallowing difficulties. If further advice is required, contact the Pharmacy Department.

Inhaled medicines

- Ensure the patient understands and is able to use devices correctly.
- Ensure the device settings are correct for each medicine delivery.
- Ensure use of the correct dose form and strength.

Parenteral fluids

- When available, high-risk medicines are purchased in a form closest to the dilution and strength in which they are to be administered so as to minimise opportunity for error in ward-based preparation.
- Pre-mixed infusion fluids of high-risk medicines are to be used in preference to those locally prepared.
- Intravenous volumetric pumps with intelligence activated (Smart pumps) are to be used, when available, to screen for dose, dilution and rate of administration.

4.2.6. Monitoring Patients Receiving High-Risk Medicines

- Regular monitoring of patients receiving HRMs is vital as;
  - it allows clinical staff to detect adverse effects before significant harm occurs
  - information from monitoring supports appropriate therapeutic decision-making regarding ongoing treatment
- Many HRMs will have specific monitoring requirements that are outlined in prescribing protocols and business rules. The type of monitoring required may include routine or more frequent vital sign observations, therapeutic drug monitoring and pathology tests. Clinical staff must be aware of and proactively monitor patients for adverse events, including known side effects, which require clinical review.

4.2.7. Restrictions on Supply and Storage in Ward Areas

To minimise the risk of medication misadventure, accessibility to high risk medicines MUST be restricted. High risk medicines MUST only stocked on wards with a clear clinical need and where risk management strategies have been implemented.

4.2.8. Purchasing of High-Risk Medicines

Purchase for safety as far as practical e.g. review label clarity, visual product discrimination, amount of manipulation and associated equipment needed in administration. Pharmacy MUST inform stakeholders of significant packaging changes for high-risk medicines, e.g. before an NMBA brand change, ensure a consultative process involving end users (such as anaesthetists and intensivists) occurs to minimise the risks.

4.2.9. Reporting of Incidents Involving High-Risk Medicines and Evaluation of Emerging Risks

- All incidents involving high-risk medicines should be reported in the incident information management system (IMs+) and regularly reviewed through quality management systems.
- All available data sources such as local incident monitoring data, external reports and published articles should be reviewed to identify any emerging or unidentified risks associated with high-risk medicines. If potential local vulnerability is identified, risk management techniques should be used to ensure systems and processes are designed to improve safety and are based on evidence from initiatives that have demonstrated significant benefit.

5. DOCUMENTATION

Monitoring of IMs+ and complaints related to administration of high risk medicines through use of IMs+ data at local site/service medication related committees and SESLHD Quality Use of Medicines Committee.

6. AUDIT / KEY PERFORMANCE INDICATORS

- The SESLHD Quality Use of Medicines Committee reviews the High-risk Medicines Register on an annual basis.
- The SESLHD Quality Use of Medicines Committee reviews and approves local protocols developed for high-risk medicines specified on the register.
- The local site/service medication related committees report and manage high-risk medication errors in the incident management system and refer risks to SESLHD Quality Use of Medicines Committee for monitoring.
- The local site/service medication related committees monitor local implementation and compliance with the NSW Health High-Risk Medicines Management Policy and escalate risks to the SESLHD Quality Use of Medicines Committee.

7. REFERENCES

1. NSW Ministry of Health Policy Directive PD2020_045 - High-Risk Medicines Management
2. NSW Ministry of Health Policy Directive PD2022_032 - Medication Handling
3. Safety Alert Bulletins (SABS) on high risk drugs, e.g. Safe use of Midazolam SN: 022/09 available from: https://www.health.nsw.gov.au/sabs/Pages/default.aspx as released from time to time
4. NSW Ministry of Health Policy Directive PD2020_047 - Incident Management
5. NSW Ministry of Health Policy Directive PD2012_006 - Safe Administration of Liquid medicines by Routes other than Injection

8. REVISION AND APPROVAL HISTORY

Date	Revision No.	Author and Approval
December 2021	DRAFT	Author: Erica Wales, Lead Pharmacist Quality Use of Medicines
March 2022	DRAFT	Draft for comments.
July 2022	DRAFT	Approved by Executive Sponsor.
August 2022	1	Endorsed by SESLHD Quality Use of Medicines Committee.
September 2022	1	Approved by Clinical and Quality Council.

Appendix 1: High Risk Drugs (AP [2] IN [2] CH-other)

Anti-infective agents	Examples: Amphotericin, Aminoglycosides (e.g. gentamicin), Penicillins, Vancomycin
Potassium and other concentrated electrolytes	Injections of Potassium, Magnesium, Calcium, Hypertonic sodium chloride
Paracetamol	Particularly IV and oral given together or regular and PRN given together
Insulin	All insulins; in particular high concentration insulins
Narcotics (opioid) & other sedatives	**Narcotics:** e.g. HYDROmorphone, oxycodone, morphine, fentanyl, alfentanil, remifentanil and opioid analgesic patches. **Benzodiazepines:** e.g. diazepam, midazolam and thiopentone **Other anaesthetic agents:** e.g. propofol
Neuromuscular blocking agents	Examples: Atracurium, Ciastracurium, Mivacurium, Pancuronium, Rocuronium, Suxamethonium and Vecuronium
Chemotherapeutic Agents	All chemotherapy agents, but in particular: Azathioprine, Etoposide, Hydroxyurea, Methotrexate and Vincristine
Heparin & anticoagulants (and thrombolytics)	Examples: Apixaban, Bivalirudin, Dabiagatran, Dalteparin, Danaparoid, Enoxaparin, Fondaparinux, Heparin, Rivaroxaban, Warfarin
Others: High-Risk Medicines identified by SESLHD, but which do not fit the above categories • Clozapine	

Appendix 2. High Risk Medicines Management Implementation Checklist

HIGH-RISK MEDICINES MANAGEMENT

IMPLEMENTATION CHECKLIST

Updated March 2020

Facility name: **Assessed by:** **Date:**

REQUIREMENTS		STATUS		
1	Facilities have a High-Risk Medicines Register in place.	Fully ◯	Partially ◯	Not ◯
		Reason partially / not implemented:		
2	A mechanism is in place for assessing safety of new medicines being considered for the facility drug formulary.	Fully ◯	Partially ◯	Not ◯
		Reason partially / not implemented:		
3	A plan, including a time-line, for completion of local high-risk medicine protocols in accordance with high-risk medicines standard requirements has been developed.	Fully ◯	Partially ◯	Not ◯
		Reason partially / not implemented:		
4	A mechanism is in place to alert relevant clinicians to changes to the high-risk medicines register.	Fully ◯	Partially ◯	Not ◯
		Reason partially / not implemented:		
5	A strategy is in place for review of protocols currently included in the High-Risk Medicines Register.	Fully ◯	Partially ◯	Not ◯
		Reason partially / not implemented:		

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March 2020

The Clinical Excellence Commission High Risk Medicines Management Implementation Checklist