Government of **Western Australia**
Department of **Health**

Guidelines for Managing Specific High Risk Medications Relevant to the Organisation

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Contents

Introduction

High Risk Medications are medications that have an increased risk of causing significant patient harm or death if they are misused or used in error.

This document has been developed as a guideline for WA Hospitals and Health Services to improve patient safety by providing risk reduction strategies and best practice recommendations for prescribing, dispensing, administering and monitoring specific high risk medications. This document supports the *MP 0131/20 High Risk Medication Policy*.

As stated in the *High Risk Medication Policy* and in accordance with the National Safety and Quality Health Service Standard: Medication Safety, hospitals and health services must maintain a High Risk Medication Register/List. At a minimum the following medications, recommended by the Australian Commission for Safety and Quality in Healthcare, and associated with the 'APINCHS' acronym, should be considered for inclusion in the High Risk Medication Register.

- A Antimicrobials
- P Potassium and other electrolytes, Psychotropic medications
- I Insulin
- N Narcotics / Opioids, Neuromuscular blocking agents
- C Chemotherapeutic agents
- H Heparin and other anticoagulants
- S Safer Systems (e.g. safe administration of liquid medications using oral syringes)

Health Service Providers (HSPs) will need to determine which medications are deemed high risk within their patient population and clinical settings to be included in a high risk medication register for the organisation. All medications carry risk of adverse events if prescribed, administered or dispensed inappropriately. If there is a high risk of death or serious injury to the patient where a medication is inadvertently misused or administered incorrectly, include the medication on the register and develop appropriate protocols. It is recommended that hyperlinks to supportive documents be added to the list, including appropriate national, state and local documents.

It is recommended that HSPs:

- maintain and periodically review their local high risk medication register/list. A structured multidisciplinary risk assessment should be undertaken to identify potential risks (including storage, prescribing, dispensing, administration and monitoring) and risk mitigation strategies for each medication class;
- maintain a quality improvement plan that includes actions to address identified risks in the management of high risk medications;
- ensure workforce orientation and ongoing education programs on medication safety include high risk medicines and strategies on how to manage these medications safely, and
  refer to standardised relevant evidence-based resources where they exist (e.g. eTherapeutic Guidelines (eTG) for Antibiotics) or develop local guidelines to support clinicians in the safe prescribing, administration and monitoring of high risk medications.

Adverse medication incidents involving high risk medicines should be reported via the Clinical Incident Management System as per *MP 0122/19 Clinical Incident Management Policy 2019* and regularly reviewed through quality management systems.

This guideline outlines the minimum recommended actions required to mitigate identified risks for specific medications associated with the 'APINCHS' acronym.

This guideline is further supported by *Appendix 1 High Risk Medication Risk Mitigation Strategies* which provides overarching suggestions for system-wide solutions for reducing medication error.

1. Anti-infectives

Specific anti-infectives that have a high risk of causing harm include amphotericin, aminoglycosides and vancomycin.

1.1 Amphotericin

Confusion between the formulations of amphotericin deoxycholate (Fungizone®), liposomal amphotericin (Ambisome®), amphotericin B (Fungizone®) and the phospholipid complex (Abelcet®) may result in errors, both in prescribing and administration.

Depending on the error involved, confusion between the different formulations can lead to either

- underdosing and loss of therapeutic effect or
- overdosing and toxic side effects.

The most significant (potentially fatal) risks to patients are concentration or rate errors with amphotericin deoxycholate leading to overdosing.

Awareness of these multiple formulations and differing dosage recommendations will help reduce the risk of under or overdosing. For specific dosing information refer to the Australian Medicines Handbook (AMH).

Recommendation:

Hospitals and Health Services implement strategies to distinguish between the different formulations and dosage recommendations when prescribing, dispensing and administering amphotericin.

1.2 Aminoglycosides

(Gentamicin, tobramycin and amikacin)

Incorrect dosing with respect to age, ideal body weight and renal function may result in significant ototoxicity and nephrotoxicity. Underdosing may result in treatment failure.

- Serum levels should be monitored in all patients expected to receive therapy for greater than 72 hours, with dose adjustment as appropriate. Patients with unstable renal function should be monitored daily.
  For further information refer to eTG and/or AMH.

Recommendation:

Hospitals and Health Services implement local guidelines and deliver medical and pharmacy education which articulate dose calculation and modifications, and monitoring requirements for aminoglycosides.

1.3 Vancomycin

Incorrect dosing with respect to weight may rarely cause nephrotoxicity and ototoxicity. Underdosing may result in treatment failures.

- Serum levels should be monitored in all patients expected to receive therapy for more than 72 hours, with dose adjustment as appropriate. Patients with unstable renal function should be monitored daily.
- Red man syndrome is a histamine-mediated reaction that presents as tingling, flushing or rash of the face, neck and upper body, muscle spasm of the chest and back, and in severe cases hypotension and shock-like symptoms if the infusion is administered too quickly. If symptoms occur, then reduce the rate of infusion.
  For further information refer to eTG and/or AMH.

Recommendation:

Hospital and Health Services maintain local guidelines and education which articulate dose calculation, rate of administration, dose modification and monitoring requirements of vancomycin.

2. Intravenous Potassium and Other Electrolytes

Please refer to the *Mandatory Standards for Intravenous Potassium* for further information.

3. Psychotropic agents

Psychotropic agents (including antipsychotics, antidepressants, benzodiazepines and stimulants) carry risks in particular patient groups or situations, including:

- Risk, particularly cardiac and sudden death, is increased when prescribed in combination or in high doses.
- Given the risk of self-harm and suicide is increased within cohorts of individuals with mental illness, psychotropics may pose an increased risk of overdose for individuals within this cohort (also noting the therapeutic impact of psychotropics can reduce suicide rates).
- Antipsychotic medications pose long term health risks which, in conjunction with associated inherent mental illness risk, may predispose patients to metabolic syndrome.
- Stimulants and sedative medications may pose a potential risk of diversion to illicit use.
- Paediatric and elderly patients are inherently more vulnerable to psychotropic medications and extra caution must be exercised when prescribing for these patient populations.

Procedures and policies must be in place regarding the safe prescription, preparation, administration and monitoring of psychotropic agents. Hospitals and health services must demonstrate that the specific requirements below are considered, where applicable.

3.1 Clozapine

Clozapine requires strict monitoring due to its potential to cause neutropenia, agranulocytosis, myocarditis, cardiomyopathy and severe constipation. Other significant adverse effects include marked sedation, weight gain, dyslipidaemia and hyperglycaemia, lowered seizure threshold, hypersalivation, asthenia, and sedation. It is recommended that hospitals and health services implement the following strategies:

- All patients must be part of a clozapine monitoring system, which mandates systematic evaluation of haematological parameters. At a minimum full blood counts are conducted weekly for the first 18 weeks then every 4 weeks unless results dictate more frequent monitoring is required.

- Concomitant use of other medications that have the potential to cause agranulocytosis is discouraged and increased vigilance should be maintained where this is necessary.
- In particular, the use of carbamazepine with clozapine is discouraged. The combination of carbamazepine and clozapine has been shown to synergistically increase the risk of agranulocytosis.
- A serious and under-recognised side effect is clozapine induced gastrointestinal hypomotility (CIGH). This can range from mild constipation to fatal bowel obstruction and/or ischaemia and fatalities reported are higher than those related to agranulocytosis.
- Stool charts and the Rome III criteria for diagnosing functional constipation should be used for monitoring patients when performing routine full blood counts as a minimum. Laxatives should be considered pre-emptively for all patients prescribed clozapine, unless contraindicated, and extra vigilance is required when other medications that cause constipation are prescribed.

Clozapine Resources:

Clozapine resources can be accessed on the 'Mental Health Charts and Clozapine Resources' page. The WA Clozapine Initiation and Titration Chart is one of a suite of medication charts mandated under the *WA Medication Chart Policy* MP0078/18.

Recommendation:

Hospitals and Health Services maintain local guidance and deliver staff education which articulate registration, dosing, prescribing, and monitoring requirements of clozapine, and audit compliance with these requirements.

3.2 Lithium

Lithium is indicated for treatment of acute mania, hypomania and for bipolar affective disorder. It is available as an immediate release and slow release preparation.

Failure to recognise the early signs of toxicity may lead to a delay in treatment and result in poor patient outcomes including rarely death. Early symptoms of lithium toxicity are varied and non-specific. They are most likely to occur when serum lithium concentration exceeds 1.5mmol/L but can occur when serum lithium levels are within the target concentration range. It is recommended that hospitals and health services implement strategies to address the following:

- Regular monitoring of patient parameters including renal function, urea and electrolytes and lithium levels to ensure toxicity does not eventuate. There are relatively narrow margins between therapeutic and toxic dosages for lithium and therefore is important. Local guidelines should contain guidance on the following pertinent aspects of lithium therapy:
  - timing of blood test in relation to last dose,
  - when to measure lithium blood level when commencing lithium therapy
  - frequency of lithium level monitoring,
  - requirements for monitoring thyroid function
  - when additional monitoring of lithium concentration is recommended (e.g. during illness)
  - other monitoring requirements for chronic side-effects
- Education is provided to staff involved in the prescribing, administration and dispensing of lithium are educated and aware of the signs and symptoms of lithium toxicity

- Neurological manifestations are the most important signs of lithium toxicity including ataxia, dysarthria, dysphagia and cognitive impairment. Severe toxicity may result in convulsions, myoclonus and coma.
- Local guidelines should contain information on factors that can increase the risk of lithium toxicity such as:
    - impaired renal function,
    - advanced age,
    - dehydration (including fluid loss from vomiting, diarrhoea and excess sweating and nephrogenic diabetes insipidus),
    - reduced salt intake,
    - concurrent illness,
    - medicines that reduce lithium clearance (for example non-steroidal anti-inflammatory drugs (NSAIDs), angiotensin converting enzyme (ACE) inhibitors, angiotensin 2 receptor antagonists and diuretics),
    - chronic supratherapeutic dosing.

Recommendation:
Hospitals and health services maintain local guidelines, deliver staff education that articulates safe dosing and monitoring requirements for lithium therapy and audit compliance with lithium monitoring.

4. Insulin

- Errors involving insulin therapy can cause serious harm or can be fatal.
- Confusion may arise between the different insulin preparations available especially if not prescribed in a consistent and clear manner.
- Intravenous insulin is lethal if given in excessive doses or in place of other medications (insulin and heparin can be potentially mistaken for one another since both are ordered in units).
- It is recommended that hospitals and health services demonstrate that the specific requirements below are considered, where applicable.

4.1 Insulin by Subcutaneous Injection

4.1.1 Prescribing insulin for subcutaneous injection

- Insulin should be prescribed on a Subcutaneous Insulin Chart with full dosage instructions. The Subcutaneous Insulin Order and Blood Glucose Monitoring Chart is recommended for use across WA public hospitals.
- Insulins are one of the few exceptions where prescribing in TRADE name is recommended (instead of generic name) to reduce confusion between insulin products.
- Care must be taken to ensure that the insulin type is fully documented including;
    - Prescribing insulin by trade name, ensuring including numerical proportions when insulins are combined (e.g. Humulin 30/70 - not just Humulin, Humalog Mix 50 - not just Humalog Mix).
    - Device type (vial/cartridge/disposable pen)
    - Time of administration (i.e. immediately before meals or specific time to be given in respect to food)
    - Dose - ensure that the word ‘UNITS’ is written in full to avoid confusion when communicating insulin dosing. The Subcutaneous Insulin Order and Blood Glucose Monitoring Chart has pre-printed dosage units to minimise the risk of dosage error.

4.1.2 Administering insulin by subcutaneous injection

- Cartridges, pen injectors or vials are for individual patient use.
- Ensure insulin is given subcutaneously at the prescribed dose using an insulin syringe or insulin pen/device specific to the brand of insulin prescribed.
- It is recommended that all insulin pen injector devices are used with the safety (retracted) pen needles.
- When a syringe is required, choose the smallest syringe that is big enough to hold the dose. The smaller the syringe, the easier it is to read the markings and draw up an accurate insulin dose.

4.1.3 Storage of insulin

- Unopened vials/cartridges/prefilled pens should be stored in a fridge (2-8 degrees Celsius)
- Insulin in use can be stored at room temperature (below 25 degrees Celsius) for 21 to 28 days, depending on the type of insulin.
- Insulin vials/cartridges/prefilled pens must be for individual patient use only.
- When the insulin is used for the first time, ensure a label is used to note the date and time of opening and the patient identification for which the insulin is to be used.
- Ensure insulin is discarded if it has been out of the fridge for 28 days or more (or earlier if insulin can only be stored for up to 21 days).
- Do not place insulin in, or close to the freezer compartment as it must not be frozen.
- Do not expose vials, cartridges or prefilled pens to sunlight or high temperatures.
- Do not use insulin if it has expired (always check the pack for the expiry date).
- Consider separating look-alike/sound-alike insulins on imprest and limiting the available options on wards.

4.1.4 High Concentration Insulins

Several high concentration insulin preparations have become available in Australia. Toujeo® and Humalog U200® are available on the Pharmaceutical Benefits Scheme (PBS).

Toujeo® has been approved for inclusion on the State Medicines Formulary (SMF) with a condition that hospitals develop strategies to manage safety risks associated with high concentration insulins.

Toujeo® (insulin glargine 300 units/mL)

- Is a high concentration insulin product that is **three times** the concentration of standard insulin preparations.
- Is only available in a prefilled disposable pen device (Toujeo SoloStar®).
- A patient may be prescribed Toujeo® if they are on large doses of insulin (to reduce the total volume needed).
- Toujeo® and Lantus® (both insulin glargine) are NOT dose-equivalent.
- Toujeo® 100 units is approximately equivalent to Lantus® 80 units.
- When switching from Lantus® to Toujeo® it is recommended by the manufacturer to use the same number of units initially and titrate up to therapeutic blood glucose level range.
- When converting from Toujeo® to Lantus® a dose reduction of 15-25% is recommended, taking into account the clinical situation.
- It is important to inform the patient/carer of any product change.

- If a patient has been using Toujeo® high concentration insulin prior to admission to hospital, it is recommended that a patient continues on this preparation during their hospital admission rather than switching to Lantus®.

The following principles should be used to assist sites to develop their own local processes to mitigate the risk of confusion between Toujeo® and Lantus® NOTE: These principles can be applied for all high concentrated insulins):

a. Prescribing
    - High concentration insulins should be prescribed on the subcutaneous insulin chart.
    - When prescribing high concentration insulins on the insulin chart, the prescriber must clearly prescribe the brand name, concentration/strength of product, dose in units and time of administration (e.g. Toujeo® (300 units/mL) 20 units at bedtime).
    - Ensure that the order is clearly documented in the Special Instructions area on the Insulin Subcutaneous Order and Blood Glucose Record Form to note that the patient is prescribed a high concentration insulin.

b. Storage and supply
    - Individual patient supply labelled with the patient's name and unique medical record number (UMRN) is the preferred method of supply of a high concentration insulin, such as Toujeo®, for inpatient use.
    - High concentration insulins should be restricted to pharmacy supply and, if approved for use on the SMF, can be stored on a limited number of approved clinical areas for after-hours supply as determined by the Drug and Therapeutics Committee of the hospital.
        - All clinical staff working in an approved clinical area that stocks a high concentration insulin will require education on safe use and supply of this high concentration insulin.
        - It is recommended that when a high concentration insulin is kept in an approved clinical area, that it is kept separate from other insulin products and labelled in a clear way to indicate that this medication is a 'high concentration insulin' to prevent selection error.
    - This medication should <u>not</u> be available on imprest to all general wards.

c. Administration
    - High concentration insulin penfills <u>must never</u> be used to draw up a dose into an insulin syringe for administration. <u>All</u> doses <u>must</u> be administered using the disposal injector pen.
    - Prior to administration, confirm with the patient that they are on a high concentration insulin (e.g. Toujeo®)
    - Assess whether the patient is able to self-administer their insulin.
    - If patient is unable to self-administer, ensure safety pen needles with automatic protective shields are used in the administration of high concentration insulins.

d. If using the patient's own supply:
    - Seek consent from the patient to use their own supply during hospitalisation and document in the medical record.
    - Store the currently used high concentration insulin in the patient's bedside medication drawer (or as per hospital policy for patient's own medication storage). Ensure that the insulin pen is labelled with the patient's name and unique medical record number (UMRN).

- Where sites do not have individual patient medication drawers, it is recommended that a local process is developed to mitigate this risk. Store the remainder of patient's own high concentration insulins away from other insulin stock as per storage requirements.
- Return the remaining patient's own high concentration insulin at discharge.

e. If patient's own supply is unavailable:
   - The high concentration insulin will need to be ordered from pharmacy for inpatient use.
   - It is recommended that the order is confirmed by a ward pharmacist prior to supply.
   - The high concentration insulin pen will need to be labelled with the patient's name and expiry date; and stored in the patient's bedside medication drawer for use during hospital admission.
   - Where sites do not have individual patient medication drawers, it is recommended that a local process is developed to mitigate this risk.
   - It is recommended that all hospitals have in place local guidelines governing the supply of high concentrated insulins outside normal pharmacy hours.
   - Assess the need for supply post discharge and liaise with the medical team/pharmacy where appropriate.

4.2 Administering Insulin by Intravenous Infusion

- Insulin should be administered via a programmable pump, ideally a pump that utilises Drug Error Reduction Software (DERS).
- Consider standardising the concentration for all intravenous insulin solutions used within the HSP, and ideally across all HSPs to minimise confusion associated with preparing and administering intravenous insulin.
- Double check the concentration and the infusion rate are consistent with the prescription to ensure the correct dilution is used for the protocol required (i.e. some hospital protocols for intravenous insulin dilution may vary depending on the indication).
- Intravenous insulin is lethal if given in excessive doses or in place of other medications (insulin and heparin are often mistaken for one another since both are ordered in units).
- A high risk situation may present when an insulin infusion is ordered for the management of hyperkalaemia, therefore is it important that hospitals have guidelines for the use of intravenous insulin in this setting.
- HSPs should ensure instructions/guidelines are available for bridging between intravenous infusion and subcutaneous insulin management.

Recommendation:

Hospitals and health services maintain local guidelines, strategies and deliver staff education to address risk associated with subcutaneous and intravenous prescribing, dispensing, administration and monitoring of insulin.

5. Narcotics/Opioids and Sedative Agents

- Fentanyl, hydromorphone, morphine, oxycodone and midazolam are the most frequently reported medications in opioid/sedative medication-related incidents.
- Incorrect dosing of opioids can lead to inadequate analgesia, excessive sedation and potentially lethal respiratory depression. The effects of these medications can also be increased by other medications and alcohol consumption.
- It is recommended that hospitals and health services demonstrate that the specific requirements below are considered, where applicable.

5.1 Prescribing and Administering Opioids and Sedative Agents

5.1.1 General principles

- Caution with prescribing in elderly patients and patients with impaired clearance. Dosing should follow “Start low and go slow” philosophy.
- Take care when prescribing a substitute opioid for a patient. Independently check doses and opioid conversion tables prior to prescribing and administration where possible. Monitor patient to assess pain level, sedation and respiratory level during this period. Refer to AMH for further information on opioid conversion.
- The risk of inadvertent overdose, over sedation or respiratory depression from concurrent prescription of other sedative opioid drugs must be considered in patients who have been administered intrathecal or epidural opioids peri-operatively.
- Monitor for cumulative sedation from medications used for symptomatic relief post-surgery, for example the use of benzodiazepines for muscle spasm or sedating antihistamines for itch.
- Regularly review the patient using the appropriate pain scoring tool to assess analgesia. Monitor sedation and respiratory levels to review for overtreatment.
- For all infusions, ensure (via independent double check) that the concentration and the infusion rate are consistent with the prescription.

Opioid Resources

- *Pain relief medications following surgery or injury – patient counselling booklet*
- *Recommendations for prescribing analgesia on discharge following surgery or acute injury – for health practitioners*

5.2 Patient Controlled Intravenous Analgesia

Hospital and health services should implement local guidelines, strategies and education to address risk associated with prescribing, dispensing and administration of patient controlled intravenous analgesia which incorporates the safety principles outlined in this standard.

5.2.1 Prescribing

- Patient controlled intravenous analgesia (PCIA) must only be prescribed and administered by staff deemed competent to do so in accordance with hospital policy. Depending on the hospital policy, a prescription is to only be initiated and altered by:
  - a medical member of an Acute Pain Service (APS) (this may include nurse practitioners qualified and authorised to prescribe opioids),
  - a palliative care consultant or registrar,
  - an anaesthetist or GP anaesthetist,
  - an intensive care Registrar or Consultant (with anaesthetics training) or emergency medicine Registrar or Consultant (with anaesthetics training) with referral to an APS medical practitioner recommended, or
  - a GP or Senior Medical Practitioner employed in a rural or remote setting working within their scope of practice.
- There should be a clearly nominated primary team or prescriber that can be called by nursing staff for assistance with PCIA, at all times (24hrs/day).
- There should be at a minimum, a once daily medical review of the patient and prescription by the prescriber or appropriate primary team member.
- The following should always be considered when a PCIA is prescribed:
  - physical or mental barriers, such as spinal cord injuries or cognitive impairment
  - concurrent sedative use
  - patient history of opioid use and concurrent opioid therapy
  - airway compromise
  - acute alcohol intoxication
  - obstructive sleep apnoea, chronic obstructive pulmonary disease (COPD) or asthma, which may increase risk of respiratory depression
  - morbid obesity
  - renal impairment
  - hepatic impairment
  - previous allergy or sensitivity to a specific opioid.
- The risk of inadvertent overdose or respiratory depression from concurrent prescription of other sedative or analgesic drugs must be considered. No additional opioids or sedatives are to be given by any route unless ordered by the authorised prescriber. This may include notification that the prescribing medical member of an APS/ anaesthetist/ GP anaesthetist/ ICU intensivist is to be consulted if analgesic or sedative prescriptions are to be altered.
- Where multiple drugs are prescribed for analgesia, it is recommended that either these are charted on the same order/medication chart; or documented in a manner which allows co-administered drugs to be easily reviewed.

- Where other drugs with sedative potential are prescribed, these are to be readily apparent upon review of the medication chart and as necessary clarified by writing 'Not to be given with PCIA'.

- Where the WA Hospital Medication Chart (WA HMC) is used in conjunction with the PCIA chart, a notice alerting users to the PCIA prescription is recommended to be inserted e.g. "PCIA chart in use" alert in the WA HMC, or "other drug" alert on the PCIA chart.

- Naloxone 400 micrograms must be available on the resuscitation trolley in any environment where a PCIA is utilised.

5.2.2 Administration and Monitoring

- The following observations specified below are recommended to be performed at the minimum intervals for PCIA.

Time since commencement of PCIA	**Observation Frequency**
0 to 2 hours	Every 30 minutes
2 to 8 hours	Every hour
8 to 24 hours	Every 2 hours
Greater than 24 hours	As warranted; but at least every 4 hours.

- Observation charts should include a description of sedation, nausea and pain scores with instructions on intervention points. A suggested scoring system is described below.

Observation	**Score Range**	**Meaning**
Sedation	0 to 3	0 – wide awake 1 – easy to rouse 2 – easy to rouse but constantly drowsy 3 – somnolent and difficult to rouse
Pain	0 to 10	0 – no pain 10 – worst pain imaginable
Nausea	0 to 4	0 – no nausea 1 – mild nausea 2 – severe nausea 3 – dry retching 4 – vomiting

- Care must be taken to distinguish the oversedated patient from one in normal sleep as the former highlights a risk of impending respiratory depression.

- **Triggers for Early Clinical Intervention**

  HSPs should have site specific deterioration, escalation or emergency response guidelines, for early recognition and response to patients whose condition is deteriorating due to overdose of opioid therapy.

  Signs/symptoms requiring urgent medication attention include:
  - Apnoeic or pulseless
  - Respiratory depression
  - tachypnoea
  - hypotension
  - cyanosis
  - pallor.

- HSPs must have local guidelines on discontinuation of PCIA.
- A recommended patient check list before removal of the PCIA should include:
    - A decision to cease the PCIA has been made by an authorised prescriber.
    - Pain relief is being controlled using appropriate alternatives e.g. oral analgesia such as paracetamol, NSAIDs or opioids.
    - Tolerating oral diet and fluids occurs before prescribing oral analgesia.
    - Consider discontinuing the PCIA when the most support is available to the patient e.g. when most nursing staff are rostered on duty and prescribing practitioners are available.
    - Any remaining opioid must be disposed of in line with the Medicines and Poisons Regulations 2016. Record the volume of Schedule 8 medication discarded on the PCIA chart.

Recommendations:

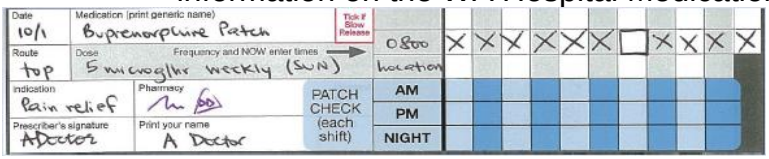
Hospitals and health services maintain local guidelines and deliver staff education which articulates dosing adjustments, opioid conversion modification and drug interaction monitoring when prescribing opioids.

Hospitals and health services demonstrate local guidelines and education that articulates the monitoring requirements related to the administration of opioids (including patient controlled intravenous analgesia).

5.3 Narcotic Transdermal Patch Delivery Systems

A number of different medications are available as a patch formulation including potent opioid analgesics (e.g. fentanyl and buprenorphine). It is important to ascertain the presence of any transdermal patches at the time of admission.

- Heat packs, electric blankets and hot baths should not be used in conjunction with transdermal patches as exposure to heat may increase the absorption of the drug from a patch. A high fever may also increase absorption.
- When prescribing and administering a narcotic transdermal patch for a patient:
    - Indicate where the patch should be applied and how often it should be rotated as per specific patch type (refer to product information)
    - Record time of application and time of removal on medication chart. Document site of application of the patch in the patient's medical record.
        - A transdermal patch check sticker is available to assist in documenting this information on the WA Hospital Medication Chart.



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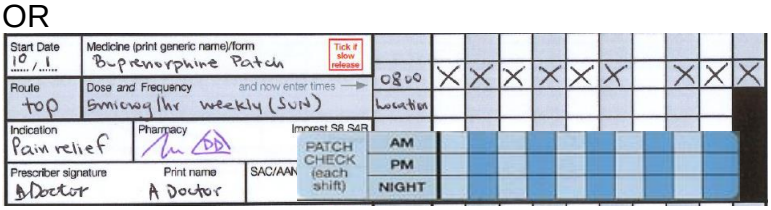


    - Ensure that the medicated patch has been removed if the prescription order has been ceased.

    - Ensure that the previous patch has been removed before applying a new patch. Both the application and removal of patch should be recorded on the medication chart.
- Transdermal opioid patches should never use in opioid-naïve patients and should only be use for chronic pain management.
- A significant amount of the drug remains in the patch after its intended application period has expired. Used transdermal patches must be disposed of carefully. The patch should be folded in half so that the sticky side of the patch sticks to itself and discarded into a secure sharps or pharmaceutical waste bin.

Recommendation:

Hospitals and health services maintain local guidelines and deliver staff education that address the risk associated with prescribing, dispensing and administration of narcotic transdermal patch delivery systems, including the assessment of any transdermal patches present on admission.

6. Neuromuscular blocking agents

Neuromuscular blocking agents (NMBAs) are considered high risk medications because inadvertent use in patients without the availability of medical staff skilled in airway support can lead to respiratory arrest, permanent harm and death. Serious incidents have occurred involving inadvertent administration of NMBAs to a patient instead of another agent (e.g. sedative).

Examples of neuromuscular blocking agents (NMBAs) include:

- suxamethonium
- pancuronium
- vecuronium
- atracurium
- rocuronium
- mivacurium
- cisatracurium

These medications are used during tracheal intubation, during surgery of intubated patients, and to facilitate mechanical ventilation of critically ill patients.

Administration errors involving these medications in Australia and internationally have been associated with look-alike packaging and labelling, and look-alike/sound-alike (LASA) medication names, resulting in selection errors. These risks can be exacerbated when NMBAs are stored with other medications. It is recommended that NMBAs are segregated and sequestered to differentiate all neuromuscular blockers from other medications.

The Therapeutic Goods Administration (TGA) labelling requirements for NMBAs have recently been modified to include a warning statement –*'WARNING: Paralysing agent'* which will appear on the labels of the primary pack (outer carton) and the container (ampoule or vial).

The following are best practice recommendations for safe management of NMBAs.

6.1 Storage requirements[1,2]

- NMBAs should only be stored in areas of the hospital/health service that routinely use these medications. This should be determined by the Drug and Therapeutics Committee of that hospital.
- The storage location of all NMBAs should be reviewed on a regular basis.
- In those areas permitted to store NMBAs, these should be stored in a clearly marked and sealed container.
- Consider segregating NMBAs from all other medications in the pharmacy by placing them in separate lidded containers in the refrigerator or other secure, isolated storage area. In critical care environments access to NMBAs should be limited to restricted areas which have authorised staff present 24 hours a day and seven days per week.
- Consider placing auxiliary labels on all storage containers and drawers that contain NMBAs that state "WARNING: Paralysing agent – causes respiratory arrest – patient must be ventilated".
- If NMBAs are kept in automated dispensing cabinets, the storage practices should be standardised throughout the hospital/health service by storing them in lock lidded pockets to eliminate selection error.

6.2 Prescribing requirements[1,2]

- Outside the operating theatre or procedural areas, orders for NMBAs should only be part of an intubation protocol to maintain a specific level of paralysis while the patient is mechanically ventilated.
- Prescribing of NMBAs should be restricted to clinicians who have adequate knowledge and training.

6.3 Preparation and administration requirements[1,2]

- These medications should only be administered by staff with experience in maintaining an adequate airway and respiratory support, and only in units where intubation and respiratory support can be provided.
- Administer all NMBA infusions via a programmable pump that ideally utilises Drug Error Reduction Software (DERS).
- Proper labelling of all syringes containing NMBAs must comply with the National Standards for User-applied Labelling of Injectable Medicines, Fluids and Lines" (the Labelling Standards) (See 9.2.2).
- Ensure all appropriate reversal agents for neuromuscular blockade are available to qualified staff that might need them in an emergency. Local policies and procedures should identify who is permitted to administer the reversal agent in an emergency and provide readily available instructions for administration.

Recommendation:

Hospitals and health services maintain local guidelines which consider the recommended minimum safety requirements for managing the storage, prescribing, preparation and administration of NMBAs.

Hospitals and health services deliver staff education which articulates the risks associated with NMBA errors.

7. Chemotherapeutic Agents and Immunomodulators

All chemotherapeutic agents are considered high risk medications.

The following information provides minimum recommendations for all chemotherapeutic agents. Additional requirements for specific chemotherapeutic agents and other immunotherapy (including monoclonal antibodies and biosimilars) are outlined individually at the end of this section.[3]

- Procedures and policies must be in place regarding the safe prescription, preparation, administration and monitoring of chemotherapeutic agents and immunomodulators.
- All staff involved in the management of cancer and its therapy must have the relevant knowledge and skills and be authorised to perform tasks including prescribing, dispensing, preparation or administration of chemotherapeutic agents and immunomodulators.
- Every hospital and health service should have a procedure in place to ensure all inexperienced staff that will be involved in the prescribing, dispensing, preparation or administration of chemotherapeutic agents and immunomodulators receives appropriate training and supervision prior to carrying out these tasks.
- Oral chemotherapy should be subject to the same procedures and precautions for prescribing, dispensing and administration as parenteral therapy.
- Oral chemotherapy should be clearly identified as cytotoxic to all staff that may handle the medication. A cytotoxic purple sticker can be placed on the dispensed medication container and/or the medication administration chart to identify this risk.
- All staff should have access to information applicable to the patient and the treatment including diagnosis, patient's history, patient's weight and height, pathology results and the treatment plan.
- All chemotherapy and targeted therapy should be prescribed on the basis of a documented, referenced protocol and a treatment plan documented for all patients. Protocols should outline all therapy, dosages and scheduling relevant to the treatment. Dose adjustments should be clearly documented in the treatment plan and duplicated on the order and/or prescription.
- All prescriptions for oral chemotherapy and targeted therapy should include a start and stop date for intermittent therapy.
- All treatment should be clinically verified by a pharmacist with specialist haematology/oncology knowledge prior to dispensing. The pharmacist should have access to the patient information relevant to the treatment.
- All chemotherapy and associated therapy should be confirmed against evidence-based treatment protocols (e.g. eviQ protocols) by a nurse (when unsure, check with a pharmacist). Therapy should be checked against the order by two appropriately trained and credentialled health professionals prior to administration.
- Patients should be given access both written and oral information about their treatment which is to include all medications, expected side effects, how to take supportive medication and who to contact in the event of an emergency or severe adverse events.
- A system should be in place for reporting adverse events, incidents and near misses with regular audits carried out to identify error prone areas or processes that require modification.
- Clinicians administering and handling chemotherapeutic agents must be aware of personal protective equipment requirements and the procedure required should a spill occur (chemotherapy spill kit procedure).

Recommendation:

Hospitals and health services maintain local guidelines, strategies and education to address risks associated with prescribing, dispensing, preparation and administration of chemotherapeutic agents and immunotherapy which incorporate the safety principles outlined above.

7.1 Vinca Alkaloids

Please refer to the *Mandatory Standard for Vinca Alkaloids* for further information.
Intrathecal administration of chemotherapeutic agents not intended for intrathecal use can be fatal.

7.2 Administration of Intrathecal Chemotherapy Requirements

The consequence of intrathecal administration of chemotherapeutic agents not intended for intrathecal use can be fatal.

7.2.1 Staff training[4]

- HSPs providing intrathecal chemotherapy must develop and maintain a record of "intrathecal-qualified" personnel, who are credentialed to prepare, dispense or administer intrathecal cytotoxic chemotherapy according to their usual professional role.
- If a person not qualified in intrathecal chemotherapy is required to prepare, dispense or administer intrathecal cytotoxic drugs, they must do so under the appropriate supervision of an intrathecal-qualified clinician, and obtain intrathecal administration training when appropriate.
- All staff involved in the prescribing, dispensing, checking or administration of intrathecal chemotherapy must receive education and training appropriate for their professional roles, as part of a formal induction, in order to become "intrathecal-qualified".
- Induction for all staff (nursing, pharmacy and medical) must cover all potential clinical hazards associated with intrathecal chemotherapy, the danger posed to patients if drugs (particularly vinca alkaloids) are accidentally administered intrathecally, and an analysis of how errors have occurred in the past.
- Hospitals must record details of the training courses to be provided and a plan on how the training will be extended to new staff members as part of the induction process.

7.2.2 Prescribing[4]

- All prescriptions for intrathecal cytotoxic chemotherapy must be signed or countersigned by a haematology/medical oncology consultant, fellow or senior registrar.
- As per the Australian Commission for Safety and Quality in Health Care "Recommendations for terminology, abbreviations and symbols used in medicine documentation" the full medication name and the route "intrathecal" be written in full on the prescription. The abbreviation '*IT*' is unacceptable and error-prone.
- Unless dictated by protocol, intrathecal chemotherapy must not be planned on the same day as intravenous chemotherapy.
-

7.2.3 Preparation, dispensing and delivery from pharmacy[4]

- All intrathecal injections must be placed inside a sealed yellow outer bag.
- All layers of outer packaging including the outer sealed bag must be labelled with the patient name, medication name and a clear warning "*For Intrathecal Use Only*".

- Syringes for intrathecal therapy must be labelled with a warning "*For Intrathecal Use Only*". To avoid obscuring information, "flag" type labels must be applied to small syringes.
- Intrathecal injections prepared by the Pharmacy Department should be delivered to the designated location under the direct supervision of an intrathecal-qualified nurse or pharmacist.
- In the case of the administration not proceeding (e.g. failed lumbar puncture) the drug must be returned to the Pharmacy Department intact and safely disposed of. If another attempt to administer the drug is required, a new dose should be prepared.
- Where circumstances make same day administration of chemotherapy drugs by intrathecal and intravenous routes unavoidable, the order of route of administration must be confirmed and the second drug to be administered shall be issued from pharmacy only after the intrathecally trained pharmacist has confirmed that the first therapy has been given successfully by examining the signed administration order.

7.2.4 Administration[4]

- Unless dictated by protocol, all intrathecal chemotherapy should be administered during normal working hours and when a full complement of intrathecal-qualified staff is present.
- Cytotoxic intrathecal chemotherapy will be administered only in designated cytotoxic suites or wards managing cancer patients, theatre or radiology suites.
- Before the cytotoxic drug is administered, the intrathecal-qualified nurse or pharmacist will verify the correct patient, route, drug and dose with the intrathecal-qualified person who administers the drug to the patient.
- The administration line must be clearly labelled with the required yellow "IntraTHECAL" label. The date and time the line was commenced should be documented on the label as per the National Standard for User Applied Labelling of Injectable Medicines, Fluids and Lines.
- Only a haematology/medical oncology registrar, consultant or other intrathecal-qualified senior medical personnel, including radiologists, may administer intrathecal chemotherapy.
- Staff administering intrathecal medicines must use checking procedures that includes a 'time out' involving at least two health professionals. Consider undertaking a 'Time Out' final patient safety check immediately before commencing the treatment. It should be carried out in a quiet place without interruption.

Recommendation:

Hospitals and Health Services should follow the recommended additional safety measures associated with the administration of intrathecal chemotherapy.

7.3 Etoposide

- Etoposide is available as the base drug etoposide and as the phosphate salt (Etopophos®).
- Etoposide phosphate is a pro-drug and is not directly interchangeable with etoposide. They contain different amounts of etoposide and cannot be directly substituted.
- Confusion when prescribing or administering the medication and can result in under or over dosing of the medication. Hospitals should stock one formulation to minimise confusion between products. It is recommended that hospitals only stock etoposide phosphate.

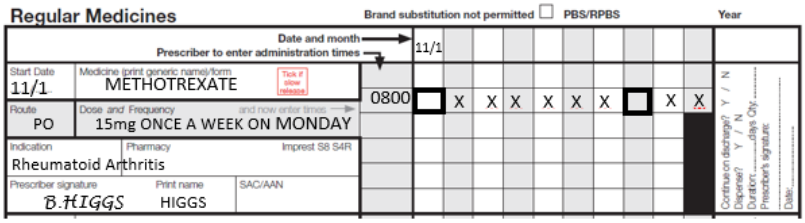
- Etoposide must be administered by slow infusion, unlike etoposide phosphate which may be rapidly infused.
- Prescriptions for etoposide should be on pre-printed charts to minimise confusion.

Recommendation:

Hospitals and Health Services develop strategies to distinguish between etoposide and the phosphate salt (Etophos®) when prescribing etoposide.

7.4 Methotrexate

- Oral methotrexate is used in the treatment of autoimmune or inflammatory disorders such as rheumatoid arthritis and severe psoriasis. Methotrexate is also used in the treatment of malignancies as part of specialised protocols.
- Australian cases with fatal consequences have been reported when oral methotrexate has been prescribed and administered more frequently than once weekly for autoimmune or inflammatory disorders.[5,6]
- When prescribing, administering and dispensing weekly doses of methotrexate, the dose and which day of the week methotrexate is to be administered must be clearly documented as part of the prescription order. The remainder of the relevant administration boxes must be crossed out to flag that dose(s) are not to be administered to reduce the risk of patients receiving unintended doses of methotrexate. (Refer to figure below).[5,6]



- Ensure that written medication information leaflets are given to patients and that they contain clear advice about the weekly dosage schedule, not a daily dosing schedule.
- Provide patients with clear written instructions that name a specific day of the week for taking the tablet(s). When possible avoid choosing Monday since it could be misread as "morning."[7]
- As methotrexate can be prescribed at more frequent dosage intervals for some indications in haematology and oncology, the prescriber should include the indication for treatment in all orders or prescriptions for oral methotrexate. This should alert pharmacists and nurses to any potential prescribing errors where once a week dosing was intended.[5,6]
- When dispensing intermittent oral methotrexate dosing at discharge, supply only the quantity required instead of full pack. (i.e. for weekly dosing – supply 4 doses for a month's supply).

Recommendation:

Hospitals and health services develop local guidelines, strategies and education to address the risk associated with prescribing, dispensing and administration of methotrexate.

7.5 Azathioprine and 6-mercaptopurine

Immunomodulatory thiopurines (azathioprine (AZA) and 6-mercaptopurine [6-MP or mercaptopurine]) are employed as second line agents in the management of ulcerative colitis and Crohn's disease; their use is limited by concerns of toxicity.[8]

- Close monitoring is required for patients on azathioprine and mercaptopurine due to the risk of serious, potentially life-threatening adverse effects.[6] The toxicity of azathioprine and 6-mercaptopurine is related to their metabolites, in particular 6-thioguanine (6-GP) and 6-methylmercaptopurine (6-MMP). The relative accumulation of these metabolites depends on genetic polymorphism of the individual enzymes.[8,9]
- Myelosuppression and liver toxicity from thiopurines can occur anytime during their use but is more frequent in the early period of treatment. Blood monitoring for immunomodulator drugs is considered the standard of care, however evidence to support frequency of blood monitoring is limited. Periodic monitoring does not always prevent bone marrow suppression or hepatic toxicity, which may be sudden in onset.[8,9]
- Clinicians should be aware of the following drug interactions due to the risk of severe myelosuppression (refer to AMH or Stockley's Drug Interactions for more detail):
    - Allopurinol: Avoid combination or reduce the dose to one-quarter of the recommended dose.
    - Febuxostat: Avoid combination
    - Trimethoprim or Trimethoprim with sulfamethoxazole (Bactrim®): avoid combination due to an increased risk of haematological toxicity.
    - Clozapine: avoid concomitant use as there is an increased risk of agranulocytosis.
- Patient counselling should also include education about the signs and symptoms of infection and unusual symptoms, which need to be reported to their doctor.[8]
- HSPs should have local protocols and guidelines (including roles and responsibilities of clinicians) relating to the monitoring of patients commencing on this type of therapy including the following aspects:
    - Thiopurine Methyltransferase (TPMT) genotype or phenotype testing prior to commencement of medication.
    - Monitoring parameters (including but not limited to full blood count and liver function tests) and frequency.
    - Provision of education (both oral and written) to patients prior to the commencement of the medication covering the risks associated with the medication and the need for regular blood monitoring.
    - Management of adverse reactions.

Recommendations:

Hospitals and health services maintain local protocols and guidelines, strategies and education to articulate genotype testing, dosage, monitoring parameters, drug interactions and management of adverse reaction related to immunomodulatory thiopurines.

8. Heparin and Other Anticoagulants

There is potential for excessive bleeding with **warfarin, heparin and other anticoagulants**. The incorrect dose or failure to monitor therapy can contribute to this event. The patient's bleeding risk must be determined and documented on the WA Anticoagulation Medication Chart (WA AMC) before commencing anticoagulant therapy. It is recommended that prescribers contact the Haematology team for advice on dosing if required.

All anticoagulants must be prescribed on the WA AMC. The WA Hospital Medication Chart (WA HMC) must be annotated (cross-referenced) to identify when the WA AMC is in use to reduce the risk of duplicated orders or dose omissions. The WA AMC must be kept together with the current active WA HMC in the patient observation folder or similar. *WA Medication Chart Policy (MP 0078/18)*

It is recommended that hospitals and health services undertake the Medication Safety Self-Assessment® for Antithrombotic Therapy in Australian Hospitals which provides a structured risk assessment process that can assist in identifying gaps in current medication safety systems and identify areas for improvement relating to antithrombotic management.

8.1 Warfarin

- Warfarin has the potential to interact with many medications that can affect the International Normalised Ratio (INR). Be aware that changing concurrent medications (by ceasing or adding a medication) or diet may result in changes to INR and the dose of warfarin may require adjustment.
- Two brands of warfarin (Marevan® and Coumadin®) are currently marketed in Australia. These brands are not bioequivalent and have different tablet strengths available.
- All new patients commencing warfarin therapy in WA (in all sectors of medical practice and all pharmacies) should receive Marevan®.
- The alternative and less frequently used brand (Coumadin®) should not be substituted for Marevan® and the two brands should never be co-prescribed. Coumadin® should be prescribed and supplied only to patients already stabilised on Coumadin® therapy.
- Substituting or switching from Coumadin® to Marevan® in stabilised patients requires close monitoring and would normally only be considered if there was a clinical need or when recommencing therapy after a period without Coumadin®.
- Medical, nursing and pharmacy staff should be made aware that the two brands are not bioequivalent, the preference of prescribing Marevan® to warfarin naïve patients and the process to obtain Coumadin® for patients stabilised on Coumadin® therapy prior to admission.

Warfarin Resources

- Guidelines for Anticoagulation using Warfarin
- Living with Warfarin Patient Counselling Booklet.

Recommendations:

Hospitals and health services develop strategies to distinguish between the two preparations (i.e. Marevan® and Coumadin®) when prescribing, dispensing and administering warfarin and must demonstrate local guidelines to articulate dose modification and monitoring requirements of warfarin therapy.

8.2 Heparin

Heparins can be sub-classified as unfractionated heparin (UFH) and the low molecular weight heparins (LMWH) such as enoxaparin, danaparoid and dalteparin.

8.2.1 Prescribing unfractionated heparin

- Ensure that the word '*Units*' is written in full to avoid confusion.

8.2.2 Administration of unfractionated heparin by intravenous infusion

- Double check that the correct number of units has been added to the syringe for infusion and that the infusion rate is consistent with the prescription to ensure the correct dose is administered to the patient.
- Double check the indication for the heparin infusion, as the bolus dose and initial rate will depend on the indication (e.g. venous thromboembolism (VTE) or acute coronary syndrome (ACS))
- It is important to make sure the correct dilution is used. The **standard dilution** is 25,000units in 500mL on the WA Anticoagulant Medication Chart.
- **Fluid Restricted Patients**
  If a patient's fluids require restriction (e.g. congestive heart failure, severe renal impairment) the **fluid restricted dilution** should be used, which is unfractionated heparin 25,000 units in 50mL of sodium chloride 0.9%. This is 10 times more concentrated than the standard dilution in the WA Anticoagulant Medication Chart and if confused may result in rate errors. A specific nomogram has been designed to guide bolus requirements and infusion rates using the fluid restricted dilution.
  It is important to double check the rate change when referring to the fluid restricted patient nomogram. Ensure this is stapled to the WA Anticoagulant Medication Chart so all staff involved in the care of the patient can refer to the appropriate nomogram for rate monitoring and adjustment. Not all sites will require this fluid restricted nomogram; therefore, HSPs will need to assess whether this nomogram is appropriate for use at their site and provide education and resources to all staff as applicable.

8.2.3 Prescribing low molecular weight heparins

- Dose adjustment according to renal function must be considered when prescribing low molecular weight heparins (e.g. enoxaparin, danaparoid and dalteparin).

8.2.4 Monitoring heparins

- The activated partial thromboplastin time (aPTT) has been used most widely for monitoring of therapeutic doses of UFH in VTE. A target ratio versus midpoint of normal range of 1.5–2.5 is employed.
- Standardisation between laboratories in the control of heparin therapy using the aPTT has not been achieved across all hospitals because of the considerable variation observed between reagents and instruments used to measure the aPTT.
- Platelet counts should be monitored every one to two days when prescribing heparin therapy. Heparins can cause thrombocytopenia which does not appear to be dose-related.
- A baseline renal function test and full blood count should be done before commencing a LMWH. Dosing is weight based and must be modified in patients with renal insufficiency (creatinine clearance ≤30mL/minute). If monitoring of LMWH is undertaken, it is recommended that an anti-Xa chromogenic assay is used. Alternatively the WHO Standard for LMWH may be used. Samples taken at 4–6 hours after subcutaneous administration are suitable for assessment of peak anti-Xa level.

Recommendation:

Hospitals and health services should maintain local guidelines, strategies and education to address the risks associated with the prescribing, dispensing, preparation and administration of heparins.

8.3 Direct-Acting Oral Anticoagulants (DOACs)

- Direct-acting oral anticoagulants include:
  - rivaroxaban,
  - dabigatran and;
  - apixaban.

DOACs were previously known as NOACs (New Oral Anticoagulants). The following key points should be considered when prescribing DOACs.

- Apixaban and rivaroxaban have no specific reversal agent.
- Idarucizumab (Praxbind®) is a specific reversal agent for dabigatran. It is a high cost medication and may not be available at all sites. Please refer to Critical Medication List
- Care is required when selecting patients for newer anticoagulant treatment and the following must be considered:
  - Dose adjustment is required in renal impairment (creatinine clearance ≤ 50mL/minute)
  - Use with caution in elderly (> 75 years) and low body weight (< 50 kg).
  - Check for drug interactions and use of other anticoagulants, antiplatelet agents and non-steroidal anti-inflammatory drugs (NSAIDs).
  - Check for any existing co-morbidities with high risk of bleeding.
  - Plan ahead for surgery and other procedures.
  - Prescribe on WA Anticoagulation Medication Chart in the regular dose orders section (reduces the risk of unintended concurrent anticoagulant prescribing).

DOAC Resources

- Clinical Excellence Commission NOAC Guidelines for Non-Vitamin K Antagonist Oral Anticoagulants[11]
- Living with a direct-acting oral anticoagulant (DOAC) – patient counselling booklet

Recommendation:

Hospitals and health services develop local guidelines and education which articulate dose modification and monitoring requirements of DOAC therapy.

9. Safer systems

Implementing safer systems can safe guard against medication errors. Examples include making errors visible by ensuring oral syringes are used for oral administration of liquids, and standardising order communication to avoid potential confusion with the intended medication, dose, route or frequency.

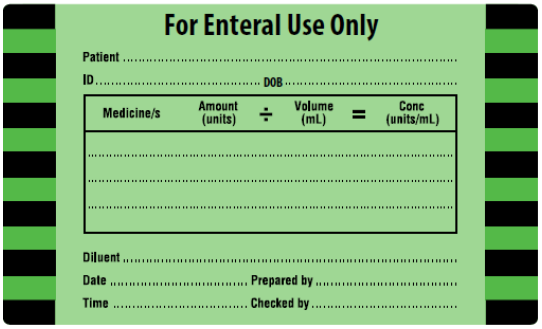
9.1 Safe administration of oral, enteral, and nebuliser liquid preparations

There is an identified risk of serious "wrong route" medication errors resulting from accidental parenteral administration of solutions intended for an oral, enteral or nebuliser delivery and incidents have been reported nationally and internationally.

Preparations intended for oral, enteral or inhaled administration which have been drawn up into parenteral luer-lock syringes and inadequately labelled have resulted in clinical incidents, specifically errors of administration via the wrong route. Administration of medications intended for oral, enteral or inhalation by the parenteral route results in a rapid absorption of the therapeutic agent into the blood stream. This can lead to a heightened risk of catastrophic outcomes which are often difficult to reverse.

9.1.1 Administration of oral or enteral solutions

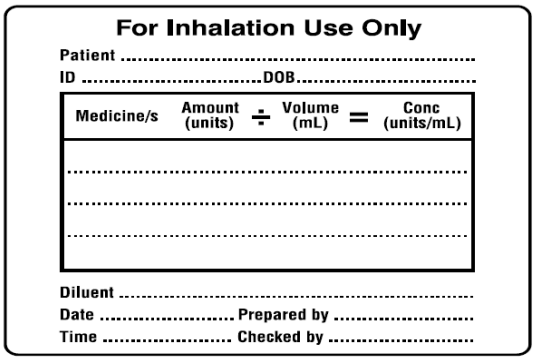
- HSPs must make oral/enteral syringes available to all clinical areas.
- Syringes should be:
  - Manufactured with non-luer connectors/taper that prevents them from being attached to a parenteral luer-fitting injectable systems.
  - Distinguishable by colour (plunger or barrel) from parenteral syringes.
  - Labelled appropriately to distinguish them from parenteral preparations (i.e. "For Oral/Enteral Use Only").
  - Compatible with administration sets designed for enteral feeding purposes. These sets should also be non-luer and distinguishable by colour from parenteral administration sets. Enteral administration sets should be clearly labelled *"For Enteral Use Only*".
  - Compatible with devices to assist withdrawal of doses from liquid containers, such as transfer straws and stoppers which avoid the use of needles to draw up liquids.
  - Stored in clearly identified, separate storage areas from parenteral syringes.
- HSPs must make '*For Enteral Use Only'* labels available to all clinical areas as per National Standard for User Applied Labelling of Injectable Medicines, Fluids and Lines.



- HSPs should ensure clinical staff receive education on safe practices for administration of oral/enteral medications using the ISO compliant systems and are aware of the requirement for labelling syringes before administration using the 'For Enteral Use Only' label.

9.1.2 Administration of solutions for inhalation

- IT is recommended that HSPs to adopt the following requirements for liquids intended for inhalation:
  - Purchased in single-use nebules wherever possible to avoid the need to draw solutions into a syringe prior to administration.
  - Where stock solutions must be used, doses should be drawn up into a non-luer syringe (oral/enteral syringe) using a compatible non-luer straw and expelled into the inhalation nebuliser pots.
  - Where a nebuliser solution must be measured from an ampoule, the dose needs to be measure using a Nutrisafe 2 connection with needle attached to the non-luer syringe.
  - If a medication is to be drawn up into a syringe, the syringe used must be labelled with the intended route of administration – "For Inhalation Use Only".
  - HSPs must make 'For Inhalation Use Only' labels available to all clinical areas as per National Standard for User Applied Labelling of Injectable Medicines, Fluids and Lines.



  - Where nebulised antimicrobials are used in a clinical setting, hospitals should have local guidelines in place that are readily available. HSPs must ensure clinical staff receive education on safe practices for administration of inhaled medications using nebules or the appropriate syringe and the requirement for labelling syringes before administration using this label.

Recommendation:

Hospitals and Health Services demonstrate strategies to address the risk associated with the administration of oral, enteral and nebuliser liquid preparations as outlined above.

9.2 Standardisation of terminology, abbreviations and symbols in the prescribing and administration of medicines

The use of inconsistent, ambiguous or non-standard abbreviations and terminology in the prescribing of medicines is a major cause of medication errors. Standardisation of terminology and abbreviations has been identified as an important strategy in reducing these errors.

- HSPs should adopt the *Recommendations for terminology, abbreviations and symbols used in medicine documentation* (the Recommendations) developed by the Australian Commission for Safety and Quality in Health Care which provide:
  - A standard for safe, clear and consistent terminology for medicines
  - A list of safe terms, abbreviations and dose designations for medicines (see the – summary sheet.)
- The Recommendations are applicable to:

    - All medication orders or prescriptions that are hand written, pre-printed, computer generated (printed hard copy) or electronic.
    - All communications and records concerning medicines including telephone, verbal orders, prescriptions, medication administration records and labels for drug storage.
- There may be specific circumstances where other terminology may be considered safe. However before these are included in local policies the standards and principles outlined in the Recommendations should be applied.

Recommendation:

Hospitals and Health Services update their current policies for prescribing terminology to comply with the principles and standards as outlined in Recommendations for terminology, abbreviations and symbols used in medicine documentation.

9.2.1 User Applied Labelling of injectable Medicines, Fluids and Lines

Labelling is a recognised risk in the safe administration of injectable medications. Preparation of injectable medications for bolus injections or infusion is complicated by multiple opportunities for error. Labelling of injectable medications is often not done or incomplete, omitting information such as name of medication, dose, patient name or time of preparation.
It has been shown that errors in injectable medication administration are less likely to occur when a single person is responsible for preparing and labelling each injectable medication and that medication in well labelled syringes are more likely to have been prepared correctly.

- HSPs must adopt the *National Standards for User-applied Labelling of Injectable Medicines, Fluids and Lines* (the Labelling Standards) which
    - Assist health care professionals to identify the correct medicine and/or fluid and its correct administration/route/conduit at all times
    - Set out requirements for label inclusions and label placement
- The Labelling Standard is based on the following practice principles:
    - All medicines and fluids removed from the manufacturer's or hospital pharmacy's original packaging must be identifiable
    - All containers (e.g. bags, syringes) containing medicines leaving the hands of the person preparing the medicine must be labelled
    - Only one medicine should be prepared at a time and labelled before the preparation and labelling of a subsequent medicine
    - Any medicine or fluid that cannot be identified (e.g. an unlabelled syringe or other container) is considered unsafe and should be discarded

9.2.1.1 Western Australian modification to the Labelling Standard

Stippling to Beige, Blue and Red Labels

- The Labelling Standard specifies a 70% stipple (70% shade of the labels primary colour) to the background of container, conduit and line labels.
- Following feedback regarding the legibility of written information on certain coloured labels, beige (subcutaneous), red (intra-arterial) and blue (intravenous) container, conduit and line labels used in WA will employ a stipple of 50% to the background area (the area inside the border) of the label. Border colours must not be altered from those specified in the Labelling Standard.

Recommendation:

Hospitals and health services maintain their current policies for administration and preparation requirements of injectable medicines, fluids and lines to comply with the principles and standards

as outlined in the National Standard for User-applied Labelling of Injectable Medicines, Fluids and Lines.

9.3 Standardisation in paediatric prescribing

Children are more prone to medication errors and are more vulnerable to harm from the effects of medication errors than adults. Dose calculation errors are one of the most common types of medication errors in children. Documenting patient weight and age, and adopting good prescribing, dispensing and administration practices can prevent patient harm associated with dosing errors.

- HSPs must adopt the requirements for all prescriptions for all children (including neonates) as outlined in the "Position statement on paediatric prescribing" developed by the Australian Commission for Safety and Quality in Health Care which promote best practice in prescribing, dispensing and administering of medications to paediatric patients.
- The Position statement only covers children 12 years and under, however it would be good practice to extend the requirements of this position statement to all paediatric patients.
- The following information should be clearly documented on all prescriptions for children:
  - Age and/or date of birth
  - Current body weight
  - Basis for the dose calculation (such as mg/kg)
  - Dose in unit of mass for example 150mg per dose

Recommendation:

Hospitals and health services revise their current policies for prescribing in paediatric patients to include age and/or date of birth, current body weight, basis for the dose calculation and dose in unit of mass.

Appendix 1 - High Risk Medication Risk Mitigation Strategies

1. Introduction

Medication errors are defined as any preventable event that may cause or lead to inappropriate medication use or patient harm while the medication is in the control of the healthcare professional, patient, or consumer.[11] They can occur at any stage of the medication-use system, including prescribing, dispensing, preparation, administration, monitoring and storage. Errors may also occur during transcription of an order or communication of medication management for a patient when transferring care to a primary health care provider.

A system for reporting and reviewing errors is an essential component of a medication safety system; the goal is to enhance patient safety and prevent patient harm. When a medication error occurs, it is important that root causes are explored. Organisations should investigate why the error occurred and what system changes can be instituted to prevent it from happening again.

A culture of patient safety, based on the principles of just culture, provides a solid foundation for safe and effective systems and teamwork. In a just culture, safety is valued, reporting of safety risks is encouraged without penalisation, and the staff, leadership, and executive team are held accountable using a clear and transparent process that evaluates the errors.

Learning about medication errors from sources external to one's hospital is a proactive way to improve patient safety. It is recommended that Health Service Providers (HSPs) share information about medication errors and their causative factors because of the risk of a similar incident occurring at another site. Organizations should prospectively design and implement strategies to reduce certain types of errors in order to prevent patient harm.

This document provides some medication risk mitigation strategies assist HSPs to implement strategies and respond to errors.

2. Reducing or eliminating the risk of error[12]

- Ensure therapeutic guidance in the form of protocols and guidelines are available for prescription and administration of high risk medications.
- Restrict supply of high risk medications to areas of specified use where possible.
- Ensure the safest means of completing a task is efficient and easily followed.
- Strategies must be applicable in various settings of the hospital/service.
- Employ a fully independent double check, carried out by a second clinician, for key high risk medicines where locally identified.
- Ensure all clinical staff have the qualifications and skills appropriate to the prescription, supply, preparation and administration tasks they undertake.
- Remove opportunity for error by separation of error-prone tasks from one another in time or place.
- Ensure that strengths of medicines are clearly visible and clarified in terms of the dosage unit or dose per volume of liquid e.g. 'mg/mL' as opposed to 'mg/5mL'.
- Ensure the route of administration is clearly identified and that oral/enteral dispensers are used to prepare and administer all liquid medicines by routes other than parenteral injection.
- Remove the need for rapid mathematical calculation and reduce options and choices by standardising concentrations of medicines available in liquids/solutions.
- Purchase for safety as far as possible;
    - review label clarity,

    - ensure visual product discrimination,
    - avoid look a-like and sound a-like medications,
    - avoid similar drug names,
    - avoid patient's own medication unless prescriber and pharmacist have reviewed for safety,
    - ensure appropriate management of medication shortages, and
    - limit amount of manipulation and associated equipment needed for administration of medications.
- Set mechanical devices (i.e. smart infusion pumps) so that they default to the safest setting.
- Low level risk-reduction strategies (i.e. staff education and passive information) should be used together with high level risk reduction strategies such as forcing functions and fail safes (such as limiting access or use, constraints, barriers or standardisation).
- Monitor use of medications by collecting data to determine the effectiveness of risk-reduction strategies for high risk medications.
- Communicate results with appropriate committees, disciplines and individuals within the HSP.

3. Making errors transparent

- Regularly review local and wider system incidents and near-misses.
- Use prospective analysis and redesign of systems to mitigate identified issues and use site specific methods to feedback relevant information to staff.

4. Minimising the consequences of error

- Monitor patients carefully according to high risk medication protocols.
- Keeping low concentration and/or low volume high risk medications so if inadvertently administered the risk of harm would be minimised.

5. Monitoring patients receiving high-risk medicines

- Patients receiving high risk medicines are vulnerable to medication error if not closely and regularly monitored.
- Requirements for therapeutic drug monitoring of high risk medicines should be written into local protocols for each relevant drug. Promptly access laboratory results which may influence decision-making for these medications, such as drug levels, renal and liver function tests.

6. Reviewing and learning for improvement

- All incidents regarding high risk medicines must be reported via the Clinical Incident Management System (Datix CIMS) to ensure appropriate implementation of risk management or improvement strategies. (As per *Clinical Incident Management Policy* OD 0611/15)
- Available data sources such as clinical incident monitoring system data, internal reports and published articles should be reviewed to identify actual or potential risks associated with high risk medicines.
- If local vulnerability is identified, risk management techniques will be used to prevent harm or mitigate impact should errors occur.

7. Strategies for Safeguarding High Risk Medications[13]

Key Strategies	Description	Examples
Failure Mode and Effects Analysis (FMEA) and Self Assessments	Proactively identify the ways that processes or medication-related equipment can fail, why it might fail, how it might affect patients and how it can be made safer; assess current systems and practices against best practices.	• Perform an FMEA on a new high-alert medication before initial use. • Perform an FMEA on a new infusion pump being considered for purchase. • Perform a FMEA on a high risk process associated with medication use. • Perform an FMEA on the use of alternative medications during a drug shortage.
Forcing Functions and Fail Safes	Employ procedures or equipment design features that will: • Prevent something from happening until certain conditions are met (forcing function). • Prevent malfunctioning or unintentional operation by reverting back to a predetermined safe state if a failure occurs (fail safe).	• Use of oral syringes that cannot connect to IV tubing ports. • Use epidural tubing without ports.
Externalise or Centralise Error-Prone Processes	Transfer error-prone tasks to an external site or centralised areas to help ensure they are completed in a distraction-free environment by those with expertise, with appropriate quality control checks in place.	• Use commercially available products. • Have a centralised pharmacy IV admixture service. • Use a specialised external service to prepare complicated solutions.
Limit Access or Use	Use constraints to restrict access to certain medications or error-prone processes; require special education or conditions for prescribing, dispensing, or administering a particular medication; require special authorisation for participation in certain tasks.	• Require special education/credentialing for the ordering, preparation, and use of certain high-alert medications (e.g. chemotherapy). • Carefully select the medications, concentration and quantities of medications for imprest stock. • Establish parameters to change IV therapy to oral therapy as soon as possible to limit IV access. • Limit the administration of certain medications unless certain criteria are met.

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