

High-Risk Medicines Management

Summary This Policy Directive outlines the requirements for the safe management and use of high-risk medicines.

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HIGH-RISK MEDICINES MANAGEMENT

POLICY STATEMENT

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

This Policy Directive includes individual policy standards for the following high-risk medicines: hydromorphone, methotrexate (oral), neuromuscular blocking agents, opioids, paracetamol, potassium (intravenous), vincristine and anticoagulants.

SUMMARY OF POLICY REQUIREMENTS

All public health facilities must maintain a high-risk medicines program in accordance with NSW Health Policy on Medication Handling in NSW Public Health Facilities.

All public health facilities must maintain as part of the high-risk medicines program, a specific high-risk medicines register. The specific high-risk medicine register must include medicines used locally within the facility identified to be at ‘high-risk’ of misadventure.

Local protocols must be developed for all identified high-risk medicines specified on the register. The protocols are to be developed in consultation with relevant specialists and overseen and approved by the District or Health Service Drug and Therapeutics Committee(s) (however named). Protocols must include a timeframe for review.

Each high-risk medicine protocol must include patient monitoring which is relevant and appropriate for the patient’s clinical circumstances. This is to ensure a timely response to adverse events or side effects associated with drug treatment.

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

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

REVISION HISTORY

Version	Approved by	Amendment notes
November-2020 (PD2020_045)	Deputy Secretary, People, Culture and Governance	Revised to incorporate an Opioid Standard
December-2019 (PD2019_058)	Deputy Secretary, People, Culture and Governance	Revised to incorporate an updated Hydromorphone Standard.
August-2015 (PD2015_029)	Deputy Secretary, Governance, Workplace and Corporate	Revised to a) incorporate hydromorphone, methotrexate (oral), neuromuscular blocking agents, paracetamol; b) update potassium (intravenous), vincristine and anticoagulants. Replaces PD2012_003, PD2009_009 and PD2005_624.
January-2012 (PD2012_003)	Director-General	High-Risk Medicines Management
February-2009	Director-General	Paracetamol Use

(PD2009_009)		
September-2005 (PD2005_624)	Director-General	Methotrexate-Safe Use of Oral Methotrexate

ATTACHMENTS

1. High-Risk Medicines Management: Procedures.

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1 BACKGROUND

1.1 About this document

This Policy sets out the requirements for the high-risk medicines register and standard management of the specified high-risk medicines. It addresses risks associated with prescribing, dispensing and administration of high-risk medicines.

This Policy supports requirements for Standard 4 (Medication Safety) of the National Safety and Quality Health Service Standards. Although most medicines have a wide margin of safety, a few drugs have a high risk of causing patient injury or death if they are inadvertently misused or administered incorrectly. Errors with these high-risk medicines may not be more common than those from other groups but their consequences can be significant¹.

1.2 Related documents

This Policy is to be read in conjunction with the following NSW Health Policies:

- [Incident Management Policy](#)
- [Medication Handling in NSW Public Health Facilities](#)
- [Safe Administration of Liquid Medicines by Routes other than Injection](#)
- [Pharmaceuticals - Preparation in NSW Public Health Facility Pharmacy Services](#)
- [Prevention of Venous Thromboembolism](#)
- [User applied Labelling of Injectable Medicines, Fluids and Lines](#)

1.3 Key definitions

Must

Indicates a mandatory action requiring compliance by staff at public health facilities, in accordance with a legislative requirement and/ or a NSW Health policy or directive.

Should

Indicates a recommended action that should be followed unless there are sound reasons for taking a different course of action.

Activated partial thromboplastin time (aPTT)

An indicator for measuring the efficiency of both the intrinsic (now referred to as the contact activation pathway) and the common coagulation pathway. It is used in conjunction with prothrombin time which measures the extrinsic pathway.

Anticoagulant

Any agent used to prevent the formation of blood clots including oral agents, such as warfarin or a non-vitamin K oral antagonist anticoagulant (NOAC), and other medications which are injected into the vein or under the skin such as heparin.

Bridging anticoagulant therapy

The administration of a short-acting anticoagulant, including subcutaneous low-molecular-weight heparin or intravenous unfractionated heparin, during interruption of oral anticoagulant therapy.

Dose error reduction software

Infusion device software that is capable of alerting the user to unsafe dose limits and programming error if standard concentrations and dose limits have been programmed into the pumps library³.

Hepatotoxicity

The capacity of a drug, chemical, or other exposure to produce injury to the liver.

Hypokalaemia

Lower than normal blood concentration of potassium.

High-Risk Medicine

High-Risk Medicines are those that have a high risk of causing injury or harm if they are misused or used in error. Error rates with these medications are not necessarily higher than with any other medicines, but when problems occur, the consequences can be more significant¹.

International Normalised Ratio (INR)

The INR is the ratio of the prothrombin time to a normal (control) sample. It is used to monitor the effects of warfarin.

Minibag

A small volume intravenous infusion bag, usually containing 50 or 100 mL of sterile fluid.

National Inpatient Medication Chart (NIMC)

The standard inpatient medication charts (adult and paediatric) used in NSW public hospitals to promote standardisation and consistency in documentation of the prescription and administration of medications.

Oral morphine equivalent daily dose (oMEDD)

The oMEDD refers to the equivalent daily dose of oral morphine. This is calculated using the total dose of opioid medication the patient has received in the last 24 hours and using a conversion factor for the specific opioid(s) used in the patient. Calculating the oMEDD helps illustrate the relative potency of different opioids the patient has been receiving and helps to effectively prescribe, manage and taper opioid medicines.

Pharmaceutical review

A minimum standard of systematic appraisal of all aspects of patients' medication management conducted or supervised by a qualified and suitably trained health professional (ideally a pharmacist) acting as part of a multidisciplinary team. It includes objective review of medication prescribing, dispensing, distribution, administration,

monitoring of outcomes and documentation of medication related information in order to optimise Quality Use of Medicines².

Pre-mixed intravenous solution

Intravenous solutions prepared in a regulated compounding facility with full labelling and expiry dating.

Second Person Check

The second person checking the preparation and administration of a medication is responsible for:

- Confirming the identity of the patient
- Confirming the selection of the correct medication and fluid
- Confirming that the dose is appropriate and the calculations are correct
- Confirming that a rate limiting device such as an infusion pump has been correctly set
- Countersigning the administration on the medication chart against that of the administering person.

(Refer to NSW Health Policy on Medication Handling in NSW Public Health Facilities for further information on requirements for second person checks).

A second person check for high-risk medicines must be conducted using independent double check principles. That is, clinicians separately check (alone and apart from each other, then comparing results) each component of prescribing, dispensing, and verifying the medicine before administering it to the patient¹.

Tall Man Lettering

Use of a combination of lower and upper case letters to highlight the differences between look-alike drug names, helping to make them more easily distinguishable¹.

Therapeutic Drug Monitoring

Refers to the individualisation of dosage by maintaining plasma or blood drug concentrations within a target range (therapeutic range or window)³.

Time-Out

The suspension of activity immediately before commencing a procedure by the team or single operator involved in the procedure to undertake a final verification of the correct patient, procedure, site, drug and route of administration. For the purposes of administering cytotoxic chemotherapy, all doses should be checked by a second person with the appropriate training and skills².

2 IMPLEMENTATION

2.1 NSW Clinical Excellence Commission

- Monitors trends of medicine related incidents.

- Provides supporting tools and information on safety and quality around high-risk medicine use, available at: www.cec.health.nsw.gov.au/patient-safety-programs/medication-safety/high-risk-medicines
- Monitor implementation of the High-Risk Medicines Management Policy.

2.2 Chief Executives

- Assign responsibility, personnel and resources to implement the policy.

2.3 Directors of Clinical Governance

- Ensure systems are in place to:
 - Implement the mandatory high-risk medicine management policy and standards.
 - Monitor compliance with the high-risk medicine management policy and standards.
- Report implementation of this policy to the NSW Clinical Excellence Commission by returning the Implementation Checklist ([Appendix 5.3](#)) within 12 months of publication of the policy.

2.4 Drug and Therapeutics Committees

- Maintain a current high-risk medicines register for each location, facility or group of facilities. Develop a strategy for a review of medicines included on the register.
- Ensure medication safety is a key consideration in all formulary decisions and that when a medicine which is considered to be high-risk is added to the formulary, then it is included in the high-risk medicines register.
- Review reports on high-risk medicine incidents, policy compliance rates and formulate corrective action if indicated.
- Refer issues requiring corrective action to the Local Health District Clinical Council and associated Quality Committees.
- Refer medicines with specific identified safety risks through the NSW Therapeutic Advisory Group to the Medication Safety Expert Advisory Committee for consideration of approval to be included as a Policy Standard in the High-Risk Medicines Management Policy.

2.5 Heads of Department

- Assign responsibility for implementation of the high-risk medicine management policy and standards.
- Ensure products and devices that support high-risk medicines safety strategies are available.
- Ensure service and models exist to facilitate compliance with safe practices in managing high-risk medicines.
- Support high-risk medicines monitoring activities.

2.6 Clinical staff involved in medication management

- Comply with this Policy and the policy standards for high-risk medicines.
- Follow the local high-risk medicine protocols.
- When prescribing and supplying high-risk medicines, give clear advice to ensure safe administration.
- Maintain knowledge base relevant to area of practice.

3 STANDARDS

All public health facilities must have a high-risk medicines management program in place, which includes systems for the management of the respective medications' handling in accordance with NSW Health Policy on Medication Handling in NSW Public Health Facilities.

The high-risk medicines program must include the following minimum elements.

3.1 A High-Risk Medicines Register

A High-Risk Medicines Register consists of a list of drugs or drug groups used within the health facility considered to be at 'high-risk' of misadventure. The register must be maintained at each facility or group of facilities. The "A PINCH" table ([Appendix 5.1](#)) lists some essential medicine groups or medicines to be considered for inclusion in the high-risk medicines register. The "A PINCH" table is not an exhaustive list, there may be other medicines used within the facility that are considered to be high-risk.

The District or Health Service Drug and Therapeutics Committee (however named) is responsible for:

- Assessing and determining the medicines to be included in the register
- Maintaining the register and associated protocols.

Before a new medicine is placed on the local health facility formulary by the District or Health Service Drug and Therapeutics Committee, the potential for error with that medication should be investigated in the literature. 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.

Protocols are to be prepared in consultation with relevant specialists, aligned with NSW Health Policy on Medication Handling in NSW Public Health Facilities, and approved by the District or Health Service Drug and Therapeutics Committees.

Protocols are to clearly articulate:

- Responsibilities for the 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 amendment
- Whether doses should be rounded off to the nearest whole number or dosage unit when appropriate and possible
- 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.

Processes must be in place to notify relevant clinical staff of changes to the register and the associated protocols.

3.2 Standards for prescribing and administering high-risk medicines

The following standards for prescribing and administering high-risk medicines apply:

- Accurate patient weight should be documented on the medication chart for all patients
- The route of administration must be clearly identified. The use of multiple routes of administration in the one prescription should be avoided for the same medicine (for example, intravenous/ oral)
- Where required, strengths of medicines must be clearly visible in terms of the dosage unit or dose per volume of liquid, for example, mg per mL
- The prescriber should complete the 'Indication' for use box on the National Inpatient Medication Chart (NIMC) for high-risk medicines
- Where Electronic Medication Management systems are in use, the indication for use should be documented according to local Electronic Medication Management guidelines
- Dose adjustments must be considered when prescribing for patient groups such as overweight, obese or underweight patients, and patients with existing clinical conditions (such as renal or hepatic impairment) that may affect drug metabolism and excretion
- Therapeutic guidelines should be followed where dosing is complex and duration of therapy substantially increases the risk of toxicity, for example aminoglycosides
- Where a second person check or witness is required according to NSW Health Policy on Medication Handling in NSW Public Health Facilities, this policy, or local protocol, the check should be conducted using independent double check principles. That is, clinicians separately check (alone and apart from each other, then comparing results) each component of prescribing, dispensing, and verifying the medicine before administering it to the patient¹. For domiciliary care and

patient transfers refer to NSW Health Policy on Medication Handling in NSW Public Health Facilities

- Medication reconciliation processes should be prioritised for these patients.

3.3 Strategies to minimise risk with high-risk medicines

The District or Health Service Drug and Therapeutics Committee must develop strategies related to high-risk medicine handling.

At a minimum, strategies related to high-risk medicines handling must include:

- Access to pre-measured medicine doses in a form that requires minimal manipulation prior to administration
- Access to standardised concentrations of medicines in solution
- Mechanisms to ensure mechanical infusion devices default to the safest setting
- Alerting clinicians in clinical handover to the use of any high-risk medicines
- Use of shelf reminders, checklists and alerts and, where possible, these should be built into information technology systems
- Specific storage or practice requirements (see [Appendix 5.2](#))
- A regular review of local and wider system incidents and near-misses and the use of prospective analysis and re-design of systems to prevent reoccurrence of the same errors.

3.4 References

1. American Pharmacists Association, Medication Errors. 2nd ed 2007, Washington DC American Pharmacists Association.
2. NSW Clinical Excellence Commission. Medication Safety Self Assessment for Australian Hospitals.
3. Birkett, D.J., Pharmacokinetics made easy, Therapeutic drug monitoring. Australian Prescriber 1997. 20: p. 9-11.

4 INDIVIDUAL HIGH-RISK MEDICINE MANAGEMENT STANDARDS

The following policy standards outline the **minimum** actions required to mitigate identified risks for particular medicines or groups of medicines. They do not contain clinical guidance on therapeutic use. These standards do not preclude the District or Health Service Drug and Therapeutics Committees from including additional actions to mitigate risk or inclusion of clinical guidance on therapeutic use in locally developed protocols.

4.1 Anticoagulants

Anticoagulant medicines are used extensively in clinical practice. They act through targeting a number of different proteins that may limit or prevent thrombus formation.

Anticoagulant medicines have a narrow therapeutic index and over or under anticoagulation can result in significant adverse patient outcomes¹.

Errors involving anticoagulant medicines can include:

- Duplication of therapy. For example, ordering pharmacological venous thromboembolism (VTE) prophylaxis for patients who are receiving therapeutic anticoagulation
- Use of a therapeutic dose when a prophylactic dose was intended and vice versa
- Failure to adjust an anticoagulant dose according to patient factors. For example, haematology parameters, biochemistry, estimated creatinine clearance, age
- Incorrect protocol use. For example, administration of a concentration of unfractionated heparin solution contrary to the protocol resulting in administration of an incorrect dose
- Incorrect use following discharge. For example, inadequate patient and/ or carer education for patients being discharged on anticoagulants resulting in adverse events.

This standard outlines the minimum actions required to mitigate risks associated with anticoagulant use. This standard does not contain clinical guidance on anticoagulant medicine use.

4.1.1 Standards

Risk mitigation strategy

District or Health Service Drug and Therapeutics Committee protocols must include the following anticoagulants where they are in use: unfractionated heparin, warfarin, low molecular weight heparin and non-vitamin K antagonist oral anticoagulants (NOAC).

District or Health Service Drug and Therapeutics Committee must approve any local protocols and ensure inclusion of the following information.

- The requirement for recording accurate patient weight (where practical) for all patients receiving anticoagulant therapy.
- Instructions for estimating renal function.
- Evidence-based dosing guidelines and guidance for prescribing (see [Prescribing](#)).
- Managing anticoagulation in patients:
 - With absolute or relative contraindications to anticoagulation
 - With previous coagulation problems, for example; bleeding, heparin induced thrombocytopenia (HIT)
 - With bleeding risk, for example, planned surgery, platelet dysfunction
 - Who are pregnant or breastfeeding.
- Monitoring for and the management of HIT.

- Monitoring for thrombocytopenia or for any new or extending thrombosis in patients receiving or recently discontinued from heparin.
- Management of bleeding in patients receiving anticoagulant medicines including referral processes.
- Instructions for switching to and from other anticoagulant medicines.
- Instructions (or reference to the local perioperative guidelines) for managing anticoagulants during the perioperative period including:
 - Medical circumstances where bridging anticoagulation therapy is indicated
 - Timing of stopping and restarting of anticoagulant medicines where required
 - Perioperative management of patients receiving antiplatelet therapy
 - Timing of neuraxial anaesthesia and regional block placement, as well as the removal of neuraxial and nerve catheters in patients receiving anticoagulant therapy
 - The need for specific consideration of individual patient and procedural risk of bleeding.
- Any specific training, qualifications, skills or competencies required to prescribe or administer anticoagulants.
- Requirements for patient and / or carer education (see [Patient information / education](#)).

Additional protocol requirements for specific anticoagulants;

Intravenous unfractionated heparin

Where possible intravenous unfractionated heparin protocols should be standardised within facilities and Local Health Districts. Where it is not possible to standardise, protocols must address how risks associated with patient transfer between and within facilities will be mitigated.

The District or Health Service Drug and Therapeutics Committee must approve any local protocols and ensure inclusion of:

- Indications for intravenous unfractionated heparin
- Clinical areas where intravenous unfractionated heparin may be used
- Instructions for unfractionated heparin dose calculation, including advice on preferred use of actual body weight, ideal body weight or medically approved adjusted body weight in dose calculations
- Recommended loading doses to be used for each indication
- Explicit doses and corresponding infusion rates for each indication
- Requirements for monitoring coagulation status
- Therapeutic range for activated partial thromboplastin time (aPTT) (in consultation with local laboratory)

- Dose adjustments based on aPTT results
- Procedures for reversal of anticoagulation.

Warfarin

The District or Health Service Drug and Therapeutics Committee must approve any local protocols and ensure inclusion of the following information.

- Guidelines for dosing, taking into account:
 - Bleeding risk factors
 - Patient age
 - International Normalised Ratio (INR) results
 - Presence of medical problems. For example, heart failure, liver disease, severe infection, recent major surgery, reduced oral intake, nutritional status and concomitant interacting medication.
- The timing of blood collection for INR testing.
- The management of a high INR result in patients receiving warfarin whether or not they are bleeding and instructions for warfarin reversal.

Prescribing

- The prescriber must determine if a female of child bearing age is pregnant or breastfeeding. If there is any doubt, a pregnancy test should be ordered.
- The indication for anticoagulation and therapeutic targets where appropriate, must be documented in the health care record. Details should include the anticoagulant name, dose, intended duration of therapy, timeframe for review and whether anticoagulation is newly initiated or a continuation of previous therapy.
- When assessing VTE risk, the prescriber must ascertain if the patient is already receiving any other anticoagulant medicines.
- Where Electronic Medication Management systems are in use, anticoagulant prescribing should be according to local protocol.
- Where National Inpatient Medication Charts (NIMC) are in use, any dedicated sections for warfarin, VTE Prophylaxis and Regular Medicines must be used for anticoagulant medicine prescribing according to the Australian Commission on Safety and Quality in Health Care NIMC User Guide.
- In adult patients creatinine clearance should be estimated using the Cockcroft-Gault formula prior to initiating renally excreted anticoagulants.

Storage and supply

- Where unfractionated heparin solutions are required, commercially prepared pre-mixed solutions must be used wherever possible.
- Where ampoules of concentrated unfractionated heparin injection are available as imprest stock, a single strength should be available.

Administration

- A second person check is required for administration of warfarin and parenteral anticoagulants.

Patient monitoring

- Instructions for monitoring patients for bleeding must be recorded in the patient health care record. For example, laboratory tests, clinical observation requirements and actions to be taken.
- Patients on anticoagulants who fall are at an increased risk of bleeding and serious trauma including brain injury and will require close observation and monitoring according to local post-fall guide.

Pharmaceutical review

- Where possible all patients receiving an anticoagulant medicine should have a pharmaceutical review.

Patient information / education

- Patients and/ or their carer who are discharged home on anticoagulant therapy should be provided with verbal and written information on their medication.
- Information and education should address:
 - Name and dose of anticoagulant
 - Intended duration of therapy and timeframe for specialist review
 - How to identify bleeding, who to contact and action to be taken
 - What to do in the case of a missed dose
 - Instruction for any laboratory testing and review
 - Any medication or food interactions and other lifestyle factors that influence therapy
 - Any specific storage and administration instructions.
- Patients and/ or their carer must be given the opportunity to discuss anticoagulant therapy with a health practitioner.
- Patients on warfarin should be provided with either a warfarin booklet for tracking warfarin therapy and results, or an update to an existing warfarin book to record INR results during the hospital stay.
- Provision of anticoagulant education should be document in the health care record and/ or in the designated section on the NIMC.
- Professional Health Care Interpreters should be utilised for patient education for patients and/ or carers who are not fluent in English or who are Deaf.

4.1.2 References

1. Therapeutic Guidelines LTD. *eTG Complete* 2014.

4.2 Hydromorphone

Hydromorphone is a potent opioid frequently used to treat moderate to severe, acute or chronic pain. Hydromorphone is 5 to 7 times more potent than morphine. Due to its high potency, errors with this medicine may result in serious adverse patient outcomes.

Incidents involving confusion between morphine and hydromorphone have occurred, including fatal incidents involving inadvertent administration of hydromorphone instead of morphine. Hydromorphone is available in a variety of strengths and formulations (short acting and long acting). Dose calculation errors using the high-concentration injectable hydromorphone can result in an overdose.

This standard outlines the minimum actions required to prevent prescription and administration errors. This standard does not contain clinical guidance on therapeutic use of hydromorphone.

4.2.1 Standards

Risk management strategy

The District or Health Service Drug and Therapeutics Committee must approve any local protocols and ensure inclusion of the following:

- A statement that hydromorphone is more potent than morphine.
- A warning statement that initiation of hydromorphone in opioid naïve patients is hazardous and rarely warranted and that specialist advice is required.
- A restriction on prescribers permitted to initiate hydromorphone. Hydromorphone initiation must be restricted to those prescribers with the appropriate qualifications and expertise.
- Reduced starting doses for patients with risk factors such as asthma, obstructive sleep apnoea or those receiving other medications that can potentiate the effects of hydromorphone.
- A process for confirming all hydromorphone orders (new and continuing) for appropriateness (including dose and route) and documenting confirmation in the medical record.
- A schedule for frequency and type of clinical observations for all patients receiving hydromorphone, with:
 - A mechanism for immediate escalation of care if respiratory depression is evident
 - The frequency of clinical observations required for patients newly prescribed hydromorphone, or for when a hydromorphone dose has been increased.
- Advice regarding the opioid conversion tool to be used for converting opioid doses to or from hydromorphone.
- In patient care areas where use is infrequent, a process for prompt removal of hydromorphone supplies.

Prescribing

- Given the high risk of unintentional overdose with hydromorphone, initiation must be limited to patients for whom other opioid medicines are inappropriate or not tolerated.
- Patients continued on hydromorphone should be referred to a relevant speciality for either consultation or review, for example, palliative care, oncology, renal supportive care, geriatrics or chronic pain team.
- Initial prescribing of hydromorphone must be restricted to clinicians with appropriate qualifications and expertise as outlined in local protocols.
- For patients already receiving hydromorphone prior to admission to a facility, the dose of hydromorphone should be confirmed, where possible, with a reliable source such as the patient's community pharmacist, general practitioner or medical specialist prior to prescribing.
- To reduce the risk of hydromorphone being confused with morphine, prescribers should also include in the order the trade name of the hydromorphone preparation, for example: hydromorphone Dilaudid.
- Opioid conversion tools should be consulted when converting opioid doses to or from hydromorphone.

Storage and supply

- Hospitals must NOT include Dilaudid® HP 50 mg in 1 mL injection on their hospital formulary or hold inventory stock of this product.
- Where possible, hydromorphone should be stored in a separate Schedule 8 medication storage unit from morphine. In patient care areas where there is only one Schedule 8 medication storage unit, hydromorphone must be separated from morphine by storing these medicines on different shelves and by placing all hydromorphone medicines in a distinctive coloured bag or container.
- Where possible, an additional sticker using Tall Man Lettering stating 'HYDRomorphone' should be applied to all inpatient hydromorphone packets and bottles. The sticker must not obscure original packet or bottle labelling.
- The following precautions should be taken in supplying hydromorphone to patient care areas:
 - Hydromorphone should not be routinely stored in patient care areas where use is infrequent. In these circumstances, the required product should be individually issued per patient, and returned to pharmacy at the end of the patient care episode. Individually dispensed hydromorphone is to be used only for the patient to whom it was dispensed.
 - High-concentration formulations of injectable hydromorphone (10 mg per mL) should not routinely be stored in patient care areas outside of palliative care units. In circumstances when high-concentrations are required, the product should be individually dispensed per patient, and removed at the end of the patient care episode.

- Patient care areas should be checked at least weekly to identify and remove inappropriately stocked hydromorphone products.
- Naloxone injection must be available for reversal in patient care areas wherever hydromorphone is used.

Administration

- In addition to witnessing requirements, a second person check (see [Key Definitions](#)) must be employed when administering hydromorphone.

Pharmaceutical review

- Where possible, a pharmaceutical review (see [Key Definitions](#)) should be completed for patients receiving hydromorphone prior to administration of the first inpatient dose with specific attention on the appropriateness of the agent for the indication, the dose prescribed in view of the patient's comorbidities and other medicines prescribed, particularly other opioids.

Patient information / education

- Patients and/ or their carer should be provided with relevant education and written information regarding hydromorphone with particular attention to adverse-effects and how they should be managed.
- Professional Health Care Interpreters should be utilised for patient education for patients and/ or carers who are not fluent in English or who are Deaf.
- For inpatients prescribed hydromorphone, the patient's family and/ or carer should be advised to alert the patient's nurse if they have concerns regarding a change in the patients' condition including an unexpected decrease in their level of consciousness or other adverse-effects associated with hydromorphone.

Staff education

- Local protocols must address any specific training, qualifications, skills or competencies required to prescribe or administer hydromorphone.
- All medical officers, pharmacists, nurses (and midwives where relevant) should receive education on hydromorphone safety. A Health Education and Training Institute eLearning module 'Safe use of HYDRomorphone' is available for this purpose.

4.3 Methotrexate (Oral)

Oral methotrexate is used in the treatment of autoimmune or inflammatory disorders such as rheumatoid arthritis and severe psoriasis¹. Methotrexate is also used in the treatment of malignancies as part of specialised protocols.

Oral methotrexate is usually taken as a **single dose once a week** (however, occasionally, in order to improve tolerance in some people, the total weekly dose is taken in divided doses at 12 hourly intervals up to a maximum of 3 doses per week).

The once a week dosage regimen is unusual compared to other medicines and has led to errors occurring with the use of oral methotrexate since clinicians and patients are much more familiar with daily dosing of medicines.

Catastrophic adverse events associated with methotrexate toxicity can occur following daily administration of oral methotrexate when weekly administration was indicated or intended.

This standard outlines the minimum requirements for the safe prescribing, storage and handling, and administration of oral methotrexate. This standard does not contain clinical guidance on therapeutic use of methotrexate (oral).

4.3.1 Standards

Risk management strategy

The District or Health Service Drug and Therapeutics Committee must approve any local protocols and ensure inclusion of:

- Recommended patient monitoring standards
- Education of staff regarding risks associated with the use of oral methotrexate
- Patient involvement in the checking processes prior to prescribing and administering.

Prescribing

- The medication history taken on admission must include when the last dose of methotrexate was taken. Prescribers must refer to the medication history when prescribing methotrexate.
- Methotrexate must be written in full. Abbreviations such as MTX must not be used.
- When a weekly dose is prescribed, the prescriber must clearly specify on the medication chart or prescription that:
 - Methotrexate is to be given once a week, written in full and not abbreviated
 - The day on which the drug is to be administered. For example, Methotrexate 5 mg orally once a week on TUESDAY
- Patients admitted on oral methotrexate, should continue to have their methotrexate prescribed on the day that they normally take their dose unless there is rationale for changing. On discharge, the patient and/ or their carer must be informed when their next dose of methotrexate is due.
- The prescriber must cross out the days on the medication chart when methotrexate is not to be administered.
- Where Electronic Medication Management Systems are in use, mechanisms should be built in to prevent inadvertent daily administration of methotrexate.
- As methotrexate can be prescribed at more frequent dosage intervals for some indications in haematology and oncology, the prescriber must 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.

Storage and supply

- As methotrexate tablets are available in two strengths (2.5 mg and 10 mg), Pharmacy Departments must take special precautions to minimise dispensing errors. Such precautions may include use of warning signs on shelves and separation of stock.
- Methotrexate tablets must not be available in wards as imprest stock or in the 'After Hours' Supply.
- In hospitals where after-hours medications are obtained through access to the Pharmacy Department directly, methotrexate tablets should be stored in a location in the Pharmacy Department that prevents after-hours access.
- All methotrexate orders must be reviewed by a pharmacist. Prior to supply being made, the pharmacist must confirm the dosage schedule is appropriate and clearly written.
 - For patients admitted at times when the pharmacy department is closed strategies must be in place to ensure pharmacist review of methotrexate orders occurs. For example, deferring administration of methotrexate until a pharmacist has reviewed the medication order.
 - For small rural hospitals where there are limited or no pharmacy services on site strategies must be put in place to ensure pharmacist review. These might include faxing the medication chart to the nearest Base Hospital or Procedural Hospital Pharmacy Department for review of the order during opening hours and using courier services to deliver methotrexate when required.
- Methotrexate must be dispensed for individual patients from a medication chart order or prescription. The label must state the dose and day of the week it is due and include a cytotoxic warning.
- Pharmacy Departments should supply only the amount required for the weekly dose, preferably on the day it is due.
- To reduce the risk of accidental daily dosing the patient's own supply should not be used.

Administration

- Nurses administering methotrexate must have an understanding of methotrexate, its uses, normal dosing schedule and adverse effects to safely administer methotrexate to inpatients.
- Nurses should confirm with the patient and / or their carer the day of the week on which the patient's dose is due, the normal dose and when it was last taken prior to administering a dose of methotrexate.
- Methotrexate must not be administered from an order that does not meet the criteria for a methotrexate order described in Prescribing.

- Where a medication order is unclear, or the nurse has reason to query the dose, he or she must contact the prescriber or a pharmacist for clarification prior to administration.

Pharmaceutical review

- A pharmaceutical review should be completed for patients receiving methotrexate.

Patient monitoring

- Clinical staff must be able to recognise patients with potential symptoms that may be signs of methotrexate toxicity or intolerance.

Patient information / education

- All patients receiving methotrexate, and/ or their carer, should be provided with information and education by the prescriber and/ or pharmacist and provided with a copy of the Consumer Medicine Information leaflet for methotrexate.
- Information and education should include:
 - Emphasis on the once a week dosage by naming the day of the week (when a weekly dose is prescribed). It should be stressed that additional doses of the medicine must not be taken 'as needed' for symptom control
 - Actions to be taken if a dose is missed
 - Information on the importance of regular monitoring tests, symptoms of toxicity and the need for early intervention if such symptoms appear
 - Emphasis on the similar appearance of methotrexate and folic acid tablets (if the patient is also on this supplement) and the difference in dosage of the two medicines
 - Emphasis on confirming with the administering nurse the day of the week on which their dose is due, their normal dose and when it was last taken prior to taking a dose of methotrexate.
- Nursing staff should also be equipped to provide information and education on methotrexate to patients.
- Patients and/ or their carer should also be provided individual written information on their dosage regimen that specifies the patient's dose and day of the week for taking the medicine.
- Professional Health Care Interpreters should be utilised for patient education for patients and/ or carers who are not fluent in English or who are Deaf.

Other considerations

- In addition to the above specific precautions for the use of oral methotrexate, staff should remain aware, when handling this drug, of the work health and safety procedures that apply to the handling of any cytotoxic drug and related waste.

4.3.2 References

1. Methotrexate In: Australian Medicines Handbook (Internet). Australian Medicines Handbook Pty Ltd. 2015 Jan

4.4 Neuromuscular Blocking Agents

Neuromuscular blocking drugs produce skeletal (including respiratory) muscle relaxation, and are used to facilitate endotracheal intubation and control of the airway, to allow mechanical ventilation and to prevent reflex muscle contraction.

Neuromuscular blocking agents are considered high-risk medicines because inadvertent use in patients without the availability of medical staff skilled in airway support can lead to respiratory arrest, permanent harm, or death¹.

Serious incidents have occurred involving inadvertent administration of a neuromuscular blocking agent to a patient instead of a sedative.

Identified contributing factors to incidents involving neuromuscular blocking agents include:

- Look-alike packaging and labelling
- Sound-alike medicine names
- Drug administration after extubation
- Use of pre-prepared unlabelled syringes
- Unsafe storage, particularly small quantities in refrigerators
- Use in clinical areas where clinical staff may be unfamiliar with the drugs and their action².

This standard outlines the minimum requirements for the safe handling of neuromuscular blocking agents. This standard does not contain guidance on therapeutic use of neuromuscular blocking agents.

4.4.1 Standards

Risk management strategy

The District or Health Service Drug and Therapeutics Committee must approve any local protocols and ensure inclusion of:

- Any specific training, qualifications, skills or competencies required to prescribe or administer neuromuscular blocking agents
- Specific neuromuscular blocking agent storage requirements
- Any additional equipment required, for example, use of 'red plunger' syringes
- Statement that ventilator support is present during and after administration and whilst these medicines have an effect
- Minimum requirements for patient responsiveness prior to extubation.

Storage and supply

Supply of these agents must be limited to only those critical care areas where there is a clinical use and patients are ventilated and monitored.

Neuromuscular blocking reversal agents must be available in clinical areas where these agents are used and stored.

In clinical areas where a small number of doses are kept refrigerated to support cardiopulmonary resuscitation, specially identified secure storage must be used.

Warning labels should be applied to stored medication including intubation packs to identify them as containing neuromuscular blocking agents.

Administration

Once prepared, labelling must comply with the appropriate standards for anaesthesia or User-applied Labelling of Injectable Medicines, Fluids and Lines Policy.

A second person check should be used prior to administration of neuromuscular blocking agents (refer to recognised practice guidelines, for example, Australian and New Zealand College of Anaesthetists Guidelines³).

4.4.2 References

1. Phillips, M.S. and R.L. Williams, Improving the safety of neuromuscular blocking agents: A statement from the USP Safe Medication Use Expert Committee. American Journal Health-System Pharmacists, 2006. 63.
2. NSW Ministry of Health, Neuromuscular Blocking Agents – Minimising Risk. 2011. Safety Information 002/11.
3. Australian and New Zealand College of Anaesthetists Guidelines for the safe administration of injectable drugs in anaesthesia. 2009.

4.5 Opioids

Opioid medicines principally act on opioid receptors in the central nervous system and gastrointestinal system, producing effects including analgesia, respiratory depression, sedation and constipation. Opioid medicines are frequently used to treat moderate to severe pain. Opioid medicines include alfentanil, buprenorphine, codeine, fentanyl, hydromorphone, methadone, morphine, oxycodone, pethidine, remifentanyl, tapentadol and tramadol (AMH, January 2020).

Errors involving opioids can include:

- Administration of an incorrect formulation. For example, administration of a short-acting formulation when a long-acting formulation was intended (and vice versa).
- Failure to adjust an opioid dose according to patient factors. For example, pain assessment, biochemistry, renal function, age, opioid tolerance and drug interactions with other medicines.
- Dose calculation errors when transitioning between different opioid medicines, formulations or routes of administration.

- Inappropriate use of opioid patches, including the use of fentanyl patches for patients with acute pain who are not opioid tolerant. Other errors involving opioid patches include prescribing and applying patches at the incorrect time interval, cutting or only partially applying patches and failing to remove a patch before applying a new patch.

In addition, the prescribing of opioid analgesia for patients discharged from hospital needs to be undertaken with caution due to the risk of dependency, adverse effects, interactions with other drugs (central nervous system depressants, in particular benzodiazepines, gabapentinoids, and alcohol), cognitive and driving impairment, and falls. There is a correlation between an increase in opioid prescribing for acute conditions on discharge from hospital and opioid-related harm including dependence, injury, overdose, antisocial behaviour and death in the community.

This standard outlines the minimum actions required to mitigate risks associated with opioid use while in hospital and on discharge. This standard does not contain clinical guidance on therapeutic use of opioids. This standard does not cover specific requirements for treatment of opioid dependence. For clinical guidance and policy direction for opioid dependence treatment in NSW, refer to:

- NSW Health Policy on Management of Opioid Dependent Persons admitted to Hospitals in NSW.
- NSW Health Clinical Guidelines on Treatment of Opioid Dependence.
- NSW Health Clinical guidelines for use of depot buprenorphine in the treatment of opioid dependence.
- Local protocols.

Refer to local protocols for additional requirements for managing opioids via the neuraxial route.

The [Hydromorphone Standard](#) outlines the minimum actions required to prevent hydromorphone prescribing and administration errors. In facilities where hydromorphone is in use, the Hydromorphone Standard must be implemented in addition to the Opioid Standard.

Refer to the Medication Handling in NSW Public Health Facilities policy for opioid prescribing, storage, supply and administration requirements, reflecting compliance with the Poisons and Therapeutics Goods Regulation 2008.

3.5.1 Standards

Risk Management Strategy

The District or Health Service Drug and Therapeutics Committee must approve any local protocols and ensure inclusion of the following:

- Requirement to consider, and provide advice on, prescribing alternatives to opioid medications, including non-pharmacological treatment when applicable.

- Requirement that patients and/ or their carers are fully informed of the benefits, risks and harms of opioid medicines including the risk of overdose, dependence and cognitive and driving impairment when applicable.
- Any additional requirements for patients on an opioid treatment program.
- Requirement that patients are screened for previous opioid adverse effects (including overdose) prior to prescribing.
- Recommendations for when naloxone must be prescribed including for take home use.
- Requirement that concomitant antiemetic and laxative medicines are prescribed when required.
- Recommendations for the use of codeine products in children and breastfeeding mothers where applicable. The Therapeutic Goods Administration has released a Safety Review on [Codeine use in children and ultra-rapid metabolisers](#).
- Recommendations for when it is appropriate to prescribe slow-release opioid medicines.
- A restriction on prescribers permitted to initiate and discharge patients on fentanyl transdermal patches and/ or fentanyl oromucosal formulations. This must be restricted to those prescribers with the appropriate qualifications and expertise.
- Where oromucosal fentanyl formulations are in use, advice that the various formulations are rapid-acting and not interchangeable. The NSW TAG [Fentanyl Oromucosal Formulation Advisory](#) provides information on rapid-acting and sublingual formulations of fentanyl.
- Recommendation regarding the opioid conversion tool to be used for converting opioid doses.
- Requirement that the oral morphine equivalent daily dose (oMEDD) (see [Key Definitions](#)) is calculated for patients with chronic non-cancer pain. Recommended actions must be provided when the calculated oMEDD meets the following circumstances:
 - Adult patients (aged up to 65 years) with an oMEDD in the following ranges: 60 -199 mg; and, 200 mg or greater
 - Patients aged over 65 years with an oMEDD of 30 mg or greater
 - Adult patients who weigh less than 50 kg with a chronic medical illness with an oMEDD greater than 1.2 mg per kg per day
 - Children with an oMEDD greater than 1.2 mg per kg per day.

The Agency for Clinical Innovation Pain Management Network's [Quick steps through Opioid Management](#) provides recommendations and resources for the management of people with chronic non-cancer pain.

- Recommendations on management and/ or referral patients where there is concern that they may develop an opioid use disorder.

- Recommendations for patients with risk factors such as asthma, obstructive sleep apnoea or those receiving other medications that can potentiate the effects of opioids such as benzodiazepines.
- A schedule for frequency and type of clinical observations for all inpatients receiving an opioid medicine is to be determined, including the frequency of clinical observations required for patients newly prescribed an opioid medicine or for when an opioid dose has been increased.
- A process for prompt removal of infrequently used opioid medicines from patient care areas.
- A process for regularly reviewing opioid medicines used in patient care areas for appropriateness in each patient care area.

Additional requirements for prescribing and dispensing opioid medicines on discharge

- Requirements for instructions for patients discharged on an opioid medicine. These must include expected duration of pain and analgesia requirements (including maximum daily doses and a detailed opioid weaning plan where required).
- Requirement that written discharge instructions are provided to patients and/ or their carers, their general practitioners and other relevant health care professionals.
- Circumstances where it is not appropriate to prescribe opioid medicines on discharge.
- Recommendations for the quantity of opioid medicine that can be supplied on discharge. Generally for acute pain, opioid requirements should be estimated on patient's use over the immediate 24 hours preceding discharge and other factors such as time since surgery, age, comorbidities, concomitant medications and nature of condition leading to pain. Supply on discharge or from an Emergency Department should generally not exceed three to five days for acute pain with a recommendation to follow-up with their general practitioner if required.
- Recommendations for when naloxone is to be supplied on discharge. Patients and their carers who are supplied with naloxone on discharge must be provided with education on responding to an opioid overdose and instruction on using the medicine. A Consumer Medicines Information Leaflet is to be provided with all discharge or outpatient dispensing of naloxone. Naloxone consumer information sheets are also available on the NSW Health [opioid overdose response and take home naloxone](#) webpage.
- Recommendation that patients and/ or their carers are provided with advice on how to safely dispose of any unused opioid medicines.

Additional requirements for opioid intravenous bolus injections, intravenous infusions and subcutaneous infusions

- Clinical areas where opioid intravenous bolus injections, intravenous infusions, subcutaneous infusions, or patient controlled analgesia (including paediatric nurse controlled analgesia) may be used.

- Any specific training, qualifications, skills or competencies required to prescribe or administer opioid intravenous bolus injections and infusions (including patient controlled analgesia and paediatric nurse controlled analgesia).
- Prescribing and administration documentation requirements. The [Agency for Clinical Innovation](#) have developed a range of pain charts and implementation toolkits.
- A rate limiting device such as an infusion pump must be used for all opioid-containing infusions. Wherever possible this should be a 'smart' pump using a pre-programmed infusion protocol. Dose error reduction software, where implemented, must be turned on and not bypassed.

Prescribing

- Given the risk of opioid misuse, alternatives to prescribing opioids should be considered, where applicable.
- Multiple opioid medicines should only be prescribed concurrently in specific circumstances.
- The use of dose ranges in the prescribing of opioids is to be avoided unless there are specific clinical criteria provided for nursing or midwifery clinicians to guide selection of the dose.
- For patients taking an opioid medicine(s) prior to admission to a facility, when possible, the dose of the opioid must be confirmed with a reliable source such as the patient's community pharmacist, general practitioner or other medical specialist prior to prescribing.
- Regular review of inpatient opioid requirements must be undertaken when clinically appropriate.
- When clinically appropriate, opioid weaning must be proactively considered.
- Where possible, when prescribing hydromorphone, oromucosal fentanyl, oral immediate and modified release morphine, and oxycodone products, prescribers should include the trade name of the product in the order.
- Opioid conversion tools should be consulted when converting opioid doses.

Storage and supply

- Where possible, only store one strength of an opioid medicine in a patient care area. If more than one strength of an opioid is required, strategies must be in place to reduce selection error.
- Where possible, store products with look-alike names and/ or packaging separately (see [Hydromorphone Standard](#) for specific requirements relating to Hydromorphone).
- Patient care areas should be checked at least weekly to identify and remove unnecessary stocked opioid products.

- Naloxone must be available in patient care areas wherever opioid medicines are used.
- Pethidine should not be included on the formulary.
- When appropriate commercially prepared pre-mixed solutions are to be considered for listing on the formulary.

Administration

- In addition to witnessing requirements detailed in NSW Health policy on Medication Handling in Public Health Facilities, a second person check (see [Key Definitions](#)) must be employed when administering opioids in accordance with NSW Health policy on Medication Handling in Public Health Facilities requirements.

Opioid transdermal patches

- Patches should not be cut or only partially applied to achieve a smaller dose.
- Patches must not be exposed to extremes of temperature. Do not use heat packs or thermal blankets on patients with an opioid transdermal patch in situ. Exposure to heat could result in a temperature dependent increase in opioid release from the patch.
- For disposal, used patches must be folded in half so that the medication is trapped within the adhesive surface, then disposed of in a 'sharps' container.
- The position of patch placement on the body must be recorded on the medication order or in the patient's health care record (as applicable).
- The time of the patch removal must be recorded on the medication order or in the patient's health care record (as applicable), signed and dated by the registered nurse / midwife and countersigned and dated by the witness to the procedure, or under the local protocol with solo nurse attendance for Hospital in the Home and community nursing / outreach services in accordance with NSW Health policy on Medication Handling in NSW Public Health Facilities.

Pharmaceutical review

When possible, a pharmaceutical review (see [Key Definitions](#)) is to be completed:

- Prior to administration of the first inpatient dose with specific attention on the appropriateness of the opioid agent for the indication, the dose prescribed in view of the patient's comorbidities and other medicines prescribed, particularly other opioid medicines or sedative agents.
- For patients discharged on an opioid medicine.

Patient information / education

- When applicable, patients and/ or their carers are to be provided with relevant education and written information regarding opioids with particular attention to:
 - Adverse effects and how they are to be managed

- Risks associated with opioid medicines including risk of drug interactions, overdose, dependence, falls, and cognitive and driving impairment if applicable
- Expected duration of pain and analgesia requirements, including maximum daily doses and a detailed opioid weaning plan (where required)
- Instructions for other pain management strategies (including non-pharmacological strategies)
- Advice, for patients receiving transdermal opioid medicine not to use heat packs or a thermal blanket.
- When appropriate, inpatients prescribed an opioid medicine, the patient's family and/ or carer are to be advised to alert the patient's nurse if they have concerns regarding a change in the patients' condition including an unexpected decrease in their level of consciousness, or other adverse effects associated with opioid medicines. A managing side effects of opioid medicines in hospital leaflet is available on the [Clinical Excellence Commission's High-Risk Medicines webpage](#).
- When required patients discharged on opioid medicines and/ or their carers are to be provided with advice on safe storage and disposal of opioids including advice to return any unused opioid medicines to a community pharmacy for disposal, if possible. When required patients who are using an opioid patch are to be provided with verbal and written information on safe handling and disposal of used patches.
- Patients who are administered and/ or supplied with opioid medicines on or prior to discharge, and carers accompanying them, must be provided with appropriate advice on sedation and fitness to drive or operate machinery (when applicable). When appropriate, written information such as NSW Health [Driving Safety and Medicines Factsheet: Patient Information](#) is to also be provided.
- A Consumer Medicines Information leaflet is to be provided with all discharge or outpatient dispensing of opioid medicines including any opioid supply from the Emergency Department.
- When required, Professional Health Care Interpreters are to be must be utilised for patient education for patients and/ or carers who are not fluent in English or who are Deaf.

Staff education

- Local protocols are to address any specific training, qualifications, skills or competencies required to prescribe or administer opioid medicines.
- Local protocols are to address opioid safety education requirements for medical officers, pharmacists, nurses and midwives. When appropriate, education is to address appropriate opioid prescribing for patients pre-operatively, during hospitalisation and at discharge. A 'Safe Use of Opioids' module is available in My Health Learning for this purpose.

3.5.1 References

- Australian Medicines Handbook, Opioid analgesics, January 2020

4.6 Paracetamol

Paracetamol is an effective analgesic and antipyretic and is well tolerated. In children and adults paracetamol is indicated as first line therapy for mild to moderate pain and symptoms of fever¹. Paracetamol may be considered a high-risk medicine for certain population groups at risk of hepatotoxicity.

Adverse events associated with paracetamol toxicity have been associated with:

- Concomitant administration of intravenous paracetamol and oral paracetamol
- Accidental overdose through ongoing administration of regular and PRN paracetamol.

This standard outlines the minimum requirements for the safe handling of paracetamol. This standard does not contain guidance on therapeutic use of paracetamol.

4.6.1 Standards

Risk management strategy

The District or Health Service Drug and Therapeutics Committee must approve any local protocols and ensure inclusion of:

- Any specific training, qualifications, skills or competencies required to prescribe or administer paracetamol
- Any restrictions to limit use of intravenous paracetamol, for example, only to be used where patients are nil by mouth, or only to be prescribed by clinicians in anaesthesia, intensive care and pain management.

Prescribing

- Dose adjustments must be considered when prescribing for underweight patients, patients with existing clinical conditions (such as renal or hepatic impairment) and any other factors that may affect drug metabolism and excretion.
- Paracetamol (and/ or paracetamol combination products) should be ordered in only one section of the medication chart. Ordering in both the regular and as required 'PRN' sections of the chart may potentially lead to overdose.
- Orders must be expressed in milligrams (mg) or grams (g) per dose².
- Orders should only specify a single route, that is; oral or rectal or intravenous².
- The maximum duration of therapy should be included on all intravenous orders.
- Orders for intravenous paracetamol should be reviewed every 24 hours².
- Orders should be written using the active ingredient drug name. However where a brand name is used on the order the active ingredient term 'paracetamol' or 'contains paracetamol' should be documented adjacent to the brand name.

Prescribing and administration

- When prescribing or administering paracetamol (including nurse / midwife - initiated paracetamol), clinicians must ascertain if paracetamol has been recently ingested, check that no other formulations of paracetamol are concurrently being prescribed or administered, and that the administration of the dose will not exceed the safe maximum daily dose of paracetamol (from all sources including combination paracetamol / codeine combinations).
- In circumstances where dose is calculated based on patient weight, for example, paediatric patients, the dose must not exceed the maximum recommended paracetamol dose.
- A second person check is required for administration of intravenous paracetamol and all doses administered to paediatric patients.

Patient information / education

- Patients and/ or their parents or carers being discharged on paracetamol should be provided with specific information and education regarding paracetamol administration. They should also be counselled that many over-the-counter products recommended for cold, cough, headache etc. may also contain paracetamol and should not be taken concurrently.
- Professional Health Care Interpreters should be utilised for patient education for patients and/ or carers who are not fluent in English or who are Deaf.

4.6.2 References

1. NSW Therapeutic Advisory Group (2008) Paracetamol Use. A Position Statement of the NSW Therapeutic Advisory Group.
2. NSW Therapeutic Advisory Group (2012) Intravenous Paracetamol Use. Addendum to the 2008 'Paracetamol Use' Position Statement of the NSW Therapeutic Advisory Group.

4.7 Potassium (Intravenous)

Potassium salts are administered intravenously to address hypokalaemia in patients who cannot receive the electrolyte orally or when rapid replacement is required. Potassium chloride is the most commonly used salt, with phosphate and acetate less often used.

Incidents involving administration of intravenous potassium can result in fatal patient outcomes¹. Adverse incidents related to intravenous potassium use can include:

- Too rapid intravenous infusion of a potassium chloride infusion related to failure to use a rate limiting device such as an infusion pump, or incorrectly programming an infusion pump
- Administration of a bolus of concentrated potassium chloride (for example, potassium chloride 10 mmol in 10 mL) as a result of a selection error. For example, mistakenly selecting a potassium chloride ampoule instead of a sodium chloride 0.9% ampoule when preparing an intravenous flush

- Failure to adequately mix a potassium chloride concentrate that has been added to an infusion prior to administration can result in the patient receiving a bolus of concentrated potassium chloride solution.

This standard outlines the minimum actions required to mitigate risks associated with intravenous potassium. This standard does not contain clinical guidance on therapeutic use of potassium (intravenous).

4.7.1 Standards

Risk mitigation strategy

The District or Health Service Drug and Therapeutics Committee must approve any local protocols and ensure inclusion of:

- Any specific training, qualifications, skills or competencies required to prescribe or administer intravenous potassium salts
- Instructions for preparation and administration practices for intravenous potassium chloride and other concentrated potassium salts
- Recommended infusion rate, infusion pump requirements and associated clinical monitoring. The maximum recommended rate in adults of intravenous potassium administration is 10 mmol per hour¹
- Recommendations regarding concentrations of administration and solutions for use in children (where applicable). Facilities should refer to [NSW Health Guideline on Standards for Paediatric Intravenous Fluids](#)
- Supply and handling of concentrated potassium salts injections, including a list of clinical areas permitted to stock potassium chloride ampoules
- Availability and storage of pre-mixed potassium chloride intravenous solutions, including a list of clinical areas permitted to stock potassium chloride 40 mmol per 100 mL minibags
- Those clinical areas which are deemed appropriate for providing the patient care (including cardiac monitoring) required for administration of intravenous potassium at rates greater than 10 mmol per hour.

Prescribing

- Oral potassium chloride should be the first choice for treatment of hypokalaemia if this route of administration is available.
- Consideration must be given to each patient's potassium intake from all sources, for example, enteral and parenteral nutrition, oral intake and supplementary fluids.
- Orders for intravenous potassium salts must be expressed in millimoles (mmol) not milligram per litre (mg/L) or percent (%).
- Where clinically feasible, prescribers must limit orders for intravenous potassium chloride to the commercially prepared pre-mixed solutions available at their facility.

- The name of the potassium salt should be used for intravenous potassium orders. For example, potassium chloride.
- Chemical abbreviations must not be used for intravenous potassium orders.
- Orders for intravenous potassium salts must have the rate, route, dilution and administration instructions fully specified on the intravenous infusion medication chart. Orders without instructions for dilution and infusion rate are not complete and must not be accepted for either dispensing or administration.
- The infusion rate or time period must be included. Orders must not contain directions to give intravenous potassium as a 'bolus 'or 'stat' dose.

Storage and supply

Pre-mix solutions

- Pre-mixed potassium chloride infusion solutions must be clearly differentiated from other intravenous fluids, for example, through use of colour coded over-pouches and labelling.
- The concentration for pre-mix solutions must be expressed in millimoles (mmol) per final volume.
- Pre-mixed, small volume intravenous solutions (minibags) containing potassium solutions must not have an additive port or, if intravenous potassium solutions are prepared in-house, the additive port must be capped.
- Where non-commercially available concentrations are required, a pharmacy-based compounding service should be used where available (see NSW Health Policy on Pharmaceuticals - Preparation in NSW Public Health Facility Pharmacy Services).
- In circumstances when a pre-mixed potassium chloride solution cannot be used and a pharmacy-based compounding service is not available, intravenous potassium solutions are to be prepared in the clinical area by staff using aseptic technique. Where this is routinely undertaken, District or Health Service Drug and Therapeutics Committee endorsed protocols must address the risks of supply and handling of concentrated potassium ampoules.
- Pre-mixed potassium chloride intravenous infusion solutions must be clearly labelled and separated from other, same size, commercial intravenous solutions (for example, sodium chloride 0.9% solution).
- Storage locations for pre-mixed solutions must be clearly identified throughout each facility.

Ampoules

- Potassium chloride ampoules should not be available as ward stock unless included in the District or Health Service Drug and Therapeutics Committee approved list of authorised clinical areas. Ampoules of other concentrated potassium salts (for example, potassium dihydrogen phosphate) should not be available as ward stock and only be available through pharmacy departments.

- Potassium chloride ampoules must not be placed on resuscitation trolleys due to the risk of inadvertent bolus administration.
- If required, potassium ampoules of strength greater than 1 mmol per mL, must only be kept in the pharmacy, clearly segregated from other strengths.

Critical care areas or operating suites

- In critical care areas or operating suites, where higher concentrations and doses of potassium are considered necessary:
 - A risk assessment should be performed to determine whether it is appropriate to keep ampoules as a stock item and if so, a District or Health Service Drug and Therapeutics Committee approved protocol for safe preparation and use must be in place
 - The range of concentrated potassium injection / infusion salts available should be limited and should not exceed 1 mmol per mL
 - Ampoules must be physically separated from ampoules of similar appearance and packaging, for example, in a separately identified and coloured box, and retained in original packaging until immediately prior to use
 - Commercially prepared, pre-mixed, concentrated, small-volume solution (for example, 40 mmol per 100 mL minibag) should be available.

Administration

- When a patient is ordered an intravenous potassium solution, commercially prepared pre-mixed intravenous potassium chloride solutions must be used wherever possible.
- If a potassium salt is added to an intravenous solution, the solution must be fully mixed by inverting and agitating the solution immediately prior to administration. Concentrated solutions of potassium **must never** be added to an intravenous solution container in the hanging position as inadequate mixing is likely and a potential potassium bolus dose may result¹.
- A rate limiting device such as an infusion pump must be used for all potassium containing infusions. Wherever possible this should be a 'smart' pump using a pre-programmed infusion protocol. Dose error reduction software, where implemented, must be turned on and not bypassed while potassium is being infused.
- The maximum recommended concentration of potassium for administration via peripheral infusion lines in adults is 40 mmol per L unless using a commercially prepared pre-mixed solution (for example, potassium chloride 10 mmol per 100 mL that has been made isotonic). Solutions stronger should be infused via a central venous access device.
- A second person check is required for the administration of all intravenous potassium solutions.

4.7.2 References

1. Medication Alert – Intravenous Potassium Chloride can be fatal if given inappropriately (2003) Australian Commission on Safety and Quality in Health Care www.safetyandquality.gov.au/publications-and-resources/resource-library/high-risk-medication-alert-intravenous-potassium-chloride
2. Australian Injectable Drugs Handbook 5th ed The Society of Hospital Pharmacists of Australia. Accessed 16/06/2015.

4.8 Vincristine

Vincristine is a neurotoxic, antineoplastic drug of the vinca alkaloid group.

Accidental administration of vincristine via the intrathecal route almost always results in central nervous system dysfunction and death¹.

This policy outlines the minimum actions required to prevent accidental intrathecal administration of vincristine. This document does not contain clinical guidance on therapeutic use.

4.8.1 Standards

Risk management strategy

The District or Health Service Drug and Therapeutics Committee must approve any local protocols and ensure inclusion of:

- A statement that only staff specifically trained and experienced in cancer treatments may prescribe, prepare, dispense or administer vincristine to patients
- Procedures that segregate chemotherapy administered by the intrathecal route from all other doses given by other routes. For example:

Pharmacy requires confirmation from the clinician that all intrathecal chemotherapy administration has been completed prior to releasing intravenous vincristine for the same patient due on the same day.

OR

If possible, choose a protocol which schedules administration of intravenous chemotherapy on different days from chemotherapy administered by the intrathecal route.

Storage and supply

- Doses of vincristine must be prepared in and administered from a minibag not a syringe¹.
- All vincristine preparations, including outer wraps, must be labelled with a prominent warning label such as, “*FOR INTRAVENOUS USE ONLY – CAN BE FATAL IF GIVEN BY OTHER ROUTES*”. The outer wrap must also state, “Do not remove covering until moment of infusion”.

Separate supply, delivery and administration of intrathecal medication

- If chemotherapy is prescribed for intrathecal administration in the Operating Suite, only the intrathecal chemotherapy is to accompany the patient to the Operating Suite. No other chemotherapy including intravenous chemotherapy is to be sent.

Administration

- Vincristine must **only** ever be administered **intravenously**.
 - A time out checklist and a second person check must be employed prior to administering vincristine to ensure:
 - The correct patient name, drug, dose and route have been checked on the bag label
 - It is being connected to a positively identified (correctly labelled) intravenous line
 - It is **being administered by the intravenous route**.

Other considerations

- Procedures must be followed that ensure safe administration techniques and stringent monitoring. Despite dilution, vincristine remains a vesicant.
- In addition to the above specific precautions for the use of vincristine, staff should remain aware, when handling this drug, of the work health and safety procedures that apply to the handling of any cytotoxic drug and related waste.

4.8.2 References

1. Clinical Oncological Society of Australia (2008) Guidelines for the safe prescribing, dispensing and administration of cancer chemotherapy.
<https://www.cosa.org.au/publications/guidelines.aspx>

5 APPENDICES

5.1 'A PINCH' – High-Risk Medicine Groups

This table is available with links to further information at the Clinical Excellence Commission website: <http://www.cec.health.nsw.gov.au/keep-patients-safe/medication-safety-and-quality/high-risk-medicines>

This list is not intended to be exhaustive and will be the basis of a dynamic register at each site to suit local formularies.

High-Risk Medicine Groups	Examples of medicines
A: Anti-infective	Amphotericin Aminoglycosides
P: Potassium and other electrolytes	Injections of potassium, magnesium, calcium, hypertonic sodium chloride
I: Insulin	All insulins
N: Narcotics (opioids) and other sedatives	Hydromorphone, oxycodone, morphine Fentanyl, alfentanil, remifentanil and analgesic patches Benzodiazepines, for example, diazepam, midazolam Thiopentone, propofol and other short term anaesthetics
C: Chemotherapeutic agents	Vincristine Methotrexate Etoposide Azathioprine
H: Heparin and anticoagulants	Warfarin Enoxaparin Rivaroxaban, dabigatran, apixaban
Other	High-risk medicines identified at Local Health District/ Facility/Unit level which do not fit the above categories

5.2 Examples of Dose Specific Safety Measures That Can Be Applied To High-Risk Medicines

Transdermal patches:
<ul style="list-style-type: none"> • Confirmation from the prescriber should be sought if multiple patches are to be applied.
<ul style="list-style-type: none"> • The time of application, site of application and time of removal should be documented on the medication chart.
<ul style="list-style-type: none"> • Transdermal patches should not be exposed to extremes of temperature.
<ul style="list-style-type: none"> • Transdermal patches should not be cut.
<ul style="list-style-type: none"> • Transdermal patches containing opioids should be securely disposed of for example, in sharps bin.
Modified release oral medicines, for example, slow release formulations:
<ul style="list-style-type: none"> • These formulations should not be dissolved, divided (unless scored) or crushed prior to administration.
<ul style="list-style-type: none"> • Pharmacy department should be contacted for advice on an alternative formulation or dose preparation if a patient has difficulty swallowing.
Medicines inhaled using devices:
<ul style="list-style-type: none"> • Ensure the patient understands and is able to use the devices correctly.
<ul style="list-style-type: none"> • Ensure the device settings are correct for each medicine delivery.
<ul style="list-style-type: none"> • Ensure use of the correct dose form and strength.
Parenteral fluids:
<ul style="list-style-type: none"> • 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 of fluids of high-risk medicines are to be used in preference to those locally prepared.
<ul style="list-style-type: none"> • The need to vary from pre-mixed infusion strengths is clearly indicated and documented in the patient's healthcare record.

5.3 High-Risk Medicines Management Implementation Checklist

Organisation / Facility:				
Assessed by:		Date of Assessment:		
Key Policy Requirements		Not commenced	Partial compliance	Full compliance
1. Facilities have a High-Risk Medicines Register in place.		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
		Notes:		
2. A mechanism is in place for assessing safety of new medicines being considered for the facility drug formulary.		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
		Notes:		
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.		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
		Notes:		
4. A mechanism is in place to alert relevant clinicians to changes to the high-risk medicines register.		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
		Notes:		
5. A strategy is in place for review of protocols currently included in the High-Risk Medicines Register.		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
		Notes:		