High-Risk Medicines Management

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Functional Sub group Corporate Administration - Information and data, Corporate Administration - Records, Clinical/ Patient Services - Medical Treatment, Clinical/ Patient Services - Pharmaceutical, Population Health - Pharmaceutical

Summary This policy is a standard of the High-Risk Medicine Management Policy and outlines minimum requirements for the safe use of intravenous vincristine, anticoagulants and potassium.

Author Branch Clinical Excellence Commission
Branch contact

Applies to Local Health Districts, Specialty Network Governed Statutory Health Corporations, Affiliated Health Organisations, Public Hospitals

Audience Administration, clinical

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

Review date 11-Jan-2017
Policy Manual Patient Matters

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Status Rescinded
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Director-General

This Policy Directive may be varied, withdrawn or replaced at any time. Compliance with this directive is mandatory for NSW Health and is a condition of subsidy for public health organisations.
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HIGH-RISK MEDICINES MANAGEMENT

PURPOSE
This policy aims to address the risks associated with the prescribing, dispensing and administration of high-risk medicines. Although most medicines have a wide margin of safety, a few drug groups have a high risk of causing patient injury or death if they are inadvertently misused or administered incorrectly. Errors with these medicines may not be more common than those from other groups but their consequences can be more devastating.¹

MANDATORY REQUIREMENTS

• All public health facilities must establish a high-risk medicines program.
• All public health facilities must maintain, as part of this program, a specific high-risk medicines register.
• All medicines regarded as high risk must be the subject of a local protocol, aligned with relevant NSW Health policy, prepared in consultation with relevant specialists and overseen by the Local Health District Drug and Therapeutics Committee(s).
• Each high-risk drug protocol must include patient monitoring which is relevant and appropriate to therapy. This is to ensure a timely response to adverse events or side effects associated with drug treatment.
• All public health facilities should employ strategies to mitigate the risk of medicines on the mandatory local high-risk medicine registers.
• Adverse incidents involving high-risk medicines should be reported in the Incident Information Management System (IIMS) and regularly reviewed through quality management systems.

IMPLEMENTATION

NSW Ministry of Health
• Provides the mandatory requirements and standards for high-risk medicines listed in this policy.
• Develops new high-risk medicine standards as the need is identified.

Chief Executive, Health Service Executives, Managers
• Ensure the mandatory policy and standards are implemented at all health facilities.

Directors of Clinical Governance
• Ensure systems are in place to:
  • Implement the mandatory high-risk medicine policy and standards.
  • Monitor compliance with the high-risk medicine policy and standards.
Drug and Therapeutics Committees

- Ensure high-risk medicines registers are current and maintained for each location, facility or group of facilities.
- 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 register.
- Receive reports on high-risk medicine incidents, policy compliance rates and formulate corrective action if indicated.
- Refer system-wide issues to the Local Health District Clinical Council and associated Quality Committees.

Heads of Department, Hospital Facility, Clinical Stream

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

Clinical staff involved in medication management

- Comply with policy and standards for high-risk medicines.
- Follow the local protocol described in the register of high-risk medicines.
- When prescribing and supplying high-risk medicines, give clear advice to ensure their safe administration.
- Maintain knowledge base relevant to area of practice.

REVISION HISTORY

<table>
<thead>
<tr>
<th>Version</th>
<th>Approved by</th>
<th>Amendment notes</th>
</tr>
</thead>
<tbody>
<tr>
<td>January 2012</td>
<td>Director-General</td>
<td>New policy and standards</td>
</tr>
</tbody>
</table>

(Ref2012_003)

ATTACHMENTS

1. High-Risk Medicines Management : Policy Standard

1 Ref: M. Cohen, Medication Errors 2nd Ed A Ph A p 317
High-Risk Medicines Management

Issue date: January 2012
PD2012_003

RESCINDED
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1 PURPOSE

To provide a standard for the management of high-risk medicines in NSW Health services

2 DEFINITIONS

**Fully independent double check**

An independent double-check of a high-risk medicine is a procedure in which two clinicians separately check (alone and apart from each other, then comparing results) each component of prescribing, dispensing, and verifying the high-risk medicine before administering it to the patient.

<table>
<thead>
<tr>
<th>Term</th>
<th>Definition</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>High risk medicine</strong></td>
<td>A medicine included in the High Risk Medicine Register</td>
</tr>
<tr>
<td><strong>Must</strong></td>
<td>Indicates a mandatory action requiring compliance.</td>
</tr>
<tr>
<td><strong>Should</strong></td>
<td>Indicates a recommended action that should be followed unless there are sound reasons for taking a different course of action.</td>
</tr>
<tr>
<td><strong>Supervise (clinical supervision)</strong></td>
<td>Clinical supervision is provided through the significant leadership and legally defined role of the Attending Medical Officer (AMO) leading a team which plays a critical role in the clinical review and care of the patient. When allowing care of their patients by junior clinicians using high-risk medicines, the AMO must not relinquish their rights or responsibilities for direct involvement in and oversight of the patient’s care.</td>
</tr>
<tr>
<td><strong>Tall Man lettering</strong></td>
<td>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 distinguishable.</td>
</tr>
<tr>
<td><strong>Therapeutic Drug Monitoring (TDM)</strong></td>
<td>Therapeutic drug monitoring refers to the individualisation of dosage by maintaining plasma or blood drug concentrations within a target range (therapeutic range, therapeutic window).</td>
</tr>
</tbody>
</table>
3 STANDARDS

A program to manage high-risk medicine consists of the following minimum elements:

3.1 High-Risk Medicine Register

A register consisting of a list of drugs or drug groups considered to be ‘high-risk’ must be maintained or referenced at each facility or group of facilities. Clinical staff must be aware of medicines on this list and of the need to take extra care in their safe storage, handling, prescription and administration with reference to local protocols.

The Drug and Therapeutics Committee determines the medicines to be included in the register and maintains the register and associated protocols.

Before a new medicine is placed on the local health service formulary by the Drug and Therapeutics Committee, a safety risk analysis must be performed. If there is a high risk of death or serious injury to the patient where a medicine is inadvertently misused or administered incorrectly, the medicine should be included in the High-Risk Medicine Register and appropriate protocols developed.

The minimum medicine groups to be considered for inclusion in the register are described in the “A PINCH” table (see Appendix 1).

3.2 High-Risk Medicine Risk Mitigation Strategies

Drug and Therapeutic Committees should develop risk mitigation strategies and consider specific interventions designed for:

- Reducing or eliminating the risk of error:
  - Ensure the safest means of completing a task is efficient and easily followed.
  - Remove opportunity for error by separation of error-prone tasks from one another in time or place.
  - Set mechanical devices so that they default to the safest setting.
  - Use oral/enteral dispensers to prepare and administer all liquid medicines by routes other than injection (refer to separate policy)
  - Remove the need for rapid mathematical calculation and reduce options and choices as far as possible through standardising concentrations of medicines in solution.
  - Purchase for safety as far as possible e.g. review label clarity, visual product discrimination, amount of manipulation and associated equipment needed in administration.
  - Use shelf reminders, checklists and alerts and, when possible, build these into information technology systems.
  - Ensure safe medicine identification by applying user labels to all doses not immediately administered. Use machine-readable code as soon as
available for checking identity and accuracy of each medicine at the point of its administration.

- **Making error visible:**
  - Employ a fully independent double-check, carried out by a second clinician, for key high-risk medicines where locally identified, as well as those for which double-checking is legally mandated.
  - Ensure all clinical staff have qualifications and skills appropriate to prescription, supply, preparation and administration tasks undertaken.
  - Regularly review local and wider system incidents and near-misses and use prospective analysis and redesign of systems to prevent recurrence of the same errors.

- **Minimising the consequences of error:**
  - Monitor patients carefully according to high risk drug protocols.

Additional strategies that may be implemented to achieve these outcomes are listed in Appendix 2.

3.3 Ensuring correct prescription and administration of high-risk medicines

- Ensure responsibility for prescribing of high-risk medicines is clearly defined.
- Ensure that the route of administration is clearly identified. The use of multiple routes of administration in the one prescription must be avoided for the same high-risk medicine (e.g. IV/Oral).
- Ensure that strengths of medicines are clearly visible in terms of the dosage unit or dose per volume of liquid e.g. mg/mL.
- Where possible, provide access to pre-measured medicine doses in a form that requires minimal manipulation prior to administration.
- When measuring and administering medicine doses, ensure any devices are used according to manufacturers’ specifications and that they are used according to their stated purpose.
- When double checking is used at the point of administration, ensure a fully independent check is used where required by policy or local protocol\(^3\),\(^4\),\(^5\). General principles for safe use of checking are identified in Appendix 4.
- Ensure that additional care is taken when administering the following dose forms. (see Appendix 3 for details)
  - Transdermal patches
  - Modified release oral medicines
  - Inhaled Medicines
  - Parenteral fluids
3.4 Using the NSW Health Inpatient Medication Chart

- The approved NSW Health inpatient medication chart (NIMC) must be used to prescribe all possible medicines except in designated high acuity areas, anaesthetics and those areas where computerised prescribing systems have been specifically authorised.
- When specialised medication charts are used in conjunction with the NIMC, relevant entries for high risk medicines should be cross-referenced e.g. intravenous therapy or pain management.
- If a modified release oral dose form is required by the prescriber, this should be indicated by ticking the relevant box on the chart.
- The Indication box should be completed for each item when prescribing medicine to assist other clinicians to distinguish the correct high-risk medicine required.
- Where medication prescribing for high acuity patients (e.g. those in Intensive Care Units) is on a separate medication chart, this should be reviewed on patient transfer to a different care level, with accurate translation of ongoing medicines to the NIMC prior to transfer.
- Intra-operative medications given by an anaesthetist must be recorded on the Anaesthetic Record.

3.5 Monitoring patients receiving high-risk medicine

Patients receiving high-risk medicines are vulnerable to medication error if not closely and regularly monitored.

Requirements for Therapeutic Drug Monitoring (TDM, see definitions) of high-risk medicines should be written into the protocols for use of each relevant drug. The required monitoring and dose amendment should be followed closely for all medicines to which TDM applies. Results of drug levels and laboratory tests such as renal and liver function tests should be promptly accessed to guide treatment.

3.6 Reviewing and learning for improvement

All incidents regarding high-risk medicines must be reviewed in order to improve practice by implementing risk mitigation strategies (refer to policy standards for individual medicine/group). Systems which may be considered to be unclear or vulnerable to misinterpretation should be reviewed and revised to promote safer practices.

All available data sources such as local incident monitoring data, external reports and published articles should be reviewed to identify any emerging or unidentified risks associated with high-risk medicines. If potential local vulnerability is identified, risk management techniques should be used to ensure systems and processes are in place to prevent harm and mitigate impact when errors occur.
4 ASSOCIATED DOCUMENTS

Medication Handling in NSW Public Hospitals PD2007_077
Safety Alert Bulletins (SABS) on high risk drugs, e.g. Safe use of Midazolam SN:022/09 available from: http://www.health.nsw.gov.au/quality/sabs/ as released from time to time

POLICY STATEMENT AND STANDARD – High-Risk Medicines Management

POLICY STANDARD – High-Risk Medicines Management - Vincristine Use

POLICY STANDARD – High-Risk Medicines Management - Potassium Chloride Use

POLICY STANDARD – High-Risk Medicines Management - Anticoagulation, Therapeutic

5 REFERENCES

1. Institute for Safe Medication Practices, Horsham, PA 19044-2321
APPENDIX 1  ‘A PINCH’ – High-Risk Medicine Groups

This table is available with links to further information at the NSW Health website: http://internal.health.nsw.gov.au/quality/natmed/high_risk_medicines.html#C2

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

<table>
<thead>
<tr>
<th>High-Risk Medicine Groups</th>
<th>Examples of medicines</th>
</tr>
</thead>
<tbody>
<tr>
<td>A: Anti-infectives</td>
<td>Amphotericin</td>
</tr>
<tr>
<td></td>
<td>Aminoglycosides</td>
</tr>
<tr>
<td>P: Potassium and other electrolytes</td>
<td>Injections of potassium, magnesium, calcium, hypertonic sodium chloride</td>
</tr>
<tr>
<td>I: Insulin</td>
<td>All insulins</td>
</tr>
<tr>
<td>N: Narcotics (opioids) and other sedatives</td>
<td>Hydromorphone, oxycodone, morphine</td>
</tr>
<tr>
<td></td>
<td>Fentanyl, alfentanil, remifentanil and analgesic patches</td>
</tr>
<tr>
<td></td>
<td>Benzodiazepines, e.g. diazepam, midazolam</td>
</tr>
<tr>
<td></td>
<td>Thiopentone, propofol and other short term anaesthetics</td>
</tr>
<tr>
<td>C: Chemotherapeutic agents</td>
<td>Vincristine</td>
</tr>
<tr>
<td></td>
<td>Methotrexate</td>
</tr>
<tr>
<td></td>
<td>Etoposide</td>
</tr>
<tr>
<td></td>
<td>Azathioprine</td>
</tr>
<tr>
<td>H: Heparin and anticoagulants</td>
<td>Warfarin</td>
</tr>
<tr>
<td></td>
<td>Enoxaparin</td>
</tr>
<tr>
<td></td>
<td>Rivaroxaban, dabigatran</td>
</tr>
<tr>
<td>Other</td>
<td>High-risk medicines identified at Local Health District/Facility/Unit level which do not fit the above categories.</td>
</tr>
</tbody>
</table>
### APPENDIX 2  Suggested general safety strategies for high-risk drugs on hospital formularies

<table>
<thead>
<tr>
<th>Strategy</th>
<th>Examples</th>
</tr>
</thead>
<tbody>
<tr>
<td>Use fail-safes</td>
<td>Set medical equipment to compensate automatically for deficiencies in human knowledge and performance or simple human factor errors e.g. Patient Controlled Analgesia pumps default to zero administration rate.</td>
</tr>
<tr>
<td>Use forcing functions</td>
<td>Use oral /enteral dispensers for non-parenteral medicines to prevent inadvertent connection to parenteral infusion lines.</td>
</tr>
<tr>
<td>Use constraints</td>
<td>Limit number and variety of medications on the formulary. Remove high-risk medicines from clinical areas.</td>
</tr>
<tr>
<td>Externalise or centralise error-prone processes</td>
<td>Use TALL Man letters, avert markers, colour coded storage. Clearly identify medicines which can be /are often confused.</td>
</tr>
<tr>
<td>Improve access to information</td>
<td>Ensure policies and protocols are readily available and accessible at all clinical points of care.</td>
</tr>
<tr>
<td>Standardise and simplify</td>
<td>Reduce options for medicine products, doses and administration techniques, e.g. prescribe standard strength, isotonic IV solutions. Limit available number of concentrations and volumes.</td>
</tr>
<tr>
<td>Consider user interfaces and natural mapping</td>
<td>Where appropriate, purchase medicine doses in ready-to-use format rather than a concentration requiring dilution.</td>
</tr>
<tr>
<td>Use differentiation</td>
<td>Purchase for safety. Avoid addition to the formulary of look-alike sound-alike drugs or poorly packaged and labelled products. Use machine-readable code for product identification where available.</td>
</tr>
<tr>
<td>Use reminders</td>
<td>Use auxiliary labels, checklists and computerised alerts.</td>
</tr>
<tr>
<td>Apply system redundancies</td>
<td>Employ fully independent double checking. Use verification systems and competency assessment. Match systems to support correct drug dose, time and administration route with correct patient</td>
</tr>
<tr>
<td>Monitor patients</td>
<td>Use close clinical monitoring to determine efficacy and quickly identify adverse reactions.</td>
</tr>
<tr>
<td>Use failure mode and effects analysis</td>
<td>Regularly review local incidents involving these medicines in the context of prevention of their recurrence. Proactively use descriptions of errors occurring at other sites to prevent future local errors. Proactively identify ways in which a medication-related process could fail, why it fails, how it might affect patients and how it could be made safer.</td>
</tr>
</tbody>
</table>
### APPENDIX 3  Examples of dose form - specific safety measures that can be applied to high risk medicines

<table>
<thead>
<tr>
<th>Transdermal patches:</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Never apply multiple patches without confirmation from the prescriber.</td>
</tr>
<tr>
<td>• Ensure each patch carries labelling of medicine and dose.</td>
</tr>
<tr>
<td>• Record time of application, site of application and time of removal on medication chart</td>
</tr>
<tr>
<td>• Ensure patch is not exposed to temperature extremes</td>
</tr>
<tr>
<td>• Do not cut patches.</td>
</tr>
<tr>
<td>• Ensure safe and secure disposal when relevant (e.g. opioid patch)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Modified release oral medicines, e.g. slow release formulations:</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Never dissolve, divide (unless scored) or crush prior to administration</td>
</tr>
<tr>
<td>• If patient has difficulty in swallowing, contact the hospital pharmacy for advice on dose preparation or use of an alternative formulation.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Medicines inhaled using devices:</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Ensure the patient understands and is able to use devices correctly</td>
</tr>
<tr>
<td>• Ensure the device settings are correct for each medicine delivery</td>
</tr>
<tr>
<td>• Ensure use of the correct dose form and strength.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Parenteral fluids:</th>
</tr>
</thead>
<tbody>
<tr>
<td>• When available, high-risk medicines are purchased in a form closest to the dilution and strength in which they are to be administered so as to minimise opportunity for error in ward-based preparation. Pre-mixed infusion fluids of high-risk medicines are to be used in preference to those locally prepared,</td>
</tr>
<tr>
<td>• The need to vary from standard pre-mixed infusion strengths, in adults or in specified paediatric groups, is clearly indicated and documented in the patient’s healthcare record</td>
</tr>
<tr>
<td>• Intravenous volumetric pumps with intelligence activated (Smart pumps) are to be used, when available, to screen for dose, dilution and rate of administration. Intelligence checks are not to be by-passed without gaining the opinion of a senior clinician.</td>
</tr>
</tbody>
</table>
**APPENDIX 4 Principles for safe use of double checking**

*Whenever two clinicians sign for administration of a dose of high-risk medicine, the following principles are to be considered:*

<table>
<thead>
<tr>
<th>Principle</th>
<th>Details</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. There must be support for creation of an environment that fosters peer critique and review. Medication areas must be designed with sufficient space to support and enable safe preparation of drugs.</td>
<td></td>
</tr>
<tr>
<td>2. It is better to limit checks to high-risk situations to avoid dilution of their effectiveness.</td>
<td></td>
</tr>
<tr>
<td>3. Double checks should not be accompanied by deference to authority, reduction in responsibility, automatic processing and allowance for intrusion of time constraints.</td>
<td></td>
</tr>
<tr>
<td>4. It must be recognised by all clinicians that it is hard to find one’s own mistakes.</td>
<td></td>
</tr>
<tr>
<td>5. Fully independent double checks should be used in situations that involve certain high-risk medicines, very complex processes, and high-risk patient populations as it is easy to overlook a mistake if guided past it.</td>
<td></td>
</tr>
<tr>
<td>6. The checker must always ask open questions prior to reviewing the order.</td>
<td></td>
</tr>
<tr>
<td>7. Local protocols and guidelines should clearly define the process of independent double checking.</td>
<td></td>
</tr>
<tr>
<td>8. A culture of learning from captured errors is to be encouraged.</td>
<td></td>
</tr>
</tbody>
</table>


High-Risk Medicines Management – Vincristine Use

NSW Health
POLICY STANDARD

Issue date: January 2012
PD2012_003

RESCINDED
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1. PURPOSE

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

Incidents which have occurred with vincristine have mostly related to its inadvertent intrathecal administration when prepared for intravenous use. Intrathecal administration of vincristine has occurred despite its preparation in large volumes of solution in syringes.

This intrathecal (incorrect) route of administration almost always results in central nervous system dysfunction and can lead to death.

This document is a standard of the High-Risk Medicine Management Policy and outlines minimum requirements for the safe use of intravenous vincristine.

2. DEFINITIONS

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

Must  Indicates a mandatory action required by a NSW Health policy directive, law or industrial instrument.

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

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 skills.

Vesicant  Any drug or substance that is capable of causing tissue destruction when extravasated.
3. VINCRISTINE USE STANDARDS

- Only staff specifically trained and experienced in cancer treatments may prescribe, prepare, dispense or administer vincristine to patients.
- All clinical staff administering vincristine must be fully trained to recognise adverse events, such as extravasation, and to administer prompt and appropriate treatment.
- Procedures must be in place 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 intrathecal chemotherapy administration (vincristine must never be administered via the intrathecal route) 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. |

3.1 Preparation of vincristine doses for intravenous administration

- Vincristine doses must be prepared in a cytotoxic drug safety cabinet or pharmaceutical isolator
- Doses of vincristine must be prepared in and administered from a minibag, not a syringe.
- For adults, doses should be diluted to 50 or 100mL in a minibag,
- For children doses should be diluted to 20-50mL in a minibag, However, more concentrated solutions may be required if the total volume to be administered needs to be reduced
- 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 injection”.

3.2 Safe administration of vincristine

- Vincristine must only be administered intravenously,
- Vincristine must never be administered via the intrathecal route.
- Administer vincristine by short-term intravenous infusion over 5-10 minutes
- Those administering vincristine must stop and take time out prior to injecting any dose to ensure
  - the correct patient, drug, dose and route have been checked on the bag label
  - it is being connected to a positively identified (i.e. labelled) intravenous line
  - it is not being administered into the central nervous system
• A central venous access device may be preferred for administration particularly in children, however if unavailable, peripheral intravenous access may be used with close monitoring for signs of extravasation. The peripheral cannula should have been inserted within the past 24 hours.

• Flush the line with sodium chloride 0.9% before and after administration of vincristine.

• Despite dilution vincristine remains a vesicant and extravasation should be avoided. Procedures must be followed that ensure safe administration techniques and stringent monitoring. Vincristine must not be given intramuscularly or subcutaneously.²

• Extravasation of vincristine may cause a severe local reaction, resulting in pain and cellulitis. If extravasation is suspected, stop infusion immediately, and start extravasation treatment according to local protocol.

3.3 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. The dose must be labelled clearly with the patient name and Medical Record Number.

4. ASSOCIATED DOCUMENTS

Safe Use of Vincristine, Safety Alert 04/06 NSW Department of Health

Cytotoxic Drugs and Related Waste - Safe Handling in the NSW Public Health System, PD2008_059 NSW Health

Cytotoxic Drugs and Related Waste Risk Management Guide 2008 WorkCover NSW

NSW Health PD2007_079 Correct Patient, Correct Procedure and Correct Site

NSW Health PD2007_077 Medication Handling in NSW Public Hospitals
5. REFERENCES

1. Cytotoxic Drugs & Related Waste - Safe Handling in the NSW Public Health System PD2008_059
2. Approved Australian Product Information Vincristine Sulfate Injection accessed 21.11.11
5. Standards Association of Australia. AS 4273: Design, installation and use of pharmaceutical Isolators, 1999 and amendment 2000
### Appendix 1: Implementation Checklist

#### High-Risk Medicine Management, Vincristine Use

<table>
<thead>
<tr>
<th>IMPLEMENTATION REQUIREMENTS</th>
<th>Not commenced</th>
<th>Partial compliance</th>
<th>Full compliance</th>
<th>Notes</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. High-Risk Medicine Management Policy on vincristine and associated protocols are readily available in all clinical areas.</td>
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<tr>
<td>2. Compliance with the vincristine use policy is regularly assessed.</td>
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<tr>
<td>3. Protocols exist to ensure that only staff specifically trained and experienced in cancer treatments may prescribe, prepare, dispense, or administer vincristine to patients.</td>
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<tr>
<td>4. All intravenous vincristine doses are administered via a minibag.</td>
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<tr>
<td>5. All minibags containing vincristine are prepared in a cytotoxic drug safety cabinet or isolator.</td>
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<tr>
<td>6. Procedures exist for separation of intrathecal doses of chemotherapy from intravenous doses in place and/or in time of administration and are practised without fail.</td>
<td></td>
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<tr>
<td>7. Prepared doses of intravenous vincristine are not released from the Pharmacy Department or supplier until the day of administration.</td>
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<tr>
<td>8. Time out procedure checklist exists and is used on all occasions vincristine is administered.</td>
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<tr>
<td>9. Extravasation guidelines are in place for all chemotherapy likely to cause tissue damage on extravasation including vincristine.</td>
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<tr>
<td>10. Cytotoxic drug spill kits are present in all areas where chemotherapy is transported or administered.</td>
<td></td>
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</tbody>
</table>
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1. PURPOSE

Potassium salts are administered intravenously to replace clinical deficiency 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.

**Adverse incidents which relate to Potassium use include:**

- **Too rapid administration**
  Patients can die as a result of receiving a potassium chloride infusion too rapidly, even when appropriately diluted.

- **Selection of the wrong ampoule**
  Potassium chloride ampoules can be mistaken for ampoules of similar appearance, for example, sodium chloride 0.9% (normal saline) when reconstituting a drug for injection. Consequently, the patient can be administered an unintended bolus of potassium.

- **Cognitive error**
  Using a potassium chloride ampoule instead of frusemide: this type of cognitive error is thought to arise due to the frequent use of potassium chloride in patients who are also receiving frusemide therapy, conditioning staff to the familiar pairing of the two drugs.

- **Preparation error**
  An intravenous infusion of potassium chloride is prepared incorrectly.

- **Use of an excessively strong solution**
  Patients can die as a result of receiving concentrated potassium chloride as a direct push injection. Cardiac arrest has also occurred when potassium chloride concentrate has been added to an infusion without mixing prior to administration.¹

This policy outlines the minimum criteria for safe therapeutic use of potassium associated with its preparation and administration in parenteral solutions.

2. DEFINITIONS

**Admixture service**
A drug compounding service, usually pharmacy-based, providing a controlled and monitored aseptic environment equipped with laminar flow workstations or isolators, staffed with skilled and validated personnel, providing aseptic dispensing of products such as parenteral nutrition, cytotoxic drug dose preparation, intravenous drug admixtures and others, e.g. eye drops and bladder instillation. Often termed CIVAS – centralised IV admixture service.²

**Diuretic**
Any drug that elevates the rate of urination and increases the excretion of water from the body. Each diuretic class does so in a distinct way.
Hyperkalaemia  The condition in which the concentration of potassium (K⁺) in the blood is higher than the normal range.

Hypokalaemia  The condition in which the concentration of potassium (K⁺) in the blood is lower than the normal range.

Isotonic solutions  A solution that has the same ionic strength or tonicity as plasma. A physiologic salt solution is one that is isotonic with plasma. Solutions that have same tonicity will result in no net flow of water across the cell membrane.

Must  Indicates a mandatory action required by a NSW Health policy directive, law or industrial instrument.

Parenteral  Taken into the body or administered in a manner other than through the digestive tract, as by intravenous or intramuscular injection.

Premixed intravenous solutions  Intravenous admixtures prepared in a regulated compounding facility with full labelling and expiry dating (e.g. CIVAS, commercial GMP licensed facility).

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

3. INTRAVENOUS POTASSIUM USE STANDARDS

3.1 Protocols

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

- Preparation and administration practices for potassium chloride and other concentrated potassium salts
- Recommended infusion rate, infusion pump requirements and associated patient monitoring

3.2 Prescription

- 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 e.g. enteral and parenteral nutrition, oral intake, supplementary fluids.
- Prescriptions 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 (see PD2007_077 Medication Handling in NSW Public Hospitals).
• Chemical abbreviations must not be used for intravenous potassium orders.

<table>
<thead>
<tr>
<th>EXAMPLE ✓</th>
<th>NOT ✗</th>
</tr>
</thead>
<tbody>
<tr>
<td>Potassium chloride</td>
<td>KCl</td>
</tr>
<tr>
<td>Potassium dihydrogen phosphate</td>
<td>KH₂PO₄</td>
</tr>
</tbody>
</table>

• Prescriptions for intravenous potassium salts must be expressed in millimoles (mmol) NOT milligram per litre or percent.

• Prescriptions with directions to give potassium chloride as a bolus or stat must never be used: always include infusion rate or time period.

<table>
<thead>
<tr>
<th>EXAMPLE ✓</th>
<th>NOT ✗</th>
</tr>
</thead>
<tbody>
<tr>
<td>Potassium chloride 10 mmol in 100mL saline IV over one hour</td>
<td>Potassium chloride 20 mmol IV now</td>
</tr>
</tbody>
</table>

• Intravenous solutions containing potassium must be prescribed as dilute solutions, except in high acuity clinical areas with cardiac monitoring.

3.3 Standardised concentrations and preparations

• Standardised intravenous solutions containing potassium must be used wherever possible and available. Premixed intravenous solutions are preferred to admixtures. Standardised concentrations include:
  • 30mmol potassium chloride per litre for adults
  • 20mmol potassium chloride per litre for children
• Preference should be given to use of solutions of isotonic strength.
• It is recognised that while use of a single standard concentration may be possible in adult patients, use of a standard concentration may only be possible within certain paediatric age groups.

3.4 Preparation of non-standard potassium admixtures

• Admixtures are not preferred. However, where non-standard concentrations are required, a pharmacy-based Centralised IV Admixture Service (CIVAS) should be used to prepare admixtures where possible.
• In the absence of a CIVAS and if a standard potassium presentation cannot be used, admixtures are to be prepared in the clinical area by staff using aseptic technique. Where this is routinely undertaken, local protocols must address the risks of the supply and handling of concentrated potassium injections.
• If a potassium salt is added to an intravenous fluid, the solution must be fully mixed immediately prior to administration by inverting the bag ten times.
• Wherever possible, when administered via a peripheral intravenous line, all potassium-containing infusion solutions should be prepared as close as possible to isotonic concentration. Solutions which are significantly hypertonic
may cause pain on administration but can be given via central intravenous lines with cardiac monitoring.

3.5 Administration

3.5.1 Intravenous Route

- A concentrated solution of any drug or electrolyte including potassium must never be added to an intravenous infusion container in the hanging position prior to or during its administration because without adequate mixing, this will result in administration of a bolus.

3.5.2 Rate of administration

- The maximum recommended rate in adults of intravenous potassium administration is 10mmol per hour unless given under emergency conditions when up to 40mmol per hour may be given in the short term with cardiac monitoring3,4.
- The total dose recommended in adults should not generally exceed 200 mmol/24 hours3.
- Refer to local protocols for rate and dosage recommendations in children.
- For all potassium containing infusions, administration must be controlled with a volumetric infusion pump.

3.5.3 Concentration of solutions

Peripheral Intravenous Route

- The maximum recommended concentration of potassium for administration via peripheral intravenous lines in adults is 40 mmol/L3,4. Stronger solutions will cause pain on administration unless prepared at isotonic strength.
- If standard premixed potassium infusion solutions do not provide the required combination of dose, fluid and rate, a more concentrated solution may be used in the short term (e.g. 10 mmol/100mL mini-bag prepared at isotonic strength).
- The treating specialist should approve administration of intravenous potassium regimens that differ from standard strength solutions.

Central Intravenous Route

- Solutions stronger than the limits specified for peripheral administration must be infused via a central venous access device using a volumetric infusion pump and with continuous cardiac monitoring during the infusion4.

Refer to local protocols for advice on concentration of solutions for use in children.
3.6 Availability and storage

- The availability of potassium chloride ampoules as stock in general ward areas has been identified as a common root cause of potassium-related errors. Potassium chloride ampoules should be removed from ward stock and replaced with standard premixed solutions for intravenous infusion, wherever possible. Ampoules of other concentrated potassium salts (e.g. potassium dihydrogen phosphate) should also be removed from ward stock and only be available through pharmacy departments.

- Premixed intravenous solutions containing potassium must be clearly labelled and separated from other same size commercial intravenous infusions (e.g. sodium chloride 0.9% solution).

- Potassium chloride ampoules must not be placed on resuscitation trolleys due to the risk of inadvertent bolus administration. They must be securely stored and readily accessible for resuscitation purposes when needed.

- In high acuity areas and operating suites where higher concentrations and doses of potassium are considered necessary,
  - a premixed concentrated small-volume infusion (e.g. 40mmol/100mL) should be available as the first option for use
  - a risk assessment should be performed to determine whether it is appropriate to keep the ampoules as a stock item and if so, a protocol for safe preparation and use should be developed
  - the range of concentrated potassium salts available should be limited
  - ampoules must be physically separated from ampoules of similar appearance and packaging eg in a separately identified and coloured box, and retained in original packaging until immediately prior to use

- Potassium ampoules of strength greater than 1mmol/mL should not be available for general clinical use. If needed, these must only be kept in the pharmacy, clearly segregated from other strengths.

3.7 Purchasing and distribution of products

- Premixed potassium intravenous solutions must be clearly differentiated from basic fluids e.g. through use of colour coded overpouches and labelling.

- Concentration must be expressed in millimoles per final volume.

- Premixed small volume intravenous solutions (minibags) containing potassium must not have an additive port or, if admixtures are prepared in-house, the additive port must be capped.

- Storage locations for pre-mixed solutions must be clearly identified throughout each facility.
4. ASSOCIATED DOCUMENTS

- POLICY STATEMENT – High-Risk Medicine Management
- POLICY STANDARD – High-Risk Medicine Management
- High Risk Medication Alert – Intravenous Potassium Chloride (October 2003) Australian Commission on Safety and Quality in Health Care

5. REFERENCES

2. Vermeij P, Quality control in intravenous additive service Pharmacy World & Science Volume 10, Number 4, 151-153, DOI: 10.1007/BF01959423
3. Australian Approved Product Information, – Sterile Potassium Chloride Concentrate last updated 21.1.10 accessed 21.11.11
### 6. Appendix 1 – Implementation and Compliance Tool

**NB:** This action planner is NOT mandatory – it is a tool Health Services may wish to use to monitor the implementation of this policy standard.

<table>
<thead>
<tr>
<th>IMPLEMENTATION REQUIREMENTS</th>
<th>Not commenced</th>
<th>Partial compliance</th>
<th>Full compliance</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Responsibility is assigned to personnel for implementation of the potassium intravenous use policy</td>
<td></td>
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</tr>
<tr>
<td>2. The Drug and Therapeutics Committee has reviewed and approved all local potassium use protocols.</td>
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<tr>
<td>3. A range of premixed potassium chloride containing intravenous solutions is continuously available in all clinical treatment areas.</td>
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<tr>
<td>4. Preloaded potassium chloride solutions are listed in all protocols requiring parenteral potassium administration.</td>
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<tr>
<td>5. Concentrated potassium injections are removed from ward stock in general clinical areas.</td>
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<tr>
<td>6. Premixed potassium solutions are prescribed wherever clinically feasible.</td>
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<tr>
<td>7. Health Service protocols are established to limit allowable concentration of potassium in intravenous solutions which can be administered in general clinical areas.</td>
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</tr>
</tbody>
</table>

**Notes:**

**Assessed by:**

**Date of Assessment:**
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Appendix 1: High-Risk Medicines Management – Therapeutic Anticoagulation, Implementation checklist .......................................................... 13
1 PURPOSE

Medicines considered to be anticoagulants act through inactivation of blood clotting factors or through inhibition of the hepatic production of coagulation factors. Patient treatment with anticoagulants is widely used to prevent extension of an existing thrombus and to prevent thrombosis in well defined patient groups, either with continuous treatment or to cover a period of surgery.

Anticoagulants are considered to be high-risk medications due to their ability to cause extensive bleeding. Pulmonary embolism or deep-vein thrombosis may also result if anticoagulants are not used at an appropriate dose when indicated. Anticoagulants have a narrow therapeutic index and over or under anticoagulation can result in significant adverse patient outcomes.

This policy aims to ensure that all patients are safely managed during anticoagulant therapy. Minimum, evidence-based requirements are given in this document for developing local protocols for the use of anticoagulant medication in hospitalised patients.

This policy standard should be read in conjunction with PD2010_077 Prevention of Venous Thromboembolism.

Where anticoagulation is required for paediatric patients, expert local advice should be sought.

2 BACKGROUND

Principles are based on the best practice statements contained in both the local and international medical and scientific literature and are taken from best practice recommendations made by well recognised scientific bodies.
### 3. DEFINITIONS

<table>
<thead>
<tr>
<th>Term</th>
<th>Definition</th>
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<tbody>
<tr>
<td><strong>Attending Medical Officer</strong></td>
<td>The Attending Medical Officer (AMO) is the senior medical practitioner who has primary responsibility for the patient during admission. This medical officer is a consultant who may be a visiting medical officer or a staff specialist. The AMO may lead a team that includes related medical staff and this team plays a critical role in the Clinical Review of the patient.</td>
</tr>
<tr>
<td><strong>Anticoagulant</strong></td>
<td>Any agent used to prevent the formation of blood clots including oral agents, such as warfarin, and other medications which are injected into the vein or under the skin such as heparin.</td>
</tr>
<tr>
<td><strong>aPTT</strong></td>
<td>Activated partial thromboplastin time. An indicator measuring the efficacy of both the intrinsic (now referred to as the contact activation pathway) and the common coagulation pathways. It is used in conjunction with the prothrombin time (PT) which measures the extrinsic pathway.</td>
</tr>
<tr>
<td><strong>INR</strong></td>
<td>International Normalised Ratio. The INR is the ratio of a patient's prothrombin time to a normal (control) sample and is used to monitor the use of warfarin.</td>
</tr>
<tr>
<td><strong>Must</strong></td>
<td>Indicates a mandatory action required by a NSW Health policy directive, law or industrial instrument.</td>
</tr>
<tr>
<td><strong>NSW Health Inpatient Medication Chart</strong></td>
<td>A standard inpatient medication chart used in all NSW public hospitals to promote standardisation and consistency in documentation of prescribing and administration of medications.</td>
</tr>
<tr>
<td><strong>Practitioner</strong></td>
<td>A practitioner is a registered health care professional e.g. doctor, nurse, midwife, nurse practitioner, pharmacist.</td>
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</tbody>
</table>
| **Pregnancy, drug use in (Australian categories C & D)** | **Category C**: Drugs that, owing to their pharmacological effects, have caused or may be suspected of causing, harmful effects on the human fetus or neonate without causing malformations. These effects may be reversible.  
**Category D**: Drugs that have caused, are suspected to have caused or may be expected to cause an increased incidence of human fetal malformations or irreversible damage. These drugs may also have adverse pharmacological effects.  
Warfarin is contraindicated in women who are or may become pregnant because the drug passes through the placental barrier and may cause fatal haemorrhage to the fetus *in utero*. Furthermore there have been reports of birth malformations in children born to mothers who have been treated with warfarin during pregnancy. |
| **Premixed**                  | In reference to an intravenous solution containing an added drug, the drug being either added under controlled conditions or the solution being commercially prepared under Good Manufacturing Practice conditions and subsequently distributed. This contrasts with immediate preparation of an admixture in the clinical setting. |
| **Should**                    | Indicates an action that should be followed unless there are sound reasons for taking a different course of action.                         |
4. THERAPEUTIC ANTICOAGULATION STANDARDS

4.1 Patient Assessment

4.1.1 In taking a patient history the attending medical officer or his/her delegate must assess risks and benefits of anticoagulant therapy specifically considering:

- Indication for treatment and selection of an appropriate anticoagulant.
- Presence of diseases or conditions that could affect dosing requirements e.g. liver disease for warfarin therapy, renal impairment for low molecular weight heparins, other factor Xa inhibitors and direct thrombin inhibitors.
- Age and body weight.
- Concomitant medications (including non-steroidal anti-inflammatory agents, existing anticoagulation and antiplatelet agents) that could affect efficacy or increase the risk of bleeding with planned therapy.
- Previous problems with anticoagulant therapy e.g. bleeding, heparin-induced thrombocytopenia (HIT).
- Presence of bleeding risks e.g. planned surgery, platelet dysfunction.
- Presence of absolute contraindications to anticoagulation (recent surgery involving brain, spine or eyes; lumbar puncture within 2 hours; active peptic ulcer).
- Presence of relative contraindications (e.g. high risk of falls).
- Pregnancy: Warfarin has a “D” classification in pregnancy. All heparins and other oral anticoagulants have a “C” classification. Both classes have caused or may be suspected of causing, harmful effects on the human foetus.
- Serum potassium level: Unfractionated heparin can raise potassium levels and may lead to hyperkalaemia when co-prescribed with another medicine that can raise potassium.

4.1.2 Where anticoagulant therapy is considered the blood tests taken at baseline should include:

- A full blood count (FBC) including haemoglobin and platelet count
- Prothrombin time/International normalised ratio (INR)
- Activated partial thromboplastin time (aPTT)
- Urea, electrolytes and creatinine (UEC) and subsequent creatinine clearance (CrCl) calculations
- Liver function tests (LFT)
- Other blood tests will depend on the clinical situation.
4.2 Dose Calculation and Decision Support

4.2.1 Standardised instructions (tables or nomograms) should be used for prescribing anticoagulants. Where necessary nomograms and protocols should be disease specific and include advice on dosing by body weight where applicable.

4.2.2 Unfractionated heparin protocols should include, based on best evidence

- instructions on heparin dose calculation to ensure consistency and protect against over-anticoagulation.
- details on the recommended loading doses to be used for each indication and requirements for frequency of monitoring of coagulation status.
- dose adjustments based on aPTT results.
- reversal of therapy, where appropriate.
- explicit doses and corresponding infusion rates for each local patient group.
- advice on preferred use of actual body weight, ideal body weight or medically approved adjusted body weight in dose calculations.
- dose adjustment through changes to the infusion rate of a solution of standardised concentration.
- the therapeutic range for aPTT results in each facility in consultation with their laboratory.

4.2.3 Dose adjustment for renal dysfunction

- Estimated creatinine clearance should be used for assessing renal function prior to initiating renally excreted anticoagulants, ie low molecular weight heparin (LMWH), danaparoid, other factor Xa inhibitors including rivaroxaban and apixaban, and direct thrombin inhibitors such as dabigatran.

- Instructions for calculating creatinine clearance should be included in the protocols. The modified Cockroft-Gault formula is recommended as it takes into account patient’s age, gender and ideal body weight and has been validated for drug dosing.

\[
\text{Creatinine clearance (mL/min)} = \frac{(140-\text{age}) \times \text{ideal wt (kg)} \times 0.85 \text{ if female}}{0.814 \times \text{serum creatinine (micromol/L)}}
\]

Ideal body weight (kg) = Females 45.5 kg + 0.9 kg/cm for each cm >152 cm. Males 50kg + 0.9 kg/cm for each cm >152 cm
• Unfractionated heparin can be given in renal impairment without dose adjustment.

• Dabigatran and fondaparinux are contraindicated in patients with creatinine clearance < 30mL/min and rivaroxaban and apixaban in those with clearance < 15mL/min.

4.2.4 Warfarin initiation and maintenance nomograms

• Dosing must take into account patient age, INR results, and presence of medical problems e.g. heart failure, liver disease, severe infection, recent major surgery, reduced oral intake, nutritional status, and concomitant interacting medication.

• Protocols should suggest starting doses for warfarin, including lower recommended doses for patients who are older than 65 years and for adult patients who have existing comorbidities.

• Doses rounded to the next clinically appropriate dosage unit (e.g. 0.5 mg for warfarin or 10mg for enoxaparin) are acceptable.

4.2.5 Assessment for obesity. Dosage recommendations may be needed for obese patients.

4.3 Prescribing

• The indication for anticoagulation (and therapeutic targets where appropriate) should be included in the health care record. Details should include the intended duration of therapy, timeframe for review and whether anticoagulation is newly initiated or a continuation of previous therapy. The NSW Health Inpatient Medication Chart includes sections for recording the indication, and in the case of warfarin, the INR target.

• Error prone abbreviations must not be used, e.g. write units in full - do not use U or IU. In handwriting, U can be misinterpreted as zero.

• When unfractionated heparin is used for therapeutic anticoagulation it should be prescribed:
  o intravenously by continuous infusion (together with intravenous loading doses where indicated) rather than intermittent injection
  o according to standard infusion protocols in each facility. In facilities that treat paediatric patients the standard may be separately applied per age group
  o by continuous subcutaneous infusion only when all other routes are unavailable and local protocols allow, and in the knowledge of the expected variability in blood levels and possible bruising at the infusion site
• For weight-dependent dosing the calculated dose and dose per weight should be included in medication orders to facilitate independent double-checking of the calculation. Patient weight should be documented on the NSW Health Inpatient Medication Chart.

• Warfarin must be prescribed for adults in the dedicated section of the NSW Health Inpatient Medication Chart or in approved electronic systems. When dose adjustment is underway, local protocols must specify that prescribing must be undertaken as early as possible each day, by the treating team.

• Principles for warfarin prescribing are available from the National Prescribing Service medication chart training program: http://nimc.nps.org.au/elearning/log/login.asp

• When warfarin therapy is initiated for a patient with active thrombosis, heparin or low molecular weight heparin therapy is recommended to continue until the INR has reached a therapeutic level for at least two consecutive days².

• Use of multiple anticoagulants and antiplatelet medicines should be rationalised as soon as feasible for each patient.

4.4 Standardised unfractionated heparin presentations

• When unfractionated heparin is used for therapeutic anticoagulation in adult patients, one of the following standard strength premixed heparin solutions should be used in each adult treatment facility:
  o Heparin sodium 25,000 Units in 250mL saline solution (isotonic) in a minibag (100 Units per mL)
  o Heparin sodium 25,000 Units in 50mL saline solution (isotonic) in a pre-loaded syringe (500 Units per mL)

• Where unfractionated heparin injection is available as ward or imprest stock, a single strength only (e.g. heparin sodium 5,000 units) should be used throughout all clinical areas including the Operating Suite.

• If heparin is used for the purpose of locking central venous access devices, the 50 Units in 5mL strength of heparinised saline is recommended for use.

• Higher dose preparations, if purchased, must be confined to the pharmacy service.

4.5 Supply of medication

• When possible, anticoagulants, either oral or parenteral, should be individually dispensed for each patient unless the patient is in a high acuity area.
• For commencement of treatment outside pharmacy hours, reserve supplies must be available via the after-hours drug supply arrangements.

4.6 Administration of medication

• Only volumetric infusion devices or syringe drivers are to be used for all IV anticoagulant infusions. Wherever possible this should be a “smart” pump using a pre-programmed infusion protocol or a protocol-specific syringe driver. Smart pump intelligence, where implemented, must be turned on and not bypassed while any anticoagulant drug is being infused.

• With each new bag/bottle of an anticoagulant infusion, or change in the rate of infusion, one practitioner prepares or selects the solution for administration and another practitioner independently verifies and documents that the medication order matches the identified patient, correct drug, correct concentration, correct route, correct rate of infusion, correct channel selection (for multiple-channel pumps), and correct administration line before starting the infusion.

• For inpatient oral therapy, warfarin administration should occur daily at 1600 hours (4pm) with the latest INR results reviewed before administration. If there is a good reason why the local INR results schedule cannot match these requirements, the local protocol is to establish another agreed standard administration time.

• Doses of warfarin and parenteral agents must be independently double-checked against the original order by a second practitioner prior to drug administration. This must be documented by both staff members signing the appropriate medication administration record.

4.7 Monitoring

4.7.1 Anticoagulant Factors

• An aPTT should be taken 4-6 hours after starting an unfractionated heparin infusion.

• For patients receiving warfarin
  
  o samples of blood for INRs should be taken at the same time of day (usually morning) so the results are available and communicated to staff before warfarin doses are prescribed.

  o a target INR should be specified for each patient by the prescriber.

• The aPTT and the INR are not used as measures of anticoagulant activity during treatment with routine doses of low molecular weight heparins, other factor Xa inhibitors such as rivaroxaban and fondaparinux, or with danaparoid. However, aPTT can be used to monitor for dabigatran toxicity.
4.7.2 Bleeding

- Instructions for monitoring patients for bleeding must be recorded in the patient healthcare record, e.g. blood tests (FBC, INR, aPTT), clinical observations using approved standard observation charts, and actions to be taken.

- Patients on anticoagulants who fall are at an increased risk of bleeding and serious trauma including brain injury, this risk increases with age and frailty. The facility's post-fall management protocols must include full assessment for bleeding and action required if a patient falls while an inpatient.

- Advice should be provided to prescribers on how to manage a patient with a high INR result whether or not they are bleeding. Patients with high INRs are at significant risk of harm and appropriate management with a reversal agent should be initiated. Actions to be taken should be detailed in the facility's anticoagulant protocols.

- There are no specific reversal agents for the newer oral anticoagulants. In the event of overdosage or bleeding, immediate discontinuation of treatment must be considered as well as mechanical and symptomatic control of bleeding. Specialist advice should be sought.

4.7.3 Other Adverse Effects

- Local protocols should recommend monitoring for thrombocytopenia and for any new or extending thromboses in patients receiving or recently discontinued from heparin. These may be a consequence of development of heparin-induced thrombocytopenia (HIT) which can be confirmed with specific functional assays. The development of HIT is a serious event for patients. Treatment of HIT requires both protection from thrombosis and choice of an agent that will not further reduce the platelet count.

- Where heparin therapy continues for more than 3-5 days, regular platelet counts should be conducted eg every 3 days for 2 weeks if unfractionated heparin, and weekly if low molecular weight heparin.

4.8 Document Perioperative Instructions

Local protocols should include instructions for managing anticoagulation perioperatively and include:

- Lists of procedures where antithrombotic agents may be continued
- Details of patients requiring bridging anticoagulation
- Timing of stopping and restarting of oral anticoagulants where required
- Timing of provision of bridging anticoagulation perioperatively
- Perioperative management of patients receiving antiplatelet therapy
4.9 Other Considerations - Warfarin

Every patient prescribed warfarin should be provided with written information on their medication which has been tailored to their needs. Patients should be given the opportunity to discuss issues related to their warfarin therapy with a health practitioner during their hospital stay. Written drug information may include the following:

- Provision of a warfarin booklet for tracking warfarin therapy and INR results.
- Update of an existing warfarin book to record INR results during the hospital stay.
- Instructions for INR testing and review after discharge.
- Intended duration of therapy and timeframe for specialist review.
- How to identify bleeding who to contact and action to be taken.
- Other educational tools e.g. Consumer Medicines Information.

Provision of written warfarin information must be documented in the medical record and/or the appropriate space on the NSW Health Medication Chart.

Older adults should be advised to be seen immediately by a health care provider if they have a bump or blow to the head, even if they do not have symptoms suggestive of bleeding.

For patients of non-English speaking background, written material concerning warfarin management should be provided in their preferred language. Interpreter services are to be used when available to assist the patient understand the importance of taking their medication as prescribed and risks and side effects that may occur.

Prior to transfer to home or to other care, patients on warfarin therapy should have a confirmed appointment with their General Practitioner (GP) or antithrombotic clinic. The GP should be advised of the indication for anticoagulation, target INR, and proposed duration of therapy. If the patient has nominated a community pharmacist, this practitioner should receive similar information. Referral for Home Medicines Review should be made prior to the patient leaving hospital.

5 IMPLEMENTATION & MONITORING

Success of policy implementation and compliance can be monitored using clinical indicators.

The clinical indicators developed by NSW Therapeutic Advisory Group (NSW TAG) in collaboration with the NSW Clinical Excellence Commission as part of the Indicators for Quality Use of Medicines in Australian Hospitals available at www.nswtag.org.au are
recommended. All were field tested and validated in Australian hospitals during the development process.


An implementation checklist is available in Appendix 1.

6 REFERENCES
2. Therapeutic Guidelines, Cardiovascular v 5, 2008
23. TGA Approved Product Information, Rivaroxaban (Xarelto R) Accessed 21.11.11
24. TGA Approved Product Information, Dabigatran (Pradaxa R) Accessed 21.11.11
25. TGA Approved Product Information, Danaparoid (Orgaran R) Accessed 21.11.11
27. TGA Approved Product Information, Apixaban (Eliquis R) Accessed 21.11.11
7 ASSOCIATED DOCUMENTS

POLICY STATEMENT – High-Risk Medicines Management

POLICY STANDARD – High-Risk Medicines Management


NSW Health PD2011_037 – Chest Pain Evaluation (NSW Health Chest Pain Pathway)

NSW Health PD2010_077 – Prevention of Venous Thromboembolism

NSW Health Safety Notice 014/11 Newer Oral Anticoagulants November 2011
Appendix 1: High-Risk Medicines Management – Therapeutic Anticoagulation, Implementation checklist

<table>
<thead>
<tr>
<th>IMPLEMENTATION REQUIREMENTS</th>
<th>Date of Assessment:</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Not commenced</td>
</tr>
<tr>
<td>1. Drug &amp; Therapeutics Committee has approved local Anticoagulation protocols.</td>
<td>□</td>
</tr>
<tr>
<td>2. All clinicians aware of Anticoagulation policy and ongoing arrangements made to update new staff.</td>
<td>□</td>
</tr>
<tr>
<td>3. Compliance with Anticoagulation policy is assessed.</td>
<td>□</td>
</tr>
<tr>
<td>4. Accessibility to stock of pre-loaded infusion fluids for all clinical areas is readily organised including after hours.</td>
<td>□</td>
</tr>
<tr>
<td>4. The reason for the use of a non-standard intravenous anticoagulant solution is documented.</td>
<td>□</td>
</tr>
<tr>
<td>5. Perioperative instructions regarding anticoagulation are documented.</td>
<td>□</td>
</tr>
<tr>
<td>6. Warfarin therapy is initiated with a starting dose defined according to local protocol.</td>
<td>□</td>
</tr>
<tr>
<td>7. No patient receiving warfarin has a measured INR greater than 4.0 without prompt review and dose adjustment.</td>
<td>□</td>
</tr>
<tr>
<td>8. All patients transferred home on warfarin receive written information prior to transfer.</td>
<td>□</td>
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