

Policy Directive: compliance is mandatory

High Risk Medicines Management Policy Directive

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Policy developed by: Public Health and Clinical Systems

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Summary

High risk medicines are medicines with a heightened risk of causing significant patient harm when used in error. The High Risk Medicines Management Policy Directive and accompanying Policy Guideline provide a standardised and consistent approach to the safe management of high risk medicines in SA Health services. The documents outline individual and health service responsibilities, support the clinical workforce, and assist hospitals and health services meet the Australian Commission on Safety and Quality in Health Care (ACSQHC) National Safety and Quality Health Service Standards, in particular Standard 4 – Medication Safety.

Keywords

High risk medicines, medicine, medication, anti-infectives, potassium, insulin, chemotherapy, opioids, anticoagulants, APINCH, High Risk Medicines Management Policy Directive

Policy history

Is this a new policy? **Y**
Does this policy amend or update an existing policy? **N**
Does this policy replace an existing policy? **N**
If so, which policies?

Applies to

All SA Health Portfolio

Staff impact

All Staff, Students, Volunteers

PDS reference

D0351

Version control and change history

Version	Date from	Date to	Amendment
1.0	02/10/2014	Current	Original version



High Risk Medicines Management Policy Directive

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Government
of South Australia

SA Health

Document control information

Document owner	Senior Pharmacist, Medication Safety, Medicines and Technology Policy and Programs, Public Health and Clinical Systems
Contributors	South Australian Medication Safety Advisory Group members South Australian Medicines Advisory Committee members
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02/10/14	Senior Pharmacist, Medication Safety, Medicines and Technology Policy and Programs, Public Health and Clinical Systems	V.1	PE Approved version.

Endorsements

Date	Endorsed by
05/06/14	South Australian Medicines Advisory Committee
12/08/14	Safety and Quality Strategic Governance Committee
21/08/14	Safety and Quality Operational Governance Committee

Approvals

Date	Endorsed by
02/10/14	Portfolio Executive

High Risk Medicines Management Policy Directive

1. Objective

Medicines are the most common intervention used in health care and a key component of disease management and prevention. The safe use of medicines is therefore an essential component of patient safety. Although most medicines have a wide margin of safety, a few medicine groups, known as high risk medicines, are recognised as having a high risk of causing significant patient harm if they are misused or administered incorrectly. Errors with high risk medicines may not necessarily occur more often than errors with other medicines, but their consequences can be more devastating.

The SA Health High Risk Medicines Management Policy Directive aims to improve patient safety and minimise patient harm through the safe storage, prescribing, dispensing, and administration of high risk medicines. Key elements include ensuring health services:

- identify high risk medicines within their organisation
- identify and manage risks associated with the use of high risk medicines
- improve staff awareness of high risk medicines, the risks associated with their use, and the strategies implemented to address these risks.

The purpose of the policy is to:

- ensure a standardised and consistent approach to the safe use of high risk medicines, including regular risk assessment and action to address risks, in South Australian health services, in accordance with national standards
- support the clinical workforce in the safe management and use of high risk medicines
- outline individual and health service responsibilities in relation to high risk medicines management
- assist hospitals and health services meet the Australian Commission on Safety and Quality in Health Care (ACSQHC) National Safety and Quality Health Service Standards¹, in particular Standard 4 – Medication Safety.

Implementation of this policy will ensure:

- evidence of organisational leadership and governance around implementing, monitoring and evaluating a strategy to safely manage high risk medicines
- demonstration of a high risk medicines management strategy, including identification of high risk medicines within a health service or area, regular identification and assessment of risks associated with high risk medicines management, taking action to reduce identified risks, and improving staff awareness of high risk medicines and the risks inherent to their use
- reporting of incidents involving high risk medicines through the Safety Learning System (SLS) is supported as per the SA Health Incident Management Policy and Guideline, including mandatory reporting of medication sentinel events involving high risk medicines.

This policy directive is to be read / administered in conjunction with the High Risk Medicines Management Policy Guideline.

2. Scope

All SA Health employees, and persons who provide services on behalf of SA Health, who are involved in medication management must adhere to this policy directive. The policy directive should be adhered to at all stages of the medication management pathway.

3. Principles

The following core principles are acknowledged:

- medicines are a key component of disease management and prevention
- although most medicines have a wide margin of safety, a few medicine groups, known as high risk medicines, are recognised as having a high risk of causing significant patient harm or death if they are misused or administered incorrectly
- errors with high risk medicines may not occur more often than errors with other medicines but their consequences can be more devastating
- risks associated with the storage, prescribing, dispensing, and administration of high risk medicines need to be considered at each stage of the medication management pathway, in accordance with the National Safety and Quality Health Service Standards ¹
- information is available from Australian and International safety organisations to guide and assist health services in implementing strategies to identify and improve safe use of high risk medicines.

4. Detail

For the purposes of this document, the minimum medicines or medicine groups for inclusion in an organisational high risk medicines management strategy, where in use, are those specified below using the Australian Commission on Safety and Quality in Health Care (ACSQHC) ² APINCH taxonomy.

A	Anti-infectives	Refers to amphotericin, vancomycin, and aminoglycosides, but may also include others.
P	Potassium and other electrolytes	Refers to injectable electrolyte preparations, e.g. potassium chloride and magnesium sulfate, but may also include other medicines.
I	Insulin	Refers to all insulins.
N	Narcotics and other sedatives	Refers to all opioids; sedatives may include benzodiazepines and other sedating agents.
C	Chemotherapeutic agents	Refers to cytotoxic chemotherapy.
H	Heparin and anticoagulants	Refers to heparins and all anticoagulants, including the New Oral Anticoagulants.

Table 1: High risk medicines acronym - APINCH

The above is not an exhaustive list. Medicines or medicine groups other than those specified above may present a high risk, e.g. neuromuscular blockers used during general anaesthesia. These should be identified and included in the organisational high risk medicines strategy where appropriate.

While the ACSQHC includes S 'Systems' in their acronym to help classify safety alerts and guidance, 'Systems' is not included for the purposes of this document as it does not pertain to an individual medicine or group of medicines. It is however acknowledged that organisations may choose to classify medicines given by a particular route or through a particular device as a high risk medicine group.

Further information regarding determination and classification of high risk medicines can be found in the associated High Risk Medicines Management Policy Guideline.

5. Roles and Responsibilities

5.1 Chief Executive, SA Health will

- ensure SA public hospitals and health services are aware of and comply with this policy.

5.2 Director, Medicines and Technology Policy and Programs Branch, SA Health will

- establish, maintain and periodically review the effectiveness of the High Risk Medicines Management Policy Directive and associated Guideline
- monitor and evaluate implementation of the directive and guideline at a Local Health Network (LHN) level through LHN reporting to the South Australian Medication Safety Advisory Group (SAMSAG)
- ensure development and maintenance of high risk medicines resources to support LHNs, including the High Risk Medicines Safety Notices
- facilitate identification of trends in high risk medicines incident reports and provision of recommendations for improved high risk medicines management through participation in the SAMSAG
- provide advice to health services in regards to specific queries regarding high risk medicines
- ensure relevant purchasing and procurement decisions relating to high risk medicines take safety aspects into account, including when considering listing medicines on the statewide formulary.

5.3 Local Health Network and Statewide Services Chief Executive Officers will

- delegate the day-to-day responsibility for complying with this policy to the relevant senior managers
- ensure governance arrangements for medication management and medication safety include specific responsibility for management of high risk medicines, including a multidisciplinary, structured approach to identifying high risk medicines, potential risks related to use of high risk medicines, and development of a framework for improvement strategies
- ensure purchasing and procurement decisions relating to high risk medicines take safety aspects into account, including when considering listing medicines on the statewide formulary
- ensure the health services under their administration have systems in place to identify high risk medicines and ensure their appropriate and safe storage, prescribing, dispensing, and administration
- ensure the health services under their administration have systems in place to ensure information about appropriate storage, prescribing, dispensing and administration of high risk medicines is available, adhered to, and referred to at the time of storing, prescribing, dispensing, and administering a high risk medicine
- ensure compliance with the mandatory National Medication Safety Alerts on high risk medicines

- ensure the health services under their administration have systems in place which facilitate effective management and notification of high risk medicine incidents (in accordance with the SA Health Incident Management Policy and Guideline).

5.4 Executive Directors, Directors, heads of service/departments and other senior managers will

- ensure the existence of a high risk medicines management strategy and high risk medicines list(s) which will be maintained and referenced at each facility or group of facilities
- ensure risks associated with high risk medicines management are identified and assessed, and that actions to reduce identified risks are implemented and evaluated
- promote staff awareness of the medicines or medicine groups contained in the high risk medicines list(s), the strategies implemented to improve their safe use, and the need to refer to it at the time of storing, prescribing, dispensing, and administering a high risk medicine
- ensure local procedures are implemented for appropriate storage, handling, prescribing, dispensing, and administration of high risk medicines
- ensure incidents involving high risk medicines are reported into the Safety Learning System (SLS) and via other appropriate pathways and managed in accordance with the SA Health Incident Management Policy.

5.5 All SA Health employees will

- ensure they are familiar with the list(s) of high risk medicines for their organisation and/or facility
- ensure they are familiar with the safe storage, prescribing, dispensing, and administration of high risk medicines in accordance with policies, procedures and local protocols
- ensure they consider the additional risks associated with high risk medicines when managing high risk medicines, e.g. at the time of storing, prescribing, dispensing, administering, and providing patient information about a high risk medicine
- report incidents involving high risk medicines via appropriate pathways including to SLS in accordance with the SA Health Incident Management Policy
- participate in education or training to ensure they have knowledge and skills relevant to their role in the safe management of high risk medicines.

6. Reporting (if applicable)

SA Health hospitals and health services are required to report compliance with safe management of high risk medicines to the relevant accrediting body when undergoing Accreditation Survey including:

- compliance with National Medication Safety Alerts for high risk medicines.²

SA Health hospitals and health services are required to report against a set of APAC key performance indicators³ including the following which apply to high risk medicines:

- SA APAC 5.4 – The percentage of patients with an INR result > 4 that have had their dosage adjusted or reviewed prior to the next warfarin dose
- SA APAC 5.5 – The percentage of patients with a toxic or sub-therapeutic aminoglycoside concentration that have had their dosage adjusted or reviewed prior to the next aminoglycoside dose
- SA APAC 7.3 – The percentage of patients commenced on warfarin during their admission that received counselling and written discharge information prior to discharge.

7. EPAS Considerations

'High dose drug alerting' is available in the initial design of the Enterprise Patient Administration System (EPAS) for a limited number of high risk medicines. At the point of prescribing, available alerts provide information to the clinician that the individual dose or daily dose is unusually high for that particular medicine. Doses specified currently apply only to the adult population and are not suitable for paediatric or neonatal dosing.

EPAS development should prioritise incorporating safeguards and alerting functions for high risk medicines for all patients, including adults, neonates and paediatrics, to support safe use of electronic medication management systems.

High dose drug alerts do not replace the requirement for clinicians to use clinical knowledge, professional judgement and appropriate drug information resources when prescribing medicines. Although an alert may not appear, a dose of a particular medicine may still be too high for an individual patient. The ultimate responsibility to ensure safe and accurate prescription of medicines remains with the prescriber.

The ACSQHC Electronic Medication Management Systems – A Guide to Safe Implementation, 2nd Edition⁴ provides advice on specifying and implementing safe electronic medication management systems in Australian hospitals and should be referred to when such systems are being considered.

Staff involved in medication management should be aware of the functions, and associated limitations, of EPAS in terms of safe prescribing of high risk medicines.

8. Exemptions (if applicable)

N/A

9. Associated Policy Directives / Policy Guidelines (if applicable)

Associated SA Health directives and guidelines

- [Accreditation Policy Directive](#)
- [Aminoglycosides: recommendations for use, dosing and monitoring Guideline](#)
- [Clinical Handover Policy Directive](#)
- [Clinical Handover Guidelines](#)
- [Handling of Hazardous Drugs and Related Wastes in South Australian Health Services Policy Directive](#)
- High Risk Medicines Management Policy Guideline
- [Incident Management Policy Directive](#)
- [Incident Management Guideline Incorporating Open Disclosure Response](#)
- [Open Disclosure Policy Directive](#)
- [Opioids: Guidelines for Prescribing on Discharge Clinical Guideline](#)
- [Patient Identification Policy Directive](#)
- [Patient Identification Guideline](#)
- [Risk Management Policy Directive](#)
- [Risk Management Framework](#)
- [Safe Handling of Cytotoxic Drugs and Related Wastes: Guidelines for South Australian Health Services 2012](#)

- [Spell it out: Standardised terminology, abbreviations and symbols to be used when communicating about medicines Policy Directive](#)
- [Spell it out: Standardised terminology, abbreviations and symbols to be used when communicating about medicines Standards](#)
- [Standing orders for the administration of drugs of dependence in a health service facility Policy Directive](#)
- [User-applied labelling of injectable medicines, fluids and lines: Policy Directive](#)

10. References, Resources and Related Documents

References

1. [Australian Commission on Safety and Quality in Health Care \(ACSQHC\), National Safety and Quality Health Service Standards, September 2012, ACSQHC, Sydney](#)
2. [ACSQHC High Risk Medicines webpage](#), including Medication Safety Alerts and Notices
3. [South Australian APAC key performance indicators for hospitals participating in pharmaceutical reform, May 2010](#)
4. [Australian Commission on Safety and Quality in Health Care \(ACSQHC\), Electronic Medication Management Systems - A Guide to Safe Implementation, 2nd edition, 2012](#)
5. Australian Council for Safety and Quality in Healthcare. Second National Report on Patient Safety – Improving Medication Safety. Canberra: Australian Council for Safety and Quality in Healthcare, 2002
6. [Institute for Safe Medication Practices, ISMP's List of High-Alert Medications, ISMP 2012](#)
7. Stowasser DA, Allinson YM, O'Leary KM. Understanding the medicines management pathway. J Pharm Pract Res. 2004;34:293-6
8. Australian Pharmaceutical Advisory Council. Guiding principles to achieve continuity in medication management. Commonwealth of Australia, Canberra, 2005











Related Documents

- [Australian Commission on Safety and Quality in Health Care \(ACSQHC\) Resources to implement the NSQHS Standards](#), including Accreditation Workbooks and Improvement Guides
- [Controlled Substances Act 1984](#)
- [Controlled substances legislation](#)
- [Council of Australian Therapeutic Advisory Groups, Achieving effective medicines governance. Guiding principles for the roles and responsibilities of Drug and Therapeutics Committees in Australian public hospitals, Council of Australian Therapeutic Advisory Groups, November 2013.](#)
- [Society of Hospital of Pharmacists of Australia \(SHPA\) Practice Standards](#) including Standards of Practice for Medication Safety and Standards of Practice for the Distribution of Medicines in Australian Hospitals

11. Other

N/A

12. National Safety and Quality Health Service Standards (if applicable)

 National Standard 1 Governance for Safety and Quality in Health Care	 National Standard 2 Partnering with Consumers	 National Standard 3 Preventing & Controlling Healthcare associated infections	 National Standard 4 Medication Safety	 National Standard 5 Patient Identification & Procedure Matching	 National Standard 6 Clinical Handover	 National Standard 7 Blood and Blood Products	 National Standard 8 Preventing & Managing Pressure Injuries	 National Standard 9 Recognising & Responding to Clinical Deterioration	 National Standard 10 Preventing Falls & Harm from Falls
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13. Evaluation of Performance and Compliance

Compliance with the High Risk Medicines Management Policy Directive will be monitored by the Medicines and Technology Policy and Programs through LHN reporting to the SAMSAG.

14. Attachments (if applicable)

N/A

15. Definitions

In the context of this document:

- **electronic medication management** means: the entire medication process from the prescriber's order, to the pharmacist's review of the medication order and supply of medicine, to the nurse's documentation of administration of the medicine, and all the processes in between.⁴
- **error** means: a failure in the treatment process that leads to, or has the potential to lead to, harm to the patient and includes an act of omission or commission. Errors rarely occur as the result of the actions of a single individual. They are usually the result of a series of system failures.⁵
- **high risk medicine** means: any medicine which has a heightened risk of causing significant patient harm when used in error.⁶
- **incident** means: an event or circumstance which could have, or did lead to unintended and/or unnecessary harm to a person, and/or a complaint, loss or damage.⁵
- **medication error** means: a failure in the drug treatment process that leads to, or has the potential to lead to, harm to the patient and includes an act of omission or commission. Errors rarely occur as the result of the actions of a single individual. They are usually the result of a series of system failures.⁵
- **medication incident** means: an incident associated with medication.⁵

- **medication management pathway** means: the cognitive and physical steps involved in the use of medicines, with a focus on the consumer.⁷
- **medication sentinel event** means: medication error leading to the death of a patient reasonably believed to be due to incorrect administration of drugs
- **medicine** means: a chemical substance given with the intention of preventing, diagnosing, curing, controlling or alleviating disease or otherwise enhancing the physical or mental welfare of people. A medicine includes prescription and non-prescription medicines, including complementary and alternative medicines, irrespective of the route of administration.⁸
- **risk** means: the chance of something happening that will have a negative impact. It is measured by consequence and likelihood.¹
- **Safety Learning System (SLS)** means: an electronic system for the reporting and management of incidents and consumer feedback across SA Health.

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